



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July 26, 2010

MEMORANDUM

SUBJECT: Formation of the Clean Air Scientific Advisory Committee (CASAC) Lead 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 lead.

This memorandum addresses the set of determinations that were used in forming the CASAC Lead Review Panel including:

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

An ad hoc expert panel of the CASAC will provide independent advice through the chartered CASAC on EPA’s technical and policy assessments that support the Agency's review of the National Ambient Air Quality Standard (NAAQS) for lead, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, Policy Assessment, and Rulemaking.

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

On October 28, 2009, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 74, Number 207, Pages 55548-55549) that it was forming a panel to review and provide independent expert advice on EPA's technical and policy assessments that support the Agency's review of the National Ambient Air Quality Standard (NAAQS) for lead, including drafts of the Integrated Review Plan, Integrated Science Assessment, Risk/Exposure Assessment, Policy Assessment, and Rulemaking. To form the panel, the SAB Staff Office sought public nominations of nationally recognized experts with expertise in one or more of the following areas, particularly with respect to lead: Atmospheric sciences; fate and transport; exposure assessment; toxicology; biokinetic modeling; epidemiology; risk assessment; biostatistics; ecology; and air quality.

- (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 (PRPs) and their contractors; 6) research universities; and 7) various industry sectors interested in, or affected by, the current or any revised Lead 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 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 Lead Review Panel 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 this CASAC Panel 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 private or public organizations facing regulatory decisions related to the release of or exposure to lead.

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

(iii) Will there be a direct and predictable effect on 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 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 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 lack of impartiality. This evaluation included responses to EPA 3110-48 confidential financial disclosure forms and the following supplemental questions:

1. 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?
2. 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.
3. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
4. 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.

(E) How individuals were selected for the Panel

On April 5, 2010 the SAB Staff Office posted a list of 28 candidates for the Panel, identified based on their expertise and willingness to be considered for the panel. This list was accompanied by a notice inviting public comments on a list of candidates to be submitted by

April 26, 2010. The SAB Staff Office received one comment from the public on this list of candidates: Dr. David Rosner, Columbia University, Mailman School of Public Health.

The SAB Staff Office Director makes the final decision about who serves on the CASAC Lead Review Panel, based on all relevant information identified by SAB staff and public comment. 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 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 to the panel. 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 lack of impartiality; (e) skills working on advisory committees and panels; 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 Lead Review Panel are as follows:

CASAC Lead Review Panel Members

Dr. H. Christopher Frey, North Carolina State University (NC), Chair
Dr. Herbert Allen, University of Delaware (DE)
Dr. Richard Canfield, Cornell University (NY)
Dr. Deborah Cory-Slechta, University of Rochester (NY)
Dr. Cliff Davidson, Syracuse University (NY)
Dr. Philip E. Goodrum, ARCADIS BBL, ARCADIS of New York, Inc. (NY)
Dr. Sean Hays, Summit Toxicology (CO)
Dr. Philip Hopke, Clarkson University (NY)
Dr. Chris Johnson, Syracuse University (NY)
Dr. Susan Korrick, Harvard University (MA)
Dr. Michael Kosnett, University of Colorado Health Sciences Center (CO)
Dr. Roman Lanno, Ohio State University (OH)
Dr. Richard Poirot, Vermont Agency of Natural Resources (VT)
Dr. Joel Pounds, Battelle - Pacific Northwest National Laboratory (WA)
Dr. Michael Rabinowitz, Harvard University (MA)
Dr. William Stubblefield, Oregon State University (OR)
Dr. Ian von Lindern, TerraGraphics Environmental Engineering, Inc. (ID)
Dr. Gail Wasserman, Columbia University (NY)
Dr. Michael Weitzman, New York University School of Medicine (NY)

