



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Memorandum

SUBJECT: Formation of Clean Air Scientific Advisory Committee (CASAC)
NO_x and SO_x Primary Review Panel

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The Clean Air Scientific Advisory Committee (CASAC), 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 (NO_x) and sulfur oxides (SO_x).

On August 7, 2006 the SAB Staff Office announced in the *Federal Register* (71 FR 44695) the formation of the CASAC NO_x and SO_x Primary Review Panel and solicited nominations for experts to supplement the statutory CASAC. This memorandum addresses the set of determinations that were necessary for forming the CASAC NO_x and SO_x Primary Review Panel (Panel). Over the next two to three years, the Panel will provide advice and recommendations to the EPA Administrator on the scientific and technical aspects of the primary (health-based) policy-relevant science and the NAAQS for both NO_x and SO_x. Specifically, this will involve the Panel's review of EPA's updated draft Integrative Science Assessment (ISA) for NO_x and SO_x health effects; and subsequently, as the basis for possible revisions to the primary NAAQS for NO_x and SO_x, the Primary NO_x and SO_x Risk/Exposure Assessment (RA), and the

Primary NO_x and SO_x Policy Assessment (PA) to be published as an advance notice of proposed rulemaking (ANPR). This memo provides background information on this Panel, and addresses the following determinations:

- (A) The type of review body that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair;
- (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, the name of the Panel, and identification of the Panel Chair.

The CASAC, augmented by additional subject-matter experts, known collectively as the CASAC NO_x and SO_x Primary Review Panel, will conduct the ongoing review of, and offer advice and recommendations to the EPA Administrator concerning, the primary (health-based NAAQS for NO_x and SO_x. Dr. Rogene Henderson, the CASAC Chair, will chair this Panel. The CASAC NO_x and SO_x Primary Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

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

Per the solicitation for nominees to form the CASAC NO_x and SO_x Primary Review Panel that was published in the *Federal Register* on August 7, 2006 (see citation above), recognized, national-level experts were sought in one or more of the following six (6) disciplines to augment the expertise of the statutory CASAC:

(a) Atmospheric Science. Expertise in physical/chemical properties of nitrogen oxides and sulfur oxides and atmospheric processes involved in the formation, transport on urban to global scales, transformation of these pollutants in the atmosphere, and movement of the pollutants between media through deposition and other such mechanisms. Also, expertise in the evaluation of natural and anthropogenic sources and emissions of nitrogen oxides and sulfur oxides and resulting ambient levels due to natural sources, pertinent monitoring or measurement methods for these pollutants, and spatial and temporal trends in their atmospheric concentrations.

(b) Exposure and Risk Assessment/Modeling. Expertise in measuring human population exposure to nitrogen oxides and sulfur oxides and/or in modeling human population exposure to pollutants from ambient and indoor sources. Expertise in human health risk analysis modeling for nitrogen oxides and sulfur oxides related to respiratory and other non-cancer health effects.

(c) Dosimetry. Expertise in evaluation of the dosimetry of animal and human subjects, including identification of factors determining differential patterns of inhalation and/or deposition/uptake in respiratory tract regions that may contribute to differential susceptibility of human population subgroups and animal-to-human dosimetry extrapolations.

(d) Toxicology. Expertise in evaluation of experimental laboratory animal studies and *in vitro* studies of the effects of sulfur oxides and/or oxides of nitrogen on pulmonary and extra-pulmonary (*e.g.*, cardiovascular, immunological) endpoints.

(e) Controlled Human Exposure. Expertise in evaluations of controlled human exposure studies of the effects of nitrogen oxides and sulfur oxides on health and compromised (*e.g.*, having pertinent preexisting disease such as asthma) human adults and children, including physicians with experience in the clinical treatment of asthma and chronic lung diseases.

(f) Epidemiology and Biostatistics. Expertise in epidemiologic evaluation of the effects of exposures to ambient nitrogen oxides and sulfur oxides and/or other major air pollutants (*e.g.*, particulate matter, ozone, carbon monoxide) on human population groups, including mortality and morbidity effects (*e.g.*, respiratory symptoms, lung function decrements, asthma medication use, emergency department visits, respiratory-related hospital admissions). Also, expertise in associated biostatistics and/or health risk analysis.

(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.

(a) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: 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) research universities; (5) environmental interest groups/non-Governmental organizations (NGOs); (6) potentially responsible parties (PRP) and their contractors; and (7) various industry sectors interested in, or affected by, the current or any revised NAAQS for NO_x and SO_x, including the power-generating and automotive industries.

(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 and 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) Does the general charge to the CASAC NO_x and SO_x Primary Review Panel involve a particular matter? A “particular matter” refers to matters that “...will involve deliberation, decision, or action that is focused upon the interests 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 CASAC NO_x and SO_x Primary Review Panel's activity in addressing the charge for the peer review of the draft NO_x and SO_x Primary ISA, RA and PA and related technical support documents 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 associated or involved with the potentially interested or affected parties, as identified in Section (3)(a) above.

(ii) Will there be personal and substantial participation on the part of 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 EPA Science Advisory Board (SAB) Staff Office has determined that *CASAC NO_x and SO_x Primary Review Panel members will be participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations that is expected to include an assessment as to whether the proposed air quality criteria (by means of the ISA) accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of these pollutants (that is, NO_x or SO_x) in the ambient air. *Therefore, participation in this review will also be substantial.*

(iii) Will there be a direct and predictable effect on CASAC NO_x and SO_x Primary Review 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 a speculative, possibility that the matter will affect the financial interest." [5 C.F.R. § 2640.103(a)(ii)]

(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 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 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.”

To ascertain whether there is any appearance of a lack of impartiality, the following five questions will be posed to each member of CASAC and prospective members of the NO_x and SO_x Primary Review Panel with respect to the forthcoming charge for the Panel:

(a) Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the CASAC NO_x and SO_x Primary Review Panel or any reason that your impartiality in the matter might be questioned?

(b) Have you had any previous involvement with the review document(s) under consideration, *i.e.*, EPA’s 1st Draft NO_x and SO_x Primary Integrated Science assessment — 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 (Federal or otherwise) 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? If so, please identify those statements.

(e) Have you made any public statements that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

(E) How individuals were selected for the Panel.

As described in Section (B) above, the SAB Staff Office announced the formation of the CASAC NO_x and SO_x Primary Review Panel in the *Federal Register* (71 FR 44695) on August 7, 2006, and requested nominations for recognized, national-level experts in one or more of the six scientific/technical expertise areas delineated in Section (B) above to augment the expertise of the statutory CASAC. In response to that solicitation, as well as from other sources, the SAB Staff Office identified 27 experts for the Panel’s “Short List.”

In December 2006, the SAB Staff Office published the “Short List” in the form of an “Invitation for Comments” memorandum and posted this on the Panel’s page on the SAB Web site at: http://www.epa.gov/sab/panels/casac_nox_and_sox_primary_panel.htm. The purpose of the “Invitation for Comments” memo is to solicit comments from members of the public or the Agency with respect to any relevant information or other documentation that the SAB Staff Office should consider in the final selection of this Panel.

The SAB Staff Office received two (2) public comments on this Short List from individuals representing the following organizations (date):

- Clean Air Watch (January 12, 2007)
- Center for Science in the Public Interest (CSPI) (January 17, 2007)

The SAB Staff Office Director makes the final decision about who serves on the CASAC NO_x and SO_x Primary Review Panel, based on all relevant information. This includes a review

of the member's confidential financial disclosure form (EPA Form 3110-48) and an evaluation of a lack of impartiality. For the EPA SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific 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 (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and, for the Panel as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, *etc.*

On the basis of the above-specified criteria, the CASAC NO_x and SO_x Primary Review Panel is as follows:

Members of the statutory (chartered) Clean Air Scientific Advisory Committee:

1. **Dr. Rogene Henderson**, Lovelace Respiratory Research Institute (NM) – CASAC Chair
2. **Dr. Ellis Cowling**, North Carolina State University (NC)
3. **Dr. James D. Crapo**, National Jewish Medical and Research Center (CO)
4. **Dr. Douglas Crawford-Brown**, University of North Carolina at Chapel Hill (NC)
5. **Mr. Richard L. Poirot**, Vermont Agency of Natural Resources (VT)
6. **Dr. Armistead (Ted) Russell**, Georgia Institute of Technology (GA)
7. **Dr. Frank Speizer**, Harvard Medical School (MA)

Additional CASAC NO_x and SO_x Primary Panel members:

1. **Dr. Ed Avol**, University of Southern California (CA)
2. **Dr. John Balmes**, University of California, San Francisco (CA)
3. **Dr. Henry Gong**, University of Southern California (CA)
4. **Dr. Terry Gordon**, New York University School of Medicine (NY)
5. **Dr. Dale Hattis**, Clark University (MA)
6. **Dr. Patrick Kinney**, Columbia University, Mailman School of Public Health (NY)
7. **Dr. Steven Kleeberger**, National Institute of Environmental Health Sciences (NC)
8. **Dr. Timothy Larson**, University of Washington (WA)
9. **Dr. Kent E. Pinkerton**, University of California, Davis (CA)
10. **Dr. Edward M. Postlethwait**, University of Alabama at Birmingham (AL)
11. **Dr. Richard B. Schlesinger**, Pace University (NY)
12. **Dr. Christian Seigneur**, Atmospheric & Environmental Research, Inc. (CA)
13. **Dr. Elizabeth A. (Lianne) Sheppard**, University of Washington (WA)
14. **Dr. George Thurston**, New York University School of Medicine (NY)
15. **Dr. James Ultman**, Pennsylvania State University (Emeritus) (PA)
16. **Dr. Ronald Wyzga**, Electric Power Research Institute (CA)

Concurred:

/Signed/

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April 2, 2007

Date