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

SEP 08 2008

DEPUTY ADMINISTRATOR

Rogene Henderson, Ph.D.
Chair, Clean Air Scientific Advisory Committee
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mail Code 1400F
Washington, D.C. 20460-0001

Dear Dr. Henderson:

Thank you for providing the Clean Air Scientific Advisory Committee's (CASAC) comments on the Environmental Protection Agency's application of the new National Ambient Air Quality Standards (NAAQS) process. CASAC's previous comments have significantly helped shape the improvements made to the process over the last two years.

As you will recall, the new process that was announced December 7, 2006 involves four major components: (1) the preparation of an integrated, policy-relevant plan and science workshop at the commencement of each new review cycle; (2) the development of a more timely and more concise integrated assessment of the policy-relevant science that would replace the voluminous air quality criteria document (3) a stand-alone document (a risk and exposure assessment) focusing on key results, observations, and uncertainties; and (4) an Advanced Notice of Proposed Rulemaking (ANPR) that reflects the Agency's views and describes a range of options along with available underlying scientific justifications.

Based on CASAC's January 23, 2008, letter to the Administrator, we are pleased with the positive feed back provided by CASAC regarding three of the four changes and that CASAC sees these changes as beneficial.

However, the letter raised a number of concerns with the policy assessment stage of the NAAQS process, citing, in particular, the Advanced Notice of Proposed Rulemaking (ANPR) we published on December 17, 2007 for the Lead NAAQS review. Specifically, the letter states that the ANPR did not provide a complete and robust explanation of the scientific evidence and risk/exposure information that might support alternative standards; that the ANPR solicited public comments on options that had already been settled by the CASAC; and that the ANPR was both unsuitable and inadequate as a basis for rulemaking.

The Agency takes CASAC's concerns very seriously. It is clear the purpose of the ANPR needs to be thought through and the ANPR needs to satisfy that purpose. In the rulemaking development process, an ANPR serves as a notice that the Agency intends to write a regulation or that it has identified an issue or concern that may need to be addressed by rulemaking. An ANPR is used to engage the public and solicit their views on the need for regulation, what form the regulation may take, or how best to address the issue. It also requests any relevant scientific or other information that might help the Agency develop a proposed rule. An ANPR does not impose any regulatory requirements, nor does it propose regulatory requirements in sufficient detail to serve, by itself, as the basis for rulemaking. Usually, the goal is to provide the public with an opportunity to provide input to the Agency before the Administrator exercises his policy judgment and proposes a standard. Based on the information the Agency receives in response to the ANPR, from public hearings, and from advisory boards, the Agency will issue a Notice of Proposed Rulemaking (NPRM) which contains more specific options, including the Agency's preferred option, for public comment. It is our intention that the ANPR play this traditional role in the NAAQS process. In this regard it would be inappropriate for the Administrator to pre-empt public comment on options because they have been previously "settled" by CASAC.

As noted in your March 6, 2006 comments to the Agency on the NAAQS process, the authority for setting NAAQS is vested with the Administrator. The Administrator, in turn, must follow the requirements of several statutes and Executive Orders, including the Administrative Procedure Act (APA), when revising the standards. The APA of 1946 governs the way in which administrative agencies of the United States propose and establish regulations, and it requires that agencies give the public a meaningful opportunity to comment on regulatory actions before decisions are made. The Administrator must be careful to reserve judgment on regulatory decisions until after the Agency has reviewed the rulemaking record, including the public comments.

Members of CASAC often have well-formed views about where a particular standard should be set before an ANPR has been drafted; nonetheless, CASAC must respect the Agency's need to follow the established procedures for arriving at a final decision. CASAC is a central and necessary source of advice to the Administrator, but this advice cannot be determinative. The Administrator cannot prejudge the outcome of a rulemaking before the public record is complete. If he did, it is likely that a court would set aside the final rule.

Another consideration the Agency must keep in mind is the role of our state and tribal partners in making decisions under the Clean Air Act. States, tribes and local governments have direct concerns regarding the protection of their citizens and must also shoulder the burden of implementing NAAQS. Given the potentially large matters at stake for states, tribes and local governments, it is important to give these entities adequate notice and the opportunity to comment. For this reason, as a matter of standard practice, the initial NAAQS rulemaking notice – the ANPR – should always solicit comment on all aspects of the statutory question of whether it is appropriate to revise a NAAQS, regardless of whether CASAC has already reached its own conclusion on this point.

CASAC members should feel free to express any policy preferences they may hold, in addition to their views of the scientific evidence before the Agency. Generally it is most helpful

to get these views early in the process. However, members should not expect that the Agency will limit public comment to only those options preferred by the advisory committee, especially in its initial request for public review.

CASAC has expressed particular concern regarding the lead (Pb) NAAQS process. We share these concerns. The late integration of the ANPR into the Pb NAAQS review cycle resulted in a compressed, hybrid approach, and thus it was not as well drafted or informative as it could have been. Some options were recommended and announced by CASAC and the Staff Paper just prior to issuance of the ANPR. The ANPR sought comment on the scientific evidence and analysis presented in the Staff Paper, the CASAC and Staff Paper conclusions, and also asked for public comment on a broader range of options, including those that the CASAC had recommended for exclusion to the Administrator. In this circumstance, we thoroughly noted CASAC's observations and findings. As discussed above, it was not the intention of the ANPR to propose specific options for the NAAQS, including the removal of certain potential alternatives. However, the ANPR certainly can, and should, provide scientific information, and uncertainties, on each of the possible standard levels that may be included in the notice.

In order to address their concerns, CASAC recommended that EPA issue an ANPR at the start of a NAAQS review cycle, either prior to or immediately after the science workshop. We have considered this recommendation keeping in mind our goal to ensure that the best available science will guide and inform Agency decision-making. In order to be able to provide adequate information, and CASAC recommendations, on the science that can be considered for NAAQS standards, the ANPR must follow completion of the Integrated Science Assessment and Risk/Exposure Assessment. The ANPR is the document that helps to bridge the gap between the Agency's scientific assessment and the judgments required of the Administrator. As such, it is imperative to have completed the scientific review in order to solicit informed public comment. In order to address your concerns and ensure that CASAC has an opportunity to fully review scientific assessments prior to publication of the ANPR, we are recommending changes to the new process. First, the risk/exposure assessment will include a broader discussion of the science and how uncertainties may effect decisions on the standard. Second, all analyses and approaches for considering the level of the standard under review, including risk assessment and weight of evidence methodologies, will be presented in the risk assessment. The ANPR will not present any new analyses for reaching a standard.

CASAC also recommends in their letter that, after CASAC review of the integrated planning document, the integrated science assessment, and the risk/exposure assessment, the Agency should issue a policy assessment document that would be furnished to the CASAC for peer-review in public-advisory meetings. As stated above, the ANPR will continue to serve as the policy document that follows the development of the scientific and risk assessment information. However, after completion of the Risk/Exposure Assessment, EPA will host a CASAC meeting for the purpose of receiving their consideration and recommendations. The CASAC will be charged with reviewing the Integrated Science Assessment and the finalized Risk/Exposure assessment, and with providing any recommendations to the Administrator under CAA Section 109 (B) (recommendation of any new national ambient air quality standards and revisions of existing criteria and standards that are appropriate) and CAA Section 109 (C). In addition, to ensure that the CASAC's discussions are always available to the public, the Agency

will create complete transcripts of all CASAC meetings and teleconferences that will be placed on the Agency's Web site.

In closing, EPA would like to reiterate our appreciation to CASAC members of the time you have taken to work with us on an improved NAAQS review process. Thank you again for all of your hard work.

Sincerely,

Marcus Peacock

Marcus C. Peacock