



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD
STAFF OFFICE

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MEMORANDIUM

SUBJECT: Formation of the SAB Panel for the review of the EPA's External Review Draft All Ages Lead Model (AALM) Documentation and Software

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The National Center for Environmental Assessment (NCEA) in the EPA's Office of Research, in collaboration with the Office of Chemical Safety and Pollution Prevention (OCSPP), has developed the All Ages Lead Model (AALM) as a tool for rapidly evaluating the impact of possible sources of lead on blood and other tissue levels in humans from birth to 90 years of age. The AALM predicts lead concentration in body tissues and organs for a hypothetical individual, based on lead exposure scenarios constructed by users. NCEA has asked the Science Advisory Board (SAB) to form a Panel to peer review the AALM model documentation and software.

This memorandum addresses the set of determinations that were used to form the ad hoc Panel of subject matter experts to conduct a peer review of EPA's *Technical Support Document for the All Ages Lead Model (AALM) – Parameters, Equations, and Evaluations (External Review Draft)* (hereafter, *Draft AALM Technical Support Document*), 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. Application of regulations regarding concerning “appearance of a loss of impartiality” pursuant to 5 C.F.R. § 2635.502 apply to members of the augmented committee;
5. Other considerations that might affect the objectivity of members of the augmented committee; and
6. How individuals were selected for the augmented committee.

DETERMINATIONS:

1. The type of review body that will be used to conduct the review, and the nature of this review.

An ad hoc Panel of the SAB of subject matter experts will be created to conduct a peer review of EPA’s *Draft AALM Technical Support Document* Draft. This Review Panel will provide independent advice to the EPA Administrator through the chartered SAB.

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

On November 1, 2018, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 83, Number 212, Pages 54923-54924) that it was forming a Panel of experts to review and provide independent expert advice through the Chartered SAB on EPA’s *Draft AALM Technical Support Document*. The SAB Staff Office sought public nomination of nationally and internationally recognized scientists in one or more of the following areas: physiologically based pharmacokinetic modeling, physiological processes related to lead, human processes controlling uptake/absorption of ingested lead, assessing pathways for lead exposure, and assessing environmental or occupational exposure to lead.

3. Financial conflict of interest consideration, including identification of parties who are potentially interested in or may be affected by the topic reviewed.

- a) Identification of parties (or class of parties) whose financial interests may be affected by the matter to be reviewed: The principal interested and affected parties for these topics are organizations or industry sectors that may be affected by policies or regulations developed on the basis of EPA’s *Draft AALM Technical Support Document*. These industry sectors include those involved in the manufacture and use, as well as activities associated with the storage, release and disposal, of lead containing waste.
- 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 financial conflict of interest; however, the general provisions in the appearance of impartiality guidelines still apply and need to be considered.

- i. Does the general charge to the Ad hoc Panel for the review of EPA's Draft AALM Technical Support Document 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 specific party means a particular matter that is focused on the interests of a specific party [5 C.F.R. § 2640.102(m)].

The activity of the Ad hoc AALM Panel for the review of *EPA's AALM Draft Technical Support Document* 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 potential regulatory decisions informed by *EPA's Draft Technical Support Document*.

- 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 members of the Ad hoc AALM Panel for the review of *EPA's Draft AALM Draft Technical Support Document* will be *participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations through the chartered SAB on the Agency's *AALM Draft Technical Support Document*. Such advice is expected to directly influence the Agency's final assessment, *therefore, participation in this review also will be substantial*.

- iii. Will there be a direct and predictable effect on panel members' financial interests? 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 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)(ii)]. The ethics regulations include an exemption allowing special government employees (SGEs) serving on federal advisory committees to participate in any particular matter of general applicability where the disqualifying financial interest arises from their non-Federal employment or non-Federal prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class [5 C.F.R. § 2640.203(g)]. (This exemption does not include the interests of an SGE arising from the ownership of stock in his employer or prospective employer.)

All members of the Ad Hoc Panel for the review of the Agency's *Draft EPA's AALM Draft Technical Support Document* submitted an EPA 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 members of the Agency's *EPA's AALM Draft Technical Support Document*.

4. How regulations concerning "appearance of a loss 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 loss of impartiality. This evaluation included information provided on the EPA Form 3110-48 confidential financial disclosure forms. *The SAB Staff Office has determined that the matter to be considered by the Ad hoc AALM Panel for the review of EPA's. External Draft AALM Software and Model Documents 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 SAB 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 provided by candidates (including on the EPA Form 3110-48), and information independently gathered by SAB staff.

As part of a determination that committee members 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 augmented committee. 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 the members selected for the Panel to review EPA's AALM Draft Technical Support Document 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 augmented committee.

6. How individuals were selected for the augmented committee.

On November 1, 2018, the SAB Staff Office posted a list of 30 candidates for the Ad hoc AALM Review Panel, that were identified based on their expertise and willingness to be considered for the panel. This list was accompanied by a notice inviting public comments on the list of candidates, to be submitted by January 23, 2017. The SAB Staff Office did not receive 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 each candidate's confidential financial disclosure form (EPA Form 3110-48), the responses to the questions above, 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 loss of impartiality pursuant to 5 C.F.R. § 2635.502; (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 of the Ad hoc *AALM Draft Technical Support Document Review Panel* are as follows:

Dr. Hugh A. Barton, Pfizer, Inc., CHAIR
Dr. Harvey Clewell, Hammer Institutes for Health Sciences
Dr. Dr. Joel Cohen, Gradient
Dr. Deborah Cory-Slechta, University of Rochester
Dr. Jeffrey Fisher, U.S. Food & Drug Administration
Dr. Philip Goodrum, Cardno Entrix
Dr. David Jacobs, Consultant
Dr. Michael Kosnett, University of Colorado, School of Medicine
Dr. Anne Loccisano, Exponent
Dr. Steven Marcus, Rutgers University
Dr. Clyde Martin, Texas Tech University
Dr. Isaac Pessah, University of California, Davis
Dr. Robert Phalen, University of California, Irvine
Dr. Ian von Lindern, Terragraphics International Foundation
Dr. Kathleen Vork, Californian Environmental Protection Agency
Dr. Michael Weitzman, New York University School of Medicine

Concurred,

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

June 7, 2019
Date