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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

November 17, 2015

MEMORANDUM

- **SUBJECT:** Formation of the Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel
- FROM: Aaron Yeow /Signed/ Designated Federal Officer (DFO) EPA Science Advisory Board Staff Office (1400R)
- THRU: Wanda Bright /Signed/ Ethics Official EPA Science Advisory Board Staff Office (1400R)
- TO: Christopher S. Zarba Director EPA Science Advisory Board Staff Office (1400R)

The Clean Air Scientific Advisory Committee (CASAC or Committee), which is comprised of seven members appointed by the EPA Administrator, was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. The CASAC provides advice, information and recommendations on the scientific and technical aspects of air quality criteria and National Ambient Air Quality Standards (NAAQS) under sections 108 and 109 of the Act. The CASAC is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. Section 109(d)(1) of the CAA requires that the Agency carry out a periodic review and revision, where appropriate, of the air quality criteria and the NAAQS for "criteria" air pollutants, including particulate matter (PM).

This memorandum addresses the set of determinations that were used in forming the CASAC PM Review Panel including:

- 1. The type of review body that will be used to conduct the review, and the nature of the review;
- 2. The types of expertise needed to address the general charge;
- 3. Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;

- 4. How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502 apply to members of the panel; and
- 5. Other considerations that might affect the objectivity if members of the panel; and
- 6. How individuals were selected for the panel.

DETERMINATIONS:

1. <u>The type of review body that will be used to conduct the review, and the nature of this review.</u>

An ad hoc expert panel of the CASAC will provide independent advice through the chartered CASAC on EPA's technical and policy assessments that support the Agency's review of the National Ambient Air Quality Standard (NAAQS) for PM, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment.

2. <u>The types of expertise needed to address the general charge.</u>

On February 4, 2015, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 80, Number 23, Pages 6086-6089) that it was forming a panel to review and provide independent expert advice through the Chartered CASAC on EPA's technical and policy assessments that support the Agency's review of the National Ambient Air Quality Standard (NAAQS) for PM, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment. To form the panel, the SAB Staff Office sought public nominations of nationally and internationally recognized scientists in the science of air pollution related to PM. Experts were sought in air quality and climate responses, atmospheric science and chemistry, dosimetry, toxicology, controlled clinical exposure, epidemiology, biostatistics, human exposure modeling, risk assessment/modeling, characterization of PM concentrations and light extinction, and visibility impairment and related welfare effects.

3. <u>Financial conflict of interest considerations, including identification of parties who are potentially</u> interested in or may be affected by the topic to be reviewed.

(a) <u>Identification of parties (or class of parties) whose financial interests may be affected by the</u> <u>topic to be reviewed:</u> The principal interested and affected parties for this topic are: research institutions; makers of air quality monitoring or emissions control equipment; and various industry sectors (for example, fossil fuel-fired electricity generation) that are significant sources of PM emissions and are affected by the current or any revised NAAQS for PM.

(b) <u>Conflict of interest considerations:</u> For Financial Conflict of Interest (COI) issues, the basic 18 U.S.C. § 208 provision states that: "An employee is prohibited from participating *personally or substantially* in an official capacity in any *particular matter* in which he, to his knowledge, or any person whose interests are imputed to him under this statute has a *financial interest*, if the particular matter will have a direct and predictable effect on that interest [emphasis added]." For a conflict of interest to be present, all elements in the above provision must be present. If an element is missing the issue does not involve a formal conflict of interest; however, the general provisions in the appearance of impartiality guidelines must still apply and need to be considered.

(i) <u>Does the general charge to the panel involve a particular matter?</u> A "particular matter" refers to matters that "...will involve deliberation, decision, or action that is focused upon the interest of specific people, or a discrete and identifiable class of people." It does not refer to "...consideration or adoption of broad policy options directed to the interests of a large and diverse group of people." [5 C.F.R. § 2640.103 (a)(1)]. A particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties [5 C.F.R. § 2640.102(m)].

The activity of this CASAC Panel will qualify as a *particular matter of general applicability* because the resulting advice will be part of a deliberation, and under certain circumstances the advice could involve the interests of a discrete and identifiable class of people but does not involve specific parties. That group of people constitutes those who are involved with organizations facing regulatory decisions related to the release of or exposure to PM.

(ii) <u>Will there be personal and substantial participation on the part of the panel members?</u> Participating personally means direct participation in this review. Participating substantially refers to involvement that is of significance to the matter under consideration. [5 C.F.R. § 2640.103(a)(2)]. For this review, the *CASAC Panel members will be participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations on the Agency's PM technical analyses, and such advice is expected to directly influence the Agency's guidance on risk assessment and risk management decisions involving PM. *Therefore, participation in this review will also be substantial.*

(iii) Will there be a direct and predictable effect on Panel members' financial interest? A direct effect on a participant's financial interest exists if "...a close causal link exists between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. ...A particular matter does not have a direct effect ...if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect." [5 C.F.R. § 2640.103(a)(i)] A predictable effect exists if, "...there is an actual, as opposed to speculative, possibility that the matter will affect the financial interest." [5 C.F.R. § 2640.103(a)(ii)]. CASAC members and prospective panelists were asked to submit Form 3110-48, a Confidential Financial Disclosure for Special Government Employees, so that the SAB Staff Office could make this determination. *The SAB Staff Office has determined that there will be no direct and predictable effect on the financial interests of CASAC PM Review Panel members*.

4. <u>How regulations concerning "appearance of a lack of impartiality" pursuant to 5 C.F.R. § 2635.502</u>, <u>apply to members of the Panel</u>

The Code of Federal Regulations at 5 C.F.R. 2635(a)(2) describes general requirements for considering an appearance of a loss of impartiality for employees of the Executive Branch (including Special Government Employees) participating in a *particular matter involving specific parties*.

The SAB Staff Office has determined that the matter to be considered by the panel is not a particular matter involving specific parties; i.e., this matter does not involve "any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation,

charge, accusation, arrest or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest" [5 C.F.R. 2637.102(a)(7)].

5. <u>Other considerations that might affect the objectivity of members of the panel.</u>

Members of CASAC panels must be scientific and technical experts who are objective and openminded, able to engage in deliberative discussions with scientists who may have disparate perspectives. To evaluate candidates, the SAB Staff Office considers information (if any) provided by the public in response to the invitation for public comment on the candidates, information provided by candidates (including on the EPA Form 3110-48), and information independently gathered by the SAB Staff Office.

As part of a determination that members of committees and panels are objective and open-minded on the topic of the review, and consistent with the agency's Peer Review Policy, the SAB Staff Office considers previous involvement in the matter before the committee or panel. This evaluation includes responses provided by candidates to the following supplemental questions:

- a. Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the panel/committee/subcommittee or any reason that your impartiality in the matter might be questioned?
- b. Have you had any current or previous involvement with the review document(s) under consideration including authorship, collaboration with the authors, or previous peer review functions? If so, please identify and describe that involvement.
- c. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- d. Have you made any public statements (written or oral) on the issue that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

The SAB Staff Office has determined that there is no reason to believe that members of the selected for the CASAC PM Panel would not be objective and open-minded and able to engage in deliberative discussions with scientists who may have disparate points of view on the matter before the panel.

6. <u>How individuals were selected for the Panel</u>

On September 2, 2015 the SAB Staff Office posted a list of 49 candidates for the Panel, identified based on their expertise and willingness to be considered for the panel. This list was accompanied by a notice inviting public comments on a list of candidates to be submitted by September 23, 2015. The SAB Staff Office received one comment from the public on this list of candidates, from EPA's Office of Children's Health Protection.

The SAB Staff Office Director makes the final decision about who serves on the Panel based on all of the relevant information, including a review of candidates confidential financial disclosure for (EPA-Form 3110-48), the responses to the questions above, public comments, and information independently gathered by SAB Staff.

For the SAB Staff Office, a balanced committee or panel is characterized by candidates who possess the necessary domains of scientific knowledge, relevant perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge. Specific criteria to be used in evaluating an individual panel member include: (a) scientific and/or technical expertise, knowledge, and experience; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working on advisory committees and panels (including objectivity and open-mindedness); and (f) for the committee as a whole, diversity of scientific expertise and viewpoints.

On the basis of the above-specified criteria, the members of the CASAC PM Review Panel are as follows:

CASAC PM Review Panel Members

Dr. Ana Diez Roux, Drexel University (PA), Chair Dr. Peter Adams, Carnegie Mellon University (PA) Dr. John Adgate, University of Colorado (CO) Mr. George A. Allen, Northeast States for Coordinated Air Use Management (NESCAUM) (MA) Dr. John Balmes, University of California at San Francisco (CA) Dr. Kevin Boyle, Virginia Tech (VA) Dr. Judith Chow, Desert Research Institute (NV) Dr. Douglas Dockery, Harvard University (MA) Mr. Dirk Felton, New York State Department of Environmental Conservation (NY) Dr. Mark Frampton, University of Rochester (NY) Dr. H. Christopher Frey, North Carolina State University (NC) Dr. Terry Gordon, New York University School of Medicine (NY) Dr. Jack Harkema, Michigan State University (MI) Dr. Joel Kaufman, University of Washington (WA) Dr. Patrick Kinney, Columbia University (NY) Dr. Michael Kleinman, University of California, Irvine (CA) Dr. Rob McConnell, University of Southern California (CA) Dr. David Peden, University of North Carolina at Chapel Hill (NC) Mr. Richard L. Poirot, Vermont Department of Environmental Conservation (VT) Dr. Stephen Polasky, University of Minnesota (MN) Dr. Jeremy Sarnat, Emory University (GA) Dr. James Jay Schauer, University of Wisconsin-Madison (WI) Dr. Elizabeth A. (Lianne) Sheppard, University of Washington (WA) Dr. Barbara Turpin, University of North Carolina at Chapel Hill (NC) Dr. Sverre Vedal, University of Washington (WA)

Dr. Ronald Wyzga, Electric Power Research Institute (CA)

Concurred,

/Signed/

Christopher S. Zarba Director and Deputy Ethics Official EPA Science Advisory Board Staff Office (1400R) November 17, 2015

Date