

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

February 25, 2013

MEMORANDUM

SUBJECT: Formation of the Clean Air Scientific Advisory Committee (CASAC) Oxides of Nitrogen

(NOx) Primary National Ambient Air Quality Standards (NAAQS) 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

Acting 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 oxides of nitrogen (NOx).

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

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

- (D) How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502 apply to members of the Panel; and
- (E) How individuals were selected for the Panel.

DETERMINATIONS:

(A) The type of review body that will be used to conduct the review, and the nature of this review.

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 NOx, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment.

(B) The types of expertise needed to address the general charge.

On October 17, 2012, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 77, Number 201, Pages 63827-63828) 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 primary National Ambient Air Quality Standard (NAAQS) for oxides of nitrogen (NOx), 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 nitrogen oxides. Experts were sought in atmospheric science, human exposure, dosimetry, toxicology, epidemiology, medicine, public health, biostatistics and risk assessment.

- (C) <u>Financial conflict of interest considerations</u>, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed.
 - (a) <u>Identification of parties who are potentially interested in or may be affected by the topic to be reviewed:</u> The principal interested and affected parties for this topic are: 1) EPA; 2) State, regional, and local air program (or air pollution control) agencies, and State regulatory officials; 3) State and local health officials; 4) public health, community, and environmental interest groups/non-Governmental organizations (NGOs); 5) potentially responsible parties (PRPs) and their contractors; 6) research universities; and 7) various industry sectors interested in, or affected by, the current or any revised primary NOx NAAQS.
 - (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 CASAC NOx Review 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 private or public organizations facing regulatory decisions related to the release of or exposure to NOx.

- (ii) Will there be personal and substantial participation on the part of the Panel members? 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 SAB Staff Office has determined that 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 NOx technical analyses, and such advice is expected to directly influence the Agency's guidance on risk assessment and risk management decisions involving NOx. 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 NOx Review Panel members.

(D) How regulations concerning "appearance of a lack of impartiality" pursuant to 5 C.F.R. § 2635.502, apply to members of the Panel

The Code of Federal Regulations at 5 C.F.R. § 2635.502(a) states that: "Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the

circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and has received authorization from the agency designee." Further, § 2635.502(a)(2) states that, "An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter."

Prospective Panel members were evaluated against the 5 C.F.R. 2635(a)(2) general requirements for considering an appearance of a lack of impartiality. This evaluation included responses to EPA 3110-48 confidential financial disclosure forms and the following supplemental questions:

- 1. 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?
- 2. 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.
- 3. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- 4. 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 conducted a review of information submitted by CASAC members and prospective panelists, including the responses to the four (4) ethics questions above and the completed confidential financial disclosure forms, along with information independently gathered by SAB staff. *The Deputy Ethics Official of the SAB has determined that there is no conflict of interest or appearance of a lack of impartiality for the members of this Panel.*

(E) How individuals were selected for the Panel

On December 26, 2012 the SAB Staff Office posted a list of 26 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 January 23, 2013. 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; 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 NOx Review Panel are as follows:

CASAC NOx Review Panel Members

Dr. H. Christopher Frey, North Carolina State University (NC), Chair

- Mr. George A. Allen, Northeast States for Coordinated Air Use Management (NESCAUM) (MA)
- Dr. Matthew Campen, University of New Mexico (NM)
- Dr. Ronald Cohen, University of California at Berkeley (CA)
- Dr. Douglas Dockery, Harvard University (MA)
- Dr. Philip Fine, South Coast Air Quality Management District (CA)
- Dr. Panos Georgopoulos, UMDNJ-Robert Wood Johnson Medical School (NJ)
- Dr. Jack Harkema, Michigan State University (MI)
- Dr. Michael Jerrett, University of California at Berkeley (CA)
- Dr. Joel Kaufman, University of Washington (WA)
- Dr. Patrick Kinney, Columbia University (NY)
- Dr. Michael Kleinman, University of California, Irvine (CA)
- Dr. Timothy Larson, University of Washington (WA)
- Dr. Jeremy Sarnat, Emory University (GA)
- Dr. Richard Schlesinger, Pace University (NY)
- Dr. Elizabeth A. (Lianne) Sheppard, University of Washington (WA)
- Dr. Helen Suh, Northeastern University (MA)
- Dr. Ronald Wyzga, Electric Power Research Institute (CA)
- Dr. Junfeng (Jim) Zhang, University of Southern California (CA)

Concurred,		
/SIGNED/	2/25/13	
Christopher S. Zarba	Date	
Acting Director		
EPA Science Advisory Board Staff Office (1400R)		