



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR  
SCIENCE ADVISORY BOARD

March 16, 2006

**MEMORANDUM**

**SUBJECT:** Clean Air Scientific Advisory Committee Members' Comments on the Agency's Process for Establishing National Ambient Air Quality Standards

**FROM:** Vanessa T. Vu, Staff Director     */signed/*  
EPA Science Advisory Board

**TO:** William Wehrum  
Assistant Administrator for Air and Radiation  
  
George Gray  
Assistant Administrator for Research and Development

In response to your memorandum to me dated February 17, 2006, I sent invitations to current and former members of the Clean Air Scientific Advisory Committee (CASAC), asking for their individual comments regarding EPA's process by which the National Ambient Air Quality Standards (NAAQS) for "criteria" air pollutants are established. As of March 16, we have received seven (7) sets of comments, which are attached for your consideration.

Thank you for requesting CASAC's input into this important Agency review.

Attachment

Attachment: CASAC Members' Individual Comments on EPA's NAAQS Process

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## **Dr. Ellis Cowling**

**Dr. Ellis Cowling  
North Carolina State University**

**March 15, 2006**

### Comments on the Experience and Value of CASAC's Advice and Counsel in Assisting EPA in Establishing National Ambient Air Quality Standards for Criteria Pollutants

The current call for a “top-to bottom” review of the processes used by EPA and its Congressionally-authorized Clean Air Science Advisory Committee (CASAC) is the latest in a long series of reviews of NAAQS-development processes during the past three and one-half decades since the creation of EPA in 1970. The reviews of which I am aware (and which I have reviewed once again in recent weeks) include evaluative reports on CASAC's performance in service to EPA in 1979, 1981, 1983, and 1987 in addition to the peer-reviewed paper on this same subject published by Morton Lippmann in 1987. In the context of the present debate, I commend each of these evaluative reports for the wisdom they collectively bring to the challenge of designing an optimum system by which NAAQS should be developed in the future.

One year ago now, Philip Hopke stepped down from his responsibilities as Chair of CASAC. In his recent written “Comments on the NAAQS Review Process,” Hopke has provided a series of carefully considered recommendations that derive from his long and experience as an effective leader of CASAC. I also commend his recommendations for consideration in the context of the present “top-to-bottom” review of the NAAQS development processes – especially:

- 1) His direct references to the explicit directives of the US Congress in establishing CASAC and defining its membership, its duties to “recommend to the Administrator any new ambient air quality standards,” and to “advise the Administrator [about] “research efforts necessary to provide the required information” and “any adverse ... effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.”
- 2) His firm comments on the “Distinctions between Science and Policy Judgments,” and
- 3) His specific recommendation that the centerpiece of every Criteria Document should be the “Integrative Synthesis Chapter” [and I would add, a very carefully crafted “Executive Summary”] for each Criteria Document and Staff Paper. Both of these major documents should be written with careful recognition of “the major take home messages” from each document. The intent being to focus CASAC's scientific reviewing attention on “the content that matters most” in informing final policy decisions by the Administrator of EPA.

Although I am a relatively recent (2004) appointee to Membership in CASAC, my impression is that the scientific review processes used can be improved substantially by taking full advantage of the experience and insights from other organizations that produce high-quality science-based policy analysis products or have studied in a rigorous way the processes by which

high-quality assessment documents are produced. These other organizations include the following:

- 1) The special science- and policy-focused subject-matter committees established by the National Research Council (NRC) within the National Academy of Sciences (NAS) — with detailed oversight and review of all NRC reports provided by the Academies' demanding Report Review Committee,
- 2) The authoritative analyses of the science-and-policy assessment processes used in various countries of the world. Two of these very rigorous analyses of the processes and quality of the resulting assessment documents have been produced by Dr. William Clark and other leaders for the "Social Learning" and "Global Environmental Assessment" projects at the Kennedy School of Government at Harvard University, and
- 3) The science and policy interface recommendations developed by the Oversight Review Board of the National Acid Precipitation Assessment Program led by Milton Russell, former Assistant Administrator for EPA, Chauncey Starr, former Director of Research for the Electric Power Research Institute (EPRI), Tom Malone, former Foreign Secretary for the National Academy of Sciences, John Tukey, Distinguished Professor of Statistics at Princeton University, and Kenneth Starr, Nobel Prize Winner in Economics.

It was my good fortune to have the opportunity to participate in all three of these organizations during the past 15-20 years:

- 1) As a member of several special science and policy subject matter committees dealing with air-quality relevant reports by the NRC, and later, as a Member for several additional years in the Report Review Committee of the NRC;
- 2) As an Adjunct Faculty Member in both the "Social Learning" and "Global Environmental Assessment" projects at the Kennedy School of Government; and
- 3) As the Liaison between the Office of the Director of NAPAP and the NAPAP Oversight Review Board led by Milton Russell.

From many lessons learned from these three experiences, permit me to offer the following generalizations regarding the value and limitations of science, and the appropriate roles that scientists, engineers, policy analysts, and decision makers can and should play in making science-based public policy decisions in general — and in particular — in the establishment of National Ambient Air Quality Standards and in management of air quality in our country:

Science is the discovery of new knowledge through research. Scientific inquiry is driven mainly by the curiosity and enthusiasm of individuals, and groups of scientists and engineers. Scientific inquiry involves hypotheses, measurements, testing, and development of conclusions and concepts based on inductive and deductive reason. Basic research is inquiry aimed at understanding the physical, biological, social, and mathematical world around us. Applied research is inquiry aimed at discovering useful guidelines for management of air quality, natural resources, business enterprises, social and governmental institutions, and the health, educational, recreational, and other services needed by society.

Science provides the power to understand natural phenomena, and, by virtue of that power, to expand the range of choices for management of nature and human institutions. Technology is the art of making things useful. Technological innovation provides the means

by which the power of science can be harnessed to drive the economic and social systems of society by providing new products, processes, and services that are needed by society.

But science and technology alone cannot provide the wisdom to make wise choices. Wisdom derives not only from science and engineering, but also from the humanities. For this reason, the power of scientific and technological innovation must be balanced and focused for the benefit of society by reflective study of philosophy, justice, aesthetics, history, religious faith, and all the pain and suffering as well as the joys and satisfactions of individuals and groups within society.

Assessment leading to formulation of wise public policy is a process by which scientific and technological evidence is marshaled for the purposes of predicting the outcomes of alternative courses of action. Assessment is not driven by individual or even collective curiosity. In its best form, assessment is driven by a prescribed set of policy-relevant issues that ideally are written down in a coherent set of policy-oriented questions for which precise answers, having to do with both science and societal values, are central. Assessment involves analyzing the quality of scientific understanding and identifying and bounding uncertainty so that decision makers can act with an appropriate interpretation of the benefits, costs, values held dear, and risks that are expected to be associated with alternative courses of action.

There are four actor groups — each with its own distinctive role and responsibility — that should play proactive roles in making air-quality management decisions: 1) scientists and engineers, 2) policy analysts, 3) decision makers, and 4) professional communicators.

The responsibility of scientists, engineers, and policy analysts is to understand and clearly communicate the scientific facts and uncertainties and to describe expected outcomes objectively. Deciding what to do involves questions of societal values where scientists, engineers, and policy analysts have no special authority. For this reason, the processes of risk assessment are very different from the processes of risk management, scientific reviewing, legislative policy analysis, and judicial review.

The proper role of scientists and engineers is to discover and communicate the facts and uncertainties associated with the facts. The proper role of policy analysts is to consider the facts and associated uncertainties in the light of values held dear by different sectors of society. Policy analysts should also provide, for consideration by decision makers, advice and counsel about alternative courses of action and the extent to which various sectors of society's interests will be affected by each alternative policy option.

In democratic societies, decision makers are those who are charged by our society to make policy decisions – captains of industry, leaders in legislative bodies, executive office officials, judges and juries in courts of law, and leaders in public-interest organizations.

Communication is also crucial in the processes of sound public decision-making — communication of research program findings, communication of alternative choices among assessment options, communication of certainties and uncertainties. Careful and precise communications are needed among all parties in decision making processes — among scientists and engineers, policy analysts, and decision makers themselves, between each of these groups, and between each of these groups and the public at large. Audiences differ widely in their interests, sophistication, and the importance of the subject to them. Scientists and policy analysts are selected and educated to discover new knowledge on the one hand and to consider alternative courses of action on the other, not necessarily because we are

excellent at communications. For this reason, professional communicators constitute the fourth important group of actors in the processes of assessment and public decision-making.

Professional communicators can also serve a vital function in ensuring that members of all actor groups do not ‘talk past each other’. Perhaps the greatest contribution that communicators can make to public policy making is to help members of these other professional groups achieve an ideal expressed well in the words of Dr. Daniel Albritton of the National Oceanic and Atmospheric Administration — if they will learn to become ‘amphibians’ in the mixed-media environment of science and public policy, then critical barriers to understanding will be decreased and appropriate use of scientific knowledge in public decision-making will be increased.

Scientific assessment of air-quality management options requires much more than just research planning and reporting. A scientific assessment will certainly involve research, but assessment is focused on reporting an integrated view of current conditions and future projections. Thus assessment includes causes and effects, management options, economic and social costs and benefits of different options, and sufficient analysis of future scenarios to identify potentially efficient and effective management approaches. A science-based assessment should provide information useful for the public, policy officials, and leaders in various stakeholder communities whose interests and values will be affected — including information on the scientific confidence to be attached to assessment findings. Research and assessment should be parallel activities with continuous feedbacks.

A major science-based assessment requires a written plan that identifies the key questions to be addressed, and indicates how measurement data, air-quality models, cost-benefit calculations, and other relevant information will be used to address the assessment questions. A written plan, developed with extensive comments by inside and outside communities (i.e., the assessment team, and the potential users of the assessment information) is an essential communication tool. For the assessment team, it establishes the goal and methodologies to be adopted, and identifies the context for the work of individual members of the team. For assessment users, it provides a clear view of the questions being addressed, the limitations of the analyses, and the schedule for the reporting of key findings and recommendations with respect to each management option under consideration.

### **Specific Comments and Recommendations for Future NAAQS Development Processes**

This past year has provided an unusual opportunity for CASAC, NCEA, and OAQPS to work together in efforts to further optimize the design and organization of Air Quality Criteria Documents and Staff Papers. During this one year, in rather rapid succession, CASAC has reviewed both planning documents, and reviewed drafts of both criteria documents and staff papers for three of the five pollutants presently recognized criteria pollutants. In each case, CASAC has been presented with very large documents that require very careful attention from the standpoint of many different scientific disciplines. The Members and Panelists in CASAC have provided these multidisciplinary perspectives.

The laws of our country require that this difficult and challenging intellectual work should be accomplished periodically (ideally every five years) by scientists, engineers, policy analysts, and decision makers who are charged by our society to do their respective parts — leading to scientifically sound, policy effective, and socially acceptable decisions in a contentious democratic society that often is resistant to change and frequently uses the courts of our country

to set demanding deadlines for the development of Criteria Documents, Staff Papers, and the promulgation and implementation of Regulations and Rules for air quality management.

**It also has become very obvious that the funds currently being provided for NCEA to produce Criteria Documents are not adequate to the task and that substantial increases will have to be provided if EPA is ever to get out of the vicious cycle of always having to develop Criteria Documents under rushed circumstances that preclude the production of optimal-quality and well-focused summaries of the science that is relevant to making wise decisions about NAAQS.**

During the past year CASAC Members and Panelists have reviewed and offered carefully considered individual and collective advice and counsel about the adequacy of the criteria documents, staff papers, and the proposed rules and regulations for ozone and other photochemical oxidants, fine and coarse particulate matter, and, most recently, atmospherically deposited lead pollutants.

In all three of these cases, CASAC has done its best to review the documents prepared by NCEA and OAQPS and to offer our individual and collective counsel and advice about the scientific content, organization, and the scientific objectivity and tone of impartiality of these very large criteria documents.

Beginning in the case of the Criteria Document and Staff Paper for Ozone and Related Photochemical Oxidants, a somewhat different organizational structure was used by NCEA.

The new organizational format called for relatively brief Main Chapters that consist of two parts:

- 1) A concise summary of “Key findings/conclusions” from earlier assessment documents, and
- 2) Carefully prepared descriptions of advances in scientific understanding that have been developed since the time of the last review and published in more recent scientific literature.

The new structure also calls for development of very detailed Annexes for each Main Chapter in which many important advances in scientific understanding are presented in much more thorough fashion than in the corresponding Main Chapter.

The final features of the new structure and organization of Air Quality Criteria Documents were development of both an Integrative Summary Chapter and an Executive Summary for the whole Criteria Document. The purpose of these two additional parts was to draw together the major findings and conclusions of scientific understanding developed within each of the Main Chapters and corresponding Annexes and to present in an integrative way the Key Findings and Conclusions (from both earlier assessment reports and description of more recent scientific advances) and thus provide a maximally useful foundation for the Staff Paper.

In the words of OAQPS, the purpose of the Staff Paper is to: “provide a critical assessment of the latest available scientific information upon which the National Ambient Air Quality Standards are to be based. Drawing upon the AQCD, staff in EPA’s Office of Air Quality planning and Standards (OAQPS) within the Office of Air and Radiation prepares a Staff Paper that evaluates policy implications of the key studies and scientific information contained in the AQCD and presents the conclusions and recommendations of the staff for

standard setting options for the EPA Administrator to consider. The Staff Paper is intended to ‘bridge the gap’ between the scientific assessments contained in the AQCD and the judgments required of the Administrator in determining whether it is appropriate to retain or to revise the primary and secondary NAAQS.”

Many Members and expert Panelists within CASAC are very pleased with the good sense of the revised structure and format of Criteria Documents. We are convinced that these innovations in the overarching method of organization of Criteria Documents will better serve the interests of the wide variety of audiences that are interested to learn more about scientific understanding of each of the criteria pollutants and their effects on both human health and welfare. Thus, many of us believe that these innovations in structure should be retained and used in the future in preparing other Criteria Documents for other Criteria Pollutants.

In doing so, it is of course important that the different target audiences for the Executive Summary, the Main Chapters of the Criteria Document itself, and the various Annexes be very well defined and well understood by all of the staff, consultants, and editors that prepare these three different treatments of the same body of scientific knowledge.

It is even more imperative that the scientific content, objectivity, and tone of impartiality of the Executive Summary and the Integrative Summary Chapter of the Criteria Document [and the Staff Paper as well!] be consistent not only with the scientific content, objectivity, and tone of impartiality of the Main Chapters of the Criteria Document itself, but also with the scientific content and objectivity of the more detailed Annexes. Differences in content of these different parts of the same Criteria Document [and the related parts of the Staff Paper] should be based primarily on their relevancy to their respective purposes and target audiences. Discrepancies in scientific content, objectivity, and tone of impartiality in these distinct parts of the Criteria Document and Staff Paper will inevitably lead to decreased confidence in the validity and reliability of the different parts of both types of documents. Thus such discrepancies must be carefully avoided. This will require a larger degree of common understanding among authors, consultants, editors, and managers of the Criteria Document and Staff Paper development processes than many Members and Panelists within CASAC believe has been achieved to date.

A useful mechanism for ensuring that there is an effective and concise summary of “Key Findings and Conclusions” in each Main Chapter is to require that an Executive Summary be prepared for each Main Chapter and that these statement of Key Findings and Conclusions from individual Main Chapters be used in constructing both the Executive Summary for the whole Criteria Document and in developing the organizational framework for the Integrative Summary Chapter.

In written comments on the Criteria Document for Ozone and Other Photochemical Oxidants dated December 2, 2005 I recommended [and affirm here once again] that all authors, consultants, editors, and managers engaged in the preparation of Criteria Documents and EPA Staff Papers take full advantage of- and use the attached published “*Guidelines for the Formulation of Statements of Scientific Findings to be Used for Policy Purposes.*”

These guidelines, written in the form of checklist questions, were developed by the members of the Oversight Review Board (ORB) of the National Acid Precipitation Assessment Program to assist scientists, engineers, and policy analysts dealing with other environmental research and assessment programs in formulating statements of scientific findings to be used in policy decision processes. As indicated earlier, the distinguished members of the ORB who prepared

these guidelines included: Milton Russell, former Assistant Administrator for EPA, Chauncey Starr, former Director of Research for the Electric Power Research Institute (EPRI), Tom Malone, former Foreign Secretary for the National Academy of Sciences, John Tukey, Distinguished Professor of Statistics at Princeton University, and Kenneth Starr, Nobel Prize Winner in Economics.

## GUIDELINES FOR FORMULATION OF STATEMENTS OF SCIENTIFIC FINDINGS TO BE USED FOR POLICY PURPOSES

The following guidelines in the form of checklist questions were developed by the NAPAP Oversight Review Board to assist scientists in formulating presentations of research results to be used in policy decision processes.

- 1) **IS THE STATEMENT SOUND?** Have the central issues been clearly identified? Does each statement contain the distilled essence of present scientific and technical understanding of the phenomenon or process to which it applies? Is the statement consistent with all relevant evidence that is available in the published literature. Is the statement contradicted by any important evidence in the published literature? Have apparent contradictions or interpretations of available evidence been considered in formulating the statement of principal findings?
- 2) **IS THE STATEMENT DIRECTIONAL AND, WHERE APPROPRIATE, QUANTITATIVE?** Does the statement correctly quantify both the direction and magnitude of trends and relationships in the phenomenon or process to which the statement is relevant? When possible, is a range of uncertainty given for each quantitative result? Have various sources of uncertainty been identified and quantified, for example, does the statement include or acknowledge errors in actual measurements, standard errors of estimate, possible biases in the availability of data, extrapolation of results beyond the mathematical, geographical, or temporal relevancy of available information, etc. In short, are there numbers in the statement? Are the numbers correct? Are the numbers relevant to the general meaning of the statement?
- 3) **IS THE DEGREE OF CERTAINTY OR UNCERTAINTY OF THE STATEMENT INDICATED CLEARLY?** Have appropriate statistical tests been applied to the data used in drawing the conclusion set forth in the statement? If the statement is based on a mathematical or novel conceptual model, has the model or concept been validated? Does the statement describe the model or concept on which it is based and the degree of validity of that model or concept?
- 4) **IS THE STATEMENT CORRECT WITHOUT QUALIFICATION?** Are there limitations of time, space, or other special circumstances in which the statement is true? If the statement is true only in some circumstances, are these limitations described adequately and briefly?
- 5) **IS THE STATEMENT CLEAR AND UNAMBIGUOUS?** Are the words and phrases used in the statement understandable by the decision makers of our society? Is the statement free of specialized jargon? Will too many people misunderstand its meaning?
- 6) **IS THE STATEMENT AS CONCISE AS IT CAN BE MADE WITHOUT RISK OF MISUNDERSTANDING?** Are there any excess words, phrases, or ideas in the statement which are not necessary to communicate the meaning of the statement? Are there so many caveats in the statement that the statement itself is trivial, confusing, or ambiguous?
- 7) **IS THE STATEMENT FREE OF SCIENTIFIC OR OTHER BIASES OR IMPLICATIONS OF SOCIETAL VALUE JUDGMENTS?** Is the statement free of influence by specific schools of scientific thought? Is the statement also free of words, phrases, or concepts that have political, economic, ideological, religious, moral, or other personal-, agency-, or organization-specific values, overtones, or implications? Does the choice of how the statement is expressed rather than its specific words suggest underlying biases or value judgments? Is the tone impartial and free of special pleading? If societal value judgments have been discussed, have these judgments been identified as such and described both clearly and objectively?
- 8) **HAVE SOCIETAL IMPLICATIONS BEEN DESCRIBED OBJECTIVELY?** Consideration of alternative courses of action and their consequences inherently involves judgments of their feasibility and the importance of effects. For this reason, it is important to ask if a reasonable range of alternative policies or courses of action have been evaluated? Have societal implications of alternative courses of action been stated in the following general form?:  
"If this [particular option] were adopted then that [particular outcome] would be expected."
- 9) **HAVE THE PROFESSIONAL BIASES OF AUTHORS AND REVIEWERS BEEN DESCRIBED OPENLY?** Acknowledgment of potential sources of bias is important so that readers can judge for themselves the credibility of reports and assessment

## **The Issue of Identical Primary and Secondary Standards**

For many years now, and for many different Criteria Pollutants, EPA has established identical primary and secondary NAAQS. In recent years, it has become more and more clear from a variety of scientific perspectives, that protection of aquatic and terrestrial ecosystems from air-borne pollutants and avoidance of significant deterioration in the quality of scenic vistas in both urban and Class I wilderness areas resulting from regional haze will require public welfare-based secondary standards that are different in form from public health-based primary NAAQS. Thus, many members of CASAC and the public at-large are looking forward to more careful consideration by EPA of secondary standards that will deal more adequately with human welfare effects of various Criteria Pollutants.

**Dr. Bernard D. Goldstein**

**Comments of Bernard D. Goldstein, M.D.**

**March 16, 2006**

Dr. Vanessa T. Vu  
Director  
EPA Science Advisory Board

Dear Dr. Vu,

Thank you for the opportunity to comment on EPA's review of the NAAQS process. I apologize for the delay in responding, in part due to the request coming a little more than a week before your deadline, and at a time when I was attending the Society of Toxicology meeting in San Diego.

Let me start with two background statements that frame my approach to these comments. First, in my teaching of environmental health policy to both public health students and to law students, I routinely present the NAAQS standard-setting process as one that represents an ideal interface between science and regulation.

Second, I have just this past week broken a more than 20-year commitment as a former EPA ORD Asst. Administrator of not being publicly critical of EPA. I have done so by being highly critical of the way that the EPA Administrator has broken faith with the NAAQS process.

The strength of the NAAQS process is that it provides an iterative interface between the science pertinent to standard setting and the regulatory process. Whatever one believes about the scientific appropriateness of the fine particulate standard chosen by Administrator Johnson, there is no question that he went beyond the range of the recommended levels reviewed by CASAC, and that he did so without the iterative interaction so valuable to the standard-setting process. The impression of disregard for this highly successful process undoubtedly will damage the credibility of EPA in general, and its NAAQS standards in particular.

The adverse impact of Administrator Johnson's recent decision goes well beyond the specifics of the fine particulate standard. Reviewing the documents from the 1980s that you sent to me, and remembering my own tenure as chair of CASAC and then AA of ORD, brings back the many discussions at the time of the CASAC process. I am proud of my small role in developing this process. I believe that the process as it has existed justifies the enormous number of hours of input by the scientific community. This input occurs because we as scientists believe that the process appropriately informs the regulator about the extent of the reasonable disagreement

among us pertinent to setting the standard. Unfortunately, EPA's recent decision tells the scientific community that it is not worth our time to be involved in EPA advisory processes.

Again, let me emphasize that this unfortunate outcome is irrespective of whether the Administrator's decision is appropriate; and let me further emphasize that the Administrator could have avoided this criticism simply by asking for additional CASAC review.

I am not a lawyer, but I have had sufficient experience teaching at law schools and the Federal Judicial Center to hazard an interpretation of the existing legal basis for the interaction between scientific advisory committees and federal regulatory agencies. The recent quotes from EPA that they do not have to listen to the advice of CASAC are of course correct – CASAC is purely an advisory committee. But I suggest that EPA carefully review the *API v. Costle* decision (42 U.S.C. 7607 (d)(8)). In that decision about the 1979 ozone standard the court indeed affirmed that EPA need only hear its scientific advisers, not follow their advice. However, the court found that EPA erred in never having submitted the ozone standard for consideration by its advisory body. In this case the court did not find that EPA's error raised a substantial likelihood that the rule would have been significantly changed, so they found in EPA's favor. Given the current CASAC response to EPA's fine particulate decision, it is not certain that a court will be so forbearing in this case. In essence, EPA may have illegally made an important regulatory decision without obtaining advice as to its scientific soundness from its congressionally-mandated scientific advisors.

Effective protection of public health and the environment is heavily dependent upon the best quality science and the effective translation of this science to those responsible for regulatory decisions. The process developed for NAAQS standards has been highly successful and has been a model for how science and scientists can and should be used to provide credible advice that can be translated into effective and defensible regulatory standards. Tampering with a process that has been so effective should not be done lightly.

I hope the above is helpful, and I would welcome further involvement in discussions about the NAAQS process.

Bernard D. Goldstein, MD  
Professor of Environmental and Occupational Health  
Graduate School of Public Health  
University of Pittsburgh

## **Dr. Rogene F. Henderson**

### **Comments by Rogene F. Henderson**

**March 6, 2006**

#### **Key Questions for the Review of the Process for Setting NAAQS**

##### Timeliness of the NAAQS review process

- *What are your views on the timeliness and efficiency of the current process for both EPA's and CASAC's reviews of the air quality criteria and the NAAQS, in terms of the time that is spent between the start of the review and the publication of the Agency's proposed decisions on the standards?*

I am in my second year as Chair of CASAC and as such, I do not have the long-term experience that many others have had in this process. This puts me at a disadvantage in knowing some historical data, but I have the distinct advantage of looking at the CASAC review as part of the NAAQS process from a fresh viewpoint. I think that people on the EPA staff and on the CASAC both work very hard on the review process, and it is well worth considering how to make the process more efficient.

One thing that seems to slow things down is what I call a "ping-pong" review process. I chaired the National Research Council's Committee on Toxicology (COT) for eight years and we once had the same problem. A subcommittee of COT was reviewing documents on recommended levels of exposure for an agency. The agency was under great pressure to meet deadlines for getting us the documents to review. Sometimes the documents were not really in good shape, but they had met their deadline. The COT would then have many comments, both editorial and scientific. The document would then go back and forth between the agency and COT until a satisfactory draft was obtained. Some of the problems I observed in chairing COT, I have observed in a somewhat magnified fashion in the CASAC process. The ping-pong process begins when the Agency is rushed to meet a deadline and submits a less than optimal document to the advisory body to review. The CASAC goes over the document carefully, commenting not only on scientific matters but on editorial points and asks to see the revised draft again. This process may go through several iterations until the CASAC is satisfied with the draft. If such an approach continues, the initial drafts submitted from the Agency may become more and more premature, because they have to meet a deadline and they know they will get the benefit of a good outside review before the draft is finalized.

To prevent that type of cycle from occurring I suggest the following:

1. All documents sent to CASAC for review should be the Agency's "best and final" version of the document. It would be more time saving to miss a deadline than to submit less than adequate documents to CASAC for review. The submitted documents should have been thoroughly reviewed in-house and should be in a form that makes it easy for CASAC to say they do not need to see it again.

2. Adequate staffing should be assigned to the task to allow a reasonable chance that credible documents can be produced in the time allowed.

3. The CASAC should provide clear scientific advice, but not editorial advice. It is a waste of valuable expert scientists' time to have to make the EPA documents readable. The NRC has an excellent editor that provides this type of review for NRC documents and I think the EPA should be responsible for the same type of editorial review of their documents.

4. I found a sense among several CASAC members that the CASAC is responsible for approving the proposed standards rather than giving advice and recommendations. The Agency should make clear to CASAC what they require in terms of scientific advice and what they consider to be policy issues, on which they do not need advice. The line between science and policy is not always apparent, and this difference should be made clear in the charge questions given to CASAC. Both the Agency and the CASAC have the same goal—to protect public health and the environment. The relationship between the Agency and CASAC should be a collaborative one, in which both groups work for the greatest good. The scientists can provide excellent expert advice and are obliged by law to recommend the range of standards that would be appropriate. In the end, however, the Administrator of the EPA has the responsibility to decide what the standards will be. If policy plays a major role in that decision, the Administrator should make the policy choices clear to the public and to the CASAC. There should be no surprises.

- *Can you identify structural changes to the process and/or key documents (e.g., the Criteria Document, Staff Paper, Risk Assessment) or changes in the Agency's management of the process that could shorten this time frame while preserving an appropriately comprehensive, transparent and policy-relevant review and allowing adequate opportunities for CASAC review and advice and for public comment on these documents?*

I think the process can be broken down into three major parts: assembly of the pertinent literature, development of an integrative chapter describing this literature, and development of the staff paper. The first two parts of the process are given in the CD. I think there is a more efficient way to accomplish the first part.

1. The literature review part of the CD could be completed without a face to face meeting. At present the CD is an unwieldy document, a compendium of all research done on the criteria pollutant of interest. The CD is a valuable resource and has been used by many students and agencies as a reference work. Progress has been made in making the document more readable by putting the most critical, new material in the main text and the rest in appendices. The role of CASAC is to look over this literature review and advise whether all the important studies have been included and if the Agency has interpreted them correctly. Recommended change: Once the literature review has been completed, a draft of each chapter could be submitted to a subgroup (2 or 3 people) of the CASAC panel for their review. Needed alterations in each chapter could be addressed via a teleconference so that by the time the full CASAC panel meets, all of the literature review chapters are acceptable to a

subgroup of CASAC. Then at the face to face meeting of the full panel, very little time would be required to describe the main points of each chapter so other members of the CASAC panel and the public will be well informed. This would allow more time to discuss the critical integrative chapter of the CD.

2. The integrative chapter of the CD should be the major point of discussion at the first face to face meeting of the CASAC panel. This is the point of departure for the subsequent development of the Staff Paper.

3. The Staff Paper is the critical document and, in my brief experience, has been well written. This is the document for which the CASAC expertise is most needed. I would suggest that meetings to discuss the Staff Paper might be extended to 2 and a half days to allow more discussion of this important piece of work. At the request of the CASAC, more time should be allowed for presentations by scientific experts who may not be on the panel.

4. The public comment period and the transparency of the process should be maintained.

#### Consideration of the most recent available science

- *To enhance the Agency's ability to take the best and most recent available science into account in making decisions on the standards, can you suggest changes in the process and/or key documents that could shorten the time between the presumptive cutoff date for scientific studies evaluated in the review and reaching proposed decisions on the standards, or that could otherwise facilitate appropriate consideration of more recent studies?*

I would suggest that critical new studies should be presented to CASAC for review and included in the Staff Paper up until the Staff Paper is finalized. In the time between the completion of the Staff Paper and the proposal of revised standards, only a study that might make a large difference in the standard settings should be considered and should be reviewed by CASAC. This would have to be a judgment call. It would not be appropriate to base decisions on papers that have not been reviewed by CASAC.

#### Distinctions between science and policy judgments

- Recognizing that decisions on the standards, while based on the available science, also require policy judgments by the Administrator, what are your views on how clearly scientific information, conclusions, and advice are distinguished from policy judgments and policy recommendations on the standards throughout the review process?
- Can you suggest changes in the process and/or changes to the format and contents of key documents that would help to make these distinctions clearer?

I think this is a difficult distinction to make and it is not clear to me where to draw the line. It would be helpful if this distinction were clearly drawn in the initial charge questions. In other words, spell out where you need science advice and what territory is policy driven.

Identifying, characterizing, quantifying, and communicating uncertainties in scientific information

- *Recognizing the importance of characterizing and clearly communicating the uncertainties in the science and quantifying uncertainties in exposure and risk estimates as explicitly as possible, what are your views on any changes in the process and/or changes to the format and content of key documents that might facilitate a more complete, quantitative, and policy-relevant characterization of uncertainties?*

How one deals with the uncertainties is a policy issue. One can say that a lot of uncertainty suggests being more conservative to be sure we are “safe.” Another policy might be that a large amount of uncertainties means that we cannot select appropriate levels until we have more information. In any case, the amount of uncertainty should be fully addressed and central estimates should be given as well as the upper and lower confidence limits. Again, the policy decisions made should be explicit and clearly stated in public.

## **Dr. Philip K. Hopke**

### **Comments on the NAAQS Review Process**

**Philip K. Hopke**

**February 24, 2006**

The Clean Air Act (Amended) calls for several things with respect to CASAC's role in the process of setting ambient air quality standards. It calls for the Administrator to:

(2)(A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.

(C) 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.

It should be noted that there is an explicit requirement for CASAC to "recommend to the Administrator" the new standard.

It is obviously better to have the Committee and its larger specific pollutant panels come to a well defined consensus with respect to its recommendations. That is the value of the formal "closure" procedure and this approach should be reinstated.

### **Timeliness of the Review Process**

#### *Comments*

Let us look at what went wrong with the review of PM standard that was completed last year. The first problem was the presentation of documents that were clearly not ready for review. The first draft CD and SP should have never been presented to the Panel. If the agency wants extended feedback to use in writing a real first complete draft, then they should consider providing a white paper that outlines the major issues they think exist and their plans for dealing with them. In both cases, these incomplete and weak documents started the process off on the wrong foot.

The format of the CD was also a problem. The placement of the detailed description of individual studies and similar levels of descriptive material causes the panel to focus on the minutiae instead of the main take home messages. What the NCEA staff really needs to do is to write the summary chapter first carefully recognizing the major take home messages and then use annexes to buttress the case. This was largely the approach in the ozone document and it can be seen how much easier it is to review this document. This is not simply a matter of a less complex subject, but being able to focus the review of the content that matters most.

We lost a year because of the GAM problem. The staff built much of its case on the epidemiology studies that used the GAM protocol and thus, it was not possible to proceed with the review of the epidemiological evidence without those studies being redone, described and reviewed. We arranged with the Health Effects Institute for an expedited review and given the magnitude of the effort needed by the original investigators, the reviewers and the NCEA staff, completion of this effort within a year was really about as timely as it could be done. It is not clear to me that this problem was adequately presented to the court in order to obtain a sufficient time period following the completion of the HEI review to complete the revisions of CD and the remainder of the process. The attempt to short circuit the process with the first draft SP was not helpful as it left too much out and thus, left too many openings for criticism. It therefore was hard to forge the consensus that provides a critical symbol of authority for the Agency to act. I believe that if the Agency had waited a few months longer to provide a more fully reasoned and complete SP, we would have come to closure in a more rapid manner.

I believe that the lack of closure on the staff paper will provide an additional point of leverage for the potential litigants to argue that there was not agreement on the scientific basis for the standard as had been the past practice.

*Recommendations on Timeliness:*

I strongly suggest the format of the CD be like that of the ozone document. Focus on the synthesis first and foremost and do not leave it to be an afterthought. Do not release documents because they want to have something out. Wait until it is ready. The time can be made up later because there will be fewer criticisms and more willingness to compromise on the criticisms if the Panel feels that a real effort has gone into crafting a complete, comprehensive and well reasoned document. This applies to both the CD and SP. Reinstate the closure process so that there is a clear and final approval of the document. I recognize that only the CASAC members have standing, but again having the record indicate that all of the panel can agree that the document adequately presents the scientific basis for the policy decisions will be valuable to the Agency as it proceeds through the full process of promulgating and implementing standards.

**Consideration of the Most Recent Available Science**

There has never been a prohibition of inclusion of seminal new work that would significantly alter our view of the pollutant in question in any manner that significantly affects the setting of the standard (indicator, concentration, time interval, statistical form). In general, the literature tends to be quite incremental and although additional papers generally will add strength to the conclusions obtained in the CD and following on into the SP, it is going to be a very rare occurrence when such a paper appears that it really changes directions. If such a paper appears, then it can certainly be included in the body of the document. There are a variety of ways that a

quick review of such a last minute addition could be made through a teleconference or even an e-mail polling of the relevant Panel. Otherwise, it is important to set a fixed cut-off date or the document will constantly be subject to revision. However, even here there could be additions to the annexes. If the CD stays away from referencing individual papers and only looks to summarize the substance of the subject derived from the body of literature in the annexes, then it is possible to add incremental material in the annex with fewer problems and such additions are easy to track and to have the panel approve.

### **Distinctions between Science and Policy Judgments**

In this case I hearken back to the law which asks the Committee to *recommend* a standard. CASAC has typically left the recommendation to the staff through closure on the SP. Now since closure has been eliminated, it becomes incumbent on the Committee to make a formal recommendation and this will clearly include more than the science. The loss of closure has helped to blur the line between scientific advice and clearly leads to the Committee taking a more active policy role. I would suggest that this direction may take the Panels in directions that, in fact, take more time to come to consensus and thus, again I argue for a return to the closure process where there was an implicit recommendation of the standard through a consensus acceptance of the SP recommendations.

### **Identifying, Characterizing, Quantifying, and Communicating Uncertainties in Scientific Information**

This has been a major role of the CASAC panels since there is enormous pressure put on the NCEA staff to come up with unequivocal statements that the regulatory staff can use to support their decisions with respect to regulations. It has typically been one of our major criticisms of the documents that they do not adequately reflect the degree of uncertainty in the science often because of selective citation of papers that support one direction versus another. We do not want the documents to reflect more uncertainty than is present in the literature, but we also do not want less. Obviously conveying uncertainty can best be done quantitatively if numerical values can be provided. More often than not, it is necessary to describe the state of the science qualitatively. The key again is the integrative summary. If we make the integrative summary the body of the CD with the supporting evidence in annexes and write that first (or at least outline the major points to be made), then everyone can focus on the key issues of what we know, what we do not know and how well we know what we do know. Such a clear statement of the related science would provide a better basis from which to build the policy review and recommendations.

### **Summary**

The best advice I can provide is to do more work up front in a more effective manner. The ozone CD provides the start for a template for how to do things. It would have been even better if the welfare portion of the document had been as effectively written as the rest of the initial draft. Getting off on the right foot and focusing on the key, bottom line issues instead of the minutia will provide a more effective and efficient approach to writing, reviewing, revising, and closing on these documents. It also provides an opportunity to put additional literature in the annexes without as much hassle as when they become part of the main document.

## **Dr. Morton Lippmann**

### **NAAQS Process Comments**

**Morton Lippmann**

**February 24, 2006**

#### **Background and Credentials**

I began my service to CASAC as a Core Consultant in 1980, became a statutory member in 1982, served as Chair from 1983 through 1987, attended CASAC meetings as a member of the SAB Executive Committee from 1987 through 2001, and have served as a member of CASAC's PM and Ozone Panels until the current year.

I wrote a review and commentary entitled "Role of science advisory groups in establishing standards for ambient air pollutants" that was published in *Aerosol Science and Technology* 6:93-114 (1987). Many of the comments and recommendations therein are still relevant today. A copy was provided by Harvey Richmond to Fred Butterfield, and it was attached to Fred's memo to current and former members of CASAC of Feb. 24.

#### **Endorsement of Dr. Mauderly's Comments**

I have read and fully endorse the Feb. 21, 2006 comments made by Dr. Joe Mauderly on the NAAQS Process, and will not elaborate on the issues that he addressed. The comments that I offer below supplement and extend the issues that need to be addressed by the current members of CASAC in the recommendations that they will be submitting to AA's Wehrum and Gray by April 3.

#### **Can the Process for Setting NAAQS be Strengthened?**

The easy answer is of course it can, and I will address how it can in text that follows. However, it is important that any changes made in the process do not weaken the long-established integrity, objectivity, and credibility of the process to the scientific community and interested stakeholders. This needs to be explicitly considered in light of the recent changes in SAB Staff management of CASAC's modus operandi in relation to its demands for discontinuing the issuance of a formal 'CASAC closure letter' on Air Quality Criteria Documents (CDs) and Staff Papers (SPs) from the CASAC review process. This management decision was unwise, and has already resulted in CASAC initiatives to offer public comments after EPA's completion of final versions of the latest PM CD and the Administrator's Proposal for PM NAAQS. I will therefore first address the need for CASAC to regain its ability to fulfill the role mandated by the Clean Air Act Amendments of 1977 to review NAAQS criteria, and the mandate of the Environmental Research and Development Demonstration Authorization Act of 1977 for SAB to review Standards. CASAC has always issued its closure letters directly to the Administrator without oversight by the SAB Executive Committee. Its independence is therefore compromised by the imposition of SAB Staff management decisions on its process.

The parts of the NAAQS setting process that can and should be strengthened are the parts played by NCEA and OAQPS, and CASAC can and should assist these EPA offices in doing so. The long gestation and document preparation times of CDs and SPs for CASAC review account for the long, drawn-out time scales of NAAQS reviews, not the times attributable to CASAC review and preparation of its reports and letters.

The most urgent need is for NCEA to prepare a first draft of each CD that is really ready for 'prime time'. Before preparing a first public review draft, NCEA needs to decide which issues are most critical to standard setting, and who among its staff and outside consultants can effectively address them. It then needs to utilize expert workshops and/or CASAC consultations to identify the literature and other information sources that are germane to these issues. Only then should it prepare or commission draft chapters or sections thereof. This first draft should include interpretive summaries of the health and welfare issues even if they remain less than complete. Informed CASAC commentary on these integrative chapters can help to ensure that any necessary feedback to the authors can lead to the incorporation of appropriate revisions, or the filling of critical knowledge gaps, in the next, and presumably final draft. If this approach is rigorously followed, there should only be no need for a third draft for CASAC review.

There is an urgent need for the development of a better and more consistent vocabulary for new CASAC Panel members and document authors before draft chapters are prepared and reviewed. Terminology that needs to be standardized and used consistently includes:

\* **sensitive subgroups:** How large and/or how extra-sensitive does a definable group have to be to warrant the setting of a NAAQS specifically designed to protect them against adverse health effects arising from their exposures to ambient air pollutants.

\* **adverse health effects:** What is an 'adverse' health effect? For the limited number of Criteria Pollutants, there should be pollutant-specific effects that are defined in advance of the CD preparation. Is there a degree of adversity that triggers the need for protection by the enforcement of a NAAQS?

\* **susceptible individuals:** For those relatively few people whose special susceptibility leaves them unprotected by NAAQS designed to protect sensitive subgroups, how can EPA and state and local agencies provide adequate guidance on measures to avoid harmful exposures.

\* **adequate margin of safety:** There is a widespread recognition that, for at least some criteria pollutants, i.e., PM, O<sub>3</sub>, and Pb, the available literature provides no evidence for the existence population-based threshold concentrations. Thus, there is a need for a new operational definition of a NAAQS that provides an adequate margin of safety. A 'policy' decision is needed on a level of public health risk that is acceptable when a NAAQS is enforced.

\* **population based thresholds:** In the absence of evidence for population based thresholds, there is a need for a 'policy' decision on the most prudent course to follow for risk assessment. Is there an alternative to the assumption that a linear or other smoothed curve that fits the best available epidemiologic data should be used? If so, it needs to be made explicitly.

\* **acceptable level of population risk:** A 'policy' decision is needed for the ground rules on what constitutes an acceptable level of population risk when the health effects data are consistent with non-threshold population-based linear or curvilinear relationships. For example, is 3 days of life-shortening of a chronically-ill senior citizen due to a peak in 24-hr PM<sub>2.5</sub>, or the loss of 1 or 2 I.Q. points in a Pb-exposed child, acceptable?

### **The Interface between Science and Policy**

CASAC has recognized, and must continue to recognize that there is a clear need for it to provide advice and guidance to the Administrator and the Congress on the science relevant to the setting of NAAQS, and must avoid, to the extent possible, on policy decisions. The difficulty in drawing such distinctions is evident if one considers my above stated needs for standardization of key elements of the terminology that CASAC confronts when dealing with NAAQS issues. Each of them approaches or crosses the line between science advice and public policy issues. The choices that must be made on defining or clarifying policy relevant to meeting the legislative mandates must be made by the Administrator and/or by Congress through revisions to established Acts, and CASAC's role must be limited to highlighting the issues at the science-policy interface and the scientific knowledge that informs these issues.

## **Dr. Joe Mauderly**

### **Comments on the NAAQS process**

**Joe Mauderly**

**February 21, 2006**

#### **Timeliness of review process**

It is extremely important to both refine and speed up the review process. Not only has it become embarrassingly common for the process to lag such that deadlines are now routinely set by legal actions, but that mode of operation easily becomes an excuse for failing to make the effort to produce the best product, or to limit CASAC review in the late stages of the process. The law says that NAAQS pollutants are to be reviewed at five-year intervals. The law does not say what the review must consist of, or how it is to be done. Either the current approach or the law needs to be changed. In fact, it is entirely possible to review the pollutants every five years (assuming a will to do so). What is not possible is to do so using the current approach.

A key improvement would be the development of better documents before they are given to CASAC and the public to review. My experience suggests that much of the time for review is incurred by the failure of authors to do a good job the first time. There is too much reliance on CASAC to edit documents, because of either the reluctance or inability of EPA managers and the original authors to review and optimize them before they are distributed. For example, it is not rocket science to determine whether or not a “synthesis” of important information at the end of a chapter is indeed a good synthesis of the foregoing material, yet it is too often left to CASAC to state the obvious before a decent synthesis is written. The same holds for chapters that are intended to integrate information from foregoing chapters. Because CASAC appropriately attempts to hold documents to a high standard, it will serve an editorial function by default, but it should not be so necessary.

One of the reasons given for the recent (apparently successful) move by EPA to relegate CASAC to a reviewer, rather than an approver, of documents is that it slows the process. That is pure balderdash. I cannot recall a single instance over my 15 years of experience with the Committee that CASAC was truly the root cause of significant delay. On the other hand, I can recall multiple instances in which, if CASAC had not the prerogative to “close” on documents, EPA was clearly on track to ignore scientific advice and move forward with inadequate documents or incorrect conclusions. If CASAC points out deficiencies that need to be remedied, it is not CASAC that is delaying the process.

There is no way to substantially shorten pollutant reviews unless a different, and more parallel process is adopted. It could be speculated that a CD development process more akin to the NRC committee process might offer possibilities. That process involves engaging scientific experts in drafting, refining, and developing consensus about documents that review equally difficult scientific issues. The process could include members of CASAC, as well as other subject matter experts (the present “Panels” set precedent). It may be that such a process could result in

development of a more concise review and interpretive document than the present CD. Voluminous material could be cataloged and summarized in tabular form at the committee's direction, by lesser credentialed EPA staffers working with the committees. This is done at NRC – staff often does the bulk of the “busywork” under the guidance of committee members. Just as NRC has many committees working simultaneously, EPA could have committees working on multiple pollutants in a parallel manner, rather than the largely linear current process. Or, of course, you could just turn the CD process over to NRC – I'd guess that the Academy would not turn down the contract.

### **Consideration of the most recent science**

This is fundamentally impossible in the strictest sense. “Science” emerges daily. In order to avoid paralysis, it is critical to develop, state, and adhere to a policy for cut-off of published information feeding into the CD and SP. However, special circumstances will inevitably arise in which post-CD information is of such novelty and importance that it is illogical (if not unconscionable) to disregard it in the final promulgation. That circumstance is not as frequent as most of us researchers like to presume; new studies reinforcing already-stated findings or conclusions do not qualify. Only information that clearly confirms exposure-response relationships for new effects of pollutants or proves markedly different estimates of known effects would qualify.

There may be an opportunity for improvement here, if it could be managed well. Assuming a sequence similar to the present (CD followed by SP, followed the proposed standards), either EPA or CASAC could assume responsibility for monitoring new published findings, and screening them for publications that truly alter our understanding of exposure-effects relationships (for either primary or secondary standards). CASAC could give a quick opinion (i.e., within weeks, not months) as to whether or not the information met the impact criteria. This process could be done by distribution of papers and conference calls.

### **Distinctions Between Science and Policy Judgments**

This takes discipline, and perhaps more than we've been willing to exert. As long as we have our present approach to regulation, there is, in fact, a distinction between science and policy. Neither scientists nor policy makers want to draw the line, or to define it or admit to it. CASAC meetings are rife with discussions about how its pronouncements will affect policy, and scientist advocates (on CASAC and its panels, as well as others) game the system to achieve their ideological policy goals. When EPA proposes or promulgates standards, it is reluctant to state clearly how science and policy enter into the decision – it wants to portray that all is based on science. These behaviors are absolutely understandable – most scientists are convinced that they know what's best for the country, and EPA Administrators don't want to admit to any motive other than the “best science”.

The problem is that the “policy” factors might logically be raised, along with the science, in the SP, but then CASAC would be placed in the position of reviewing policy. As appealing as that might be to some members and panelists, that does not seem to be their statutory role (and is seldom their expertise). To adequately review “policy” issues would require an expanded spectrum of expertise on CASAC.

One possibility is to constitute either a CASAC-linked group or some independent, but conceptually similar peer review group to deal with policy. That is a remote possibility indeed! No administration on either side of the isle would welcome policy by independent expert consensus.

At present, my only suggestion is that the Administrator make explicit (much more so than at present) just how science and policy separately bore on the proposed standard, and how the two were integrated. That is asking for more transparency than agencies and administrations (of any political stripe) are likely to be willing to yield. To the extent that non-science (?) policy impacts could be made clear, it might reduce the tendency on the part of scientists to conclude that they just haven't yelled loudly enough.

### **Identifying, Characterizing, Quantifying, and Communicating Uncertainties in Scientific Information**

There needs to be a more explicit characterization of uncertainty in estimates of causality and exposure-response relationships (again, for both primary and secondary standards). At present, assessments of "uncertainty" are almost completely focused on the mathematical uncertainty of effects estimates (i.e., confidence intervals on measurements of exposures and effects). This is important of course, but I would like to see a more rigorous discussion of "certainty" in a broader sense. For example, how do the magnitudes of health effects of air pollution rank in comparison to other voluntary and involuntary health risks? Because air pollutants seldom, if ever, exert novel effects, what portion of the total public health effect is plausibly attributable to a pollutant (or to pollution)? What do we know about the relative benefits, and cost-benefit relationships, of different approaches to reducing health burdens that are exerted in part by air pollution? I care not that these issues might not fall within many folks' definition of "scientific information", or that EPA is not supposed to take cost into account in promulgating standards (does any thinking person actually believe that they shouldn't, or don't?). We delude ourselves and miss opportunities to inform policy makers and promote a rational public understanding of risk if we continue to view the "uncertainty" issue as solely one of statistical methodology and data quality, while advocating for the special importance of the particular effects (no pun intended, but if the shoe fits –) by which we make our living.

## **Dr. George T. Wolff**

### **Comments on the NAAQS Review Process**

**George T. Wolff**

**March 3, 2006**

I welcome the opportunity to provide comments to Mr. Wehrum and Dr. Gray on the NAAQS review process. I have been an active member of the SAB for the past twenty-one years, and participated on numerous SAB committees. During that time, I also participated in seven NAAQS reviews and was chair of CASAC for four of them. The lengths of the reviews ranged from three years for CO, NO<sub>2</sub>, SO<sub>2</sub>, and PM (1994-1996 review) to six years for the recent PM review.

While I will address Mr. Wehrum and Dr. Gray's specific questions, I would first like to discuss some historical aspects of the reviews that I believe have relevance to the review process. The previous PM review was completed within three years (1994-1996) under a court-ordered deadline. So it is possible to complete a review and come to closure within a three year period. However, a consensus was not reached in that review on the concentration level of the standards. I refer you to the table (which I have appended) in the June 13, 1996 closure letter (EPA-SAB-CASAC-LTR-96-008). Individual Panelists' recommendations for the annual PM<sub>2.5</sub> standard ranged from 15 to 30 µg/m<sup>3</sup> and for the 24-hour standard from 20 to 75 µg/m<sup>3</sup>. The closure letter explains this "diversity of opinion":

"The diversity of opinion also reflects the many unanswered questions and uncertainties associated with establishing causality of the association between PM<sub>2.5</sub> and mortality. The Panel members who recommended the most stringent PM<sub>2.5</sub> 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<sub>2.5</sub>/PM<sub>10</sub> ratio to estimate local PM<sub>2.5</sub> 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 contrast to the 1994-1996 review, the 1999-2005 review took 6 years, was not allowed to seek closure on the documents, but achieved a majority opinion in support of lowering both the annual and 24-hour standards. There were some important differences in the process that lead to the different outcomes.

There were two important reasons why the review took so much longer. The first was the GAM software issue which was beyond the control of the Agency or the Panel, and this added at least a year onto the process. A second more important reason is that the documents (the Criteria Document (CD) and Staff Paper (SP)) given to the Panel to review were far inferior to the ones

given to the previous panel. In the 1994-96 review, the Agency acknowledged in the documents the numerous and large uncertainties that caused CASAC's "diversity of opinion," and as a result produced more objective documents. Even though some members disagreed with the Agency's interpretation of the data and EPA's ultimate recommendations, they approved of the documents, because they contained relatively balanced discussions of the uncertainties.

The recent review began with the Agency attempting to minimize the uncertainties by selectively citing new studies (in whole or in part) that supported their 1997 decision and ignoring other studies (or other results in the cited studies) or rationalizing results they did not like away. This is the main reason why the review took so long. Drafts were sent back for revisions not for significant technical errors but to remove biases and achieve more balance. Each subsequent draft was more balanced, but numerous biases still remained in the final documents. A closure requirement could have further reduced the biases. I say more on the closure issue later.

A second significant difference between the reviews is the composition of the Panel members. In the 1994-96 review, there were a number of Panel members who were skeptical that the epidemiology studies demonstrated cause and effect including one biostatistician and one epidemiologist who were not authors of the studies that found statistical links between PM and health endpoints. As a result, the Panel expressed "a diversity of opinion."

When the new Panel was formed, most of the Panel members who supported a causal role in 1996 were invited back to be on the new panel. Most of the skeptics were not. Instead they were replaced by individuals that, on the balance, were more supportive of the Agency's position. In fact, by the time the Panel concluded the review, seven out of 22 members had been authors of papers that purport causality. No epidemiologist or statistician who questioned causality was a member of the Panel. This lack of balance on the Panel predetermined the outcome of the review.

### Timeliness of the Review Process

As indicated above, many of the previous reviews were completed in a three year time-frame, which I consider to be timely. However, the process can still be improved. The limiting factor here is the quality of the documents. Efforts must be made to produce objective, unbiased documents. Brevity needs to be a goal. There has been much discussion over the years over how the CD, in particular, needs to be shorter. A template needs to be developed and followed that stresses brevity and objectivity and maximizes the use of tabular summaries of the studies.

The recent decision by the Agency to eliminate the need for CASAC closure will shorten the process, but, in my opinion, was a bad decision, and I fear that quality will suffer. The iterative review process leading to closure gave the Agency incentive to produce a document that CASAC would approve. Removing that incentive could lead to inferior products.

A word about public comments – Over the years there have been numerous excellent scientific comments produced by various organizations. Unfortunately, they typically arrive a day or two before the CASAC meeting, which gives the members insufficient time to digest them. I suggest that there be a cutoff date of ten days to two weeks before the meeting. As of now, relevant public comments on the CD and SP go into a black hole and are only addressed if EPA wants to

or a CASAC member or two push for it. Some Agency response to the public comment documents should be prepared and provided to CASAC.

### Consideration of the Most Recent Available Science

The present PM review represents the extreme because of the length of the review. The cutoff date was adhered to with the understanding that exceptions would be made if we all agreed that a new study was exceptionally important, and, of course, we had to wait for the GAM re-analysis studies. Aside from the GAM re-analyses studies, there were several additional papers considered, but EPA only included those supportive of their position and excluded others that members of the Panel suggested. Thus, there is a need for explicit criteria as to which studies qualify as “exceptionally important.”

### Distinctions between Science and Policy Judgments

The selection of a particular level for a standard is a policy judgment. CASAC’s job is to insure that the range, form and averaging time recommended in the Staff Paper have a scientific basis. In questioning the recommendations in the January 17, 2006 NPRM, CASAC has clearly overstepped their boundaries and ventured into the policy arena.

### Identifying, Characterizing, Quantifying, and Communicating Uncertainties in Scientific Information

The Agency has not done an adequate job here. In the PM review, only the statistical uncertainties were considered. The Agency completely ignored the larger uncertainties associated with various assumptions made by individual investigators including, but not limited to, the selection of the appropriate model, choice of temporal smoothing functions, control of confounders including meteorological parameters, adequacy of exposure metrics, selection of lag structures etc. It is not that the Agency is unaware of these uncertainties; they just choose to ignore them in the risk assessment. When the GAM re-analyses were being conducted, some of the investigators conducted sensitivity analysis by varying some of these assumptions within plausible limits. They found that they got a spectrum of results, both positive and negative. This led the HEI Special Panel of their Review Committee to write in their commentary:

“Neither the appropriate degree of control for time in these time-series analyses, nor the appropriate specification of the effects of weather, has been determined. This awareness introduces an element of uncertainty into the time-series studies that has not been widely appreciated previously.”

To insure that such uncertainties are incorporated into the Agency’s SOP will require high level intervention from senior EPA management and the selection of individuals to CASAC who have an appreciation of the importance and significance of these uncertainties.

**From June 13, 1996 Closure Letter (EPA-SAB-CASAC-LTR-96-008)**

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

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

<sup>1</sup> not present at meeting; recommendations based on written comments

<sup>2</sup> declined to select a value or range

<sup>3</sup> recommends a more robust 24-hr. form

<sup>4</sup> prefers a PM<sub>10-2.5</sub> standard rather than a PM<sub>10</sub> standard

<sup>5</sup> concerned upper range is too low based on national PM<sub>2.5</sub>/PM<sub>10</sub> ratio

<sup>6</sup> leans towards high end of Staff recommended range

<sup>7</sup> desires equivalent stringency as present PM<sub>10</sub> standards

<sup>8</sup> if EPA decides a PM<sub>2.5</sub> NAAQS is required, the 24-hr. and annual standards should be 75 and 25  $\mu\text{g}/\text{m}^3$ , respectively with a robust form

<sup>9</sup> yes, but decision not based on epidemiological studies

<sup>10</sup>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<sub>2.5</sub> pollution problems

<sup>11</sup>only if EPA has confidence that reducing PM<sub>2.5</sub> will indeed reduce the components of particles responsible for their adverse effects

<sup>12</sup>concerned lower end of range is too close to background

<sup>13</sup>the annual standard may be sufficient; 24-hr level recommended if 24-hour standard retained