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May 16, 2014

Clean Air Scientific Advisory Committee  
U.S. Environmental Protection Agency  
Washington, DC

Comments for Clean Air Scientific Advisory Committee May 28, 2014 Teleconference Meeting: Policy Assessment Must Build on Scientifically Sound Risk and Exposure Assessments to Avoid “Arbitrary and Capricious” Policy Judgments in Setting National Ambient Air Quality Standards

This meeting of the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel is a continuation of the March 25-27, 2014 CASAC public meeting which considered three important draft documents; (1) Health Risk and Exposure Assessment (REA) for Ozone – Second External Review Draft (January 2014), (2) Welfare Risk and Exposure Assessment for Ozone-Second External Review Draft (January 2014), and (3) Policy Assessment (PA) for the Review of the Ozone National Ambient Air Quality Standards – Second External Review Draft (January 2014). The availability of these documents was announced in the Federal Register on January 29, 2014.

I offered written comments to CASAC on March 24, 2014 and written comments to the Environmental Protection Agency Ozone Docket on March 24, 2014 as a prelude to the CASAC Ozone Review Panel public meeting on March 25-27, 2014 in Chapel Hill, NC. I also offered brief oral comments by telephone to the CASAC Panel on March 26, 2014. Subsequent to the CASAC Panel meeting, I reviewed the extensive public comments offered to the CASAC Panel and reviewed a transcript of the meeting. After the announcement of the May 28, 2014 Telephonic Meeting of the CASAC Ozone Review Panel, I began to review documentation posted on the EPA CASAC web site as background material for the May 28<sup>th</sup> Conference Call. This included draft letters (still works in progress) from the CASAC Chair, Christopher Frey, to Administrator Gina

McCarthy, documenting the views of the CASAC Ozone Panel on the three draft documents reviewed at the March 24-27, 2014 meeting. This included written comments from 15 of the 20 members of the CASAC Ozone Review Panel. The content of the draft letters and the individual written comments of the 15 Panel members focused on responding to the Charge Questions provided to the Panel in advance of the March meeting.

As a matter of record, all three draft documents build on the Integrated Science Assessment document prepared by the EPA staff. That documentation had been reviewed by the CASAC Ozone Review Panel and found to be a satisfactory summary of the available science on ozone; the source of precursor compounds, its formation and degradation, its distribution in ambient air, and its health and welfare effects. These assessments included a brief history of the NAAQS for photochemical oxidants which have most recently focused on Ozone as an indicator. The substantial progress made in reducing ambient Ozone across the USA was briefly reviewed. The Integrated Science Assessment provided the critical foundation for developing the Risk and Exposure Assessment documents.

The draft Risk and Exposure Assessment documents, one to inform the review of the primary health-based standard and the other to inform the review of the secondary welfare-based standard provided critical input for development of the Policy Assessment document. The final Policy Assessment document will inform the critical Policy Judgments that must ultimately be made by the EPA Administrator in either re-affirming or modifying the four elements of the Ozone Primary and Secondary Standard; the indicator, the averaging time, the numerical level or concentration, and the statistical form.

The NAAQS review process is dependent upon an orderly development of the documents; first, the Integrated Science Assessment; second, the Risk and Exposure Assessments, and finally, the Policy Assessment. The primary role of CASAC is to advise on the process and, ultimately, the content and quality of the documents to ensure they are of high scientific quality to inform the Administrator's policy judgments on the four elements of the NAAQS.

At this juncture, let me applaud the efforts of the EPA staff in creating the several drafts of each document. It has been a herculean effort. I also applaud the efforts of the CASAC Ozone Review Panel who have expended hundreds of hours reviewing and commenting on the documents. It has been a challenging journey and it is not over.

At the March 24-27, 2014 meeting, both the public and CASAC members noted that while the Second Drafts of the Health and Welfare Risk and Exposure Assessments were substantially improved over the earlier drafts, further revisions were needed. Indeed, the revisions called for

were so substantial that the EPA staff has indicated the necessary and essential revisions required to prepare a final Health Risk and Exposure Assessment document and a final Welfare Risk and Exposure Assessment document cannot be completed prior to the scheduled May 28, 2014 CASAC Panel meeting. In my opinion, the outcome of some of the calculations required document revisions is unknown and cannot be predicted at this time. Without question, it is essential that CASAC and the public be given the opportunity to review and comment on the proposed final Risk and Exposure Assessment documents. It is important that CASAC knows what it is approving, a promissory note from the EPA staff is not sufficient.

It logically follows that if the Risk and Exposure documents have not been finalized, then the current draft documents provide an uncertain basis for informing the contents of the final Policy Assessment document. This is the key document that will inform the Administrator's Policy Judgments on all four elements of the Ozone NAAQS; the indicator, the averaging time, the numerical level, and the statistical forms. It is apparent that general agreement exists that ozone is the appropriate indicator for ambient photochemical oxidants. There is also general agreement on the use of an 8-hour averaging time for the primary or health-based standard. The selection of a numerical level and a statistical form should go hand-in-hand. I submit that consideration of the statistical form for the primary standard has not been given adequate attention in the draft Health Risk and Exposure Assessment and the related portions of the Policy Assessment. The Health Risk and Exposure document must be revised and then reviewed. In my opinion, documentation of the science-base to be used in making policy judgments on the welfare effect averaging time, numerical level and form of the secondary standard is close at hand. Nonetheless, questions raised by CASAC Panel members and the Public on the draft Welfare Risk and Exposure document indicate a need for revision and then review of the proposed final Welfare document. The revisions in the Risk and Exposure documents will, in turn, require revision and review of the Policy Assessment document.

In short, CASAC, at its May 28, 2014 meeting, should focus its attention on providing advice to the EPA staff that will aid in finalizing the Welfare Risk and Exposure Assessment and Health Risk and Exposure Assessment documents. After clearly documenting the expectations for those documents, I recommend that the CASAC Panel turn its attention to the science presented in the Policy Assessment document. This will allow the CASAC Panel to offer carefully considered advice to the EPA staff on how to finalize the Policy Assessment document. The proposed final Policy Assessment will need to be reviewed by the CASAC Panel.

In my opinion, CASAC should not consider the May 28<sup>th</sup> teleconference meeting of 3-hour duration and a possible continuing with a 3-hour teleconference on June 4<sup>th</sup> as the final meetings for the current Ozone NAAQS review. As I have noted, the science has not yet been adequately assembled and presented in the Risk and Exposure Assessment documents. Thus, an opinion offered by the CASAC Panel on the completeness of the Policy Assessment document would be premature and could lead to the CASAC Panel drawing arbitrary and capricious advisory conclusions based on an incomplete exposition of the science on ozone health and welfare effects. I urge the CASAC Panel to work with EPA staff to determine when EPA anticipates being able to release final Risk and Exposure Assessment documents and a proposed, final Policy Assessment document. With this information in hand, it would be appropriate for CASAC to schedule a one to two day public face-to-face meetings of the CASAC Panel to focus on a review of the Policy Assessment document. I cannot over-emphasize the importance of this being a face-to-face public meeting of the CASAC Panel. The information provided by the public to CASAC prior to and at the March 25-27, 2014 meeting was clearly of substantial value. Moreover, I suspect even more value can be gleaned by careful review of the written comments provided by the public and CASAC members. The input provided by the CASAC Panel members was important, but not complete. Public comments are important! It is notable that five CASAC Ozone Review Panel Members have not yet provided written comments for the record. It is understandable that the CASAC Chair, Dr. Frey, might not offer written comments. However, the basis for the other four Panel members not offering written comments is not apparent.

In closing, I wish to offer some summary suggestions to the CASAC Ozone Panel as it moves forward in completing its role in the current Ozone NAAQS review.

(1) In my opinion, the Panel members need to focus on their role in providing scientific advice to the EPA Administrator setting aside any personal ideological preferences as to the final Ozone NAAQS. The Panel's role is not that of a standard setting committee. The Administrator, under the Clean Air Act, has the sole authority to make the policy judgments essential to re-affirming the existing Ozone NAAQS or promulgating a new NAAQS. The policy judgments of the Administrator must be informed by science, however, the science is not sufficient to dictate a particular standard.

(2) Having listened to portions of the March meeting and reviewed a transcript of the meeting, I am compelled to express my concern at the "tone" of some Panel members comments, especially as regards the setting of a numerical level for the primary or health standards. The "tone" of the comments focused on limiting the policy judgment options of the Administrator in

proposing a standard. In my opinion, the comments of some Panel Members apparently reflected their own personal ideological preference for the standard, a preference that involves both science and their policy preferences. As eager as some Panel members may be to prescribe the specific numerical level of the standard or draw a sharp science-based upper bound on the level. I urge them and the Panel to avoid the temptation. Indeed, if the Panel feels compelled to be specific as to the level and form of the Standard, each Panel member's preference should be documented in the Public Record.

(3) In my opinion, some CASAC members may have developed the view that each review of a particular NAAQS must lead to a more stringent standard. I think that such an orientation is inappropriate. In my opinion, the Administrator, in considering the science that will inform her policy judgments, should have the flexibility to consider policy judgments that re-affirm the existing NAAQS.

(4) I urge CASAC to address the missing element of the draft Policy Assessment; that is a contextual on morbidity and mortality as influenced by multiple factors across the USA. The Administrator needs that context for deciding "how low is low enough" for the Ozone NAAQS. One CASAC Panel member made an oblique reference to this issue when noting that the projected impacts of ozone on Chronic Obstructive Disease offered in the documents was not realistic. Indeed, the great variability in baseline morbidity and mortality for specific health endpoints city-to-city, region-to-region and across the USA is scientific information that the Administrator should have in hand in considering any projections of ozone-related morbidity and mortality for the current or projected standards. I urge that the CASAC Panel request that such information be included in the final Policy Assessment document. This is scientific information readily available from CDC.

(5) I express concern at the CASAC Panel's excessive focus on the Agency's Charge Questions. These questions are no doubt well intentioned. However, I submit the questions (and the assignment to a few individuals to prepare responses to each question) have a stifling influence on scientific discussion. As a long-time observer of the NAAQS review process, I am disappointed at the limited amount of scientific discussion at recent CASAC meetings. The meeting agendas have been so jam-packed that limited time is available for "give and take" discussion. One solution is to ask all of the CASAC Panel members to "weigh in" on the scientific discussion that bear critically on the science under-girding "how low is low enough." Further, each Panel member should address the question that has not been asked by the EPA staff. The question is whether all

of the relevant science on ozone health and welfare effects has been assembled in a contextual manner that will inform the Administrator's policy judgments on the Ozone NAAQS.

The CASAC Ozone Panel is offering scientific advice on matters that have enormous impact on society. I submit that such advice cannot be adequately formulated and discussed in telephonic conferences; at least one additional face-to-face meeting of the CASAC Ozone Review Panel is needed for this Ozone NAAQS Review.

Respectfully,

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