

**Public Comment on the  
CASAC Review of EPA's Integrated Science Assessment for Particulate Matter  
(External Review Draft – October 2018)**

**PROCEDURAL IRREGULARITIES**

PREPARED BY:

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SUBMITTED TO

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These comments addresses unusual and potentially inappropriate written communications and operating procedures pertaining to the CASAC meeting held on December 12-13, 2018 regarding the Integrated Science Assessment for Particulate Matter, as well as other concerns with procedural irregularities. Collectively, these procedural issues undermine the credibility of the review.

**12-17-18 Follow-up Questions for Dr. John Vandenberg (EPA) from Dr. Tony Cox**

**Chair unilaterally sending written comments to EPA** - On December 17, 2018, Dr. Tony Cox of the EPA Clean Air Scientific Advisory Committee issued a letter addressed to John Vandenberg, Director of the National Center for Environmental Assessment, stating that he would “greatly appreciate answers to the following hypothetical conceptual questions,” followed by three hypothetical questions, and 10 questions regarding causal definitions. Many of these questions are multipart, and approximately 7 of the 8 pages of the letter are devoted to these questions. The letter is signed “Dr. Tony Cox”, “Chair”, “Clean Air Scientific Advisory Committee.” Based on my 10 years of experience with CASAC review panels and the chartered CASAC, including serving as Chair of CASAC from 2012 to 2015 and serving as chair of three CASAC review panels, I cannot recall any situation in which the chair of CASAC has unilaterally written a letter posing questions to EPA in this manner.

There is a difference between situations in which one or more CASAC members propose an information request in the public view at a public meeting, versus individual members submitting requests post hoc in an ad hoc manner. In the former case, the public has advance notice of a particular time, place, and meeting location/call-in information, and an ability to observe and potentially comment on the topic or interaction. Furthermore, such information requests should be made via the advisory body as a whole rather than on behalf of an individual. In the latter case, the public has no prior expectation and no systematic way of being informed unless they happen to repeatedly visit a meeting webpage.

As a matter of well-established precedent, EPA may consider comments from individual CASAC members when such comments are included as an attachment to a quality-reviewed letter from CASAC

to the Administrator, but typically will prioritize its efforts to 'consensus' advice from the chartered CASAC. 'Consensus' means that the comments were deliberated at a public meeting of the CASAC, not that all members agree with the advice. In fact, 'consensus' advice can represent diversity of opinions and indicate that not all members agree on a particular topic.

In this particular instance, the written communication is signed "Chair, Clean Air Scientific Advisory Committee." This is the same signature used on quality-reviewed letters from CASAC to the Administrator that convey CASAC's consensus advice and, therefore, might be construed to be a request from the chartered CASAC rather than a post hoc and ad hoc request from an individual member. There is no disclaimer that this communication is on behalf of an individual member and does not represent a request from the chartered CASAC. As such, the communication is potentially misleading and was developed outside of an appropriate FACA process. No one, not even the chair, can speak for CASAC. CASAC speaks for itself via letters to the Administrator that have been approved by the chartered CASAC.

FACA committees should have clear operating procedures. The well-established precedent of CASAC is that members prepare written pre-meeting comments. In so doing, members may identify issues for which they would like clarification or more information from EPA. Those issues are properly and appropriately raised during deliberations at the public meeting. If any raised issues rise to the level at which CASAC would like to request more information, such requests are made at the public meeting with the knowledge of the public. In view of the public, CASAC may interact with EPA staff to assess the feasibility of obtaining responses to the request and the request may possibly be modified based on EPA feedback. EPA may also indicate that they are unable to respond to a request because, for example, it is outside of scope or has significant resource implications. Alternatively, in view of the public, CASAC may convey a request to EPA for more information, and EPA might assess later whether it has the resources or inclination to address the request, with a reply that follows at a later time.

The other avenue that CASAC members have for making their concerns and advice known to the agency is to revise their pre-meeting comments and submit post-meeting individual comments. Such comments are typically included as an appendix to a quality-reviewed letter from CASAC to the Administrator and can indicate concerns or recommendations on the part of individual members for additional information that EPA could provide in a revised document. Based on public deliberations by the chartered CASAC, the chartered CASAC may elect to incorporate comments from an individual member into its consensus advice regarding responses to charge questions or into its letter to the Administrator.

The formal process for how CASAC can and should interact with EPA is not amenable to an ongoing dialectic approach of individual members peppering the agency staff with questions in a post hoc and ad hoc manner. The public has a right to expect that interactions between CASAC and EPA will take place at publicly noticed meetings in the full view of the public.

However, the concern here is not primarily that such communication be identified as being from an individual and not on behalf of the chartered CASAC, but that such post hoc and ad hoc communications that circumvent the public meeting should not occur because they do not represent a clear operating procedure and potentially may be contrary to statute and guidance.

Even if this type of communication may not be prohibited, this not a good practice, is contrary to well established precedent for CASAC, and sets a bad precedent.

#### **12-14-18 Follow-up Questions to the Health Effects Institute from Dr. Tony Cox.**

**Chair posing follow up questions to HEI** - On December 14, an email was sent from the CASAC Designated Federal Officer on behalf of the chair of CASAC to the director of the Health Effects Institute conveying “follow-up” questions from Dr. Cox. It is not clear that this type of communication is consistent with CASAC operating procedures or with FACA, and it poses some of the same concerns as Dr. Cox’s communication to Dr. Vandenberg regarding the appearance that a member of CASAC is claiming or implying to act on behalf of the chartered CASAC in making the request, and is making a request that may have resource implications for the recipient. Moreover, the email appears to be requesting a public comment: “What is HEI’s current understanding of the state-of-the-art in what has been learned so far from accountability studies of PM<sub>2.5</sub>?”. It is unusual for CASAC to specifically request public comments from some but not all members of the public. A request for public comment is properly conveyed via a Federal Register notice of a public meeting of the CASAC. As for a list of all reports that HEI has published on accountability studies, this could be obtained by the CASAC member based on their own literature search, since HEI reports are publicly posted on the HEI website. Studies “now in the pipeline” are irrelevant until such time as they are published with peer review prior to the closing date for the ISA literature review.

To the extent that individual members of CASAC may perceive deficiencies in the literature review of the draft ISA, they are free to include such concerns in their individual member comments and to raise such concerns for deliberation by the chartered CASAC at a public meeting.

#### **CASAC Chair Memo to Chartered CASAC (Undated)**

**Chair independently creating charge questions** - It is highly unusual and inappropriate for the chair of CASAC to, in effect, create their own set of charge questions, as was the case in the undated “CASAC Chair Memo to Chartered CASAC”. Although the memo is undated, the file name includes “10302018” which implies it may have been issued on October 30, 2018. However, it was not publicly disclosed until December 12, 2018 and thus members of the public did not have an opportunity to consider this memorandum in deciding whether to prepare public comments. The content of this memo, and the failure to provide this memo publicly in a timely manner, is inconsistent with proper operating procedures of CASAC.

It is inappropriate for an individual member of the CASAC, including the chair, to issue detailed questions for the other members of CASAC. CASAC does not exist to answer questions posed by the chair. CASAC exists to provide advice to EPA. EPA formulates charge questions and CASAC is expected to address the charge questions. CASAC may offer other advice as it deems appropriate. CASAC members are nominally expert scientists and can judge for themselves regarding what are the key scientific issues to consider in formulating their own comments. Members of CASAC should be informed that they have no obligation whatsoever to answer the ad hoc questions that were posed by the chair.

#### **Ad Hoc Changes to Procedures**

**Inexperienced membership** - The apparent lack of understanding of, attention to, and respect for proper operating procedures seems to be a culture of the current CASAC. For example, during

deliberations on December 12, 2018, the chair suggested that an ad hoc “tiger team” could be formed to provide additional expertise. During deliberations on December 13, 2018, another CASAC member stated “if there is a creative way to do something different than before, I and others are open to that”. It was unclear as to who the “others” may be, but the comment could be interpreted to mean that communications may have taken place outside of the proper public deliberative process. The middle of a review process of a national environmental regulation is not the appropriate forum for exploring ‘creative’ ways to do things particularly given that clear procedures have existed for some time. Possibly the lack of attention to proper procedures is a result of inexperience. One of the implications of the October 31, 2017 memorandum by former Administrator Scott Pruitt to increase the rate of member turnover on EPA advisory panels is that the current CASAC is largely inexperienced with regard to CASAC itself. With five new members only recently appointed a few months ago, and with the other two members having been appointed only in recent years, this CASAC has little institutional memory or experience in terms of CASAC procedures. The chair of CASAC has no prior experience with CASAC.

## Conclusion

In general, the procedural irregularities identified above significantly undermine confidence that the chartered CASAC is compliant with applicable operating procedures and laws and further undermines the credibility of the review process. At the next public meeting of CASAC, EPA should publicly issue clarifications for the benefit of the public, and the members of CASAC, on how CASAC should conduct its work consistent with clear operating procedures, with FACA, with the Sunshine law, with EPA's peer review handbook, and with other applicable laws, regulations, policies, and procedures. Furthermore, EPA and CASAC should address how recent deviations will be addressed, and how future deviations will be avoided. Given the numerous irregularities identified above, the most appropriate approach to partially restoring integrity to the review process is to restart the review process only after all members have been fully informed of and agree to adhere to well defined process. To fully restore integrity to the review process would entail following all of the recommendations set forth by Frey *et al.* (November 26, 2018) and Frey *et al.* (December 10, 2018), in addition to the recommendations given here.

## References:

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