

**Comments to the Clean Air Scientific Advisory Committee Ozone Panel on the Document:
Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards
(First External Review Draft – August 2012)**

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Introduction

This meeting of the Clean Air Scientific Advisory Committee Ozone Panel is remarkable in that it is addressing in a single meeting four inter-related documents. These documents are:

1. Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Third External Review Draft, June 2012, EPA/600/R-10/076C).
2. Health Risk and Exposure Assessment for Ozone (First External Review Draft, Updated August 2012).
3. Welfare Risk and Exposure Assessment for Ozone (First External Review Draft, Updated August 2012).
4. Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards: First External Review Draft (August 2012).

The development of those documents was formally initiated in September 2008. As draft documents have been developed they have been released for public comment and review by the Clean Air Scientific Advisory Committee Ozone Panel (hereafter referred to as CASAC). Advice has been offered and new drafts prepared and the next documents in the process developed to ultimately inform the EPA Administrator's decision on the affirmation or revision of the National Ambient Air Quality Standards for Ozone set on March 27, 2008.

In this document, I briefly comment on the overall process being used to affirm or revise the NAAQS for Ozone. The comments I offer are my own professional views informed by my personal involvement in the NAAQS setting process since the early 1970s, including service on numerous CASAC Panels and serving as Chair of CASAC.

COMMENTS

1. Dynamic and Cumbersome Process

The current process can be viewed as an exercise in using evolving and ever-changing science to inform policy judgments on the four elements of each NAAQS; (a) the indicator, (b) averaging time, (c) the level, and (d) statistical form for determining attainment of the NAAQS. The latter are all determinant and static until legally revised. Each change in the NAAQS triggers innumerable actions by federal, state and local authorities and, in turn, actions by the public and private sector. Despite efforts by many individuals to streamline the overall NAAQS review and revision process, the process has become more complex and cumbersome. In my opinion, the long drawn-out process that is still attempting to gather, synthesize and

integrate science has resulted in premature development of risk and exposure assessments and even more pre-mature development of policy assessments. The process is clearly flawed. Even the most ardent follower of the process is challenged to keep track of the changing landscape of what has been assembled and interpreted.

2. Challenge of Using Science to Inform Public Policy Judgments

I submit that one of the difficulties with the current process is that it is inappropriately expecting the science to provide public policy decisions. Scientific knowledge can and should inform public policy decisions. However, it is not possible for science to establish what is or is not an acceptable public health or welfare risk; such judgments are in the realm of policy and involve considerations beyond science. In the absence of clear evidence for an absence of harm, every decision as to a level and form of a NAAQS is a policy decision as to an acceptable level of risk.

3. Consensus Masquerading as Science

In my opinion, the essence of science is not about achieving consensus. In my opinion, consensus is a sociological phenomena well suited to religious, political and fraternal organizations that wish to espouse a common set of beliefs. I do not disagree with the utility of assembling scientific information and identifying areas of general agreement and areas of uncertainty as a basis for formulating and testing hypotheses and using science to inform public policy decisions. I am concerned that the current NAAQS process, including that being used in the current Ozone revision, is being driven by a view that if enough effort is expended, a “wall of ozone science” will be created that is so solid and consistent that the level and form of the NAAQS Ozone will be clear to any observer of the wall, including the EPA staff, CASAC and the EPA Administrator. This is a misguided view of the role of science in informing public policy decisions.

4. Science and Personal Preferences

In my opinion, the EPA staff (and their contractors and consultants) are not neutral, impartial participants in the review process. Each staff member brings to the process both their scientific, legal, or other professional expertise and their personal ideologies and preferences related to the final rule. For some of these individuals success will be defined by issuance of a more stringent NAAQS. There may be some who would define success as reaffirmation of the current NAAQS or even increasing the level of the Standard. Thus, I am

concerned that for all of these documents the authorship of specific components is anonymous, i.e. the Agency speaking. The proposed and final rule is written in the voice of the EPA Administrator to conform to the specific requirements of the Clean Air Act. In my opinion, I think the authors of specific chapters in each of the documents related to the setting of the NAAQS should be identified.

The importance of identified authorship relates in part to recognition that those documents are not merely a review and synthesis of the science; it is an “evaluation of the most policy relevant science, including key science judgments ---.” The Public has a right to know who is making the key science and policy judgments reached in the various documents. It is important that these specific judgments and how they were arrived at be clearly documented.

Likewise, the individual members of CASAC and the CASAC Ozone Panel are not neutral, impartial participants in the Review Process. In making this comment, I am not questioning the scientific credentials of any current or past member of CASAC or CASAC Panels. These individuals typically have extraordinary scientific credentials and are drawn almost exclusively from academic, government or non-profit institutions.

In the case of some CASAC Panel members, the situation is complicated by their role in reviewing science they have conducted and reported in the literature. These individuals have a vested interest in seeing their findings used. As with Agency Employees, a successful outcome for a particular NAAQS review may be viewed by some CASAC Panel Members as a more stringent NAAQS. In some cases, CASAC Panel members have previously expressed opinions on the need for more stringent standards. For example, 11 of the 23 members of this current CASAC Ozone Panel were part of the previous CASAC Ozone Panels that expressed the collective policy opinion of the need for a more stringent standard, specifically a standard at the level of 60-70 ppb. Other members of the current panel have signed a letter that was sent to the Administrator again recommending a more stringent standard set at the level of 60-70 ppb. Such views are clearly not only interpretations of science but represent their personal preferences as to a particular policy outcome, a more stringent Ozone NAAQS.

The NAAQS review process has become even more complicated in recent years by requests from EPA staff to CASAC members to provide data and interpretations beyond that which appeared in the original manuscripts. These actions, irrespective of how well intended

they are, blur the distinction between developing scientific information and reviewing it in an independent and impartial manner.

5. Public Availability of Raw Data

It is apparent that policy judgments involved in the review and setting of NAAQS in recent years have been heavily influenced by the results of a relatively few epidemiological studies. The importance of such studies is exemplified by EPA obtaining from the investigators' raw data that did not appear in the original publications or supplements for EPA's use in conducting further analyses. I have already commented on the challenges these practices pose for CASAC members. However, the issue is even broader.

In my opinion, the answer to this long-standing issue of availability of raw data is straightforward. I urge that if the results of any particular scientific study are to be used to inform public policy judgments, such as the settings of NAAQS, the original raw data undergirding the open literature publications and releases to the Agency should be made available to other qualified scientists. This approach will enable others to attempt to replicate the original reported analyses and extend the analyses and, perhaps, interpretations. I applaud the Johns Hopkins University investigators who have pioneered that approach with the National Morbidity, Mortality and Air Pollution Studies (NMMAPS) data sets. A similar approach is needed for all data from key papers that are used in the setting of the NAAQS, irrespective of the public or private sources of the funding for the research.

6. Policy Assessment Document

In my opinion, the present draft document is largely a place holder and a promissory document for the Second Draft of the Policy Assessment. The present document does not include the critical section 4.4 – “Summary of Staff Conclusions on the Primary O₃ Standard.”

The document does contain a section 4.3 – “Additional Analyses to Inform Second Draft Policy Assessment.” In my opinion, the additional analyses are an attempt to try to again “stack” the science to give an answer that is beyond the role of science – the specific level and form of the revised NAAQS in the range of the pre-determined levels of 70 to 60 ppb.

It is clear that as a range of levels with the same statistical form are examined from 75 ppb to 60 ppb at each lower integer there will be a reduction in the calculated number of morbidity or mortality events. The outcome of the exercise is predictable before it is conducted.

Likewise, if the level is held constant and the statistical form is shifted the outcome is predictable. From analyses already performed, it is apparent that the number of calculated avoided events associated with Ozone reductions to achieve attainment of the current standard of 75 ppb (annual fourth-highest daily maximum 8-hour concentration, averaged over 3 years), would be small relative to the incidence of those events from all other causes. The additional analyses proposed will not make the policy decision for the EPA Administrator as to how low is low enough.

7. Background Ozone

With each turn of the crank, the various NAAQS documents have provided a more complete picture of current Ozone levels (concentration over space and times) and the relative role of natural processes, Ozone arising outside of the United States and Ozone generated in the U.S. from anthropogenic ozone precursors. It is increasingly apparent that the levels of ozone attributable to controllable sources of precursors are quite small compared to background. In my opinion, this information must be clearly displayed and should inform the Administrator's policy judgments on how low is low enough for any revision of the Ozone NAAQS. In considering the critical importance of uncontrollable background ozone, it would be useful for the next draft Policy Assessment to evaluate the impact of changing the statistical forms of the standard, i.e. to a lower percentile form or increased number of allowable days.

8. Multi-pollutant Orientation

When the total suite of Ozone NAAQS documents is reviewed, it is remarkable how little explicit attention has been given to considering the role of co-pollutants and specifically the other criteria pollutants. This is especially surprising recognizing that one of those pollutants, NO₂, is a precursor to ozone. It would be appropriate for the next draft of the Ozone Policy Assessment to include a section on "Multi-Pollutant Considerations." In my opinion, that would be valuable in providing perspective to the Administrator on any revision of the Ozone NAAQS recognizing it is only one of the criteria pollutants impacting on air quality and its health impacts. Viewing the NAAQS for all criteria pollutants as a suite of standards should help inform the Administrator's policy judgments as to how low is low enough for any potential revision of the Ozone NAAQS.

Conclusions

It is important that current knowledge of ozone, from source to health and welfare impacts, be used to inform the policy judgments to be made by the Administrator in considering any revision of the Ozone NAAQS. It is important to recognize that irrespective of how refined the description of the science, it cannot identify the specific level and form of the Ozone NAAQS. The policy judgment of how low is low enough must be made by the Administrator informed by available scientific knowledge (McClellan, 2012).

Reference

McClellan, R. O. (2012). Role of Science and Judgment in Setting National Ambient Air Quality Standards: How Low is Low Enough? *Air Quality, Atmosphere and Health Journal* **5(2)**: 243-258.