

March 15, 1996

EPA-SAB-CASAC-LTR-96-005

Honorable Carol M. Browner  
Administrator  
U.S. Environmental Protection Agency  
401 M. Street SW  
Washington, DC 20460

Re Closure by the Clean Air Scientific Advisory Committee (CASAC)  
on the draft Air Quality Criteria for Particulate Matter

Dear Ms. Browner:

The Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) has held a series of public meetings during its peer review of the Agency's draft documents which will form part of the basis for your decision regarding the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM). The Committee has held public meetings on December 12-13, 1994 (planning and introductory issues); August 3-4, 1995 (review of the initial draft Criteria Document); December 14-15, 1995 (review of the revised draft Criteria Document and the first draft of the Staff Paper); and February 29, 1996 (review of the revised draft Criteria Document - specified chapters only). A review of the revised draft Staff Paper is planned for May 16-17, 1996. The primary Agency draft documents that we have reviewed are the: a) *Air Quality Criteria for Particulate Matter* (the Criteria Document prepared by the National Center for Environmental Assessment - Research Triangle Park, NC - ORD), and b) *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (the Staff Paper prepared by the Office of Air Quality Planning and Standards - Research Triangle Park, NC - OAR).

As part of our review process, we have kept you informed of our findings through two letter reports: a) *Clean Air Scientific Advisory Committee (CASAC) Comments on the April 1995 draft Air Quality Criteria for Particulate Matter* (EPA-SAB-CASAC-LTR-95-005; August 30, 1995); and b) *Clean Air Scientific Advisory Committee (CASAC) Comments on the November, 1995 Drafts of the Air Quality Criteria for Particulate Matter and the Review of the National Ambient Air Quality Standards for*

*Particulate Matter: Policy Assessment of Scientific and Technical Information (OAQPS Staff Paper)*, (EPA-SAB-CASAC-LTR-96-003, January 5, 1996).

The Clean Air Scientific Advisory Committee, supplemented by a number of expert Consultants (hereinafter referred to as the Panel) reviewed a revised draft of the PM Criteria Document and a first draft of the Staff Paper for Particulate Matter at a meeting on December 14-15, 1995 in Chapel Hill, NC. At that meeting and in subsequent written comments by individual members which were provided to EPA Staff, the Panel made numerous recommendations for improving the draft document. The Panel was impressed with the breadth and scope of the latest revision of the draft Criteria Document and agreed that, except for Chapters 1 (Executive Summary), 5 (Sources and Emissions), 6 (Air Quality), and 13 (Integrative Synthesis), only minor revisions would be necessary to make the remainder of the draft Criteria Document satisfactory for providing an adequate scientific basis for regulatory decisions on PM based on available information. However, the Panel felt that Chapters 1, 5, 6, and 13 required major revisions which the Panel would need to review again.

On February 29, 1996, the Panel again met in Chapel Hill, NC to review revised drafts of Chapters 1, 5, 6, and 13 of the Criteria Document. While Chapter 13 can be improved, as suggested below, I want to take this opportunity, on behalf of the entire Panel, to commend Dr. Lester Grant and his staff in the National Center for Environmental Assessment (NCEA) for producing its best ever example of a true integrative summary of the state of knowledge about the health effects of airborne PM and the associations between the effects and the various available indices of PM exposure. NCEA has outlined some of the options for your subsequent choice of available PM indicators for a NAAQS by examining the degrees of association between various health indices and PM indicators including total suspended particulate (TSP), thoracic particulate ( $PM_{10}$ ), fine particulate ( $PM_{2.5}$ ), sulfate particulate ( $SO_4^{2-}$ ), acid particulate ( $H^+$ ) and carbonaceous particulate (BS and CoH), with available knowledge from dosimetry, results of controlled human exposure studies in humans and laboratory animals, and mechanistic understandings. This thorough review and evaluation also provides an important starting point for focussing the future PM research program on studies that can better identify the compositional and particle size characteristics of the most biologically active agents within the  $PM_{10}$ . We were especially impressed that this integrative summary could be produced in the short time period since our review of the initial rough draft in December 1995.

This letter is a summary of our findings and conclusions from the February 29th meeting. Our comments reflect our satisfaction with the improvements made in the scientific quality and completeness of these chapters. The changes made in these chapters are consistent with our earlier recommendations. However, the Panel provided additional comments to your staff at the meeting and subsequently in writing. Although we feel that it is essential to have these additional comments considered for

incorporation in the Criteria Document, we did not feel that it was essential to review another revised version and, thus, we came to closure on the entire Criteria Document anticipating incorporation of our suggested changes. It was our consensus that although our understanding of the health effects of PM is far from complete, a revised Criteria Document which incorporates the Panel's latest comments will provide an adequate review of the available scientific data and relevant studies of PM. With the incorporation of our suggested changes, the revised Criteria Document will be very comprehensive and will provide an adequate scientific basis for regulatory decisions on particulate matter based on available information. However, a number of members have expressed concern that since we are closing on the Criteria Document before we will be able to see the revised version, we have no assurance that our comments will be incorporated. I will return to this concern later.

I would like to summarize for you the Panel's major comments on Chapters 1, 6, and 13. There were no major comments on Chapter 5. In Chapter 6, Panel members raised issues concerning the definition and level of background PM concentrations. The Panel has provided the Agency with guidance in the written comments to resolve these concerns. This is an important issue because some studies suggest effects at levels which approach background concentrations.

Of the 17 members of the Panel present, five were satisfied with Chapter 13 as is, four had no substantive comments because their expertise was outside of Chapter 13, and eight had some substantive comments on one or more aspects of the chapter which I summarize below. The members who were satisfied with the chapter praised the Agency for making a compelling case for  $PM_{2.5}$  being the best available surrogate index for the causal agent. They thought EPA presented a large body of consistent and coherent studies and that they were appropriately presented as an integrative synthesis. The issues raised by the other Panel members regarding Chapter 13 fell into three categories. First, several Panel members felt that additional discussions of the inherent errors associated with air sampling, estimating human exposure from central monitoring data, and relating these data to excess mortality and morbidity were necessary so that the uncertainties of the relative risk estimates would be better appreciated.

Second, about half of the Panel members expressed concern that the case made in the Criteria Document for  $PM_{2.5}$  being the best available surrogate for the principal causative agent in  $PM_{10}$  may be overstated, and that EPA has not adequately justified its rejection of other alternative explanations discussed next. In addition, it needs to be acknowledged that large particles (e.g.,  $d \approx 4.0 \mu m$ ) may be responsible for acute respiratory effects, especially in susceptible groups such as asthmatics.

Third, several Panelists pointed out that a number of recently published (or in-press) studies (including the Health Effects Institute study), which were conducted to

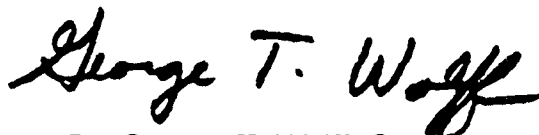
critically evaluate some of the epidemiological studies using alternative models or including additional gaseous pollutant data, present a different perspective of the PM/mortality issue than the one presented in this chapter. Collectively, these reanalyses have confirmed the reproducibility of the earlier studies, but they also present a more complicated relationship in which causality does not appear to be unambiguously attributed to any single pollutant let alone a specific portion of the PM. EPA on the other hand emphasized a PM causal conclusion based on the pattern of associations across multiple sites having different pollutant mixtures. These results need to be discussed adequately in Chapter 13.

Our only comments on Chapter 1, the Executive Summary, were that it reflect the revisions that have been recommended for Chapters 6 and 13.

As mentioned above, Panel members have expressed concern that the Agency may not be responsive to some of our comments or may misinterpret them since we will not have another opportunity to review the final document. This concern is another unfortunate consequence of the court-mandated "accelerated" time schedule, but nevertheless, it is a real concern. We anticipate being advised of text changes made in response to our concerns prior to or at the May 16-17, 1996 meeting, and we can advise you afterward about whether our concerns have been adequately addressed by the Agency.

On behalf of the Panel, I would like to thank EPA staff for their considerable efforts in preparing the Criteria Document on the accelerated schedule. We look forward to seeing the revised final version once it is completed. The Panel also looks forward to reviewing the revised Staff Paper during the public meeting presently scheduled for May 16-17, 1996.

Sincerely,

A handwritten signature in black ink that reads "George T. Wolff". The signature is written in a cursive, flowing style.

Dr. George T. Wolff, Chair  
Clean Air Scientific  
Advisory Committee

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