Attachment 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 15, 2005

FROM: Marcus Peacock MP
DEPUTY ADMINISTRATOR

TO: Dr. George Gray
Assistant Administrator for the Office of Research and Development

Bill Wehrum
Acting Assistant Administrator for the Office of Air and Radiation

RE: National Ambient Air Quality Standards

An essential component of EPA's mission is to ensure that the best available science guide and inform agency decision making. This principle has been and continues to be a major focus of the agency. Under the heading "Achieving Results," the 2003-2008 EPA Strategic Plan notes that, "EPA's approach to conducting and using science in service to the Agency's mission will ensure that Agency policies, decisions, and other activities reflect high-quality scientific information relevant to current and future environmental issues." EPA must follow guidelines and procedures so that "our work meets the highest standards of scientific excellence."

Using best available science to accelerate environmental progress and protect public health is a top priority for the Administrator. To help achieve this goal, the Administrator has asked me to examine whether the process for setting National Ambient Air Quality Standards (NAAQS) can be strengthened. The current NAAQS process has been in place for over 20 years, with some aspects required by law, and therefore not amenable to changes except through new legislation. Other important aspects of the NAAQS process, however, are discretionary—the agency has established practices that set parameters for how science supports decision making. The Administrator is interested in determining whether those practices reflect the most rigorous, up-to-date, and unbiased scientific standards and methods.

To fulfill the Administrator's directive, I am asking you to establish and co-chair an agency working group to determine whether (and if so, how) the agency utilizes the best available science to set the NAAQS. In its examination, the working group should conduct a top-to-bottom review of the NAAQS process.

The working group should consider four reports (1998, 1999, 2000, and 2004) conducted by the "Committee on Research Priorities for Airborne Particulate Matter," which was created by the National Academy of Sciences (NAS), as well as "Science and Judgment in Risk Assessment," in which the NAS offered specific recommendations on how EPA can improve its risk assessments.

In addition, the working group should focus on the nexus between scientific analysis and standard setting, including the degree to which we are successful in separating the exposition of scientific information from the development of risk management strategies and policy judgments. It should also examine whether the process for compiling the Criteria Document allows for consideration of the most relevant, objective, and up-to-date scientific data. The working group should address and propose ways to ensure broad participation of the scientific community in the NAAQS process. Finally, the working group should consider whether and how these objectives can be satisfied within the statutory 5 year review period.

It is imperative that the NAAQS process adheres to the highest scientific standards so we can continue to make environmental progress and protect public health. The working group is charged with issuing specific recommendations to me no later than April 3, 2006. I look forward to working with you and the agency's top scientific experts on this very important subject.

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?
  - 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 timeframe 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?
- 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?
- 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?
- 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?

Attachment 3-A

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 al 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 adequate 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, O3, 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 PM2.5, 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_2, SO_2, 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 $PM_{2.5}$ standard ranged from 15 to 30 $\mu g/m^3$ and for the 24-hour standard from 20 to 75 $\mu g/m^3$. 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 $PM_{2.5}$ 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 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 μg/m^3)

		$PM_{2.5}$ 24-hr	$PM_{2.5}$ Annual	PM_{10} 24-hr	PM_{10} 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 PM_{10} standard
[5] concerned upper range is too low based on national $PM_{2.5}/PM_{10}$ ratio
[6] leans towards high end of Staff recommended range
[7] desires equivalent stringency as present PM_{10} standards
[8] if EPA decides a $PM_{2.5}$ NAAQS is required, the 24-hr. and annual standards should be 75 and 25 μg/m^3, 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

Attachment 3-B

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March 18, 2006

TO: Dr. George Gray
Assistant Administrator for the Office of Research
and Development

Bill Wehrum
Assistant Administrator for the Office of Air and Radiation

THRU: Vanessa Vu
Director, Science Advisory Board Staff Office

FROM: Roger O. McClellan 

RE: Comments on National Ambient Air Quality Standards Review Process

Summary

The process by which National Ambient Air Quality Standards (NAAQS) have been developed in accordance with the requirements of the Clean Air Act, including the role of the Clean Air Scientific Advisory Committee (CASAC), has evolved over nearly three decades. In my opinion, this process is one of the Agency's most successful efforts in the use of science to inform public policy decisions, i.e., the setting of NAAQSs for criteria pollutants. However, the process can be improved and is deserving of the critical review it is currently being given by the Agency's senior management. I urge that all elements of the NAAQS setting process be reviewed from (a) the identification of research priorities for the Agency's research on criteria pollutants to (b) funding and conduct of research through (c) the creation of Criteria Documents, (d) conduct of risk assessments, (e) development of Staff Papers to (f) the policy decisions and public comment periods that ultimately result in (g) continuation of existing standards or their revisions.

It is clear CASAC has an important and critical role in the process. In my opinion, that role is to ensure that all of the available scientific literature and its attendant certainties and uncertainties is reviewed, interpreted, synthesized and integrated to inform the policy decisions that must ultimately be made by the Administrator. A major challenge in the overall process is that scientific information, especially in the life sciences, always contains significant biological variability and usually has substantial

uncertainties. Moreover, the issues at hand involve human health and welfare issues that people highly value. The scientists involved in the NAAQS process, both within the Agency and from outside, including CASAC members, are not only highly competent scientists, they have personal values that influence their decisions on all matters extending from the interpretation of individual papers to the range of numerical levels considered for setting a NAAQS. In my opinion, the major challenge to improving the NAAQS setting process is to have as complete an exposition of the scientific information relevant to setting the Standard as possible with an even-handed consideration of uncertainty without infusion of personal values. Value considerations should only be considered in the policy decision.

In my opinion, the Criteria Document development process needs to be streamlined with more attention given to evaluation, synthesis and integration of information relevant to decisions on the four elements of the NAAQS; (a) indicator, (b) averaging time, (c) numerical level, and (d) statistical form. More concisely written criteria documents that relate the critical information, including even-handed exposition of uncertainties, will allow the CASAC to focus on these critical components and avoid becoming bogged down in editorial detail and review of material not relevant to setting of the NAAQS. Substantially more attention needs to be given to developing risk assessments that more adequately consider alternative exposure-response models and consider the full range of uncertainty in the underlying scientific information. More adequate risk assessments will also consider confounders that impact on the estimated risks of a particular pollutant and also serve as a benchmark for the reality of the risk assessment process.

Better risk assessments, carried out by multiple organizations, will lead to improved Staff Papers. When presented with improved Risk Assessments and Staff Papers, CASAC can first focus on the quality of the analyses irrespective of the specific outcome of the analyses. I applaud the presentation in the Staff Papers of relatively broad ranges for standard setting. I view the ranges as reflecting scientific uncertainty. Indeed, I urge that in future documents the range not necessarily be anchored at the upper bound by the current standard. This is the case because the previous NAAQS was set based on both science and policy considerations. The ranges in the Staff Paper should be science-based and reflect any uncertainties in the science. The CASAC review of the Staff Papers should focus on the scientific content and avoid the temptation to introduce personal policy preferences in the range endorsed by CASAC. In my opinion, CASAC needs to avoid endorsing narrowly defined ranges, such as it recently did in suggesting a range of 13-14 $\mu g/m^3$ for the annual $PM_{2.5}$ standard. In my view, this places CASAC in the role of setting the standard and ties the hands of the Administrator in considering policy options. In my opinion, the substantial quantitative uncertainties in $PM_{2.5}$ exposure-response relationships speak against CASAC proposing such a narrow range.

Recent efforts by the Science Advisory Board staff to relegate CASAC to a role similar to other SAB Committees have been totally inappropriate and requires critical review and reversal. CASAC is a scientific advisory committee charged with responsibility for advising on matters of extraordinary national importance. All of

CASAC deliberations and its conclusions need to be reached in public sessions. The current excessive use of teleconferences without attendant transcripts should be reduced. There is a need for CASAC to provide much more succinct, science-based letters to the Administrator including the use of "closure letters" at critical junctures in the process. The objective should be to ensure that the science as presented in the Staff Paper is appropriately documented to inform policy decisions. If necessary, this may require that CASAC representatives participate in dialogue with the Courts to avoid the imposition of Court-imposed time schedules that may not allow adequate time for the preparation and CASAC's iterative review required to ensure scientific quality. CASAC should avoid the temptation of creating in its letters an alternative to the Criteria Documents or Staff Papers, the focus should be on achieving scientifically acceptable EPA documents. In commenting on contentious issues, CASAC should also avoid striving for a single consensus view when there are divergent science-based opinions within the CASAC Panel.

There is a critical need for the Executive Branch and the Congress to work together to amend the Clean Air Act to increase the review cycle from 5 years to 10 years. The 5-year cycle is no longer appropriate and needs to be lengthened to be better matched to how new information is acquired and to allow for an improved process of evaluation, synthesis and integration of information prior to presentation of documents to the CASAC.

COMMENTS

These comments have been prepared in response to your request of February 17, 2006 for input to your review of the process used to periodically review and revise, as appropriate, the air quality criteria and National Ambient Air Quality Standards (NAAQS) as required by Sections 108 and 109 of the Clean Air Act. My comments consist of a background section, a section on the operation of the Clean Air Scientific Advisory Committee and from sections that address the key questions you have posed.

Professional Background

I will briefly review my personal involvement with CASAC as background for consideration of my comments. My professional experience has been in the fields of inhalation toxicology, aerosol science and risk analysis. I have also had extensive experience serving on numerous U.S.E.P.A. Advisory Committees beginning with service on the Agency's first Science Advisory Board and continuing today with service on the current CASAC PM Panel. This included chairing an *ad hoc* Committee to review the Agency's first Criteria Document on Airborne Lead, service on the first EPA review panel for particulate matter, service on numerous CASAC panels that have considered all of the Criteria Pollutants, service as a CASAC member including four years (1988-1992) as Chair of CASAC, service on the CASAC PM and Ozone panels that advised on the last round of standard setting and service on the current CASAC PM Panel.

In addition to my EPA service, I have served on numerous other advisory committees in both the public and private sectors that have been concerned with air quality issues. This has included the National Academy of Sciences/National Research Council Committee (NAS/NRC) that prepared the report – "Science and Judgment in Risk Assessment" and the more recent NAS/NRC "Committee on Research Priorities for Airborne Particulate Matter" that prepared four reports (1998, 1999, 2000 and 2004).

Personal Reflections on CASAC Modus Operandi

Prior to the creation of the EPA in 1970, responsibility for administering the Clean Air Act and earlier air quality statutes was vested with the National Air Pollution Control Administration which had an independent Clean Air Advisory Committee. With creation of the EPA, a number of "inherited" advisory committees, including the Clean Air Committee, were abandoned. In their place the EPA created a Science Advisory Board which had a number of discipline- oriented committees; Health, Engineering, Ecology, etc. I served as a member of the original EPA Science Advisory Board Executive Committee by virtue of my chairing the Board's only original issue-oriented standing committee, the Environmental Radiation Exposure Advisory Committee.

In the early 1970s, air quality issues were handled by the SAB on an *ad* hoc basis. An example was the handling of a review of lead as an air pollutant. Lead had not been included as one of the original criteria air pollutants. The National Resources Defense Council (NRDC) took legal action to have lead listed as a criteria pollutant and ultimately prevailed in the Appeals Court (NRDC vs Train). Thus, EPA was required to prepare a criteria document on airborne lead and the decision was made to have the document subjected to external peer review. Since a formal clean air scientific review committee did not exist, I was asked to chair an *ad hoc* committee to review the lead criteria document. The *ad hoc* committee met in public sessions, reviewed the report, received input from the EPA staff and heard public comments.

The Committee's initial conclusion was that the original criteria document on airborne lead was inadequate and needed to be substantially revised. EPA was operating under a court-ordered deadline to issue a NAAQS for lead, a deadline that did not allow adequate time for revision of the lead criteria document. However, the Agency and interested parties persuaded the Court to extend the deadline to allow preparation of a scientifically adequate document rather than merely meeting an arbitrary "date certain" deadline. The *ad hoc* committee reviewed subsequent revisions of the document. Ultimately, a document was created that the *ad hoc* committee approved as being a scientifically adequate basis for setting the National Ambient Air Quality Standards for lead and issued a "closure letter" to the EPA Administrator. The key points being made are that the scientific basis for the NAAQS for lead was reviewed and a decision was made by the *ad hoc* committee as to when the documentation was scientifically adequate for regulatory decision making.

In my opinion, the approach taken by the *ad hoc* committee dealing with lead as a criteria pollutant influenced the decision of the Congress in amending the Clean Air Act

in 1977 to explicitly call for the creation of an independent Clean Air Scientific Advisory Committee (CASAC). The CASAC, in accordance with the Clean Air Act (1977), has periodically reviewed the scientific basis for setting and revising the NAAQS for all the criteria pollutants. I have participated in most of those reviews and served as Chair of CASAC (1988-1992). CASAC has reviewed all of the Criteria Documents for criteria air pollutants prepared by EPA's Office of Research and Development and in some cases, health assessment documents for specific pollutants, such as diesel exhaust. In every instance, the CASAC modus operandi has included rigorous review of the document, receipt of input from the EPA staff and receipt of extensive written and oral comments from interested parties. Until recently, all of these activities were carried out in public face-to-face sessions. On many occasions, the CASAC has offered comments to the Agency on iterative draft documents and, when it deemed the documentation scientifically adequate for regulatory decision making, provided a "closure letter" to the EPA Administrator. Without question, the CASAC has played a critical role in ensuring that the "final" criteria documents were of high scientific quality.

As the Criteria Documents grew in size the CASAC recognized the value of having documentation that could bridge from the science of the criteria document to the regulatory decision-making process. This was the genesis of the "Staff Papers" prepared by EPA's Office of Air Quality Planning and Standards. The CASAC reviewed the Staff Papers, received EPA input, received public comments and deliberated in public sessions on the scientific adequacy of the documentation. Frequently, the CASAC advised the Agency that the current version of the Staff Paper was not scientifically adequate and needed to be revised. In a manner similar to that followed with the Criteria Documents the CASAC provided a "closure letter" on the Staff Paper to the EPA Administrator when it deemed the Staff Paper scientifically adequate for regulatory decision making. The "closure letters" on the Staff Papers have typically included comments on the proposed range for setting the NAAQS.

The discussion here is not intended to be an exhaustive review of all of CASAC's activities; rather the review has focused on the modus operandi of CASAC as a standing independent scientific committee. The activities of the CASAC, in my opinion, have been in accord with the language and intent of the Clean Air Act (1977) and consistent over time with the evolution of CASAC practices that have received substantial public and legal scrutiny. The modus operandi has proved successful in helping to ensure that the NAAQSs are science-based.

It now appears that parties within the EPA, but unknown to the public, have changed the modus operandi of the CASAC. The arguments for change have been made in "administrative sessions" of the CASAC and, thus, have not been made public. As best I can discern the changes are intended to relegate the CASAC to a status similar to other Committees under the SAB umbrella operating under the Federal Advisory Committee Act (FACA) rules. The motivation for the changes has not been publicly articulated. Does the Agency believe that its ability to carry out the mandates of the Clean Air Act have been impaired by previous rigorous CASAC review and the use of a "closure letter" process? If so, this should be publicly documented. I would argue that to

the contrary, even the delays resulting from CASAC's call for more rigorous documentation of the science have contributed to more defensible NAAQSs.

Is the argument one that the CASAC is operating in a manner that is different from some other EPA FACA committees? If so, then the differences need to be publicly documented. Even if differences do exist in how CASAC operates versus other FACA committees that does not make the CASAC past modus operandi inappropriate. The critical issue is whether the CASAC has and is operating in a manner consistent with the Clean Air Act language calling for an independent CASAC and FACA. Over the past 25 years, numerous Chairpersons and members of CASAC have appeared before Congressional Committees. My impression is that the Congress has consistently held a favorable view of the CASAC's modus operandi and its role in implementing the Clean Air Act. I am not aware that either the Congress or senior members of the Executive Branch have advocated changes in how CASAC carries out its responsibilities.

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?

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?

In my opinion, the CASAC and its numerous Review Panels have generally participated in the NAAQS review process in a timely and efficient manner. Indeed, I think the CASAC Review Panels have, on some occasions, been excessively concerned with meeting court-imposed time schedules rather than focusing on the scientific quality of the end product. In my opinion, that occurred with the current Particulate Matter review when serious statistical issues arose delaying the finalization of the Criteria Document. The issue was further confounded by the Agency prematurely releasing a draft Staff Paper. I note it was released prematurely because the Criteria Document was not yet finalized. A draft Staff Paper should never be released to CASAC and the public prior to the Criteria Document being finalized. Because of the Court-ordered schedule, the CASAC Review Panel did not have time for an iterative in-depth review of the Staff Paper. Indeed, the CASAC PM Panel offered comments on key aspects, namely the $PM_{10-2.5}$ indicator, of the Staff Paper after it was finalized in June 2005. As a result, the Staff Paper did not meet the scientific quality standards I expect. In my opinion, this contributed to what I view as a needless debate over whether the Annual $PM_{2.5}$ Standard proposed by the Administrator was scientifically out of bounds as charged by some

members of the CASAC PM Panel. They argued that the Panel had recommended that the Annual $PM_{2.5}$ standard be set in the range of 13 to 14 $\mu g/m^3$.

The Staff Paper related an upper bound of 15 $\mu g/m^3$ which was selected by the Administrator. My personal opinion is that 14 $\mu g/m^3$ and 15 $\mu g/m^3$ are both consistent with the available scientific evidence and the substantial quantitative uncertainty in the health benefits at these ambient concentrations. The bottom line is that the NAAQS review process schedule should be driven by concern for scientific quality and not by court-imposed deadlines. My personal experience is that the Courts will yield to a scientific quality standard if appropriate progress is being made. With regard to the recent round of the Particulate Matter review, I am at a loss as to why EPA attorneys were not willing to argue for scientific quality of the products as trumping meeting court-imposed deadlines that were unrealistic.

A major factor in the timeliness of the NAAQS review process relates to the timeliness of the EPA staff preparation of the (a) Criteria Document, (b) Risk Assessments, and (c) Staff Papers. The time required for their development is dependent upon the efficiency and knowledge of the staff and the resources available. In my opinion, the Criteria Documents could be substantially reduced in scope and size if the documents were to focus on the knowledge base used for decisions on the four elements of the NAAQS; (a) indicator, (b) averaging time, (c) numerical level, and (d) statistical form. There is no need to create an encyclopedia covering everything known on each criteria pollutant. Moreover, I suspect that at least some of the EPA contractors drafting chapters for the Criteria Documents do not really understand the need to focus on the four elements of NAAQS. However, they are not alone; many new CASAC Panel members are slow to grasp this concept.

The efficiency with which Criteria Documents and Staff Papers are developed could be substantially enhanced if the process were to incorporate modern informatic tools and processes. For example, it would be helpful if every piece of literature considered for potential citation in the Criteria Documents should be available in an electronic file searchable by EPA staff, authors, CASAC Panel members and the public.

Increasingly, the contents and quality of Staff Papers are built on formal quantitative risk assessments. The development of these risk assessments is a weak link in the overall NAAQS review process. I find it disappointing that the EPA staff are apparently not capable of carrying out these crucial analyses. I say “apparently incapable” because the assessments are actually conducted by EPA contractors. I am concerned that so much dependence is placed on one risk assessment performed by a single contractor. In my view, the risk assessments are not state-of-the-art and tend to over-emphasize scientific certainty and under-state the substantial scientific uncertainty present in the quantitative estimates of health risks for current air quality and the projected health benefits of various potential standards. A big step forward would occur if multiple parties, including the EPA staff, were to develop risk assessments. I am not at all concerned about having “dueling” risk assessment results. It would be refreshing to

have the opportunity to see how different parties use and model the available scientific data.

The last step in the process bridging from the science on a particular criteria pollutant to the NAAQS is the Staff Paper. As noted earlier, draft Staff Papers should not be released until after the Criteria Document is finalized and the risk assessment is available. The premature release of the PM Staff Paper, based on a Criteria Document that was still being revised and did not adequately document uncertainty, led to an extended period of time for the various special interests to advocate for specific final PM standards**.** Unfortunately, the authors of the Staff Paper are limited in their ability to characterize the certainty/uncertainty in the science when only a single and, perhaps, flawed risk assessment is available. I have been pleased that Staff Papers have wisely identified relatively broad ranges for potentially setting standards. For example, I think the staff's use of a range of 12-15 $\mu g/m^3$ for the Annual $PM_{2.5}$ standard reflected their views of the uncertainty in the underlying science. I think the CASAC PM Panel narrowing the range to 13 to 14 $\mu g/m^3$ reflected some CASAC members lack of appreciation of the scientific uncertainties. Other individuals argued for consideration of the margin of safety, which is a policy consideration for the Administrator, and reducing the upper bound of the range to 14 $\mu g/m^3$. Alternatively, some of the Panel members perhaps wanted to make a "policy statement" that they wanted the current $PM_{2.5}$ standard reduced below 15 $\mu g/m^3$.

As I close this section, I want to enter a plea for transparency and public deliberation on the contents of the Criteria Documents, Risk Assessments, and Staff Papers. I think it was a travesty that the only face-to-face meeting on the last draft PM Staff Paper was only a day and a half in length complemented by brief teleconferences. Moreover, a transcript does not exist for many of these "public meetings." The result is that little deliberation occurred in public. Fortunately, Panel members were given the opportunity to append their individual comments to the CASAC PM Panel letter. I urge you to carefully review the transcript of the April meeting and the CASAC letter and individual comments to gain an appreciation of the extent to which the scientific uncertainties were considered.

More recently, the CASAC PM Panel held a brief teleconference to discuss the Agency's Proposed Rule. The meeting involved very limited deliberation, to the extent 20 individuals can deliberate on a teleconference and reached few firm conclusions. Moreover, a decision was initially made to not append comments of individual members to the CASAC PM Panel letter to the Administrator. The stated reason, off the record, was a desire to present the Administrator with a clear consensus letter. In my view, this approach does not serve the Administrator, the Agency, or the scientific community well. By suppressing divergent views an artificial sense of scientific certainty is conveyed.

The last comment I make on the timeliness of the NAAQS review process is the desirability of the Agency working with Congress to amend the Clean Air Act to extend the review cycle from 5 years to 10 years. Five years is a short period of time in the world of scientific research. A review every 10 years would provide more adequate time

to develop new information and to interpret, synthesize and integrate it for use in the NAAQS setting process. Moreover, extending the review cycle to 10 years would allow for more realistic planning and conduct of the kind of research that has the greatest impact on revision of the NAAQS. In my view, the kind of research conducted in the past has been inappropriately truncated to fit the 5-year review cycle.

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 take exception to the use of the evaluative word, best, in the question – "To enhance the Agency's ability to take best and most recent available science into account ---." Best is an evaluative word; what is best to me may not be best to another scientist. In my opinion, during the development of the Criteria Documents all of the available published literature available by a presumptive cutoff date should be evaluated and considered for inclusion in the Criteria Document. I suggest that what is included in the Criteria Document should be those published papers that have bearing on the four elements of the NAAQS, namely, (a) the indicator, (b) the averaging time, (c) the numerical level, and (d) the statistical forms. I recognize that in taking this approach, a substantial number of papers, including some published by CASAC Panel Members, may not appear in the Criteria Document. The list of evaluated, but not cited, papers could be included as an Appendix or Supplement to the Criteria Document.

If the approach I have suggested is taken, the Criteria Document will be shortened and the interval between the cut-off date and presentation of the document to the CASAC Panel will be shortened. If the EPA staff were to routinely evaluate papers as they are published rather than waiting until an external contractor prepares a prospective chapter, the papers could be more readily integrated into the Criteria Document. I emphasize the need for evaluation, integration and synthesis of a body of literature because that should be the intent of the Criteria Document. It should not be a mere recitation of what is found in a series of papers. This integration and synthesis function is an area where the staff preparing the Criteria Document frequently falls short. All too often they depend on the CASAC Panel to carry out this function. If the EPA staff were to provide a Criteria Document with improved integration and synthesis of the available relevant literature, the CASAC Panels could focus on critical issues. For example, in my view the CASAC PM Panel spent much too little time in public sessions deliberating on the nature of the exposure-response function for $PM_{2.5}$ and $PM_{10-2.5}$ and the associated uncertainties.

In my opinion, the Criteria Document did not adequately explore the difficulty, if not the impossibility, of demonstrating the presence or absence of thresholds. Even less attention was given to exploring the potential range of exposure-response models and the

validity of using a single linear exposure-response function down to levels approaching background. Quite simply, the recent PM Criteria Document overstated the degree of scientific certainty of knowledge on these matters. This continued in the Risk Assessment and Staff Paper. The result was a presentation of results expressed as "body counts" at levels in the range of the current NAAQS that understated the substantial uncertainty that I viewed as being present. I ask – is it reasonable to conduct a risk assessment for different regions of the United States and with PM of markedly different composition and population with markedly different patterns of disease and, basically, using a single exposure-response coefficient? I think this approach is a misuse of science to achieve a pre-determined objective held by some individuals – a reduction in both the annual and 24-hour $PM_{2.5}$ standard.

Distinction 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?

The issue of separating scientific evaluations from policy decisions is vexing and is increasingly an issue in the functioning of the CASAC Panels. It would be helpful if, at each step in the NAAQS process including each meeting of the scientists preparing the Criteria Documents and the Staff Paper and their review by CASAC, if each participant were reminded – *"Every individual should recognize the distinction between scientific evaluation and policy decisions and recognize that the matters being dealt with are at the interface of science and policy. Each individual participant is asked to leave their individual ideologies and thoughts on policy decision outcomes at the door before deliberating on the science."* This is not a matter of an individual's employment, i.e., academic, government, industry, etc. or political affiliation. It applies to all participants. This is an especially vexing issue for scientists involved in evaluating their own research results or that of close colleagues. In today's resource constrained world everyone wants to have their work used in the public arena, moreover, they would like to see the door left open or opened wider for them to do more work on the topic under consideration. Indeed, some individuals, including CASAC Panel Members, desire a "sense of accomplishment" – some individuals interpret that as – did we participate in lowering the NAAQSs? Some have suggested that there would be a "limited sense of accomplishment" if only the 24-hour $PM_{2.5}$ standard were lowered and the Annual $PM_{2.5}$ standard was left unchanged. Yes, scientific evaluations and policy decisions do get inter-twined by individual scientists in expressing their own personal preferences on life science issues.

Repeatedly, one hears the view expressed that is necessary to be "protective of public health." I agree, however, I think that precautionary considerations are part of the policy decision, not the interpretation and integration of the science.

I think the NAAQS setting process can be improved if participants (and this includes EPA staff, EPA contractors and CASAC Panel members) are continually reminded of the need for distinguishing between scientific evaluation and policy decisions. This is not an end of NAAQS process issue. It needs to start with evaluation of the published literature and carry through to the final rule making. It is critical that at each step all of the uncertainties be exposed. It is not appropriate, as happens all too often, to argue that this is a human health issue and it is necessary to be conservative. There is a need to relate <u>all</u> of the scientific uncertainties and then let the degree of conservatism be addressed in a Policy decision. Scientists are reluctant to take that approach because they generally have a deep-seated mistrust of the individuals making the policy decisions. This issue is becoming increasingly important in dealing with the NAAQS for criteria pollutants and the challenge of deciding "how low is low enough." This was exemplified by the recent "fire storm" over the issue of the Administrator proposing to continue the Annual $PM_{2.5}$ standard at 15 $\mu g/m^3$ and many on the CASAC PM Panel who argued it should be set no higher than 14 $\mu g/m^3$. I personally know of no scientific information or scientific methodology that would conclude 14 $\mu g/m^3$ is scientifically acceptable and 15 $\mu g/m^3$ is scientifically unacceptable.

<u>Identifying, Characterizing, Quantifying and Communicating Uncertainties in Scientific Information</u>

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?

I have already opened the discussion on scientific uncertainties. This is probably the weakest aspect of the total NAAQS process and presents, albeit controversial, the greatest opportunities for improvements in the process. Unfortunately, this is a long and steep slope to ascend. The roots of the issue begin with the funding, planning, conduct and reporting of research. Research gets funded on the "sky is falling" issues and on the perpetuation of the "sky is falling" issues. Only limited attention is given to developing "issue-resolving" research strategies. Moreover, when the research is reported, a "the sky is falling" paper may consider some risk factors like PM or O_3 in isolation to magnify their importance.

Indeed, many epidemiological papers fail to adequately consider other potentially serious confounders such as cigarette smoking and other air pollutants and local and regional demographic differences. Many of the laboratory studies using isolated cell systems or laboratory animals use single exposure/dose levels and one or a very few short-term observation periods. The emphasis, time and time again, is on demonstrating

hazards that can be automatically equated to occurring in humans. In short, few research investigations are planned and conducted with a view to quantitatively assessing human risk. All too often, it is not appreciated that at the end of the NAAQS process, it is necessary to be quantitative. Inevitably, in the NAAQS process papers that yield negative outcomes are given scant attention. The view frequently expressed is that "you know you cannot prove a negative, the study design must be flawed." The evaluation "playing field" is clearly not level. Negative findings need to be more adequately considered when relating the scientific uncertainties that under-gird the NAAQS.

In my opinion, the development and presentation of comparative risk data, especially when it is for the same population studied to evaluate a pollutant effect, is extremely valuable for policy-decision making. I recognize that the Administrator is forced by the Clean Air Act to consider each Criteria Pollutant on a pollutant by pollutant basis. Nonetheless, in making a policy decision on "how low is low enough," I think the Administrator would be well served by knowing what were the quantitative estimates for excess risk for cigarette smoke and other pollutants for the same disease outcomes in making policy decisions on a given criteria pollutant. In some cases, the exposition of such data can prove very insightful.

The final steps in the NAAQS process where uncertainties are dealt with for communication to the Administrator are in the Risk Assessment and Staff Paper. Both the Risk Assessment and Staff Paper do a poor job of acknowledging and characterizing scientific uncertainties. Because these documents are linked, the difficulty starts with the Risk Assessment. This is especially unfortunate since some individuals look at any number (as reflected in body counts) as being highly precise and certain. In my view, they are usually very uncertain.

The NAAQS process could be improved by opening up the risk assessment process. The present system typically uses a single EPA contractor organization which may well have an excessively close relationship to the EPA staff. The EPA staff are experts in this arena. Why not have them conduct risk assessments? This might well be complemented by having several other organizations preparing risk assessments. Such a process might illuminate some of the uncertainties and how they influence the quantitative estimates of risk and the attendant bounds. I would be pleased to have "dueling risk assessments" if they helped reveal the underlying scientific uncertainties.

With regard to characterizing uncertainties, I think it appropriate to raise the issue of eliciting "expert judgments." I have participated in these processes working with EPA contractors, so I can speak from experience. In my experience, the "playing field" does not start level. It would appear that the EPA exerts a strong influence in introducing the key studies to be considered in the process and in selecting the participants. In the process I participated in there was major emphasis given to attempting to elicit linear exposure-risk coefficients. I was disappointed to learn that the process I participated in has been extended by EPA staff to a larger group of participants. One could argue that the participants have been overly selected by EPA, perhaps to help ensure the answer is that which is desired by EPA staff. Again, the emphasis is apparently on arriving at a

single linear exposure-response coefficient. To help ensure agreement, I understand the process is designed to be iterative with the group re-assembled to review and refine the first round outcome. I am of the opinion that it would be useful to have a much larger and more diverse group of expert participants involved and place the emphasis on eliciting not only a "central estimate," but the range of uncertainty in the opinions. Of even greater importance, it would be useful for EPA to support a much broader program of research on alternative methods for evaluating exposure-response relationships for extraordinarily low levels of excess risk attributed to air pollutants.

Selection of CASAC Members and CASAC Panel Members

Beyond the questions asked, I think it is important to give some attention to how CASAC members and CASAC Panel members are identified and selected. I want to start the discussion by relating my personal high regard for each individual I have served with on CASAC Panels – it probably is well in excess of 100 individuals. I will also relate the view that service on CASAC and the CASAC Panels is demanding and has few rewards. However, I am concerned that member selection deserves careful review and scrutiny.

The present process is alleged to be open and transparent. While the "public calls" for candidates via the Federal Register and calls to professional organizations have appeal, it also has shortcomings. Increasingly, professional organizations have taken an advocacy role by publishing in Professional Journals their views on desired outcomes for NAAQS, i.e., an Annual $PM_{2.5}$ standard of 12 $\mu g/m^3$. I belong to at least one of these organizations and view it as being a highly meritorious Professional Society. However, I am concerned that in advancing its views, it is expressing a view based on both science and policy considerations. It is appropriate to ask on what basis such organizations nominate candidates for CASAC Panels? In the nomination process there is a perception that any industry association is a "kiss of death" for participation on a CASAC Panel or, indeed, SAB Committees concerned with hazard/risk issues.

My concern for individual scientists being able to disentangle science and policy issues covers the landscape – academic, government, industry and non-government organization employees. Few individuals do it well and many cannot do it at all – that is human nature. I also have concern for the role of the EPA staff in nominating individuals or encouraging the nomination and selection of individual members of CASAC or CASAC Panels. Part of the concern for the role of EPA staff relates to the perception in some quarters that the EPA staff, in general, is quite "risk averse." I am also concerned at the use of a two-tired system; one for selecting CASAC members allegedly appointed by the Administrator and consultants appointed by the SAB office. It would appear that the former appointments receive more scrutiny than the latter. I suggest both CASAC members and consultant appointments deserve the same degree of scrutiny. The process by which CASAC members and consultants are selected deserves careful review.

CASAC Processes

The CASAC occupies a relatively unique role within the EPA. It is a Congressional mandated independent scientific committee, however, it is housed within and managed by the Office of the Science Advisory Board. I have very serious concerns about how the CASAC has been managed by the SAB in recent years. There appears to have been an effort to "stove pipe" the CASAC into the same mode of operation as other SAB committees. The SAB staff supporting CASAC appear to give little consideration to the historical context for CASAC's operation. Major attention has appropriately been given to creating a CASAC that functions flawlessly and seamlessly in accordance with all the applicable statutes.

In my opinion, little attention appears to be given to creating and managing a process that values scientific discussion and deliberation. Major process issues have been announced in "executive sessions" without any explanation to the public. When questioned, the answer on some occasions is the lawyers recommended the change, for example, abandoning the "closure letter" process in favor of offering "advisory letters" and issuing letters from CASAC despite the fact that the matter in question was considered by an entire CASAC Panel. Irrespective of the basis for the decisions, since they relate to a public science advisory committee, they should be announced and explained in public sessions.

The SAB Office has apparently abandoned the process of creating "transcripts" for all CASAC meetings. Transcripts are needed for all meetings, irrespective of whether they are face-to-face meetings or teleconferences. This is unfortunate since the proceedings of all CASAC Panel meetings should be available for public review. Indeed, as a past CASAC Chair, I can relate that I found such transcripts very useful in recalling what occurred at a given meeting and in the development of letters to the Administrator. The use of teleconferences has become a part of the modus operandi for CASAC Panels. Teleconferences may be useful for conveying information; they are not effective for scientific discussion and deliberation among a Panel of 20 members. For example, I am at a loss as to why a teleconference was used for discussing and reaching a CASAC position on matters of such importance as (a) the $PM_{10-2.5}$ Indicator or (b) the CASAC PM Panels views on the Proposed PM Rule. If these matters are of substantial national importance, and I think they were and are, then in my opinion they deserved a face-to-face meeting of the CASAC PM Panel. On these, as well as other CASAC matters, I have heard budget constraints advanced as dictating the actions. I find this a "hollow argument" for an Agency with a budget in excess of $8 billion per year. If the work of CASAC is of vital national importance, and I think it is, then I think the Administrator and staff need to find the funds to have CASAC do its work in the appropriate manner. That has not been happening.

Additional CASAC Member Individual Comments on EPA's NAAQS Process

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Dr. James Crapo

March 20, 2006

The following are my thoughts about how the NAAQS process could be improved:

Timeliness and Efficiency of the Current Process for both EPA's and CASAC's Review of the Air Quality Criteria and the NAAQS

Having served on CASAC during the recent and ongoing reviews of ozone, PM, and lead, it is my observation that the current process has evolved into an inefficient and ineffective process. This leads to major delays and reduces the ability of CASAC to provide rigorous scientific input into EPA staff recommendations and policy decisions. The most critical discussions of each topic are often delayed until the process is under court order to proceed and adequate time is not available for effective and thoughtful interactions.

The current process requires that a first and second draft of the air quality criteria document (AQCD) be prepared [by NCEA-RTP for a given criteria air pollutant] and discussed by CASAC, which is then followed by a first and second draft of staff papers which are discussed by CASAC, leading to a final CASAC letter to the Administrator. This process produces expansive review documents on the literature underlying each subject area but adds years to the review cycle and inhibits effective discussion of the critical issue, *i.e.*, whether or not there are adverse health effects at current air quality standards. The AQCDs contain no conclusions regarding the air quality standard and CASAC is inhibited from meaningfully discussing this issue during the process of reviewing the AQCD. The majority of CASAC time is often spent on reviewing literature rather than discussing the critical issue of whether or not adverse health effects exist at current air quality standards. Finally, the majority of the literature discussed in the AQCD focuses on levels that are not relevant to current environmental conditions in the United States or the air quality standards. In each review cycle there are only a small number of critical scientific studies that address the form and standard of the current NAAQS. These critical articles are nearly lost in the massive size of the current AQCD and the process established for its review.

The current review of the air quality standard for lead illustrates the above problems. The current air quality standard for lead was set in 1978 and EPA has not conducted a review of this standard in the past 15 years. The World Health Organization has set an air quality standard for lead that is 3 times lower than the current U.S. standard. This was done in the 1980s. The most recent AQCD for lead is a massive document requiring enormous time by the EPA staff to prepare and which is still not comprehensive. In addition, after weeks of review and a two-day meeting discussing this document, CASAC has not yet discussed the question of whether or not the current NAAQS for lead is adequately protective of human health. I would conclude that the current process does not allow the EPA and its [Clean Air] Scientific Advisory Committee to

effectively address their charge to carry out a timely and effective review of air quality standards for the United States.

I would recommend that the entire process be changed along the following guidelines:

– Requirement for a comprehensive AQCD should be eliminated.

– A short AQCD (page-limited) focused only on scientific studies that address relevant air pollutant levels in the United States and which address adverse health effects at those levels should be prepared.

– The staff papers should be incorporated into the AQCD reducing this to one document which could undergo two or at most three reviews.

– The air quality document should begin with an interpretation (staff recommendation) on the quality of current science relative to the question of adverse health effects at the existing air quality standard. The document should then defend that staff interpretation of the scientific literature through its summary of studies that directly address the critical question.

– Comprehensive summaries of the literature should be placed in an appendix and only articles deemed to be relevant to the question of the current form and standard for each regulated air pollutant should be included in the primary document.

– The discussions at CASAC meeting should focus on whether or not the current air quality standard is adequately protective of human health.

The above recommended process would be far more efficient in both the use of EPA staff time and the time of CASAC members. It would dramatically reduce current inefficiencies and allow the EPA to meet its obligation for a timely review of air quality criteria and NAAQS. It would also allow CASAC to have a more effective role in defining the scientific basis for changing or not changing current NAAQS.

<u>Consideration of the Most Recent Available Science</u>

The above recommended change in the process for EPA and CASAC review of air quality criteria and NAAQS will substantially enhance our ability to consider the most recent available science. No cut-off for a published article to be discussed in the preparation of the final document would need to be imposed. Because critical articles relevant to the final decision would be considered up to and including the final draft of the document, there would be opportunity for them to be considered by EPA staff and discussed by CASAC. By restricting the focus to only articles that directly deal with the question of current air quality levels and the presence or absence of adverse health effects at current air quality standards, there would be no need to impose a cut-off for consideration of best science.

In summary, the EPA NAAQS review process and policy judgments can be made far more efficient if changes are made to require preparation of smaller documents that focus on the

question of the adequacy of current air quality standards to protect human health and to allow both staff and CASAC to focus on this question from the inception of each review cycle. The process could ideally be completed in less than one year, requiring two and at most three cycles of discussions with CASAC and should result in a more effective statement to the Administrator regarding the science that should be used as a factor in making policy judgments.

Sincerely,

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Attachment 3-D

Dr. Frederick J. Miller

Comments on the NAAQS process

Frederick J. Miller

March 24, 2006

Over the last 30 years, I have seen the NAAQS process unfold from both sides of the table – first as an EPA employee coauthoring chapters in Criteria Documents (CD) and interacting with members of CASAC, later as an ad hoc CASAC reviewer, and since 2000 as an EPA appointed regular member of CASAC. Others who have served on CASAC have provided their insights and suggestions for improving the NAAQS process. I offer the following comments on the strengths and weaknesses of the NAAQS process and how, in my opinion, this process needs to be changed.

Timeliness and Efficiency of the Current NAAQS Review Process

With each review cycle for a NAAQS pollutant, the number of available scientific publications has grown exponentially. Because the Agency has viewed the CD as needing to be exhaustive in the review of all available peer-reviewed papers, the NAAQS CDs have greatly expanded in size, thereby requiring longer and longer periods of time for review and more iterations if the documents are not of high quality or if they contain biased discussions of the studies. This has led to court ordered time schedules and a less than desirable process – in short, the current process is broken and needs to be fixed.

Recommendation – Change the structure and focus of the CD

We need to know if effects are occurring below the levels of current NAAQS standards and if current standards are adequately protective of public health. Thus, the main focus of the CD should be to identify and discuss any new studies, for which there will usually be few, that establish effects below the levels of current standards. In addition studies that are relevant to the indicator for the standard, the averaging time, and the statistical form should be included. All other studies should be relegated to appendices tables if the Agency is required to or wants to be "complete" in its review of the literature.

If the structure and focus of the CD were done as suggested above, CASAC and Agency staff could have more interactive discussions on these results and interpretations of these critical studies. CASAC would be in a better position to identify if there are other studies that are relevant to the indicator variable, averaging time, numerical level, or statistical form. And most importantly, discussions at CASAC meetings could focus on whether or not current standards protect public health with an adequate margin of safety. This new focus might also enable the CD and Staff Paper to be combined into a single document, as has been recommended by CASAC member, Dr. James Crapo.

Consideration of the Most Recent Available Science

Since scientific research is iterative, there is no magical date when all is known about an issue. The lengthy time for preparation and review of the CD and Staff Paper for a

NAAQS pollutant is a by-product of the current process. If the CD structure and focus is changed as suggested above, the ability to incorporate the most recent available science would be greatly improved because the time interval for the process would be significantly shortened compared to what it is now.

Recommendation – Incorporate critical new science

If the CD focuses on studies that impact our knowledge about pollutant effects at or below the levels of current standards, there should be ample time in the review cycle to consider critical new science. The new science must, however, meet the following criteria: (1) be judged to be of such a nature that it could change the indicator variable, averaging time, numerical level, or statistical form of the standard, and (2) have been reviewed and vetted by CASAC. The second criterion is absolutely essential for maintaining the objectivity, credibility, and integrity of CASAC in fulfilling its statutory mandate. I agree with others who have noted that the recent EPA management change eliminating the long-standing finalization of the CD and the Staff Paper via a CASAC closure letter was unwise. The inclusion of newly available science should not be done by bypassing CASAC review of this new science.

Additional CASAC Member Individual Comments on EPA's NAAQS Process

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Dr. Sverre Vedal

March 29, 2006

I would like to comment briefly on two of the key questions posed to CASAC panelists.

Consideration of the most recent available science

First of all, I am concerned that the science that we have available for review already is not providing us with a complete, or entirely valid, picture. This contention is based on the well-documented publication bias present in the air pollution field, at least for population-based findings. An illuminating demonstration of this bias is the contrast between conclusions contained in Health Effects Institute (HEI) scientific reports and some published journal articles derived from the same findings. While there are undoubtedly several causes of this publication bias, investigators, journal editors, and even the journal peer review process, are partly to blame. What is the alternative to limiting what we consider science for the purpose of the CASAC review to the published literature? While I am not intending to promote HEI specifically, one precedent was recently set by HEI in addressing the statistical software problem in time series studies. This process occurred outside the traditional publication process and provided EPA with the information needed in an efficient and credible manner. Generalizing such a process to the task of assessing larger scientific questions may hold some promise and be worthy of consideration. Clearly this would take resources that are currently not available.

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

The uncertainties in the epidemiological estimates of effect, estimates that are now the primary bases for recommendations on changes to the NAAQS, are not adequately reflected in the current risk assessment and risk analyses. A formal probabilistic risk assessment that fully takes into account identified uncertainties is needed.

Sverre

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Summary of Major Stakeholder Comments[1]

Planning

Criteria for selecting studies

- A careful set of criteria for studies should be defined *a priori* and reviewed by CASAC
    - Could support meta-analysis (N)

Identify issues with management

- At the beginning of the process, identify issues that need to be focused on in the next review, and get senior (political) management input at that time as to whether that is the direction where they want us to go (I)

Maintain status quo

- Generally, thinks the process works very well and is not "broken"; applauds OAQPS (S)
- Does not want to see any major changes (E)

Resources

- Wonders whether resources are adequate (S)
- On the timeliness issue, very simple answer: EPA needs to devote adequate (well-allocated) resources to make it happen every 5 years (E)

Welfare effects

- Don't forget about welfare effects (E)

Science assessment

Time between "closure" and final regulation

- Time between closure and proposal an issue (N)
    - Perhaps the concern about the "newest" science is overstated – very rare that a single new study (or a small handful) is that important
- Remember, new science is not always the best science. Need defensible criteria to determine best science (S)
    - Having clear criteria could help CASAC in its review

Continuous study collection with criteria for evaluation

- EPA needs to take advantage of electronic methods better to collect information better on studies (N)
    - Current reliance on big tables and long text is cumbersome. Possible models:
        - Database used in the Surgeon General's report
        - NAS PM Research committee database
        - Anderson's work for the European Union
        - HEI's work in Asia

[1] Note: N = National Academy of Sciences (NAS) chairs
I = Industry stakeholders
S = State stakeholders
E = Environmental stakeholders

    - A Microsoft Access database, set up correctly, can be used in a lot of different ways, and could serve more than the needs of the NAAQS (N)
        - Need young computer whizzes on staff to do this – get people in-house
        - Developing such a database should be continuous and not tied to the development of a specific Criteria Document (N)
- The Agency should have an ongoing process for reviewing new studies as they appear. The Criteria Document could just compile these reviews, with description of uncertainties (I)
- Early on, do a notice requesting papers to submit, set clear criteria up front for how EPA would review these studies. Bring all the uncertainties forward in the write-up, but note that this does not mean ignore if there is uncertainty. (I)
- Continual data collection (surveying scientific literature) rather than doing everything all at once, using a database (E)
- Need clear guidance on how studies are to be reviewed (S)
- EPA needs a continuous review process (S)
    - Perhaps EPA could do an annual report on new science (at least for PM and ozone) and get CASAC review to answer whether the new science changes the overall view of the science – giving a head-start on the Criteria Document process

Need for a more concise science assessment/criteria document

- Current model for synthesis (200-page "synthesis" with a paragraph at the end that pulls it all together) is not the best approach (N)
- Criteria Document should be a true update rather than a rehash of older work (N)
- Criteria Document is too long (S)
- Combine Criteria Document and Staff Paper into a single step with one peer review (S)
    - Others on this call believe these should be maintained as distinct documents; there is already some overlap in their development, but perhaps this could be increased
- Need to explicitly compare what we knew in the last review vs. what we know now (I)

Uncertainty

- Criteria Document needs to be better in its qualitative approach to describing uncertainty (N)
- There are different types of uncertainty – real scientific uncertainty and people who just disagree with the science outcome. When Criteria Document cites "other points of view," need to be explicit about whose views these are to assess whether honest scientific arguments or something else (E)
- Stakeholders always want more analysis. Need to discuss strength/weakness of studies and try to understand uncertainties for standard setting, but can go overboard (S)

Risk/exposure assessment

Positive statements re: risk assessment

- Risk assessments done by OAQPS are quite thorough and transparent (N)
- Sensitivity analyses that are done now are very helpful and well done (E)

Recommended improvements

- Expedite implementation of the NAS recommendations on benefits assessment (I)
- The choices made in the assessment need to be clearly delineated. Needs to be more transparency in the assessments to highlight what we look at or choose not to look at (I)

Negative statement

- "Risk" is just a means of "writing off" some anonymous individuals who will be hurt or killed by air pollution (E)

Policy assessment

Avoid premature review

- First draft of Staff Paper often brought to CASAC in a form that is too incomplete (N)

Eliminate Staff Paper

- Get rid of the Staff Paper and put all that information into an ANPRM for everyone (including CASAC) to review just once (I)

Maintain current approach

- EPA risk assessment and Staff Paper do an excellent job getting at uncertainties; CASAC is the cause of EPA having to chase down a lot of insignificant loose ends (S)
- Staff Paper is a good thing – should not be done or influenced by political leadership. Keep politics out of it (E)

CASAC review and advice on criteria and standards

Need clearer guidance as to CASAC role

- CASAC needs clear guidance — that it can speak of the adequacy of standards, but that its arguments must be grounded in science (N)
    - Need to better articulate CASAC's scientific rationale for judgments; population protected (a policy call) versus the nature of the dose response curve (science)
- CASAC should be reviewing what management wants to do, not staff recommendations
    - But if we want this, need to add policy specialists on CASAC
- Need a "lecture" at the beginning of the process for CASAC members — that they advise but do not make policy (I)

Need for formal "closure"

- Get rid of "closure" (S)

Bias

- Need to address the issue of bias (real or perceived). For example, with respect to CASAC members (I)
    - the choice of CASAC members;
    - concern that certain members are reluctant to contradict EPA staff because that might stop the flow of grand money;
    - lead reviewers of individual chapters who also wrote cited papers;
    - publication bias (always mentioned, then swept under rug);
    - insufficient time for public comment at meetings
    - inappropriate contact between EPA staff and CASAC members (e.g., CASAC dinners)

- inappropriate conduct of CASAC members during public comments (e.g., side conversations)
- members who have clear policy goals in mind

How to address CASAC comments

- EPA needs to do a better job of managing CASAC process. Need to hear from all members, but perhaps not necessary to address every individual comment (S)
  - EPA is too deferential
  - Perhaps use decision science to identify what the important issues/uncertainties are and limit resources on other topics, even if CASAC members are stressing them

Issues related to CASAC roster, structure

- Perhaps there should be a CASAC subcommittee that reviews the risk assessment (N)
- Would be a good idea to have a State technical and policy person (2 individuals) on CASAC (S)
  - It should be science only – keep policy people off CASAC (differing state opinions)

Rulemaking

Decouple regulatory process from scientific assessment process

- The short time for review is a problem for EPA; concern that decisions must be made before science is fully vetted. Perhaps when the clock runs out, EPA could as a matter of routine, just reaffirm and let the process run its course (I)

Continual management role

- Maintain management communication throughout (I)

Decision criteria

- Science/policy distinctions? A fallacy. NAAQS must be set on science, protect health with adequate margin of safety. NAAQS decisions should not be based on other considerations such as how nonattainment is affected (E)
- Uncertainty – must err on the side of protecting public health, whole reason for an adequate margin of safety (E)

Concerns regarding current process review

- A post-April 3 process is needed before any recommendations are acted upon (E)
- Several NESCAUM member States expressed concern about their lack of participation (S)
- Consider input from states other than NESCAUM and California (I)

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Office of the Chairman

March 13, 2006

Memorandum

TO: Lydia Wegman, Kevin Teichman

FROM: Jon Samet

SUBJECT: NAAQS Process

I am writing to elaborate on comments made during our telephone discussion on Monday, March 6th. I am pleased to have the opportunity to provide input as the US Environmental Protection Agency (EPA) considers the process by which the National Ambient Air Quality Standards (NAAQS) are set. This process now has long historical precedent and it has proven successful in many respects. However, as I noted in our discussion, the process has become "dated" and could be made more efficient and informative.

Any revisions to the process should reflect the increasing challenge posed by the extent of the scientific information available in regard to the setting of a particular NAAQS. In the example of particulate matter (PM) the peer-reviewed literature available, even for a five-year interval, is extraordinary in its diversity and abundance. The long-used format for gathering the evidence for assessment, assembling a large, tabular volume, is no longer effective. In the instance of epidemiologic research alone, tables may include numerous studies, easily 100 or more in some lines of investigation, and characterizing the key advances made from bullet tables and tedious text is very difficult.

Consequently, I suggest consideration of moving to a database approach that would better use available information management technology. As an example, we have developed an Access database that has been used for assembling evidence on smoking and health. Core information about each publication is complemented by tables that capture the study data. Once all of the information is abstracted into the database, there is potential to generate files for analysis, including quantitative summaries using meta-analysis. The project carried out by Ross Anderson and colleagues at St. George's in London is another model; Ross has been supported by WHO-Euro to assemble a database of the findings of time-series studies. The time-series study example is useful, as many such studies have been published, and any synthesis of the evidence needs to explore heterogeneity and to look at summary measures.

The EPA also needs to give formal consideration to methods for evidence synthesis. For example, what is the role of quantitative meta-analysis? Should Bayesian approaches be considered?

The current NAAQS process has a mandated five-year time frame, although that period is almost invariably exceeded. The development of the Criteria Document usually begins several years in

advance of anticipated deadline and often moves hastily at its end. As an alternative, I suggest that EPA maintain a unit with the dedicated task of keeping an up-to-date database of evidence. Done properly, this database could serve the information needs for Criteria Documents on the various Criteria pollutants; in fact, the same study may be relevant.

Another major issue for consideration is the process for moving from the Criteria Document to the Staff Paper and its recommendations. The algorithms for this translational step are varied and, in the recent example of PM, have included a risk assessment. The conduct of a risk assessment was informative in this instance, but the policy framework for interpreting the results was not explicit. The process would be better served if the translational steps were better spelled out so that there was greater transparency. The review of the Staff Paper by CASAC might be more effective if the underlying framework were evident.

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Phone 617-259-2000 Fax 617-742-9162
Arthur N. Marin, Executive Director

March 15, 2006

Lydia Wegman
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency
Research Triangle Park, NC 27711

Re. *Key Questions for the Review of the Process for Setting NAAQS*

Dear Ms. Wegman:

NESCAUM offers the following comments and suggestions regarding the review of EPA's process for setting National Ambient Air Quality Standards (NAAQS) based on observations stemming from our participation in the recent particulate matter NAAQS review. NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

Overall, the process for setting NAAQS works reasonably well at the EPA staff and the Clean Air Scientific Advisory Committee (CASAC) level, except for the habitual tardiness of completing the review. Agency staff and CASAC are to be commended for their comprehensive and dedicated efforts. NESCAUM offers the following perspective regarding the key questions to which you have solicited feedback. These thoughts are offered in addition to the feedback provided on our March 3, 2006 telephone conversation with EPA staff and the State of California.

Timeliness of the NAAQS review process

An overriding concern is the overly long time between the start of the review and the publication of the Agency's proposed decisions on standards. EPA should strictly follow the Clean Air Act's requirement to conduct reviews every five years. Given the difficulty of achieving this requirement, management efforts should focus anew on how best to assure this objective. Its successful implementation will minimize unnecessary and preventable public health impacts. Possible suggestions – some of which may already be in place – include:

- Conduct the Criteria Document literature review early on as a cumulative multi-year process with formal report summaries every six to 12 months. These could be internal documents or shared externally. Consider this process as creating preparatory interim materials for the first draft of the Criteria Document (CD). The expectation would be to avoid a massive effort to evaluate years of material simultaneously; invariably such "crash" efforts take longer than expected and overwhelm staff. If EPA already uses such a process, consider expanding its scope so that each interim deliverable accomplishes as much as possible (e.g., literature review, analysis, interpretation, integration) as soon as possible (e.g., within the first 1-3 years of the next review cycle). Each subsequent report

could integrate previous materials so that the final interim report will represent a cumulative approximation of a first draft CD. This could also help reduce CASAC's work load in reviewing early CD drafts.

- Likely this process would require pre-established transparent protocol regarding various criteria, including literature selection and analysis procedures. It would also require organizational cohesion and suppleness across EPA subject-area groups. Preferably, this protocol would provide staff with clear guidelines so that each interim report was subject to the same "recipe" of steps. This could help to ensure consistency and continuity within each review process as well as across separate review processes. It could also facilitate understanding among CASAC and public participants of analytical methods EPA uses when preparing the CD.

- Reduce the length of the CD. View the document as an update of science rather than an encyclopedic report. To the extent EPA can conduct timely 5-year reviews, this will help to reduce the tendency of CDs to become unwieldy.

- Evaluate the feasibility of concurrently preparing the CD and Staff Paper (SP). Revisit original assumptions and arguments made that advocated for the temporal separation of each document's preparation. If the cumulative CD process described above is used (or augmented, if already used), perhaps early iterations of the SP could be prepared based on early interim CD deliverable reports.

- EPA's relation to the CASAC deliberation process should continue to maintain Agency deference accorded to individual and collective committee views and proceedings. CASAC's internal deliberation process, however, should incorporate additional mechanisms to limit the influence that certain members could exert if this influence unduly slows or roils the review process. Do not allow actions to exert a pell-mell and instantaneous effect on the committee's schedule and overall decision-making process. Otherwise, throughout the course of 2-3 years such delays can snowball, placing a difficult and perhaps unnecessary burden on other CASAC members and EPA staff. Perhaps CASAC leaders could communicate more definition and expectation to committee members before the process begins; perhaps employ more "rules of order" during committee proceedings. I recall examples where a very small CASAC contingent appeared to invoke a final hour public comment or overly dwell on scientific uncertainty with the effect of delaying both CASAC and EPA's ability to move forward with the revision process. The collective effect of these instances was likely nontrivial. It might be worth analyzing CASAC meeting transcripts to identify the frequency and severity of such cases. While it is commendable to act upon public comments and raise uncertainty issues, some type of leadership oversight, group consensus, and vigilant awareness should accompany these actions. This would ensure minimization of inconsequential concerns that could negatively impact process timeliness and schedule-keeping.

- It is important that CASAC and EPA continue to provide adequate opportunities for public comment. The periodic scheduling approach of reducing individual comments from 5 minutes to 3 minutes should be reconsidered. For commenters that have devoted extensive resources and time to preparing detailed materials that make use of original data, 3 and even 5 minutes can be insufficient. Nonetheless, the wisdom of providing equal time to all parties should prevail. The recent practice of allowing groups to stack individual public comment periods covering separate topics seems arbitrary and requires the group to expend more resources to attend the meeting. This could give an unfair advantage to groups with substantial resources. Regardless of what means EPA uses to schedule public comments, the Agency should provide an explicit policy well in advance of the meeting rather than right before or during the meeting, whenever possible.

- Given their heavy workload and responsibilities in reviewing EPA materials, is it realistic to assume that CASAC members will have adequately reviewed public comments materials submitted to them in advance? NESCAUM experienced this effect: CASAC members who had not devoted time to deliberation of public comment materials received in advance of the meeting admitted they had "not been aware of" materials from our 3-minute presentation. Afterwards, they wished they had been aware of these materials during meeting deliberations. Perhaps EPA could prepare a document that overviews public comment materials that are submitted in advance. The Agency could share this overview document with CASAC members. This might make it easier for CASAC members to consider public comments, especially those comments that provide data analysis deemed by EPA as relevant and credible.

Consideration of the most recent available science

- If EPA can adhere to a strict 5-year schedule then the Agency will not table (for upwards of a decade) studies that appear at the end of the review cycle and which miss cutoff dates. The above comments on timeliness of review using a cumulative yearly process could serve to shorten the time between the presumptive cutoff date for scientific studies evaluated in the review and proposed decision dates.

- EPA's Administrator should not base standard-setting decisions on studies that CASAC has not reviewed and which have not been subject to public comment. Such a last-minute process could undermine the peer review and public accessibility intent of the Clean Air Act. The management problem leading to lack of timely NAAQS revision should not interfere with the need for transparency and orderly scientific review. If EPA considers studies published after the cutoff date so ground-breaking and important that they require inclusion, then EPA could conduct a mini-review subject to CASAC and public comments. Regardless, the Agency should discourage such a process and lay out in advance criteria for deciding that a late-breaking study is ground-breaking.

- The Agency should lay out criteria used to determine what science is "best" and to delineate what science is "most recent."

- Is the "best" and "most recent" science necessarily the strongest science? Care should be taken in determining how these concepts are understood and utilized. The "newness" of studies should not be construed as *a priori* more relevant or stronger than "older" studies in a manner that mistakenly accentuates their bearing on the process. The potential for this is likely more subconscious than conscious, and should be guarded against. "Best" science may not be the most relevant science, depending on how it is defined. For example, an innovative and nimble small-scale study with plausible findings based on new data might not be as rigorous as a large-scale comprehensive study with airtight findings replicating previous studies. But the public health relevance of the former study could be more important. What if emerging hypothesis-driven data capture an important public health concern that should be addressed precisely because the consequences of not acting could outweigh the consequences of waiting? Should the process detach these potentially informative findings from decision makers? This could have the unintended result of relegating important information into lesser categories of "non-best" science. Does the current process ignore that data until it becomes absolute, if this is how "best" science is defined? Is the "best" science good enough to identify public health risks? Perhaps plausibility should be incorporated into any criteria used to define "best" and "most recent" available science. Moreover, lack of timeliness in conducting NAAQS reviews every five years would exacerbate the potential negative impact of these considerations.

- Is the "best" and "most recent" science actually "available" in a comprehensive way? Academic frameworks of knowledge pursuit largely drive the current composition and manner of CASAC. These frameworks often collect knowledge generated from within their sphere of familiarity. Local, state, and federal frameworks using knowledge generated from within their respective spheres within the arena of public health decision making are responsible for the implementation of standard setting. How certain are we that these spheres overlap? To what extent do NAAQS reviews incorporate local and state public health science? To what extent is academic science incorporated into everyday local and state decision making? Such considerations could recommend state public health agency representation on CASAC as well as within the formulation of criteria for "best" and "most recent" document selection used in the decision-making process for setting NAAQS.

- Broad multi- and interdisciplinary staff expertise – both within EPA and across to relevant public health agencies (local, state, federal, tribal) with overlapping interventions and mandates relating to ambient air quality – should be emphasized when considering "best" and "most recent" and "available" science. Periodic assessments of this capacity should occur.

Distinctions between science and policy judgments

- Science should inform policy judgments; policy should follow the science. Science should not be misconstrued or unduly influenced to support policy goals based on issues other than health. If policy judgments are expected to be based upon scientifically-informed public health decision making, then they should be, with no exceptions.

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

- Over time, scientific uncertainty will be resolved incrementally. The more current and frequent the chance to update science to inform standard setting, the better public health protection society will enjoy. From a public health perspective, decision making with absolute certainty is unrealistic. Public health decision making must be conducted in spite of uncertainty.

- Uncertainty should not be construed as an excuse to delay decision making or to minimize public health concerns stemming from decision making. Nor should uncertainty be construed as a pejorative concept. Uncertainty is a part of the scientific process. Thus, the 5-year review cycle should be adhered to strictly as science adds to our knowledge over time. Timely NAAQS review is perhaps the best remedy for addressing scientific uncertainty in standard setting.

- CASAC should determine how best to handle the numerous uncertainties of scientific information they are tasked to review. The committee should not use uncertainty as an excuse for delay or fixation. Rather, when issues of uncertainty arise – whether small, moderate, or large – the committee should collectively have a clear-cut method of addressing uncertainty and then move on toward completing its job in a timely manner, uncertainty notwithstanding.

Thank you for the opportunity to provide these perspectives.

Sincerely,

Philip Johnson
Senior Scientist

cc: NESCAUM Directors
Arthur Marin, Executive Director

Attachment 4-D

AMERICAN LUNG ASSOCIATION
ENVIRONMENTAL DEFENSE

March 22, 2006

Mr. Marcus Peacock
Deputy Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. N.W.
Washington, D.C. 20460

Re: Requested Comments on the Process for Setting NAAQS

Dear Deputy Administrator Peacock,

This letter is in response to your staff's invitation to comment on the process for setting National Ambient Air Quality Standards, as part of a review you requested in a December 15, 2005 memo.

On January 18, 2006, we wrote you the attached letter expressing our concern that the process outlined in your memo was far too abbreviated to provide for adequate public input and review. We expressed our concern that any reconsideration of the process for setting the NAAQS must allow for a full and open opportunity for public comment. To date you have not responded to our letter.

We therefore respectfully reiterate our concerns about the approach EPA is undertaking. First and foremost, to the extent that a review is necessary, EPA must ensure that the process is transparent and open to full input from both the expert scientific community and the lay public. The extremely limited amount of time that you have set for this process hampers meaningful public involvement. Indeed, we ask you to re-consider this accelerated, truncated and opaque process and to instead engage in a deliberative, transparent and inclusive dialogue with the wide range of affected interests. The Agency has provided scant public information about the concerns that have prompted this review. At the same time, only an extremely limited set of organizations and individuals are even aware that this review is taking place. The inaccessible rationale for this process and the limited opportunity for informed public involvement have precluded the meaningful public input that is the hallmark of rigorous public policy.

The NAAQS review process must meet two requirements mandated in the Clean Air Act: that the review of the science and the standard occur every five years and that the result is a standard that protects public health with an adequate margin of safety. These dual pillars comprise the statutory foundation for evaluating the NAAQS process.

The extant NAAQS review process succeeds in three essential respects. First, the process provides frequent and significant opportunities for public comment, including opportunities to

comment on the work plan for the review, protocols, the draft criteria document, staff paper and risk assessment, and on CASAC's letters and input. Second, the criteria documents developed for each NAAQS review provide valuable and thorough reviews of the science of air quality impacts on public health. Third, the process allows independence for EPA staff scientists to develop recommendations that are purely based on the science as "requisite to protect the public health" and provide "an adequate margin of safety."

Prompt and regular reviews are required by law and are essential to protect human health. If EPA seeks to improve the process, we recommend allocating sufficient staff and resources to complete the reviews on the required five-year schedule. Congress clearly intended that the public benefit from the most current scientific understanding of the health risks from air pollution. EPA's failure to meet those cycles is not just a missed deadline; failure means that some of our most vulnerable citizens literally risk life and health because dangerous levels of air pollution are not recognized and addressed promptly. Furthermore, keeping to the five-year cycles resolves the issue of how to incorporate emerging research. With a regular review cycle, unlike the current pattern, emerging research becomes grist for the analysis that will immediately follow.

In addition to sufficient resources, we would recommend the following measures to shorten the time required within each review period:

- EPA should examine whether use of automated search processes, publication notification services, improved database technology and electronic publishing could streamline and modernize the literature search and assessment process by enabling a continuous review of new scientific literature as it is published.
- NCEA staff should summarize the conclusions in the last criteria document and focus their efforts on reviewing research published since the last review, rather than beginning anew with the science in each cycle. The criteria document should clearly identify concentrations at which effects are observed.
- OAQPS staff should use the assessment of the science from the criteria document in the staff paper, and concentrate on original analysis of air quality, health impacts, and sensitive populations and other analyses that inform the policy recommendations.

The result must protect public health with an adequate margin of safety.
The second requirement is to produce a standard that protects public health with an adequate margin of safety. The basis of the standard must be a scientific review of objective peer-reviewed research and analysis.

The Act requires an "independent, scientific review committee" to review the science and to recommend any revisions to the standard. The clear direction of this was to create an open, transparent process for scientific review and deliberation to provide an independent assessment of the science. Without question, this open review is integral to this process and must not be short-circuited. The CASAC review process has consistently provided open public discussion and assessment.

The staff paper likewise provides valuable scientific recommendations from the staff to the Administrator, with the opportunity to provide such recommendations insulated from political and economic considerations, consistent with the Clean Air Act. Like the criteria document, the staff paper is subject to peer review and thoroughly vetted in open forum. The process must allow the EPA staff to develop recommendations that are exclusively based on the public health science, without consideration of either politics or cost. This valuable process has stood the test of time.

As the reviewing courts have repeatedly held, the Clean Air Act clearly separates the process of setting NAAQS from the process of implementing them. If the Administrator follows that dictate, the decision to set the NAAQS therefore will be based on science—on what limits should be set to protect public health with a margin of safety. Policy considerations such as implementation priorities and costs come later during the implementation of those standards.

Fundamental to the protection of public health is the requirement to include the margin of safety. From the beginning Congress intended this to be the key means to address the issues of uncertainty. Even during the drafting of the Clean Air Act, the writers understood clearly that uncertainty would always exist and developed the margin of safety requirement to adapt to that reality. Analytical efforts to quantify uncertainties in scientific information must not delay public health protection.

We hope that our comments are useful in clarifying ways that will both promote the review of the science and the standards every five years and produce standards that protect public health with an adequate margin of safety. We also reiterate our request for the Agency to re-consider the current process. We respectfully ask you to instead carry out a process that is inclusive, transparent and informed by a more rigorous dialogue with the interested public and clearer illumination of the Agency's own rationale for undertaking this process.

Sincerely,

Paul G. Billings
Vice President, National Policy and Advocacy
American Lung Association

Jana Milford
Staff Scientist
Environmental Defense

Cc: George Gray, Ph.D., Assistant Administrator for Research and Development
William Werhum, Assistant Administrator for Air and Radiation
Lydia Wegman, OAQPS
John Bachmann, OAQPS

American Lung Association * Clean Air Watch * Clean Air Task Force * Environmental Defense * National Environmental Trust * National Parks Conservation Association * Natural Resources Defense Council * Physicians for Social Responsibility * Sierra Club * Union of Concerned Scientists U.S. Public Interest Research Group

January 18, 2006

Mr. Marcus Peacock
Deputy Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. N.W.
Washington, D.C. 20460

Dear Deputy Administrator Peacock,

We have reviewed your memorandum of December 15, 2005 establishing an EPA working group to conduct a "top to bottom" review of the National Ambient Air Quality (NAAQS) review and standard setting process. While we welcome all appropriate efforts to strengthen the NAAQS review and setting process, we are concerned about the potentially political nature of this review. We strongly encourage you to ensure that any changes to the NAAQS process be considered and adopted using a process that allows the same kind of scientific and public input afforded by the standard-setting process itself.

The stated purpose of the review is to ensure that the NAAQS process adheres to the highest scientific standards. The memorandum requests a broad review that would examine elements of the NAAQS process that are mandated by the Clean Air Act as well as elements that are not. The review will include both the preparation of the Criteria Document and the review and setting of NAAQS standards which are separate mandates under the Act.

As you know, the establishment of the National Ambient Air Quality Standards is the foundation of the Clean Air Act from which crucial activities under the Act designed to reduce air pollution and protect public health and the environment derive. The process EPA uses to prepare and adopt Criteria Documents and review and establish NAAQS standards has evolved over many years in response to statutory mandate, scientific method, and regulatory and administrative custom. This process provides a highly refined evaluation of the latest scientific knowledge to obtain measures needed to protect public health and the environment while accommodating broad scientific and public input. The current process, which is the fundamentally same as was used to establish the ozone and PM 2.5 NAAQS in 1997, has withstood substantial judicial scrutiny. (See American Trucking Assn. v. USEPA, 175 F.3d 1055-56 (D.C. Cir. 1999))

Your memorandum sets an April 3 deadline for recommended changes. We believe this is far too short a period to solicit, obtain and evaluate recommended changes to the NAAQS process from the broad spectrum of stakeholders who participate in the standard setting process.

Second, we believe recommendations should be sought from the Clean Air Scientific Advisory Committee as well as the Clean Air Act Advisory Committee both of which have significant expertise on the establishment and implementation of NAAQS standards. Consultation with the Children's Health Protection Advisory Committee would also be appropriate, given the impact of air pollution on children and babies.

Finally, to the extent EPA identifies changes to the NAAQS review and standard setting process that it endorses, it should seek public comment on such changes prior to their adoption. In particular, EPA should seek public comment on any changes it supports that require amendments to the Clean Air Act.

We share your goal of ensuring that the best available science guide and inform EPA decision making in the NAAQS review and standard setting process. We believe that the current process does this well. We urge a careful and open process for identifying NAAQS process improvements and look forward to the opportunity to providing our best recommendations and advice.

Sincerely,

Paul G. Billings
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National Policy & Advocacy
American Lung Association

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Executive Director
Clean Air Watch

Conrad G Schneider
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Elizabeth Thompson
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March 27, 2006

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Re: API Comments on the National Ambient Air Quality Standards Setting Process Review

This letter constitutes the comments of the American Petroleum Institute (API) on EPA's current review of the National Ambient Air Quality Standards (NAAQS) standard-setting process. API is the primary trade association of America's oil and natural gas industry, and represents more than 400 members involved in all aspects of the oil and natural gas industry. It draws on the experience and expertise of its members and staff to support a strong and viable oil and natural gas industry. API members are dedicated to continuous efforts to improve the compatibility of their operations with the environment, while economically developing energy resources and supplying high quality products and services to consumers.

As the owners and operators of the most of the nation's refineries, and as the suppliers of much of the Nation's energy, API's members have a significant stake in the effective and efficient development of the NAAQS under the Clean Air Act (CAA). We appreciate the Environmental Protection Agency's (EPA or Agency) fact finding efforts to suggest improvements to the periodic review process for those standards. API historically has played an active role throughout the NAAQS review process, including reviewing and commenting on the drafts of Criteria Documents (CD) and Staff Papers (SP) for various criteria pollutants. API has also provided comments to the Clean Air Science Advisory

Committee (CASAC) when it has met to review NAAQS-related documents and develop recommendations to the Administrator.

API was pleased to participate in a stakeholder call held by the Agency on February 23, 2006, and submits these written comments to augment the discussion.

1. **The Staff Paper is a *policy* document, and as such, should have input from senior EPA management.**

Although the Clean Air Act requires that NAAQS be established based on science and without regard to cost, EPA's assumptions of "no threshold" and linear exposure response relationships essentially make establishment of any non-zero risk standard a *policy* decision, not a scientific one. It is therefore inappropriate and unreasonable to have these policy decisions debated by career staff, CASAC scientists and the media without any input from senior EPA policymakers.

The Act has no requirement for a SP, nor does it include any prohibition against EPA senior management participating in the process. Either senior management should participate early, and throughout, the SP process, or the SP should be eliminated altogether, replaced by an Advanced Notice of Proposed Rulemaking (ANPRM) and stakeholder forums to provide additional input.

Alternatively (or perhaps in addition), policy makers should be added as consultants to the CASAC panel, to better educate the technical panel members in policy-related issues surrounding standard setting.

2. **The 5-year review of NAAQS is insufficient to adequately review a NAAQS; the requirement for review should be modified legislatively to an "as needed" basis.**

Although the current review is targeted at administrative improvements, raising the need for a statutory change to the 5-year review cycle is warranted in the context of improving the NAAQS development process. The current process for revising a standard is a tedious and time-consuming one that involves a lengthy Agency assessment of the relevant health research and development of a CD which is then reviewed by CASAC. This often requires multiple drafts and reviews prior to finalization. EPA staff then develops a SP, also reviewed by CASAC, which contains their standard-setting recommendations. This, too, often requires multiple drafts and reviews. EPA then generates a proposed rule to modify or reaffirm the existing standards, along with an accompanying Regulatory Impact Analysis, and other risk analyses documents. Only after the process is complete can the Administrator, in conjunction with staff and interagency review, develop a final rule. This process clearly requires more than 5 years to complete.

API recommends a legislative change to require EPA to modify criteria pollutant NAAQS only "as needed," so that a thorough review of the science and policy issues surrounding a NAAQS review can be conducted without the artificial and unreasonable time constraints currently imposed by the CAA. Further, from a practical standpoint, there should be no new NAAQS established until the current NAAQS has been implemented.

Alternatively, to protect against overly extended periods between reviews, such legislation could include a requirement that a NAAQS review for each criteria pollutant be *initiated* within 5 years of promulgation of the previous standard *or* 1 year of final designations of non-attainment with the previous standard, whichever is later.

This approach would also reduce the potential for future litigation forcing EPA into settlements with individual stakeholders. EPA should not be forced to enter into consent decrees that mandate timetables to review NAAQS and to complete related rulemakings (e.g., implementation) without the opportunity for broad stakeholder input.

Detractors from the above approach may claim that environmental quality could suffer; API would disagree. Due to implementation of the existing NAAQS through State Implementation Plans (SIPs), as well as the Clean Air Interstate Rule (CAIR), Tier 2 mobile source requirements, off-and on-road vehicle rules mandating ultra-low sulfur diesel fuels and accompanying vehicular controls, New Source Performance Standards (NSPS), Prevention of Significant Deterioration (PSD) and New Source Review (NSR) requirements and Maximum Achievable Control Technology (MACT) rules, extending the 5-year review to "as needed" would not reverse current emission reduction trends. While additional research is pursued, the nation's air quality will continue to improve, and public health protection will continue to increase due to the programs already in place.

3. **Until legislation can address the 5-year review requirement through legislation, EPA should simply reaffirm the existing standard if the review is not complete within 5 years.**

This reaffirmation approach has been used in the past (most recently by Administrator Carol Browner) where EPA indicated that the evaluation of the science did not warrant a modification to the NAAQS *at that time*. It did not – nor would it in the future – mean that the review would have to wait an additional 5 years. If the review required, say, 7 years, then reaffirmation could occur 5-years after the previous final rule, with another final rule promulgated 2 years after reaffirmation, starting the 5-year clock again.

4. **The Agency should review new NAAQS-related research as it is made available, with key information placed in a publicly available database.**

This would provide a less rushed and more complete review process. The logging of these studies into a public database would better ensure all studies are given equal weight and add transparency to the review of scientific information.

5. **The SP would be strengthened with a formal inclusion of the disbenefits concept, as mandated by the courts.**

American Trucking Associations, Inc., et al. v. EPA, 175 F. 3d 1027 (D.C. Cir., 1999), required that EPA include a formal evaluation of the disbenefits of proposed rules. Examples of these "missing" disbenefits include:

a. The 'NOx disbenefit.' NOx control hastens formation of marginally reduced peak ozone in the more populated areas, thereby increasing net population exposure and effects;

b. The 'UVB disbenefit.' Ozone control permits higher surface level UVB exposure thereby increasing population skin cancer, cataracts, and immune deficiency;

c. A potential 'VOC mineralization disbenefit.' Ozone control reduces atmospheric OH radical levels and consequently the rate of VOC photo oxidation, thereby increasing atmospheric lifetimes of organic air toxics.

Similarly, EPA should recognize and evaluate the broader public health implications of imposing costly standards that offer limited and uncertain health benefits. There is an apparent disbenefit that the Agency has not addressed to date, regarding the linkages between regulatory costs and family health. Serious health problems arise when a family's living standards decline. Costly government regulations adversely affect productivity, which in turn dampens real income. There is an income-mortality connection that needs to be addressed. Greater attention to such risk comparisons could result in valuable gains to the environment and public health.

To date, EPA has not incorporated an adequate review of these disbenefit issues into their NAAQS review process, despite Court mandates to do so. Greater effort must be put on evaluating disbenefits to ensure the adequacy of future NAAQS reviews.

6. **The opportunity for bias or lack of candor must be removed from the CASAC review process.**

As discussed on the February 23 conference call, there are numerous instances where at least the opportunity for, or the appearance of bias, is present in the CASAC review process. The following areas of concern were specifically identified:

a. There is no transparency in the selection or retention of CASAC members or consultants;

b. Some CASAC members/consultants who disagree with EPA conclusions may be reluctant to stand up for their positions, given that some members/consultants may be seeking future research grants from EPA, or may be concerned that their research may be reviewed by colleagues on CASAC (who tend to agree with EPA) in the future;

c. Some CASAC members may be reluctant to insist on changes, given the short timeframe and EPA's "we must meet our deadline" stance;

d. CASAC's lead reviewers for specific chapters in CD or SP reviews are often the very same researchers who conducted the studies discussed in that chapter. This clearly introduces the potential for an appearance of bias in the review of the chapters;

e. Publication bias is often discussed in CASAC meetings, but never taken into account in conclusions. Publication bias, the tendency [on average] to produce results that appear significant, because negative or near neutral results are almost never published, can be statistically significant. If it is accepted that a CASAC review will almost certainly be subject to publication bias to some extent, that leaves the problem of estimating how big a problem it is, and what to do about it;

f. Experts whose opinions vary from EPA's – and are not chosen to be incorporated into EPA's conclusions – are not given equal time to present their findings to CASAC;

g. Public comments often do not appear to be seriously considered within the CASAC process. The time allotted to the public at CASAC meetings is often insufficient to adequately present oral testimony. In addition, some CASAC members often appear distracted by other activities/conversations during the public testimony period; and

h. There has been contact between EPA staff and CASAC (private meeting rooms, social dinners, etc.) that could give EPA staff at least the appearance of additional opportunities to convince CASAC members of their own positions.

While some of the issues listed above may, in fact, be perceptual problems, rather than examples of true bias, EPA must nonetheless address these issues directly. Only by doing so can stakeholders have confidence in the adequacy and objectivity of NAAQS reviews.

7. **EPA must fully respond to public comment throughout the review process.**

The public is encouraged to provide written comments to EPA on draft CD and SP documents. However, EPA often fails to address these comments when developing their next draft, instead focusing only on issues raised by CASAC. This becomes even more problematic when EPA establishes a deadline for public comment that follows the CASAC meeting. In such cases, not only does EPA often not address public comments, but CASAC cannot even review them. While EPA will address many public comments in the proposed rule, it is well after the issues have been debated by CASAC and staff opinions have been presented in the media.

API appreciates that the Agency is reviewing the current standard-setting method to both improve the evaluation of the science, and incorporate policy makers throughout the process. API suggests the EPA revisit the efficacy of the current process and modify it to allow a measured review of evolving knowledge and experience. Part of that review may lead the Agency toward a method used in the past with a new standard that was not ripe; namely, reaffirming the existing standard.

Please feel free to contact me with any questions regarding these comments. I look forward to your final report.

Sincerely,

Kyle B. Isakower, Director
Policy Analysis