



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

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

July 18, 2006

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Johnson:

The members of the Clean Air Scientific Advisory Committee (CASAC) were pleased and honored to meet with the EPA Assistant Administrators for the Office of Research and Development and the Office of Air and Radiation, as well as with members of the Agency's National Ambient Air Quality Standards (NAAQS) Process Review Workgroup, during our public meeting on June 29, 2006 in Durham, NC.

The CASAC had been asked to provide its input on improving the Agency's process for reviewing the NAAQS for criteria air pollutants. In our letter to you dated May 12, 2006, we expressed our preliminary comments on the Assistant Administrators' April 3, 2006 memo to the EPA Deputy Administrator that forwarded the NAAQS Process Review Workgroup's March 2006 report.

Since our May 12 letter, the Agency posed a series of discussion questions for the CASAC relating to the following five topical areas: NAAQS Review Plan; Science Assessment; Risk/Exposure Assessment, Policy Assessment/Rulemaking, and General Issues. CASAC members considered these and other questions and discussed them with Agency officials and staff at our June 29 meeting. The CASAC's recommendations follow.

NAAQS Review Plan

The CASAC wishes to reiterate that the key science question to be addressed by the CASAC as a part of the NAAQS review process is: *What scientific evidence has been developed since the last review to indicate if the current Primary and Secondary National Ambient Air Quality Standards are satisfactory, or if they need to be revised in order to protect both public health and public welfare and the environment?* To this end, the CASAC strongly recommends that the initial step in the review process for a criteria air pollutant should be the convening of a *science workshop* by the Agency. The purpose of this workshop would be to identify important new scientific findings regarding the pollutant in question including: low-concentration effects on both public health and public welfare; current trends in atmospheric chemistry and pollutant

distributions; characterization of both anthropogenic and natural sources of pollutant or precursor emissions; and appropriate risk assessment approaches for this particular pollutant. The science workshop would be open to the public and the CASAC would be invited to attend. Prior to the workshop, the CASAC could provide input to the Agency to identify subject-matter experts and key new scientific studies and findings to be discussed at the workshop. At the conclusion of the science workshop, the CASAC would then conduct a public consultation to provide its advice to EPA regarding *the key policy-relevant science issues* that need to be addressed for the criteria air pollutant under review.

The CASAC supports the EPA Workgroup's concept of an Integrated Plan (IP) and a draft Risk/Exposure Assessment (RA) methodology. The CASAC recommends that these be developed *following* the science workshop so that the IP and the RA will can be informed both by the discussions at the workshop and the post-workshop CASAC consultation. The CASAC would then further advise EPA on the draft IP and RA by means of a public teleconference consultation which would take place approximately four months after the workshop.

Science Assessment

In the past, considerable time and energy have been expended by EPA staff and the CASAC in developing and reviewing air quality criteria documents (AQCD). The AQCD has become a voluminous compendium of knowledge about the pollutant under review. However, much of what is in the AQCD is not relevant to the key question for the NAAQS review noted above. This may be because the reported studies were published and considered prior to the last review, or because the studies did not address the key scientific question(s) relevant to standard-setting.

Nevertheless, during our meeting with the Assistant Administrators and representatives of the EPA's Workgroup, it was pointed out that the assimilation of all known data on a pollutant was essential for litigation purposes. Therefore, the CASAC recommends that such a repository of scientific information be maintained in an *electronic database*, but adds that there is no need for the CASAC to review the contents of that database in detail. The members of the pollutant-specific CASAC panels formed for NAAQS reviews are carefully selected for their cutting-edge knowledge in their scientific and technical fields and therefore are already familiar with the key studies that are related to EPA's standards-setting process. Advice concerning those key studies can be given for development of the agenda for the science workshop.

The CASAC recommends that the Science Assessment (SA) document be roughly equivalent to the integrative synthesis chapter in the current AQCD, and include an integrated assessment of relevant scientific information for both the primary and the secondary standards. The first draft of the SA and the RA would be developed at the same time, based on information presented at the science workshop, and would be reviewed by the CASAC at a public meeting about one year after the workshop. From CASAC's perspective, this should offer ample time given the streamlined nature of the SA. This is especially true in light of the Agency's much-appreciated intent to conduct "continuous compilation/characterization of new [scientific] studies," as proposed in the EPA Workgroup's report. *The CASAC views this ongoing compilation and characterization effort as an essential element both of a more focused SA and in meeting the statutory five-year NAAQS review cycles for the six criteria air pollutants.*

The CASAC also wishes to underscore the *critical need for EPA to provide adequate financial and human resources to support the NAAQS reviews*. This would include sufficient funding to develop and maintain the electronic database. More importantly, there is a need for additional scientific staff or consultants who would: augment the current Agency staff; oversee the new electronic database; and perform the continuous scientific-study compilation and characterization activities. Streamlining the review process may save time, but it is not likely to save money. *In the view of the CASAC, there is no higher Agency priority than the ongoing review of the NAAQS for the criteria air pollutants*. Therefore, this should be commensurately reflected by the budgetary and personnel resources that the Agency dedicates to this most-important, statutorily-mandated obligation.

Risk/Exposure Assessment

The CASAC emphatically does *not* recommend establishing a separate subcommittee on risk/exposure assessments, since in its judgment all scientific disciplines are needed to inform the risk-assessment process. What is more, considering the science- and risk-assessment processes together provides the opportunity to move in new directions, such as considering the critical-load approach used in Europe for setting ecological (secondary) standards. Notwithstanding, members of the EPA NAAQS Process Review Workgroup pointed-out that quantitative risk assessment is an academic discipline in itself. The CASAC agrees and acknowledges the need to include experts in quantitative risk assessment on future NAAQS review panels. This solution appeared to be acceptable to the EPA Workgroup and the CASAC.

Policy Assessment/Rulemaking

At the June 29 meeting, the CASAC asked for an explanation of what “policy” means in the context of the Policy Assessment (PA) document. Agency staff explained that the new PA document would represent a streamlined version of the current EPA Staff Paper, and would offer ranges of possible standards (*e.g.*, by indicator, level, averaging time and statistical form) as a suite of options for CASAC and public review and comment. The CASAC wishes to review both a first and second draft version of the PA, before the issuance of a Notice of Proposed Rulemaking (NPR or proposed rule). We also recommend that the CASAC review the first draft PA in a public meeting concurrent with its review of the second draft SA and RA, about six to nine months after its initial review of the SA and RA. If the quality of the initial draft of the PA is scientifically adequate, there may be no need for review of the second draft document. However, this cannot be presumed *a priori*. Furthermore, the CASAC feels comfortable with its options for providing additional advice to the Administrator after a given proposed rule is issued.

There was also a discussion of the situation when the Agency political management might disagree with its own staff on the range of options for rulemaking. The CASAC suggested that this was an internal issue to be worked out by Agency officials with its career staff. One member of CASAC further pointed out that it is the role of scientists to advise the policy analysts, who then present options to the Administrator to make the final policy decision. The CASAC of course recognizes that science may not be the only factor to be considered in NAAQS rulemaking. Nonetheless, if the Agency proposes either a Primary or a Secondary National Ambient Air Quality Standard that is not consistent with the scientific advice of either

the CASAC or its own scientific staff, the rationale for this decision should be clearly stated in the proposed rule.

General Issues

The CASAC agrees with the EPA Workgroup's goal to expedite the NAAQS process so that it is completed within the legally-mandated five-year review cycle. In the current situation, the Agency is perpetually caught in a bind of needing to "hurry things along" in order to meet a court-ordered deadline or consent decree. This inevitably leads to Agency documents being rushed-out for CASAC and public review before they have had enough internal Agency review to eliminate redundancies, inconsistencies, or other editorial problems. Insufficient internal Agency review prior to external review inevitably results in a plethora of editorial comments from the CASAC and additional delays in the process. If the process could be stabilized on a firm schedule, including proper internal Agency editorial review, the goal of achieving the statutory five-year cycle for all six criteria pollutants might yet be realized. In support of this goal, as an enclosure (Appendix A) to this letter, the CASAC offers an alternative timeline for the Agency's NAAQS reviews that reflects our specific recommendations contained herein.

Finally, the CASAC addressed the question of the value of using the term "closure" in letters to the Administrator to indicate the CASAC did not need to see a given document again. The original definition of closure in the context of the CASAC was found in a 1979 Agency memo on the recommended procedures for involving the CASAC in the NAAQS review, as is repeated herein as follows:

"Closure represents a 'sense of the committee' determination upon the scientific adequacy of a criteria document [and, subsequently, a staff paper] for regulatory purposes at a specific point in time, based upon the information currently available."

However, through the ensuing years the term "closure" has come to imply "approval" — a meaning that goes beyond the purview of an advisory body. Therefore, to avoid any further misunderstanding of the term, the CASAC proposes to go back to the original wording of the 1979 memo. When the CASAC thinks that the science presented in a particular document is adequate for rulemaking, it will affirmatively state so in the closing paragraph of the final letter to the Administrator regarding the review of that document. (As stated in the 1979 memo, this does not mean that minority opinions do not exist, and, when necessary, individual members are permitted to document these.) At the June 29 public meeting, the CASAC asked members of the EPA NAAQS Workgroup if this new procedure would address the Agency's needs vis-à-vis any future litigation and they agreed that it did.

In closing, the CASAC recognizes and genuinely appreciates the time and effort of Agency officials and members of the NAAQS Process Review Workgroup in meeting with us. We request feedback from EPA concerning the above recommendations. It is our sincere hope

that we can continue to work together to guarantee the highest-quality and most-efficient process for the Agency's ongoing NAAQS reviews.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Enclosure

cc: Marcus Peacock, Deputy Administrator
Charles Ingebretson, Chief of Staff
George Gray, Assistant Administrator, Office of Research and Development
William Wehrum, Acting Assistant Administrator, Office of Air and Radiation
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Appendix A: CASAC Alternative Timeline for EPA NAAQS Reviews

Elements of Process	Year 1				Year 2				Year 3				Year 4				Year 5																		
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N
EPA continuous compilation/ characterization of new studies	[Horizontal Stripe]																																		
EPA Science Workshop on "State of the Science," Key Policy-Relevant Science Issues, and Risk-Assessment Approaches	[Diagonal Stripe]																																		
EPA Draft Integrated Plan (IP) & Draft Risk/Exposure Assessment (RA) Methodology ; CASAC consultation [teleconference]					[Diagonal Stripe]		[Plain/No Stripe]																												
EPA 1st Draft Science Assessment (SA) & 1st Draft RA ; CASAC review					[Diagonal Stripe]		[Plain/No Stripe]																												
EPA 2nd Draft SA, 2nd Draft RA, & 1st Draft Policy Assessment (PA) ; CASAC review					[Diagonal Stripe]		[Plain/No Stripe]																												
EPA 2nd Draft PA ; CASAC review [teleconference]									[Diagonal Stripe]		[Plain/No Stripe]																								
EPA Proposed Rule (NPR) ; additional CASAC advice & recommendations (if necessary) [teleconference]													[Diagonal Stripe]		[Plain/No Stripe]		[Horizontal Stripe]																		
EPA Final Rule																					[Diagonal Stripe]														

Key: Agency Actions [Diagonal Stripe] CASAC Advisory Activity [Plain/No Stripe (Bold Outline = face-to-face meeting)] CASAC Optional Advisory Activity [Horizontal Stripe]

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