



January 30, 2009

MEMORANDUM

SUBJECT: CASAC Review of Integrated Science Assessment for Particulate Matter: First External Review Draft

FROM: John Vandenberg, Ph.D
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TO: Holly Stallworth, Ph.D
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The draft *Integrated Science Assessment for Particulate Matter: First External Review Draft* (ISA) prepared by the Environmental Protection Agency's (EPA) National Center for Environmental Assessment – Research Triangle Park Division (NCEA –RTP) as part of EPA's ongoing review of the national ambient air quality standards (NAAQS) for particulate matter (PM) was released on December 22, 2008. The draft ISA will be reviewed by the Clean Air Scientific Advisory Committee (CASAC) PM NAAQS Review Panel (the CASAC PM Panel) at a public meeting to be held in Chapel Hill, NC on April 1–2, 2009. I am requesting that you forward the draft ISA to the CASAC PM Panel to prepare for that review.

The purpose of the draft ISA is to identify, evaluate, and summarize scientific information on the health and welfare effects associated with PM. The ISA is intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health which may be expected from the presence of [a] pollutant in ambient air” (Clean Air Act, Section 108; 42 U.S.C. 7408). This first external review draft ISA integrates the scientific evidence for review of the primary (health-based) and secondary (welfare-based) NAAQS for PM and provides draft findings, conclusions and judgments on the strength, coherence and plausibility of the evidence. The draft ISA is supported by five Annexes that provide more comprehensive and detailed information on the relevant evidence available from the disciplines of atmospheric sciences and human exposure (Annex A), dosimetry (Annex B), clinical studies (Annex C), toxicology (Annex D), and epidemiology (Annex E). These Annexes are provided with the ISA for the Panel's information. The CASAC PM Panel is being asked to review the draft ISA. NCEA-RTP will also address comments received on supporting material in the Annexes, to the extent that Panel members wish to review and provide comments on the Annexes.

Following the review of the draft ISA, NCEA-RTP staff will produce a second draft ISA, which will be released for CASAC and public review in the summer of 2009. Subsequent steps in the NAAQS review process include risk and exposure assessments, and a draft plan for these assessments will be sent to the CASAC in the next month.

Charge to the CASAC PM Panel

We ask the Panel to focus on the following questions in their review:

1. The framework for causal determination and judging the overall weight of evidence is presented in Chapter 1. Is this framework appropriately applied for this PM ISA? How might the application of the framework be improved for PM effects?
2. Chapter 2 presents the integrative summary and conclusions from the health effects evidence at the beginning of the ISA with the evidence characterized in detail in subsequent chapters. (Environmental and public welfare effects evidence is evaluated and summarized in Chapter 9.) Is this a useful and effective summary presentation? How does the Panel view the inclusion in Chapter 2 of only health categories with causal determinations of (a) likely to be a causal relationship or (b) a causal relationship?
3. To what extent are the atmospheric chemistry and air quality characterizations clearly communicated, appropriately characterized, and relevant to the review of the PM NAAQS? Does the information on atmospheric sciences and exposure provide useful context and insights for the evaluation of human health effects of PM in the ISA?
 - a. Is accurate and appropriate information provided regarding PM source characteristics, techniques for measuring PM and its components, policy-relevant background PM, and spatial and temporal patterns of PM concentration? Are the analyses and figures presented in Chapter 3 effective in depicting ambient PM characteristics?
 - b. Is the evidence relating human exposure to ambient PM and errors associated with PM exposure assessment presented clearly, succinctly, and accurately? Are there PM exposure issues that should be expanded, shortened, added or removed?
 - c. To what extent does the Panel find Annex A appropriate, adequate and effective in supporting the ISA?
4. The dosimetry of PM is discussed in Chapter 4. The primary focus is on factors that might lead to differences in deposition and clearance between individuals, species, and as a function of the physicochemical properties of particles. Is the review of basic dosimetric principles presented in sufficient detail? Are the new particle translocation data adequately and accurately described? Recognizing an overall goal of producing a clear and concise chapter, are there topics that should added or receive additional discussion? Similarly, are there topics that should be shortened or removed? To what

extent does the Panel find Annex B appropriate, adequate and effective in supporting the ISA?

5. Chapter 5 is intended to support the evaluation of health effects evidence for both short-term and long-term exposures to PM. Some potential modes of action may underlie a number of health outcomes and may contribute to health effects of both short- and long-term exposures. Thus, the potential modes of action are described briefly in Chapter 5, and some specific study findings are discussed in more detail in the relevant sections of Chapters 6 or 7. What are views of the Panel on this approach and on the characterization of potential modes of action for PM-related effects in Chapter 5?
6. To what extent are the discussion and integration of evidence on the health effects of PM from the animal toxicological, human clinical, and epidemiologic studies, technically sound, appropriately balanced, and clearly communicated? Does the integration of health evidence focus on the most policy-relevant studies or health findings?
 - a. Are the tables and figures presented in Chapters 6 and 7 appropriate, adequate and effective in advancing the interpretation of these health studies? To what extent does the Panel find Annexes C, D and E appropriate, adequate and effective in supporting the ISA?
 - b. In Chapters 6 and 7, toxicological studies were included in the PM ISA text if they were conducted at PM concentrations $<2 \text{ mg/m}^3$. The toxicological focus in these chapters was on inhalation studies, with intratracheal instillation studies and in vitro studies included only if they contributed significantly to the understanding of health effects from exposure to PM. The toxicological studies excluded from the text are presented in Annex D. What are the Panel members' thoughts on this approach and the selection criteria?
7. What are the views of the Panel on the conclusions drawn in the draft ISA regarding the strength, consistency, coherence and plausibility of the evidence for health effects of PM? In evaluating the evidence to draw preliminary judgments on causality, EPA carefully considered evidence from the various scientific disciplines for the PM indicators and general health or environmental effect categories. Examples of a few specific health categories are listed below that were particularly difficult in reaching a causal determination. We would appreciate CASAC comments on all of the causal determinations presented in this first draft ISA.
 - Short-term exposure to $\text{PM}_{2.5}$ and cardiovascular and respiratory morbidity.
 - Short-term exposure to $\text{PM}_{2.5}$ and mortality.
 - Short-term exposure to $\text{PM}_{10-2.5}$ and respiratory and cardiovascular morbidity, and mortality.
 - Long-term exposure to $\text{PM}_{2.5}$ and mortality.

8. What are the views of the Panel on the definitions of susceptibility and vulnerability in Chapter 8? Are the characteristics included within the broad susceptibility and vulnerability categories appropriate and consistent with the definitions used?
9. How useful and complete is the scientific evidence presented and summarized in Chapter 9 regarding the effects of atmospheric PM on the environment, including (a) effects on visibility, (b) effects on individual organisms, (c) direct and indirect effects on ecosystems, (d) effects on materials, and (e) effects on climate? To what extent do the discussions and integration of evidence correctly represent and clearly communicate the state of the science?
10. This first external review draft PM ISA is of substantial length and reflects the copious amount of research recently conducted on PM. EPA has attempted to succinctly present and integrate the policy-relevant scientific evidence for the review of the PM NAAQS. Does the Panel have opinions on how the document can be shortened without eliminating important and necessary content?

We look forward to discussing these issues with the CASAC PM Panel at our upcoming meeting. Should you have any questions regarding the draft PM ISA, please feel free to contact Dr. Mary Ross (919-541-5170, ross.mary@epa.gov) or Dr. Lindsay Wichers Stanek (919-541-7792, stanek.lindsay@epa.gov).

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