



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

January 29, 2009

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

MEMORANDUM

SUBJECT: Formation of Clean Air Scientific Advisory Committee Ozone Review Panel

FROM: Holly Stallworth, Ph.D. */signed/*
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400F)

TO: Vanessa Vu, Ph.D.
Director
EPA Science Advisory Board Staff Office (1400F)

THRU: Anthony Maciorowski, Ph.D. */signed/*
Deputy Director
EPA Science Advisory Board Staff Office (1400F)

This memorandum documents the process and addresses the set of determinations used in forming the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (Panel), specifically: the type of review body and the nature of the review; the type of expertise needed, financial conflict of interest considerations; appearance of a lack of impartiality considerations; and how individuals were selected for the Panel.

DETERMINATIONS:

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

The Clean Air Scientific Advisory Committee (CASAC), augmented additional subject-matter experts – known collectively as the CASAC Ozone Review Panel – will conduct peer review of the Agency's technical documents which form the basis for EPA's decisions on the primary (health-based) and secondary (welfare-based) NAAQS for ozone.

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

On June 26, 2008, the EPA Science Advisory Board (SAB) Staff Office announced the formation of the CASAC Ozone Review Panel in the *Federal Register* (73 FR 36319) and sought public nominations for nationally-recognized experts in one or more of the following nine (9) disciplines to supplement the expertise of the statutory CASAC:

Atmospheric Science. Expertise in physical/chemical properties of ozone and other photochemical oxidants, their precursor substances, and atmospheric processes involved in the formation, transport, and degradation of ozone and other photochemical oxidants in the atmosphere, including interaction with global climate and stratospheric ozone. Also, expertise in the evaluation of natural and man-made (anthropogenic) sources and emissions of precursors of tropospheric ozone and other photochemical oxidants, pertinent monitoring/measurement methods for such substances, and spatial/temporal trends in atmospheric concentrations of them.

Exposure Modeling and Assessment. Expertise in measuring human population exposure to ozone and/or in modeling human exposure to ambient and indoor pollutants.

Dosimetry. Expertise in measuring and/or estimating tissue doses of reactive gases in human and animal populations.

Toxicology. Expertise in evaluation of experimental toxicological effects and mechanisms of action of ozone and/or other photochemical oxidants in animal studies.

Controlled Human Exposure. Expertise in evaluation of controlled human exposure studies and/or ex vivo investigations of the effects of ozone and/or other photochemical oxidants on healthy and compromised human adults and children.

Epidemiology. Expertise in evaluation of the effects of exposures to ambient ozone and/or other ambient air co-pollutants on human population groups.

Risk Assessment and Biostatistics. Expertise in quantitative human health risk assessment and uncertainty analysis.

Ecological Effects. Expertise in evaluation of the effects of exposures to ambient ozone and/or other major ambient air co-pollutants on human population groups.

Ecological Resource Valuation. Expertise in valuation and benefits assessment approaches and models of ecological resource and other welfare effects.

- 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.
- i) 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 review are: (1) EPA; (2) State, regional and local air program (or air pollution control) agencies, and State regulatory officials; (3) public health, community, and environmental interest groups/ non-Governmental organizations (NGOs); (4) research universities; and (5) various industry sectors interested in, or affected by, the revised NAAQS for ozone.
 - ii) 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.
 - (a) Does the overall charge to the CASAC Ozone 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 Ozone Review Panel’s charge to review the scientific and technical aspects of the primary and secondary science qualifies 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 above.

- (b) 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

Ozone 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 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 this pollutant (that is, ozone and related photochemical oxidants) in the ambient air. Therefore, participation in this review will also be substantial.

- (c) Will there be a direct and predictable effect on CASAC Ozone 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)] 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 Ozone Review Panel members.*

- 4) 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 four questions were be posed to prospective panelists with respect to the forthcoming charge for the Panel:

- 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?
- Have you had any 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.
- Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
- 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.*

5) How individuals were selected for the Panel.

The SAB Staff Office evaluated all nominations and identified 39 experts as candidates for membership on the Panel. In November 2008, the SAB Staff Office published the “Short List” for this Panel on the CASAC website (www.epa.gov/casac). The SAB Staff Office requested public comment and received no public comments on this Short List.

The SAB Staff Office Director, taking all factors into account, makes the final decision about the membership of the Panel being formed. Specific criteria used in evaluating individual candidates include: (a) scientific and/or technical credentials and expertise, knowledge, and experience; (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of 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 and viewpoints.

On the basis of the above specified criteria, the CASAC Ozone Review Panel is as follows:

CASAC members:

1. Dr. Jonathan Samet, University of Southern California (CA), Chair
2. Dr. Joseph Brain, Harvard University (MA)
3. Dr. Ellis Cowling, North Carolina State University (NC)
4. Dr. James D. Crapo, National Jewish Medical and Research Center (CO)

