



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C. 20460

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

January 14, 2014

MEMORANDIUM

SUBJECT: Augmenting the Clean Air Scientific Advisory Committee (CASAC) for the Sulfur Oxides (SO_x) Primary National Ambient Air Quality Standards (NAAQS) Review

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THRU: Wanda Bright /signed/
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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 2. 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 sulfur oxides.

This memorandum addresses the set of determinations that were used in augmenting the CASAC for the SO_x Review 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 loss of impartiality” pursuant to 5 C.F.R. § 2635.502 apply to members of the committee or panel;
5. Other considerations that might affect the objectivity of members of the committee or panel; and
6. How individuals were selected for the committee or panel.

DETERMINATIONS:

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

The chartered CASAC augmented with additional experts (the Augmented CASAC) will provide independent advice on the EPA’s technical and policy assessments that support the agency’s review of the primary (health-based) NAAQS for SO_x, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment.

2. The types of expertise needed to address the general charge.

On July 22, 2013, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 78, Number 140, Pages 43880-43881) that it was forming a panel to review and provide independent expert advice through the Chartered CASAC on the EPA’s technical and policy assessments that support the agency’s review of the primary NAAQS for SO_x, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, and Policy Assessment. The SAB Staff Office sought public nomination of nationally and internationally recognized scientists in the science of air pollution related to SO_x. Experts were sought in atmospheric science, human exposure, dosimetry, toxicology, epidemiology, medicine, public health, biostatistics and risk assessment. The SAB Staff Office subsequently determined that the review would be conducted by the chartered CASAC augmented with additional experts.

3. Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic reviewed.
 - (a) Identification of parties (or class of parties) whose financial interests may be affected by the matter to be reviewed: The principal interested and affected parties as a class for this topic are: research institutions; makers of air quality monitoring or emissions control equipment; and various industry sectors (including fossil fuel-fired electricity generation) that are significant sources of SO_x emissions and are affected by the current or any revised primary SO_x NAAQS.

(b) Conflict of interest considerations: 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 financial conflict of interest; however, the general provisions in the appearance of impartiality guidelines still apply and need to be considered.

(i) Does the general charge to the CASAC augmented for the SO_x Review involve a particular matter? 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 the Augmented CASAC 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 SO_x.

(ii) Will there be personal and substantial participation on the part of the committee/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 members of the Augmented CASAC *will be participating personally in the matter*. Members will be providing the agency with advice and recommendations on the agency’s SO_x technical analyses, and such advice is expected to directly influence the agency’s risk assessment and risk management decisions involving SO_x. *Therefore, participation in this review also will be substantial.*

(iii) Will there be a direct and predictable effect on the Augmented CASAC members’ financial interests? 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 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)(ii)]. The ethics regulations include an exemption allowing Special Government Employees (SGEs) serving on federal advisory committees to participate in any particular matter of general applicability where the disqualifying financial interest arises from their non-Federal employment or non-Federal prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class [5 C.F.R. § 2640.203(g)]. (This exemption does not include the interests of an SGE arising from the ownership of stock in his employer or prospective employer.)

CASAC members and prospective panelists were asked to submit EPA 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 members of the CASAC Augmented for the SO_x Review from their participation on the augmented committee.*

4. How regulations concerning “appearance of a loss of impartiality” pursuant to 5 C.F.R. § 2635.502. apply to members of the committee or 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 loss of impartiality. This evaluation included information provided on the EPA Form 3110-48 confidential financial disclosure forms. *The SAB Staff Office has determined that the matter to be considered by the CASAC Augmented for the SO_x Review 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. Other considerations that might affect the objectivity of members of the committee or panel.

Members of CASAC panels must be scientific and technical experts who are objective and open-minded, 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 the members selected for the CASAC Augmented for the SO_x Review 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. How individuals were selected for the committee or panel.

On September 30, 2013, the SAB Staff Office posted a list of 37 candidates for the Augmented CASAC, identified based on their expertise and willingness to be considered for the panel. This list was accompanied by a notice inviting public comments on the list of candidates, to be submitted by October 21, 2013. The SAB Staff Office has not received any comments from the public on this list of candidates.

The SAB Staff Office Director makes the final decision about who serves on a review panel based on all of the relevant information, including a review of each candidate's confidential financial disclosure form (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 breath 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 loss of impartiality pursuant to 5 C.F.R. § 2635.502; (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 Augmented for the SO_x Review are as follows:

CASAC Augmented for the SO_x Review

Dr. Ana Diez-Roux, University of Michigan (MI) (Chair)
Mr. George A. Allen, Northeast States for Coordinated Air Use Management (NESCAUM) (MA)
Dr. John R. Balmes, University of California at San Francisco (CA)
Dr. James Boylan, Georgia Department of Natural Resources (GA)
Dr. Aaron Cohen, Health Effects Institute (MA)
Dr. Alison Cullen, University of Washington (WA)
Dr. Delbert Eatough, Brigham Young University (UT)
Dr. Christopher H. Frey, North Carolina State University (NC)
Dr. William C. Griffith, University of Washington (WA)
Dr. Steven Hanna, Hanna Consultants (ME)
Dr. Jack Harkema, Michigan State University (MI)
Dr. Kazuhiko Ito, New York City Department of Health (NY)
Dr. Daniel Jacob, Harvard University (MA)
Dr. Farla Kaufman, California EPA (CA)
Dr. David Peden, University of North Carolina at Chapel Hill (NC)
Dr. Richard Schlesinger, Pace University (NY)
Dr. Elizabeth A. (Lianne) Sheppard, University of Washington (WA)
Dr. Frank Speizer, Harvard Medical School (MA)
Dr. Helen Suh, Northeastern University (MA)
Dr. James Ultman, Pennsylvania State University (PA)
Dr. Ronald Wyzga, Electric Power Research Institute (CA)

Concurred,

/signed/

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Director and Deputy Ethics Official
EPA Science Advisory Board Staff Office (1400R)

January 14, 2014
Date