



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

December 6, 2021

MEMORANDUM

SUBJECT: Formation of the 2021 Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel

FROM: Aaron Yeow
Designated Federal Officer (DFO)
EPA Science Advisory Board Staff Office (1400R)

THRU: Wanda Bright
Ethics Official
EPA Science Advisory Board Staff Office (1400R)

TO: Thomas H. Brennan
Director
EPA Science Advisory Board Staff Office (1400R)

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 2021 CASAC Lead Review Panel including:

1. The type of review body that will be used to conduct the review, and the nature of the review;
2. The types of expertise needed to address the general 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. Other considerations that might affect the objectivity if members of the panel; and
6. 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.

An ad hoc expert panel of the CASAC will provide independent advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the primary and secondary NAAQS for lead.

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

On September 8, 2021, the EPA SAB Staff Office announced in a Federal Register Notice (86 FR 50345-50346) that it was forming a panel to review and provide independent expert advice through the Chartered CASAC on the scientific and technical aspects of air quality criteria and the primary and secondary NAAQS for lead. To form the panel, the SAB Staff Office sought public nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to criteria pollutants, in the following fields, especially with respect to lead: air quality; environmental fate and transport; exposure and biomarker assessment; biokinetic modeling; toxicology; epidemiology; risk assessment; biostatistics; and ecology.

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 (or class of parties) whose financial interests may be affected by the topic to be reviewed: The principal interested and affected parties for this topic are 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 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 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 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 *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 technical analyses on lead, 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)]. 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 the CASAC 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(a)(2) describes general requirements for considering an appearance of a loss of impartiality for employees of the Executive Branch (including Special Government Employees) participating in a *particular matter involving specific parties*.

The SAB Staff Office has determined that the matter to be considered by the panel is not a particular matter involving specific parties; i.e., this matter does not involve "any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest" [5 C.F.R. 2637.102(a)(7)].

5. Other considerations that might affect the objectivity of members of the panel.

Members of CASAC panels must be scientific and technical experts who are objective and open-minded, able to engage in deliberative discussions with scientists who may have disparate perspectives. To evaluate candidates, the SAB Staff Office considers information (if any) provided by the public in response to the invitation for public comment on the candidates, information provided by candidates (including on the EPA Form 3110-48), and information independently gathered by the SAB Staff Office.

As part of a determination that members of committees and panels are objective and open-minded on the topic of the review, and consistent with the agency's Peer Review Policy, the SAB Staff Office considers previous involvement in the matter before the committee or panel. This evaluation includes responses provided by candidates to the following supplemental questions:

- a. 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?
- b. 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.
- 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 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 Office has determined that there is no reason to believe that members of the selected for the 2021 CASAC Lead Review Panel would not be objective and open-minded and able to engage in deliberative discussions with scientists who may have disparate points of view on the matter before the panel.

6. How individuals were selected for the Panel

On October 28, 2021 the SAB Staff Office posted a list of 31 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 November 18, 2021. The SAB Staff Office did not receive any comments from the public on this list of candidates.

The SAB Staff Office Director makes the final decision about who serves on the Panel based on all of the relevant information, including a review of candidates confidential financial disclosure for (EPA-Form 3110-48), the responses to the questions above, public comments, and information independently gathered by SAB Staff.

For the SAB Staff Office, a balanced committee or panel is characterized by candidates who possess the necessary domains of scientific knowledge, relevant 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; (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 (including objectivity and open-mindedness); and (f) for the committee as a whole, diversity of scientific expertise and viewpoints.

On the basis of the above-specified criteria, the members are as follows:

2021 CASAC Lead Review Panel Members

Dr. Elizabeth A. (Lianne) Sheppard, University of Washington (WA), Chair

Mr. George Allen, Northeast States for Coordinated Air Use Management (NESCAUM) (MA)

Dr. James Boylan, Georgia Department of Natural Resources (GA)

Dr. Judith C. Chow, Desert Research Institute (NV)

Dr. Deborah Cory-Slechta, University of Rochester (NY)

Dr. Christina H. Fuller, Georgia State University School of Public Health (GA)

Dr. Philip Goodrum, GSI Environmental Inc. (NY)

Mr. Perry Gottesfeld, Occupational Knowledge International (CA)

Dr. Daven Henze, University of Colorado Boulder (CO)

Dr. Howard Hu, University of Southern California (CA)

Dr. Chris Johnson, Syracuse University (NY)

Dr. Susan Korrick, Harvard Medical School (MA)

Dr. Bruce Lanphear, Simon Fraser University (British Columbia)

Dr. Joel G. Pounds, Independent Consultant (MI)

Dr. Brian Schwartz, Johns Hopkins University (MD)

Dr. William Stubblefield, Oregon State University (OR)

Dr. Brisa Sánchez, Drexel University, (PA)

Dr. Kathleen Vork, California Environmental Protection Agency (CA)

Dr. Marc Weisskopf, Harvard T.H. Chan School of Public Health (MA)

Concurred,

December 6, 2021

Thomas H. Brennan
Director and Deputy Ethics Official
EPA Science Advisory Board Staff Office (1400R)

Date