



August 3, 2009

MEMORANDUM

SUBJECT: Transmittal of *Risk and Exposure Assessment to Support the Review of the SO₂ Primary National Ambient Air Quality Standard: Final Report*, and response to CASAC comments on the *Risk and Exposure Assessment to Support the Review of the SO₂ Primary National Ambient Air Quality Standard: Second Draft*

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TO: Angela Nugent
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Attached is the final document, *Risk and Exposure Assessment to Support the Review of the SO₂ Primary National Ambient Air Quality Standard: Final Report* (henceforth referred to as the REA). This 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 purpose of the REA is to convey the approach taken by staff to characterize human exposures and health risks associated with ambient SO₂, to present the results of those analyses, and provide staff's policy assessment based on its assessment of the evidence and results of the air quality, exposure, and risk assessments.

In preparing the final REA, OAQPS staff has made a number of changes from the second draft. Many of these changes are in response to the major comments offered by the Clean Air Scientific Advisory Committee Oxides of Sulfur Primary NAAQS Review Panel (the Panel) following its peer review of the *Risk and Exposure Assessment (REA) to Support the Review of the SO₂ Primary National Ambient Air Quality Standards: Second Draft* (henceforth referred to as the second draft REA). The Panel presented its major comments on the second draft REA as bulleted points in a letter to the Administrator dated May 18, 2009, and included additional comments in attachments to the letter. Our responses to the Panel's major comments and several other key comments are noted below.

I am requesting that you forward this memorandum and the attached electronic file containing the final REA to the Panel members. This memorandum as well as the

final REA will also be available on the following website:
http://www.epa.gov/ttn/naaqs/standards/so2/s_so2_cr_rea.html

- *Every chapter in this or any REA (as well as in the ISAs) should end with a summary section of findings relevant to setting the NAAQS, as presented in Chapter 10 in this REA. Each chapter's summary section should state the key findings/conclusions in the chapter and specifically address: What scientific evidence and scientific insights have been developed since the last review that either support or call into question the current public-health-based and/or current public-welfare-based NAAQS, or indicate that alternative levels, indicators, statistical forms, or averaging times of the standards are needed to protect public health with an adequate margin of safety and to protect public welfare?*

Chapters 2-10 each now contain a “Key Observations” section that states the key findings and/or conclusions presented in those chapters. Chapter 1 is the introduction to the REA and thus, does not have a “Key Observations” section.

- *CASAC found the discussions of uncertainty in individual REA chapters to be lacking in clarity, with incomplete descriptions of methods and findings. The panel recommends rewriting with more complete description of methods and highlighting of key findings, perhaps with bullets, rather than in lengthy text. Sensitivity analyses need to be distinguished from those addressing uncertainty. More explicit chapter-by-chapter discussions of uncertainty characterization will inform the summary discussions in Chapter 10 about the NAAQS.*

The discussion of uncertainty and variability has been revised and includes a discussion and justification of the approach being used for qualitative evaluation of uncertainty in Chapter 6 and separate expanded discussions of uncertainty and variability in the air quality (Chapter 7), exposure (Chapter 8) and health risk assessment (Chapter 9). Each chapter has a summary table highlighting the key sources of uncertainty and the staff ratings of uncertainties, in addition to summary statements supporting staff ratings. Chapter 10 includes a summary discussion of the key uncertainties in the air quality, exposure, and risk assessments.

- *The health endpoints in the clinical studies, increase in airway resistance (sRaw) and decrement in forced expiratory volume in one second (FEV₁), need to be better framed as indicative of an adverse consequence of SO₂ exposure. There needs to be expanded discussion of the clinical implications of these endpoints and why these endpoints are considered informative measures for setting the NAAQS.*

The REA now includes a discussion of what constitutes an adverse health effect from SO₂ exposure (section 4.3). This discussion concludes that moderate or greater increases in sRaw or decrements in FEV₁ can be clinically significant in

some asthmatics. This discussion also concludes that moderate or greater decrements in FEV₁ and/or increases in sRaw are adverse to the health of asthmatics. The rationale for this conclusion is presented in detail in section 4.3, but in brief, is based on: 1) guidelines published by the ATS, 2) conclusions from the ISA and previous NAAQS reviews, and 3) advice from CASAC. We also note that the clinical implications of these lung function responses are referenced during the policy discussion in section 10.3.3.

- *Chapter 3 needs extensive revision. It reads poorly and does not satisfactorily define or address the key concepts of susceptibility and vulnerability. The EPA should carefully compare the content of this chapter, and particularly the definitions of these concepts, to that of similar chapters in other ISAs and REAs, and even to other EPA documents using these concepts. CASAC found the discussion of vulnerability and susceptibility in the ISA and REA for particulate matter to be better developed and more informative.*

Chapter 3 has been significantly revised, particularly with respect to the discussion of the key concepts of susceptibility and vulnerability. As recommended by the Panel, the discussion of susceptibility and vulnerability (section 3.1) now very closely resembles the discussion presented in the most recent draft of the ISA for PM. In addition, other sections in Chapter 3 have been edited to read more clearly.

- *To the extent possible, the REA should better address the representativeness of the locations with SO₂ monitors considered in the REA, as well as the representativeness of Greene and St. Louis Counties, where the risk analysis was carried out.*

The final REA includes an expanded section 8.10 regarding the representatives of the Greene County and St. Louis study areas. This section includes a number of factors relevant to the air quality, exposure, and lung function risk assessments (e.g., population density, SO₂ emissions and emission densities, variability in ambient monitoring concentrations, time spent outdoors, asthma prevalence rates). In addition, Chapter 9 (section 9.5) now includes discussion addressing the representativeness of these two locations considering the results of the quantitative lung function risk assessment. Chapter 10 includes a discussion of the representativeness of these two locations considering the results of the air quality, exposure, and risk assessments from a policy perspective.

- *The REA should explain what considerations and analyses will be needed to inform a decision with regard to changing or revoking the 24-hour and annual average standards, if a one-hour standard is implemented.*

Recognizing that the decision to retain or revoke the current standards is largely a public health policy judgment to be made by the Administrator, staff presents in section 10.5.4.2 that it is reasonable to conclude that if a new 99th percentile 1-

hour daily maximum standard is selected with a level from the upper end of the range that staff has identified for consideration, then in addition to setting a 99th percentile 1-hour daily maximum standard, consideration should also be given to retaining the existing 24-hour and/or annual standards. However, if the selected level of a 99th percentile 1-hour daily maximum standard is in the lower end of the range, it could reasonably be concluded that consideration should be given to revoking the current 24-hour and/or annual NAAQS.

In addition to responding to the key points raised in the Panel's May 18, 2009 letter to the Administrator, we also note the following changes are also responsive to comments from the Panel:

- Section 2.3 presents background information on the SO₂ monitoring network.
- The health discussion presented in Chapter 4 has been significantly re-written. Rather than presenting the scientific evidence on a study by study basis, the health discussion integrates the controlled human exposure and epidemiologic evidence as it relates to the ISA's conclusion of a causal relationship between short-term exposure to SO₂ and respiratory morbidity.
- The discussion of potential alternative standards presented in Chapter 10 has been expanded to include a more comprehensive evaluation of 98th and 99th percentile forms (section 10.5). More specifically, this discussion contains a more comprehensive evaluation of the number of 5-minute benchmark exceedences given 98th or 99th percentile 1-hour daily maximum standards at a given level (section 10.5.3.2). Moreover, we have included two additional figures (Figures 10-1 and 10-2) that compare stability of design values based on 98th, 99th or 4th highest daily maximum forms. In brief, this additional information strengthens staff conclusions presented in the second draft REA that consideration be given primarily to 1-hour daily maximum standards with a 99th percentile or 4th highest form.
- The "level" discussion for potential alternative standards in Chapter 10 has been re-written for greater clarity.
- The lung function risk assessment now includes risk estimates based on both the probit and 2-parameter logistic exposure-response models.
- Chapter 7 has additional characterization of the ambient monitoring network, including maps of ambient monitoring locations, the variability-type of monitors in each data analysis groups used, and both empirical and logistic-modeled curves used to estimate the probability of 5-minute benchmark exceedences associated with 1-hour daily maximum and 24-hour concentrations. We also provide a comparison of the number of benchmark exceedences when using the 98th and 99th percentile forms at both the 100 and 200 ppb 1-hour daily maximum standard levels.

- Chapter 8 has additional characterization of the dispersion modeled 1-hour concentration distribution (section 8.4.5.1), improved illustration of upper percentiles of 1-hour ambient air concentrations (Figures 8-9 through 8-12), and added two new sections on the body-surface area (8.5.4) and ventilation algorithms (8.5.5) used in estimating moderate or greater activity levels.

Should you have any questions regarding this memorandum, or the final REA, please contact Dr. Michael J. Stewart (919-541-7524; email stewart.michael@epa.gov).

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