

Questions for Non-Member Consultants on the PM PA from Dr. Steven Packham

Introduction

The purpose of the NAAQS is to protect public health with an adequate margin of safety. The CASAC is required to review the scientific evidence and knowledge used to establish criteria for pollutants regulated by the NAAQS and to advise the Administrator on whether attainment and maintenance of existing, new and revised NAAQS- allowing [for] an adequate margin of safety - are requisite to protect the public health.

The Overarching context for CASAC Reviews of NAAQS

In the transmittal and charge question memorandum from Director Sasser,¹ reference is made to the two sections of the Clean Air Act governing the establishment and revision of the NAAQS. Director Sasser notes that, since the early 1980s, the independent review function has been performed by the CASAC of the EPA's Science Advisory Board.

A number of other advisory functions are also identified for the committee by section 109(d)(2)(C), which reads:

Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

The Historical Context

The NAAQS review process has evolved over time. Important insights into the role of the CASAC can be gained from studying its history. A *Review of the Process for Setting the National Ambient Air Quality Standards*, published in 2006, memorializes the beginning of official and substantive changes in the nature of CASAC reviews.

Currently, five documents (the Integrated Review Plan (IRP), the Preamble to the Integrated Science Assessment (ISA Preamble), the ISA (the Integrated Science Assessment document intended to replace former Criteria Documents), and the Human Exposure Risk Assessment (HERA) and lastly the Policy Assessment (PA)) set the scope of scientific knowledge and evidence and the rather prescriptive review process for the present CASAC.

Imagine a flow of hundreds of pre-selected scientific studies moving through the IRP-ISA Preamble-ISA-ERA-PA review pipeline in which the CASAC reviews are essentially limited to responding to Charge Questions such as those given from page 3 of the aforementioned memo.

¹Erika N. Sasser, Director, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, United States Environmental Protection Agency

Specific Charge Questions for Review of the Draft PA

1. **Chapter 1 – Introduction:** To what extent does the CASAC find that the information in Chapter 1 is clearly presented and that it provides useful context for the review?
2. **Chapter 2 – PM Air Quality:** To what extent does the CASAC find that the information in Chapter 2 is clearly presented and that it provides useful context for the review?
3. **Chapter 3 – Review of the Primary PM2.5 Standards:** What are the CASAC views on the approaches described in chapter 3 to considering the PM2.5 health effects evidence and the risk assessment in order to inform preliminary conclusions on the primary PM2.5 standards? What are the CASAC views regarding the rationales supporting the preliminary conclusions on the current and potential alternative primary PM2.5 standards?
4. **Chapter 4 – Review of the Primary PM10 Standard:** What are the CASAC views on the approach described in chapter 4 to considering the PM10-2.5 health effects evidence in order to inform preliminary conclusions on the primary PM10 standard? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current primary PM10 standard?
5. **Chapter 5 – Review of the Secondary Standards:** What are the CASAC views on the approach described in chapter 5 to considering the evidence for PM-related welfare effects in order to inform preliminary conclusions on the secondary standards? What are the CASAC views regarding the rationale supporting the preliminary conclusions on the current secondary PM standards?
6. **Chapters 3 to 5:** What are the CASAC views regarding the areas for additional research identified in Chapters 3, 4 and 5? Are there additional areas that should be highlighted?

Consultants, you will appreciate that the **Draft PM PA** is a draft of the last-and-final document to be reviewed by the CASAC before a final report to the Administrator is prepared on the adequacy of the existing PM NAAQS. With this in mind, please consider offering answers, thoughts or suggestions prompted by some, if not all, of the following questions:

- Are there areas (e.g., specific aspects of biological causation, pulmonary toxicology, or causality in epidemiology) in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised PM NAAQS to protect public health with an adequate margin of safety?
- Can you suggest additional specific scientific disciplines and areas of biomedical informatics and research (e.g., systems biology methods for clarifying biological causal pathways, mechanisms, modes of action, quantitative causal dose-response relationships) that should be included in future reviews of other criteria pollutants?
- Can you describe the research efforts necessary to provide the required information? To what extent has the needed research already been done, or started? For example, are there crucial experiments or research initiatives that could clarify the shape of the PM2.5-chronic inflammation causal dose-response relationships at relevant exposure concentrations? Are there specific data analyses (e.g., testing for confounding by weather variables over more days prior to mortality) that could clarify the causal interpretation of epidemiological associations relied on in the draft PA to simulate effects of interventions?
- Can you suggest additional areas of scientific literature review on species and individual human organism's capacities of adaptation to inhaled environmental stressors that might help establish margins of safety when exposed to ambient levels of air pollution?
- Could you provide additional information on the relative contributions to air pollution concentrations and resulting health effects of natural and anthropogenic activity? For example, is either one alone, or are both natural and anthropogenic activities together, sufficient to cause the magnitudes of adverse health effects attributed to PM2.5 in the Draft PA?
- Could you provide additional information on any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards?

Again, thank you for your willingness to share your time and expertise with the CASAC.