



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Memorandum

SUBJECT: CASAC Ozone Review Panel Selection Memorandum of Determinations

FROM: Fred Butterfield / *Signed* /
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This memorandum addresses the set of determinations that were necessary for forming the Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel (Panel). Over the next several years, the Panel will provide advice and recommendations to the EPA Administrator on the Agency's updated draft "Air Quality Criteria for Ozone and Related Photochemical Oxidants" (Ozone AQCD); and, subsequently, as the basis for possible revisions to the national ambient air quality standards (NAAQS), on the updated draft "Staff Paper and Risk Assessment Ozone and Related Photochemical Oxidants" (Ozone Staff Paper). This memorandum provides background information on this CASAC Panel, and addresses the following determinations:

- (1) The type of review body that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair;
- (2) The types of expertise needed to address the 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) How individuals were selected for the Panel.

DETERMINATIONS:

- (1) 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, which comprises 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, in part to provide advice, information and recommendations on the scientific and technical aspects of issues related to air quality criteria and NAAQS under sections 108 and 109 of the Act.

The U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment National, Research Triangle Park (NCEA-RTP), with the Agency's Office of Research and Development (ORD), is reviewing and, as appropriate, revising the EPA document, *Air Quality Criteria for Ozone and Related Photochemical Oxidants*, EPA-600/AP-93/004aF-cF, published in 1996. Section 109(d)(1) of the CAA requires that EPA carry out a periodic review and revision, where appropriate, of the air quality criteria and the NAAQS for "criteria" air pollutants such as ozone.

On January 31, 2005, NCEA-RTP made available for public review and comment a revised draft document, *Air Quality Criteria for Ozone and Related Photochemical Oxidants (First External Review Draft), Volumes I, II, and III*, EPA 600/R-05/004aA, bA, & cA. Under CAA sections 108 and 109, the purpose of the revised document is to provide an assessment of the latest scientific information on the effects of ambient ozone on the public health and welfare, for use in EPA's current review of the NAAQS for ozone. Detailed summary information on the history of the current draft air quality criteria document (AQCD) for ozone and related photochemical oxidants is contained in a recent EPA *Federal Register* notice (70 FR 4850, January 31, 2005).

In response to EPA's request, the SAB Staff Office announced the formation of a Panel to supplement the chartered CASAC. This body will be known as the CASAC Ozone Review Panel. The Panel will be chaired by the Chair of the Clean Air Scientific Advisory Committee.

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

Per the solicitations for nominees to form the CASAC Ozone Review Panel that were published in the *Federal Register* on June 12, 2003 (68 FR 35212) and again on November 24, 2004 (69 FR 68350), recognized, national-level experts were sought in one or more of the following seven disciplines, to augment the expertise of the chartered CASAC:

- (a) 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.

(b) Exposure and Risk Assessment/Modeling. Expertise in measuring human population exposure to ozone and/or in modeling human exposure to ambient and indoor pollutants. Also, expertise in human health risk analysis modeling for ozone or other pollutants causing respiratory and/or other non-cancer health effects.

(c) Ecological Effects and Resource Valuation. Expertise in evaluation of: patterns of exposure to ozone and/or other photochemical oxidants of ornamental and/or agricultural plants and/or natural ecosystems and their components; effects of ozone and other photochemical oxidants on natural ecosystems (especially terrestrial) and their components (both flora and fauna), ranging from biochemical/sub-cellular effects and identification of indicators of pathophysiological effects at the individual plant level, to effects on species and populations, on up to include impacts on increasingly more complex (*e.g.*, landscape) levels of ecosystem organization. Also, expertise in (i) ecosystem risk assessment and (ii) ecological resource valuation/economics.

(d) Dosimetry. Expertise in conducting and/or evaluation of the dosimetry of animal and human subjects, and animal-to-human dosimetry extrapolations, 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 to ozone and other photochemical oxidants.

(e) Toxicology. Expertise in conducting and/or evaluation of experimental laboratory animal studies of the potential health effects of ozone and/or other photochemical oxidants on respiratory and non-respiratory (*e.g.*, lung defense/other immune function mechanisms) endpoints.

(f) Controlled Human Exposure. Expertise in conducting and/or evaluation of controlled human exposure studies of the effects of ozone and other photochemical oxidants on healthy and compromised (having pertinent preexisting chronic disease, *e.g.*, asthma) human adults and children, including medical doctors (M.D.) with experience in the clinical treatment of asthma.

(g) Epidemiology and Biostatistics. Expertise in epidemiological evaluation of the effects of exposures to ozone and other photochemical oxidants and/or other ambient air co-pollutants on human population groups, including effects on mortality and/or morbidity (*e.g.*, respiratory symptoms, lung function decrements, asthma medication use, respiratory-related hospital admissions) endpoints. Also, expertise in associated biostatistics and/or health risk analysis.

(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.

(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) 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.

(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 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 activity in addressing the charge for the peer review of the draft Ozone AQCD and the draft Ozone Staff Paper 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.

The Special Government Employees (SGEs) who are to serve on the CASAC Ozone Review Panel for this review are part of a group of people who could represent organizations that in the future might be regulated by EPA or seek grant or contract funding for projects in research areas identified by the Panel. *Thus, the matter does involve deliberation that focuses upon the interests of a distinct and identifiable group of people, that is, the community that may be subject to EPA regulations or receive grant or contract funding from the Agency related to the topics under review or consultation by the Panel.*

(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 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.*

(iii) 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)]

Each CASAC Ozone Review Panel member could conceivably have financial links to the Agency in the form of existing or pending grants, cooperative agreements, contracts, or other funding. Furthermore, each of these individuals could submit proposals for such grants, cooperative agreements, contracts or other funding in the future.

In determining whether a member's or candidates' participation has a direct and predictable effect on their financial interest, the SAB Staff Office has evaluated the process for awarding grants and whether it could directly tie a person's actions in this review to financial gain. In evaluating this factor, the requirement is that a person's actions in participating in the matter must have a "close causal link" to their financial interest. Further, the link must be predictable, that is actual and not "speculative." In the case of members of the CASAC Ozone Review Panel, the "chain of causation" is attenuated and contingent upon the occurrence of events that are speculative. Thus, while Panel members may, in the course of this review, provide 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 ozone and related photochemical oxidants in the ambient air, provision of this advice would have no direct correlation with an individual Panel member's receipt of current or future grants, cooperative agreements, contracts, or other funding from the Agency.

Moreover, selection of grant recipients follows a complex two-stage process in which independent reviewers judge the scientific quality of a proposal and then Agency representatives judge the relevance of the proposal to answering major scientific questions within the subject area. Thus, actual selection of grant recipients is mediated by a chain of events that attenuates any direct linking of a grant to a panel member's participation in this or subsequent CASAC Ozone Review Panel reviews, consultations or other activities. Therefore, any effects from participating in this review would not be direct, nor would they be predictable. Accordingly, no conflict-of-interest as defined by 18 U.S.C. § 208 exists in association with grant holding by members of the CASAC Ozone Review Panel.

Furthermore, because the procedures for awarding grants, cooperative agreements, contracts, or other funding differ, each specific situation has been evaluated to determine if a direct and predictable effect exists between an Ozone Review Panel member's participation and

their financial interest. Finally, matters in which Panel members have grants, cooperative agreements, contracts or other funding from EPA that are for work that fits conceptually or specifically within the expected work of this Panel have been evaluated under the requirements for considering “appearance of impartiality” under 5 C.F.R. § 2635.502, as discussed below in Section (4).

(The U.S. Office of Government Ethics requires that all Special Government Employees (SGEs) submit confidential financial disclosure statement on an annual basis. For members of EPA Federal advisory committees, this is the Confidential Financial Disclosure Form (EPA Form 3110-48). In addition, all Clean Air Scientific Advisory Committee members and CASAC panel and subcommittee members are required to update their EPA Form 3110-48 whenever there have been substantive changes, or whenever they are participating in an advisory activity.)

As a result of a review of the Agency’s Confidential Financial Disclosure Form (EPA Form 3110-48) provided by each prospective CASAC Ozone Review Panel member, the SAB Ethics and Federal Advisory Committee Act (FACA) Policy Officer, in consultation with the EPA Alternate Agency Ethics Official, as necessary, has determined that there is no financial conflict-of-interest presented for the CASAC Ozone Review Panel. In addition, the Panel’s advice on the particular matter under review will not have a direct effect on the financial interest 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.”

As noted above in Section (3)(b)(i), the CASAC Ozone Review Panel’s activity in addressing the charge for the peer review of the 1st draft Ozone AQCD 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. However, as also noted above in Section (3)(b)(iii), the chain of events for a grant is attenuated by certain factors that do not constitute a conflict of interest; thus, the criterion for “appearance of impartiality” at 5 C.F.R. § 2635.502(a) is not met. EPA grant, cooperative agreement, contracts or other funding may present a different situation, and each Panel member was evaluated to determine whether his or her financial

interest in existing grants, cooperative agreements, contracts or other funding constitutes an “appearance of impartiality.”

Even though circumstances for some specific candidates for the Ozone Review Panel may raise neither formal conflict-of-interest nor formal appearance concerns, each candidate has been preliminarily evaluated against the five 5 C.F.R. § 2635(a)(2) general requirements to ensure that lack of an appearance of impartiality issues do not preclude their participation. Information used in this evaluation has come from Panel members’ EPA 3110-48 forms and other staff research. For those CASAC Ozone Review Panel members who hold grants, cooperative agreements, contracts or other funding, or who are involved with organizations subject to regulation by EPA, the SAB Staff Office has determined whether the “reasonable person” criterion is met in the following manner:

(a) Those who are employed by the EPA regulated community were considered to meet this criterion; and

(b) Those who have pending grants, cooperative agreements, contracts or other funding that could be directly received from EPA were considered to have met the criterion.

To further ascertain whether there is any potentially-disqualifying involvement with the specific topic of the CASAC Ozone Review Panel’s upcoming meetings which might indicate the appearance of a lack of impartiality, the following five questions were posed to each of the prospective selectees for the Ozone Review Panel with respect to the 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 Ozone 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.*, the *Air Quality Criteria for Ozone and Related Photochemical Oxidants (First External Review Draft)*; or the forthcoming *Review of the National Ambient Air Quality Standards for Ozone and Related Photochemical Oxidants: Policy Assessment of Scientific and Technical Information (First Draft)*, or the related draft technical support document, *Ozone and Related Photochemical Oxidants Health Risk Assessment for Selected Urban Areas: First Draft Report* — 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? 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.

(These or similar questions are also asked of all Clean Air Scientific Advisory Committee members and CASAC panel and subcommittee members for any CASAC advisory activity.)

Accordingly, as a result of a review of the EPA Form 3110-48 and the responses to the above (5) questions provided by each prospective member of the CASAC Ozone Review Panel, the SAB's Deputy Ethics Official, in consultation with the SAB Ethics and FACA Policy Officer, has determined that there is no appearance of a lack of impartiality on the part of the selectees for the CASAC Ozone Review Panel.

(5) How individuals were selected for the Panel.

On June 12, 2003, the SAB Staff Office announced the formation of the CASAC Ozone Review Panel in the *Federal Register* (68 FR 35212) and requested nominations for recognized, national-level experts it was seeking in one or more of the following seven disciplines delineated in Section (2) above. In response to this June 2003 *Federal Register* notice, as well as from other sources, the SAB Staff Office received nominations for scientific experts, and in February 2004 published a "Short List" of 24 technically-qualified candidates on the SAB Web site at URL: http://www.epa.gov/sab/pdf/casacozonerpanel_shortbios.pdf for the purpose of soliciting comments from the public. The SAB Staff Office received public comments on this Short List from the following organizations:

- The Clean Air Trust (February 23, 2004)
- The Center for Science in the Public Interest (CSPI) (February 26, 2004)
- The Annapolis Center (March 8, 2004)

Given the lengthy period of time that had elapsed since its first announcement, and in view of the fact that several candidates on the previously-published Short List informed the CASAC DFO that they were no longer available to serve on the CASAC Ozone Review Panel, the SAB Staff Office reopened the public nomination process for experts to serve on this Panel. Per the follow-on notice which appeared in the *Federal Register* (69 FR 68350) on November 24, 2004, the SAB Staff Office re-announced that it was seeking recognized, national-level experts to serve on the CASAC Ozone Review Panel in the same seven disciplines as per the previous (June 2003) *Federal Register* notice. In response to this second solicitation, as well as from other sources, the SAB Staff Office received additional nominations for scientific experts, and a second Short List of CASAC Ozone Review Panel candidates was posted on the SAB Web site at URL: http://www.epa.gov/sab/pdf/casac_ozone_shortlist_bios_dec2004.pdf for a 28-day public comment period beginning on December 20, 2004. The SAB Staff Office received no public comments on this Short List.

The SAB Staff Office Director, in consultation with the CASAC Chair and EPA, makes the final decision about who serves on the CASAC Ozone Review Panel during the "Panel Selection" phase. 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 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.

Additional information on the CASAC Ozone Review Panel may be found on the SAB Web site at URL: <http://www.epa.gov/sab/panels/casacorpanel.html>.

The seven current members of the statutory (chartered) Clean Air Scientific Advisory Committee are as follows:

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. Frederick J. Miller**, Consultant (NC)
5. **Mr. Richard L. Poirot**, Vermont Agency of Natural Resources (VT)
6. **Dr. Frank Speizer**, Harvard Medical School (MA)
7. **Dr. Barbara Zielinska**, Desert Research Institute (NV)

Additionally, on the basis of the above-specified criteria, the following sixteen (16) experts were selected as members of the CASAC Ozone Review Panel:

1. **Dr. John Balmes (M.D.)**, University of California, San Francisco (CA)
2. **Dr. William (Jim) Gauderman**, University of Southern California (CA)
3. **Dr. Henry Gong (M.D.)**, University of Southern California (CA)
4. **Dr. Paul J. Hanson**, Oak Ridge National Laboratory (TN)
5. **Dr. Jack Harkema**, Michigan State University (MI)
6. **Dr. Philip Hopke**, Clarkson University (NY)
7. **Dr. Michael T. Kleinman**, University of California, Irvine (CA)
8. **Dr. Allan Legge**, Biosphere Solutions (Canada)
9. **Dr. Mort Lippmann**, New York University (NY)
10. **Dr. Maria Morandi**, University of Texas, Houston (TX)
11. **Dr. Charles Plopper**, University of California, Davis (CA)
12. **Dr. Armistead (Ted) G. Russell**, Georgia Institute of Technology (GA)
13. **Dr. Elizabeth A. (Lianne) Sheppard**, University of Washington (WA)
14. **Dr. James S. Ultman**, Pennsylvania State University (PA)
15. **Dr. Sverre Vedal (M.D.)**, University of Washington School of Medicine (WA)
16. **Dr. James V. Zidek**, University of British Columbia (Canada)

Concurred:

/ Signed /

April 12, 2005

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Date