



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)
Particulate Matter (PM) Review Panel

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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. 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 airborne particulate matter (PM).

This memorandum addresses the set of determinations that were necessary for forming the CASAC PM Review Panel (Panel), including:

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

The members of the chartered (statutory) CASAC, supplemented by additional subject-matter experts — known collectively as the CASAC Particulate Matter Review Panel — will provide advice and recommendations to the EPA Administrator on the scientific and technical aspects of the primary (health-based) and secondary (welfare-based) policy-relevant science criteria and the NAAQS for particulate matter. Specifically, this will involve the Panel’s review of the Agency’s updated draft Integrative Science Assessment (ISA) for PM health and welfare effects; and, subsequently, as the basis for possible revisions to the Particulate Matter NAAQS, the PM Risk/Exposure Assessment (RA), and the PM Policy Assessment (PA) to be published as an advance notice of proposed rulemaking (ANPR).

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

On March 8, 2007, the EPA Science Advisory Board (SAB) Staff Office announced the formation of the CASAC PM Review Panel in the *Federal Register* (72 FR 10527) and sought public nominations for nationally-recognized experts in one or more of the following eleven (11) disciplines to supplement the expertise of the statutory CASAC:

(a) Atmospheric Science. Expertise in evaluating the physical/chemical properties of particulate matter including transport of particulate on urban to global scales, transformation of primary particles in the atmosphere to secondary particles, and movement of particulate matter between media through deposition and other such mechanisms. Expertise in evaluating natural and anthropogenic sources and emissions of PM and resulting ambient levels, pertinent monitoring or measurement methods for particulate matter, and spatial and temporal trends in PM atmospheric concentrations.

(b) Human Exposure and Risk Assessment/Modeling. Expertise in measuring general population exposure to PM and/or in modeling exposure to particulate matter emitted from ambient and indoor sources. Expertise in human health risk analysis modeling for PM related to respiratory, cardio-vascular, and other non-cancer health effects as well as cancer. Expertise in characterizing uncertainty in exposure and risk analyses.

(c) Dosimetry. Expertise in evaluating the dosimetry of animal and human subjects, including identifying factors associated with differential patterns of inhalation and/or deposition/uptake in various respiratory tract regions that may contribute to differential susceptibility of sensitive subpopulations and animal-to-human dosimetry extrapolations.

(d) Toxicology. Expertise in evaluating and interpreting experimental laboratory animal studies, including animal models simulating sensitive subpopulations (*e.g.*, children, older adults, individuals with preexisting respiratory or cardiac disease), and *in vitro* studies of the effects of

PM on pulmonary and extrapulmonary (*e.g.*, cardiovascular, immunological) endpoints and cancer.

(e) Controlled Human Exposure. Expertise in evaluating and interpreting controlled human exposure studies of the effects of PM on the general population and sensitive subpopulations (*e.g.*, children, older adults, individuals with preexisting respiratory or cardiac disease). Experts would include physicians with experience in the clinical treatment of cardiopulmonary diseases, including asthma, chronic obstructive pulmonary disease (COPD), and diabetes.

(f) Epidemiology and Biostatistics. Expertise in evaluating epidemiological evidence of the effects of exposures to ambient PM and other major air pollutants (*e.g.*, ozone, SO₂, NO₂, carbon monoxide) on the general population and sensitive subpopulations (*e.g.*, children, older adults, individuals with preexisting respiratory or cardiac disease). Expertise in evaluating a broad range of health endpoints, including mortality and morbidity effects (*e.g.*, respiratory symptoms, lung function decrements, asthma medication use, physiological changes or biomarkers for cardiac changes, cardiopulmonary-related emergency department visits, cardiopulmonary-related hospital admissions, cancer). Expertise in using biostatistical models to interpret epidemiological evidence.

(g) Effects on Visibility Impairment. Expertise in evaluating and interpreting studies of the effects of particulate matter on local visibility impairment as well as regional haze. Expertise would include evaluating visibility trends and conditions in Class I, urban, and non-urban areas, studies of economic value of improving visual air quality, and approaches to assessing public perceptions of visibility impairment and judgments about the acceptability of varying degrees of visibility impairment.

(h) Ecological Effects. Expertise in evaluating the effects of exposure to particulate matter on agricultural crops and natural ecosystems and their components, both flora and fauna, ranging from biochemical/sub-cellular effects on organisms to increasingly more complex levels of ecosystem organization. Appropriate expertise disciplines include: aquatic chemistry; aquatic ecology/biology; limnology; terrestrial ecology; forest ecology; grassland ecology; rangeland ecology; terrestrial/aquatic biogeochemistry; terrestrial/aquatic nutrient cycling; and terrestrial/aquatic wildlife biology and soil chemistry.

(i) Other Welfare Effects. Expertise in evaluating the effects of particulate matter on other public welfare effects, including damage to materials, and also the atmospheric interactions of PM as related to global climate conditions.

(j) Ecosystem Exposure and Risk Assessment/Modeling. Expertise in deposition modeling across a range of scales from local watershed to landscape to continental; static and dynamic ecosystem response models; integrated assessment models; identification of bioindicators useful for tracking ecosystem change; and methods and approaches for estimating damage to ecosystems.

(k) Resource Valuation. Expertise in ecological resource and other welfare effects valuation and/or economic benefits assessment approaches and models.

(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) public health, community, and environmental interest groups/non-Governmental organizations (NGOs); (5) potentially responsible parties (PRP) and their contractors; (6) research universities; and (7) various industry sectors interested in, or affected by, the current or any revised PM NAAQS, 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 PM 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 Particulate Matter Review Panel’s activity in addressing the charge for the peer review of the draft PM 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 (C)(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 SAB Staff Office has determined that *CASAC Particulate Matter 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 this

pollutant (that is, particulate matter) in the ambient air. *Therefore, participation in this review will also be substantial.*

(iii) Will there be a direct and predictable effect on CASAC Particulate Matter 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 PM 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 PM 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 Integrated Plan for the Review of the Particulate Matter NAAQS — 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.

The SAB Staff Office evaluated all nominations and identified 55 experts as candidates for membership on the Panel. In June 2007, the SAB Staff Office published the “Short List” for this Panel on its Web site at: http://www.epa.gov/sab/pdf/casac_pm_rev_panel_inv_for_comments_shortlist_bios_june_2007.pdf. The SAB Staff Office received comments on this “Short List” from the following five members of the public:

- P. Brock Williams, Ph.D., University of Missouri Medical School (July 2, 2007)
- Kevin J. Kelly, M.D., University of Missouri Kansas City School of Medicine (July 2, 2007)
- Mr. Mark Bryant, Wadesville, IN (July 5, 2007)
- Praveen K. Amar, Ph.D., P.E., Northeast States for Coordinated Air Use Management (NESCAUM) (July 13, 2007)
- Daniel W. Nebert, M.D., University of Cincinnati Medical Center (July 15, 2007)

The SAB Staff Office Director makes the final decision about who serves on the CASAC PM 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 an appearance of a lack of impartiality. For the 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 PM Review Panel is as follows:

CASAC members:

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. **Dr. Donna Kenski**, Lake Michigan Air Directors Consortium (IL)
6. **Dr. Armistead (Ted) Russell**, Georgia Institute of Technology (GA)
7. **Dr. Jonathan M. Samet**, Johns Hopkins University (MD)

Panel members:

1. **Dr. Lowell Ashbaugh**, University of California (CA)
2. **Mr. Ed Avol**, University of Southern California, (CA)
3. **Dr. Wayne Cascio**, East Carolina University (NC)
4. **Dr. H. Christopher Frey**, North Carolina State University (NC)
5. **Dr. David Grantz**, University of California, Kearney Agricultural Center (CA)
6. **Dr. Joseph Helble**, Dartmouth College (NH)
7. **Dr. Philip Hopke**, Clarkson University (NY)
8. **Dr. Morton Lippmann**, New York University School of Medicine (NY)
9. **Dr. William Malm**, National Park Service (CO)
10. **Mr. Charles Thomas (Tom) Moore, Jr.**, Western Governors' Association (CO)
11. **Dr. Robert F. Phalen**, University of California, Irvine (CA)
12. **Dr. Kent Pinkerton**, University of California, Davis (CA)
13. **Mr. Richard L. Poirot**, Vermont Agency of Natural Resources (VT)
14. **Dr. Frank Speizer**, Harvard Medical School (MA)
15. **Dr. Helen Suh**, Harvard University School of Public Health (MA)
16. **Dr. Sverre Vedal**, University of Washington (WA)

Concurred:

/Signed/

October 23, 2007

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Date