THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

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Ana V. Diez Roux, M.D., Ph.D., M.P.H. Chairwoman Clean Air Scientific Advisory Committee Science Advisory Board U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, D.C. 20460

Dear Dr. Diez Roux:

Thank you for your April 15, 2016, letter providing the Clean Air Scientific Advisory Committee Sulfur Oxides Review Panel's comments on the U.S. Environmental Protection Agency's Integrated Science Assessment for Sulfur Oxides – Health Criteria (External Review Draft – November 2015). We at the EPA greatly appreciate the panel's thorough review and constructive comments.

My staff is carefully considering your comments and recommendations as well as the comments we received from the public. We are making revisions to address both consensus and individual CASAC comments. Enclosed is an overview of the major revisions we are incorporating into the Second External Review Draft of the ISA for Sulfur Oxides – Health Criteria. Some of the key changes we are making in response to the CASAC's comments are highlighted below.

We are paying particular attention to several important points that the CASAC panel raised, including the need to:

- revise the language for the executive summary to make it more understandable for a nontechnical audience;
- clarify source categories and definitions of major sources of sulfur oxides;
- update the air-quality analysis to incorporate more recent data;
- reorganize and clarify the discussion of human exposure to sulfur oxides to distinguish between issues relevant to all criteria air pollutants and those that are specific to SO₂;
- revisit determinations made within the causal framework for short-term SO₂ exposure and cardiovascular effects as well as for long-term SO₂ exposure and total mortality, reproductive/developmental effects, and cancer; and
- clarify the discussion of potential at-risk populations.

To address the CASAC panel's recommendations for improving the executive summary, we are revising that section to make it more accessible to a general audience and more clearly summarize the key findings of the ISA with minimal technical jargon.

In the chapter on atmospheric sciences we are clarifying the description of source categories and the definition of major sources to identify more clearly the different sources contributing to human exposure to ambient SO₂. In response to the CASAC panel's recommendations we are adding additional material

on the chemistry and transformation of sulfur oxides, measurement methods for SO₂, relationships between SO₂ concentrations measured at different averaging times, dispersion modeling and relationships between SO₂ concentrations and concentrations of co-pollutants. We are also updating the air-quality analyses to represent more recent SO₂ concentration data.

We are reorganizing the chapter on exposure to ambient SO₂ to more clearly distinguish material that applies to criteria pollutants in general from material that is specific to SO₂ exposure. We are also moving material on monitoring methods and co-pollutant exposure from the exposure and atmospheric sciences chapter to help eliminate redundancy and improve clarity and flow.

We greatly appreciate the CASAC panel members' consideration of the draft ISA's treatment of potential SO₂ effects outside the respiratory system and their recommendations on the level and quality of evidence for these effects. The second external review draft will reconsider the causal determinations for short-term exposure and cardiovascular effects and for long-term exposure and total mortality, reproductive and developmental effects, and cancer in light of the CASAC panel's advice.

The CASAC panel also offered advice on the characterization of populations and lifestages potentially at greater risk of health effects due to SO₂ exposure. We are revising this chapter to more clearly articulate the types of factors that contribute to increased risk and clarify the approach used to categorize the body of evidence for potential at-risk populations and lifestages. As the panel recommended, we will also better integrate material on effect modification between the at-risk chapter and the health effects chapter.

We recognize that our efforts to protect the environment can be only as good as the science upon which it is based. Independent critical reviews such as yours help ensure that we use the best science to protect public health and our nation's environment. Please accept my gratitude for your hard work.

Sincerely,

Gina McCarthy

Enclosure

ATTACHMENT

Overview of Revisions to the Draft ISA for Sulfur Oxides - Health Criteria in Response to CASAC Peer Review Comments dated April 15, 2016

Executive Summary

Both the Executive Summary and Chapter 1 are being revised to reflect changes made to the subsequent chapters. The language is being simplified for a non-technical audience by removing scientific jargon. The revised Executive Summary will emphasize a number of important points raised by the CASAC panel, including the basis for the current 1-hour SO₂ standard, definitions of short- and long-term exposure, the relationship between 5-minute average and 1-hour average SO₂ concentrations, and ambient background levels of SO₂.

Chapter 1 - Summary of the Integrated Science Assessment

Chapter 1 is being revised to more clearly characterize the rationale for the use of SO_2 as an indicator for gaseous sulfur oxides and describe the basis for the current 1-hour SO_2 standard. As with the Executive Summary, revisions made to subsequent chapters will be reflected in Chapter 1.

Chapter 2 - Atmospheric Chemistry and Ambient Concentrations of Sulfur Oxides

Revisions to Chapter 2 are aimed at improving characterization of sources, atmospheric chemistry and fate, measurement methods, environmental concentrations, dispersion modeling, and copollutant concentrations for gaseous sulfur oxides. The chapter is being revised to clarify the amount and geographic location of emissions of sulfur oxides and other copollutants from major sources, particularly those emitting more than 2000 tons/year identified under the Data Requirements Rule. Staff are expanding the atmospheric chemistry section to provide more information on other sulfur-containing species and their relationship to gaseous sulfur oxides, particularly SO₂. To better integrate material across chapters, information on personal monitoring techniques and emerging sensor technology is being brought forward into Chapter 2 from Chapter 3. Also, discussion of the capabilities of the various monitoring methods in the regulatory network will be expanded and clarified.

The air quality analyses in Chapter 2 are being updated to reflect more recent SO_2 concentration data. Staff are working with the U.S. EPA's Office of Air Quality Planning and Standards (OAQPS) to generate maps of upper-percentile SO_2 concentrations to provide background for OAQPS's design value analyses. The analysis of relationships between 5-minute average and 1-hour SO_2 concentrations is being revised to ensure correspondence

between 5-minute and 1-hour values and place the results in context of empirical relationships for air pollution concentrations of various averaging times. Maps of sources near urban areas are being revised and updated to better characterize emissions from different source types and the potential influence of these sources on urban SO₂ concentrations. Staff are also expanding the section on dispersion modeling to describe additional dispersion models and published model performance evaluations to help inform subsequent model analyses conducted by OAQPS. Relationships between SO₂ and copollutant concentrations will be moved to the exposure chapter and discussed in more detail, particularly for scenarios leading to high copollutant correlations.

Chapter 3 - Exposure to Ambient Sulfur Dioxide

Chapter 3 is being reorganized to more clearly describe exposure characteristics that are relevant for all criteria air pollutants and highlight those that are specific to SO_2 . The reorganization will also include moving material on personal monitors and emerging sensors to Chapter 2, bringing in and expanding upon discussion of copollutant concentrations from Chapter 2, moving material on breathing rate to Chapter 4, and refocusing the material on air quality modeling to emphasize applications for exposure assessment. Definitions for key terms will be provided to better support the discussion of ambient exposure and implications for epidemiologic studies. The discussion of air exchange rates and indoor reaction of SO_2 is being expanded and placed in context with published data. To provide a better foundation for interpretation of epidemiologic studies, the chapter will discuss time scales of exposure and the potential impact of the discrepancy between hourly or daily exposure metrics used in epidemiologic studies and the 5-10 minute exposures used in controlled human exposure studies. The discussion of probabilistic exposure modeling is being updated to reflect recent advancements to inform any modeling conducted by OAQPS.

Chapter 4 - Dosimetry and Mode of Action

Revisions are being made to the dosimetry section to define relevant terms and place SO_2 -specific information in a more general context of inhaled gas uptake and distribution. Staff will also consider the potential impact of obesity on dosimetry. In the mode of action section, the discussion of potential effects outside the respiratory system is being revised and clarified to better characterize the potential importance of this pathway. The chapter will also be revised to reframe any discussion of health effects that does not directly address dosimetry or mode of action.

Chapter 5 - Integrated Health Effects of Exposure to Sulfur Oxides

A key revision to Chapter 5 will be the reconsideration of determinations made under the causal framework for short-term exposure and cardiovascular effects, as well as long-term

exposure and total mortality, reproductive and developmental effects, and cancer. To the extent possible, staff will reframe the discussion to focus on the most informative studies, while maintaining appropriate treatment of the entire body of evidence for various health effects. Chapter 5 is also being revised to more thoroughly consider the potential impact of exposure measurement error and copollutant confounding on the results of epidemiologic studies. The discussion of exposure-response functions will be reframed to more appropriately reflect the limited evidence available.

Chapter 6 – Populations and Lifestages Potentially at Risk for Health Effects Related to Sulfur Dioxide Exposure

Chapter 6 is being revised to more clearly identify the three main categories of factors leading to increased risk of SO₂-related health effects, i.e., exposure to elevated concentrations, greater internal dose, and personal or behavioral factors. The approach for classifying the evidence and identifying populations at increased risk is being clarified, and information on activity patterns is being added. Staff will consider ways to better integrate relevant health information from Chapter 5, particularly effect modification.