



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

January 23, 2008

EPA-CASAC-08-008

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

Subject: Clean Air Scientific Advisory Committee Recommendations Concerning the
Implementation of EPA's Revised NAAQS Review Process

Dear Administrator Johnson:

We, the seven members of the Clean Air Scientific Advisory Committee (CASAC or Committee), are writing to express our serious concerns regarding the implementation of the Agency's revised process for reviewing the National Ambient Air Quality Standards (NAAQS) for criteria air pollutants, as described in a series of memoranda written by EPA Deputy Administrator Marcus Peacock dated December 15, 2005, December 7, 2006, and April 17, 2007. The CASAC's mandate under the Clean Air Act is to provide its independent scientific advice and recommendations on the adequacy and basis of existing, new, or revised NAAQS that are requisite to protect both public health and public welfare, and, in the case of the protection of public health, to do so with "an adequate margin of safety." This letter is also written in reply to the Deputy Administrator's memo of January 3, 2008 to Dr. Rogene Henderson, CASAC Chair, in which he requested more information regarding the Committee's specific concerns about the Agency's new NAAQS review process.

EPA's Revised NAAQS Review Process

The Agency announced the results of its "top-to-bottom review of the NAAQS process" in the Deputy Administrator's memo of December 2006. The revised EPA NAAQS review process would include: (1) a *science workshop* convened by the Agency at the beginning of each NAAQS review cycle to discuss the new scientific evidence acquired since the last review of each pollutant, and to receive CASAC and public input concerning policy-relevant questions and/or science issues, as the basis for the development of an *integrated planning document* (as recommended by the Committee); (2) the replacement of the voluminous air quality criteria document (AQCD) with an *integrated science assessment* (ISA) — a more concise, integrated assessment of the policy-relevant science (as also recommended by the CASAC) — which will enable the Committee to more efficiently review the underlying scientific criteria for each air pollutant and thus be able to devote more time to assessing the technical analyses of the criteria as these pertain to rulemaking; (3) the publication of a stand-alone *risk/exposure assessment*

document that is “focused on key results, observations, and uncertainties”; and (4) the replacement of the Staff Paper with a *policy assessment* that reflects the views of EPA management, to be published in the *Federal Register* as an advance notice of proposed rulemaking (ANPR). This policy assessment would “describe a range of options for standard setting, in terms of indicators, averaging times, [statistical] form, and ranges of levels for any alternative standards,” along with the underlying scientific justification and supporting data and analyses for each of these, to “help ... ‘bridge the gap’ between the Agency’s scientific assessment and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the standards.”

CASAC’s Evaluation of the Implementation of EPA’s Revised NAAQS Review Process

The Committee has now had the opportunity to participate in each of the steps in EPA’s new review process — albeit not sequentially, for a single air pollutant. The CASAC’s experience with the early phases in the new NAAQS review process has been favorable. The Agency’s science workshop to kick-off the review of the particulate matter (PM) NAAQS was excellent. The integrated planning documents reviewed by the Committee have been appropriate. While there were no dedicated science workshops for the NO_x and SO_x primary NAAQS reviews — and the associated ISAs are still undergoing development — these documents seem to be moving in the right direction and show promise of becoming much more efficient and useful than were the previous AQCDs in providing the scientific background information for NAAQS reviews.

However, EPA chose to implement its revised process in the middle of the current review cycle of the lead standards — thus resulting in a “hybrid” process that combined elements of the old and the new NAAQS processes — which revealed significant problems that exist in the latter steps of this new review process. To begin with, an Agency Staff Paper is conspicuously absent from this revised NAAQS process. The Staff Paper is a document that has been highly-valued by CASAC for its thorough analysis of the new scientific evidence in the AQCD, its presentation of the possible alternatives for the standards to be considered by the Administrator and, most importantly, its provision of the scientific evidence undergirding those alternatives. Under the revised NAAQS process, as noted above, the Staff Paper would be replaced by a *policy assessment* to be published as an ANPR. Nevertheless, on the basis of how the policy assessment was described in the Deputy Administrator’s December 2006 memo, the Committee was reassured that it would be *functionally identical* to the former Staff Paper in terms of presenting the information and supporting analyses describing the range of options for setting the NAAQS, along with a complete and robust explanation of “the alternative underlying interpretations of the [associated] scientific evidence and risk/exposure information that might support such alternative standards.”

Unfortunately, as discussed extensively in the Committee’s recent letter to the Administrator concerning the CASAC Lead Review Panel’s review of the ANPR for the NAAQS for Lead (EPA-CASAC-08-007, dated January 15, 2008), this was not the case. *The ANPR for the Lead NAAQS did not contain any such “policy assessment” of scientific and technical information as described in the Deputy Administrator’s December 2006 memo.* Rather, this document simply laid out *all* NAAQS policy options for consideration by the Committee and the public while omitting the fundamental scientific rationale for many of them, or even the relative scientific merits of the different alternatives. Accordingly, *the CASAC found the ANPR for the Lead NAAQS to be both unsuitable and inadequate as a basis for rulemaking.*

Thus, in EPA's recent, partial implementation of its revised process in the Lead NAAQS review, there is a stark contrast between the empty and regressive nature of the ANPR — which is not a *true* policy assessment — and the scholarly and complete scientific analyses presented in EPA's Staff Paper. Indeed, if such an ANPR were to be the benchmark for subsequent NAAQS reviews, the Agency would have *failed* in its responsibility to “ensure that the best available science [will] guide and inform Agency decision making” while adhering to the “highest scientific standards” so that NAAQS-related decisions “would be informed by the best available science without compromising the scientific integrity [*i.e.*, soundness and transparency] of the process,” as stated in the Deputy Administrator's previously-cited memoranda.

The ostensible purpose of replacing the Staff Paper with an ANPR was to permit Agency policymakers to influence the options that were presented for CASAC and public review. However, the ANPR for the Lead NAAQS offered no scientifically-justified alternatives. Instead, the ANPR solicited public comment on options for lead standard-setting that had already been considered in public advisory meetings and “settled” (that is, dismissed on scientific grounds by both the CASAC and EPA staff) — which serves only to *undermine* the scientific foundation of the NAAQS reviews. Moreover, far from inducing greater efficiencies, the Agency's ANPR — by its illogical contemplation of a *greater* number of options as time progresses — unavoidably slows-down the NAAQS review process.

What Needs to be Modified in EPA's Revised NAAQS Review Process

Fortunately, the new NAAQS review process is still “a work in progress” — and it can be modified to the mutual benefit of all concerned. First, an advance notice of proposed rulemaking belongs at the *beginning* of this review process, not at the end. The CASAC has become aware that, in other parts of the Agency, an ANPR (which EPA had not previously used in its NAAQS rulemaking activities) is employed to *initiate* a rulemaking process — and so is wide-ranging to take into account all possible options that might be considered. Such a broad ANPR is an inappropriate tool to utilize at the conclusion of a comprehensive NAAQS review, since it essentially puts the whole process in reverse. *Therefore, the CASAC recommends that EPA issue an ANPR at the start of a NAAQS review cycle, either prior to or immediately after the science workshop.*

Toward the end of the NAAQS review cycle — that is, *after* the CASAC's review of the integrated planning document, the ISA, and the risk/exposure assessment — *the Agency should issue a policy assessment document* as stated in the Deputy Administrator's December 2006 memo that will, in fact, describe the range of specific policy options under consideration for setting the standard (including all four elements of a NAAQS), accompanied by supporting scientific data and rigorous analyses. Furthermore, *it is essential that this policy assessment document be furnished to the CASAC for peer-review in public advisory meetings, in the same manner as multiple drafts of the Staff Paper were provided to the Committee for review under the previous process.* It cannot be overstated that, in order to fulfill its Congressionally-mandated and thus legal role, the Committee needs to conduct a thorough and open evaluation of this “best available science,” *i.e.*, the scientific justification and underlying analyses of the various options for standard-setting that the Agency formerly presented in the Staff Paper — which of course will now include the viewpoints of EPA management. Obscuring or weakening such an independent scientific review would subvert both the vital interests of the CASAC and the public's confidence in this NAAQS review process — a result that the Agency surely neither intends nor desires.

In closing, the CASAC reiterates its request that the Agency modify its revised NAAQS review process to put the ANPR at the *beginning* of the process, rather than at the end, and provide the Committee and the public with a *genuine policy assessment of scientific and technical information*, as was formerly contained in the Staff Paper. Such a change is required to allow the CASAC to maintain the transparency and the scientific soundness of the NAAQS review process — and thus fulfill its statutory mandate under the Clean Air Act to make scientifically-informed recommendations to the EPA Administrator concerning the adequacy and basis of the NAAQS.

Sincerely,

/Signed/

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cc: Marcus C. Peacock, Deputy Administrator