

June 13, 1996

EPA-SAB-CASAC-LTR-96-008

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

Subject: Closure by the Clean Air Scientific Advisory Committee (CASAC) on the Staff Paper 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); February 29, 1996 (review of the revised draft Criteria Document - specified chapters only, and the Office of Air Quality Planning and Standards (OAQPS) Risk Assessment Plan); and May 16-17, 1996 (review of the revised draft Staff Paper). 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), 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), and c) *A Particulate Matter Risk Analysis for Philadelphia and Los Angeles* (draft), 1996, Prepared by Abt Associates for US EPA.

As part of our review process, we have kept you informed of our findings through three 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); 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), and c) *Closure by the Clean Air Scientific Advisory Committee (CASAC) on the draft Air Quality Criteria for Particulate Matter* (EPA-SAB-CASAC-LTR-96-005, March 15, 1996).

The Clean Air Scientific Advisory Committee, supplemented by a number of expert Consultants (hereinafter referred to as the "Panel"), reviewed a first draft of the Staff Paper for Particulate Matter at the December 14 and 15, 1995 meeting 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 met again on May 16, 1996 in Chapel Hill, NC and on May 17, 1996 in Research Triangle Park, NC to review a revised draft of the Staff Paper and the recommendations contained within the Staff Paper for the level and form of the proposed PM NAAQS. This letter is a summary of our findings and conclusions from that meeting.

It was the consensus of the Panel that although our understanding of the health effects of PM is far from complete, the Staff Paper, when revised, will provide an adequate summary of our present understanding of the scientific basis for making regulatory decisions concerning PM standards. Seventeen of the twenty-one Panel members voted for closure. There were two no votes, one abstention, and one absence. However, most of the members who voted for closure did so under the assumption that the Agency would make significant changes to the next version of the Staff Paper which is due by July 15, 1996 (a court ordered mandate). The desired changes have been articulated to your staff at the meeting and subsequently in writing.

The Panel endorses the EPA Staff's recommendation not to establish a separate secondary PM NAAQS for regulating regional haze and agrees that there is an inadequate basis for establishing a secondary NAAQS to reduce soiling and material damage effects.

The attached table (Table I) summarizes the Panel members' recommendations concerning the form and levels of the primary standards. Although some Panel members prefer to have a direct measurement of coarse mode PM ($PM_{10-2.5}$) rather than using PM_{10} as a surrogate for it, there is a consensus that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time. A majority of the members recommend keeping the present 24-hour PM_{10} NAAQS, at least as an option for the Administrator to consider, although those commenting on the form of the standard strongly recommended that the form be changed to one that is more robust than the current standard. There was also a consensus that a new $PM_{2.5}$ NAAQS be established, with nineteen Panel members endorsing the concept of a 24-hour and/or an annual $PM_{2.5}$ NAAQS. The remaining two Panel members did not think any $PM_{2.5}$

NAAQS was justified. However, as indicated in Table I, there was no consensus on the level, averaging time, or form of a $PM_{2.5}$ NAAQS. At first examination of Table I, the diversity of opinion is obvious and appears to defy further characterization. However, the opinions expressed by those endorsing new $PM_{2.5}$ NAAQS can be classified into three broad categories. Four Panel members supported specific ranges or levels within or toward the lower end of the staff's recommended ranges. Seven Panel members supported specific ranges or levels near, at, or above the upper end of staff's recommended ranges. Eight other Panel members declined to select a specific range or level, but most had comments which appear as footnotes in Table I.

A number of Panel members based their support for a $PM_{2.5}$ NAAQS on the following reasoning: there is strong consistency and coherence of information indicating that high concentrations of urban air pollution adversely affect human health, there are already NAAQS that deal with all the major components of that pollution except $PM_{2.5}$, and there are strong reasons to believe that $PM_{2.5}$ is at least as important as $PM_{10-2.5}$ in producing adverse health effects.

Part of this diversity of opinion can be attributed to the accelerated review schedule. While your staff is to be highly commended for producing such quality documents in such a short period of time, the deadlines did not allow adequate time to analyze, integrate, interpret, and debate the available data on this very complex issue. Nor does a court-ordered schedule recognize that achieving the goal of a scientifically defensible NAAQS for PM may require iterative steps to be taken in which new data are acquired to fill obvious and critical voids in our knowledge. The previous PM NAAQS review took eight years to complete.

The diversity of opinion also reflects the many unanswered questions and uncertainties associated with establishing causality of the association between $PM_{2.5}$ and mortality. The Panel members who recommended the most stringent $PM_{2.5}$ NAAQS, similar to the lower part of the ranges recommended by the Staff, did so because they concluded that the consistency and coherence of the epidemiology studies made a compelling case for causality of this association. However, the remaining Panel members were influenced, to varying degrees by the many unanswered questions and uncertainties regarding the issue of causality. The concerns include: exposure misclassification, measurement error, the influence of confounders, the shape of the dose-response function, the use of a national $PM_{2.5}/PM_{10}$ ratio to estimate local $PM_{2.5}$ concentrations, the fraction of the daily mortality that is advanced by a few days because of pollution, the lack of an understanding of toxicological mechanisms, and the existence of possible alternative explanations.

In recommending that the staff carry out a risk assessment, it was the expectation of CASAC that the risk assessments would narrow the diversity of opinion by evaluating how all of the uncertainties propagate throughout the entire model.

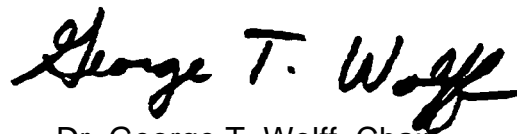
However, not all of the uncertainties could be included and the combined effect of all of them could not be examined. The Panel recommended that additional analyses be conducted to present combined uncertainties. However, currently the risk assessments are of limited value in narrowing the diversity of opinion within the Panel.

The Panel is unanimous, however, in its desire to avoid being in a similar situation when the next PM NAAQS review cycle is under way by a future CASAC Panel. The Agency must immediately implement a targeted research program to address these unanswered questions and uncertainties. It is also essential that we obtain long-term PM_{2.5} measurements. CASAC is ready to assist the Agency in the development of a comprehensive research plan that will address the questions which need answers before the next PM review cycle is completed. We understand that your staff is preparing a PM research plan for our review later this summer. We look forward to providing our comments on this important matter.

CASAC recognizes that your statutory responsibility to set standards requires public health policy judgments in addition to determinations of a strictly scientific nature. While the Panel is willing to advise you further on the PM standard, we see no need, in view of the already extensive comments provided, to review any proposed PM standards prior to their publication in the Federal Register. In this instance, the public comment period will provide sufficient opportunity for the Panel to provide any additional comment or review that may be necessary.

Thank you for the opportunity to present the Panel's views on this important public health issue. We look forward to your response to the advice contained in this letter.

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

TABLE I
Summary of CASAC Panel Members Recommendations
(all units $\mu\text{g}/\text{m}^3$)

		PM_{2.5} 24-hr	PM_{2.5} Annual	PM₁₀ 24-hr	PM₁₀ Annual
Current NAAQS		N/A	N/A	150	50
EPA Staff Recommendation		18 - 65	12.5 - 20	150 ¹³	40 - 50
Name	Discipline				
Ayres	M.D.	yes ²	yes ²	150	50
Hopke	Atmos. Sci.	20 - 50 ³	20 - 30	no	40 - 50 ⁴
Jacobson	Plant Biologist	yes ²	yes ²	150	50
Koutrakis	Atmos. Sci.	yes ^{2,5,6}	yes ^{2,5,6}	no	yes ⁴
Larntz	Statistician	no	25-30 ⁷	no	yes ²
Legge	Plant Biologist	≥ 75	no	150	40 - 50
Lippmann	Health Expert	20 - 50 ³	15 - 20	no	40 - 50
Mauderly	Toxicologist	50	20	150	50
McClellan	Toxicologist	no ⁸	no ⁸	150	50
Menzel	Toxicologist	no	no	150	50
Middleton	Atmos. Sci.	yes ^{2,3,12}	yes ^{2,5}	150 ^{3,13}	50
Pierson	Atmos. Sci.	yes ^{2,9}	yes ^{2,9}	yes ⁴	yes ⁴
Price	Atmos. Sci./ State Official	yes ^{3,10}	yes ¹⁰	no ^{3,4}	yes ⁴
Shy	Epidemiologist	20 - 30	15 - 20	no	50
Samet ¹	Epidemiologist	yes ^{2,11}	no	150	yes ²
Seigneur	Atmos. Sci.	yes ^{3,5}	no	150 ¹³	50
Speizer ¹	Epidemiologist	20 - 50	no	no	40 - 50
Stolwijk	Epidemiologist	75 ⁷	25-30 ⁷	150	50
Utell	M.D.	≥ 65	no	150	50
White	Atmos. Sci.	no	20	150	50
Wolff	Atmos. Sci.	≥ 75 ^{3,7}	no	150 ³	50

¹ not present at meeting; recommendations based on written comments

² declined to select a value or range

³ recommends a more robust 24-hr. form

⁴ prefers a PM_{10-2.5} standard rather than a PM₁₀ standard

⁵ concerned upper range is too low based on national PM_{2.5}/PM₁₀ ratio

⁶ leans towards high end of Staff recommended range

- ⁷ desires equivalent stringency as present PM₁₀ standards
- ⁸ if EPA decides a PM_{2.5} NAAQS is required, the 24-hr. and annual standards should be 75 and 25 µg/m³, respectively with a robust form
- ⁹ yes, but decision not based on epidemiological studies
- ¹⁰ low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have PM_{2.5} pollution problems
- ¹¹ only if EPA has confidence that reducing PM_{2.5} will indeed reduce the components of particles responsible for their adverse effects
- ¹² concerned lower end of range is too close to background
- ¹³ the annual standard may be sufficient; 24-hr level recommended if 24-hour standard retained

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