

Additional CASAC Member Individual Comments on EPA's NAAQS Process

Dr. James Crapo

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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.

Consideration of the Most Recent Available Science

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,

James D. Crapo, M.D.
Professor of Medicine
National Jewish Medical and Research Center
and
Director, Clinical Science Ph.D. Program
University of Colorado Health Sciences Center

National Jewish Medical and Research Center
1400 Jackson Street, Denver, CO 80206
Tel: 303-398-1436; Fax: 303-270-2243; E-mail: crapoj@njc.org
<http://www.NationalJewish.org>

**Roger O. McClellan, DVM, MMS, DSc (Honorary),
Diplomate-ABT, Diplomate-ABVT, Fellow-ATS
Advisor, Toxicology and Human Health Risk Analysis
13701 Quaking Aspen Place N.E.
Albuquerque, NM 87111-7168
Tel: 505-296-7083
E-mail: roger.o.mcclellan@att.net**

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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 $\mu\text{g}/\text{m}^3$ for the annual $\text{PM}_{2.5}$ 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 $\text{PM}_{2.5}$ 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 NAAQs 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 µg/m³.

The Staff Paper related an upper bound of 15 µg/m³ which was selected by the Administrator. My personal opinion is that 14 µg/m³ and 15 µg/m³ 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 $\mu\text{g}/\text{m}^3$ for the Annual $\text{PM}_{2.5}$ standard reflected their views of the uncertainty in the underlying science. I think the CASAC PM Panel narrowing the range to 13 to 14 $\mu\text{g}/\text{m}^3$ 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 $\mu\text{g}/\text{m}^3$. Alternatively, some of the Panel members perhaps wanted to make a "policy statement" that they wanted the current $\text{PM}_{2.5}$ standard reduced below 15 $\mu\text{g}/\text{m}^3$.

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 all 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 µg/m³ and many on the CASAC PM Panel who argued it should be set no higher than 14 µg/m³. I personally know of no scientific information or scientific methodology that would conclude 14 µg/m³ is scientifically acceptable and 15 µg/m³ is scientifically unacceptable.

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?

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 O₃ 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 µg/m³. 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-tiered 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.

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

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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Sverre Vedal, MD
Department of Environmental and Occupational Health Sciences
University of Washington
4225 Roosevelt Way NE, Suite 100
Seattle, WA 98105-6099
phone: 206-616-8285
fax: 206-685-4696
email: svedal@u.washington.edu