



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

Memorandum

SUBJECT: CASAC Lead Review Panel Selection Memorandum of Determinations

FROM: Fred Butterfield */s/ Fred Butterfield*
Designated Federal Officer (DFO)
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)

VIA: Daniel Fort */s/ Dan Fort*
Ethics & FACA Policy Officer
EPA Science Advisory Board Staff Office (1400F)

This memorandum addresses the set of determinations that were necessary for forming the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel (Panel). Over the next two years, the Panel will provide advice and recommendations to the EPA Administrator on the Agency's updated draft "Air Quality Criteria for Lead" (Lead AQCD); and, subsequently, as the basis for possible revisions to the national ambient air quality standards (NAAQS), on the updated draft Staff Paper, risk assessment and related technical support documents for Lead (Lead Staff Paper). This memo provides background information on this CASAC 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.

BACKGROUND:

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 such as lead. On December 1, 2005, EPA’s National Center for Environmental Assessment National, Research Triangle Park (NCEA-RTP), within the Agency’s Office of Research and Development (ORD), made available for public review and comment a revised draft document, *Air Quality Criteria for Lead (First External Review Draft), Volumes I and II*, EPA/600/R-05/144aA–bA. This 1st draft Lead air quality criteria document (AQCD) represents a revision to the previous EPA document, *Air Quality Criteria for Lead*, EPA–600/8–83/028aF–dF (published in June 1986) and an associated supplement (EPA–600/8–89/049F) published in 1990. Under CAA sections 108 and 109, the purpose of the revised AQCD is to provide an assessment of the latest scientific information on the effects of ambient lead on the public health and welfare, for use in EPA’s current review of the NAAQS for lead. Detailed summary information on the revised draft AQCD for lead is contained in a recent EPA *Federal Register* notice (70 FR 72300, December 2, 2005).

In anticipation of the publication of the 1st draft Lead AQCD, on September 6, 2005 the SAB Staff Office announced the formation of the CASAC Lead Review Panel in the *Federal Register* (70 FR 53001) and solicited nominations for experts to supplement the statutory CASAC. In addition, as Designated Federal Officer (DFO) for this *ad hoc* Panel, I solicited additional nominations and self-nominations from qualified individuals for service on this Panel from September to December 2005.

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 Lead Review Panel will conduct this ongoing review. The Panel, which will consist of the seven members of the chartered CASAC supplemented by additional subject-matter experts, will be chaired by Dr. Rogene Henderson, the Chair of the Clean Air Scientific Advisory Committee. The CASAC Lead 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 Lead Review Panel that was published in the *Federal Register* on September 6, 2005 (see citation above), recognized, national-level experts were sought in one or more of the following disciplines to augment the expertise of the statutory CASAC:

(a) Chemistry, environmental sources, transport and deposition of lead. Includes expertise in: (1) inorganic and organometallic chemistry of lead; (2) methods of measuring environmental sources and source strengths from smelters, coal combustion plants, vehicles (historic and modern) and natural sources; (3) atmospheric transport, including methods of detecting transported lead (*e.g.*, isotope analysis) in the gas phase, liquid phase, particle phase (both primary and resuspended); and (4) deposition of lead, including measurement of deposition rate as a function of surface properties.

(b) Multimedia routes of human exposure to lead. Includes knowledge of measurement methods (*e.g.*, air sampling methodology) and observed environmental concentrations for multimedia human exposure pathways via inhalation and ingestion (relevant concentrations for various sources: soil, dust, drinking water, food, as well as others such as lead-based paint, pica for paint or soil, *etc.*).

(c) Modeling of multimedia human exposure uptake/absorption of lead to predict internal biokinetic distribution (blood/bone lead burdens):

(1) Lead exposure pathway assessment. Expertise in the physical and chemical properties of lead and the biogeochemical processes involved in the pathways involved in human exposure to lead. These pathways include:

- (i) air (both direct inhalation and deposition to surfaces likely to be contacted by humans);
- (ii) drinking water (from typical sources including municipal systems, bottled water, public drinking fountains, and private wells);
- (iii) food (including market sources, home gardens and recreational and subsistence fishing/hunting); and
- (iv) soil/dust ingestion.

(2) Lead uptake/absorption. Expertise in the processes of uptake or absorption of lead in the digestive tract and lungs, including knowledge of digestive processes that affect the form of lead thus making it more (or less) available for absorption. Experience on the fate of inhaled particles is also desirable, including olfactory uptake.

(3) Internal biokinetic distribution and physiological effects of lead. Expertise on the physiological processes that determine the distribution of absorbed lead among the various organs and tissues of the human body. This would include expertise on the mechanisms of transport within the human body, the organs and tissues that accumulate significant amounts of lead, the concentrations at the organ/tissue level that might impair physiological processes, and the residence times (or other measures of potential impact) of lead in these tissues and organs.

Expertise on the various mechanisms and routes of elimination and the mechanisms of this elimination is desirable.

(4) Tissue concentrations of lead. Includes expertise on measurement methods and observed concentrations for various biological tissues, including blood, teeth, and bone lead concentrations and lead levels in soft tissues such as brain, kidney, *etc.*

(5) Human growth and activity patterns. Expertise on growth patterns and typical human activity patterns from prenatal to elderly, including recreational, occupational, leisurely, and household activities. This would include knowledge of published data and of modeling applications.

(6) Exposure assessment modeling. Expertise and experience in measuring human population exposure to lead and/or in modeling human exposure to ambient and indoor pollutants. Expertise in relating indicators of human exposure to potential health outcomes and quantification of risk related to adverse health outcomes.

(d) Lead-induced health effects. Experience in epidemiologic/clinical evaluation and/or evaluation in laboratory animals or in *in vitro* test systems of lead-induced effects on:

- neurological development and other neurological endpoints;
- cardiovascular function;
- immune system function;
- heme synthesis;
- genotoxic effects; and
- carcinogenicity.

(e) Risk assessment and uncertainty characterization. Expertise in human health risk assessment for lead or other pollutants causing non-cancer and cancer health effects, including Bayesian statistical approaches and biostatistics. Expertise in designing uncertainty characterization frameworks for complex multi-media health assessments involving use of PBPK models, empirical data, microenvironmental exposure modeling and concentration-response functions drawing on both toxicological and epidemiological data. Specific areas of expertise should include probabilistic methods and Bayesian techniques.

(f) Evaluation of environmental effects of lead on terrestrial and aquatic ecosystems. Includes expertise and/or knowledge of most current methods and state-of-the-science for assessing: modes of action of lead in plants, animals, and microorganisms; exposure of aquatic and terrestrial organisms to lead in various forms and from various sources; bioavailability of lead and factors which modify the lead uptake by aquatic and terrestrial ecosystems; ecosystem responses at a range of spatial and temporal scales; lead sources, fate, transport, and mobility using stable isotopes; and critical loads for lead in aquatic and terrestrial ecosystems.

(g) Evaluation of economic effects of lead. Experience in evaluating economic effects of lead on consumptive-use ecological entities such as agriculture, commercial forests, aquaculture, shell fisheries, and commercial fisheries; and ability to monetize non-consumptive-use

ecological entities such as recreation, aesthetics, biodiversity, and other ecological goods and services that are not typically assigned a monetary value.

(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 lead.

(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 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 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 Lead Review Panel’s activity in addressing the charge for the peer review of the draft Lead AQCD and the draft Lead Staff Paper 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 Lead 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, lead) in the ambient air. *Therefore, participation in this review will also be substantial.*

(iii) Will there be a direct and predictable effect on CASAC Lead 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)]

As a result of a review of the Agency's Confidential Financial Disclosure Form (EPA Form 3110-48) provided by each prospective CASAC Lead Review Panel member, the SAB's Deputy Ethics Official, in consultation with the SAB Ethics and FACA Policy Officer (who also serves as the EPA Alternate Deputy Ethics Official for the SAB Staff Office) has determined that there is no financial conflict-of-interest presented for the CASAC and the members of the 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 Lead Review Panel members.

(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 were posed to each member of CASAC and candidates for the Lead 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 Lead 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 Lead AQCD — 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.

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 Lead Review Panel, the SAB’s Deputy Ethics Official, in consultation with the SAB Ethics and FACA Policy Officer (who also serves as the EPA Alternate Deputy Ethics Official for the SAB Staff Office) has determined that there is no appearance of a lack of impartiality on the part of the CASAC Lead Review Panel.

(E) How individuals were selected for the Panel.

As noted in Section (1) above, the SAB Staff Office announced the formation of the CASAC Lead Review Panel in the *Federal Register* (70 FR 53001) on September 6, 2005, and requested nominations for recognized, national-level experts it was seeking in one or more of the seven scientific/technical expertise areas delineated in Section (2) 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 19 experts for the Panel’s “Short List.”

In December 2005, the SAB Staff Office published the “Short List” on the Panel’s page on the SAB Web site at URL: http://www.epa.gov/sab/panels/casac_lead_review_panel.htm, for the purpose of soliciting comments from members of the public with respect to any relevant information or other documentation that the SAB Staff Office should consider in the selection of this Panel. Nominees were selected for the “Short List” on the basis of whether they possessed the relevant scientific and/or technical expertise, knowledge, and experience, pursuant to the aforementioned *Federal Register* notice.

The SAB Staff Office received one (1) public comment on this Short List from an individual representing the following organization (date):

- Interdisciplinary Environmental Clinic of Washington University in St. Louis, on behalf of the Missouri Coalition for the Environment (January 9, 2006)

The SAB Staff Office Director made the final decision about who serves on the Panel, based on all relevant information. 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.*

Additional information on the CASAC Lead Review Panel may be found on the SAB Web site at URL: http://www.epa.gov/sab/panels/casac_lead_review_panel.htm.

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 thirteen (13) supplemental experts were selected as members of the CASAC Lead Review Panel:

1. **Dr. Joshua Cohen**, Harvard University School of Public Health (MA)
2. **Dr. Deborah Cory-Slechta**, University of Medicine and Dentistry of New Jersey and Rutgers State University (NJ)
3. **Dr. Bruce Fowler**, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (GA)
4. **Dr. Andrew Friedland**, Dartmouth College (NH)
5. **Dr. Robert Goyer**, Former Deputy Director, NIEHS; Professor Emeritus, Univ. of Western Ontario, Canada (NC)
6. **Mr. Sean Hays**, Summit Toxicology (CO)
7. **Dr. Bruce P. Lanphear**, Cincinnati Children’s Environmental Health Center, and the University of Cincinnati (OH)
8. **Dr. Samuel Luoma**, U.S. Geological Survey (CA)
9. **Dr. Paul Mushak**, PB Associates, and Albert Einstein College of Medicine (NC & NY)
10. **Dr. Michael Newman**, Virginia Institute of Marine Science (VA)
11. **Dr. Michael Rabinowitz**, Marine Biological Laboratory (MA)
12. **Dr. Joel Schwartz**, Harvard University School of Public Health (MA)
13. **Dr. Ian von Lindern**, TerraGraphics Environmental Engineering, Inc. (ID)

Concurred:

/s/ Vanessa Vu

February 2, 2006

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

Date