



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

October 11, 2005

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Memorandum

SUBJECT: SAB *Ad Hoc* All-Ages Lead Model (AALM) Review Panel Selection
Memorandum of Determinations

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This memorandum documents the set of determinations that were necessary for forming the EPA Science Advisory Board (SAB) *Ad Hoc* All-Ages Lead Model (AALM) Review Panel (Panel). This Panel will conduct a peer review of the AALM (*i.e.*, the general charge) that was recently developed by the Agency's Office of Research and Development (ORD), National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP), and will provide the EPA Administrator with advice and recommendations on the All-Ages Lead Model.

The face-to-face meeting of this Panel will take place on October 27-28, 2005 at the SAB Conference Center, 1025 F Street, N.W., Suite 3700, Washington, DC. Additional information concerning the SAB *Ad Hoc* AALM Review Panel — including the specific charge to this Panel from NCEA-RTP (forthcoming) — may be found on the SAB Web site at the following URL: http://www.epa.gov/sab/panels/ad_hoc_aalm_rev_panel.htm.

This memorandum provides background information on this *ad hoc* SAB Panel, and addresses the following determinations:

- (1) The type of review body that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair;
- (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) How individuals were selected for the Panel.

BACKGROUND:

The SAB was established by 42 U.S.C. § 4365 to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App.

In November 2004, EPA’s National Center for Environmental Assessment, Research Triangle Park, NC (NCEA-RTP) requested that the SAB conduct a review of the All-Ages Lead Model. The AALM is designed to predict lead concentrations in body tissues and organs for a hypothetical individual, based on a simulated lifetime of lead exposure. The precursor to the AALM was the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children, which underwent peer review by the SAB in 1991.

In response to this request from NCEA-RTP, the SAB Staff Office published a notice in the *Federal Register* (70 FR 9642) on February 28, 2005 which announced the formation of an SAB *ad hoc* panel for this review — to be known as the SAB *Ad Hoc* AALM Review Panel — and requesting public nominations of qualified experts to serve on this panel. In addition, as Designated Federal Officer (DFO) for this *ad hoc* Panel, I also solicited nominations and self-nominations for service on this panel from additional individuals from May to July 2005.

DETERMINATIONS:

- (1) The type of review body that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair.

This review will be conducted by an SAB *ad hoc* panel, which will be known as the SAB *Ad Hoc* AALM Review Panel.

The Panel will be chaired by Dr. Meryl Karol, Associate Dean for Academic Affairs at the University of Pittsburgh, who is a member of the statutory (chartered) SAB appointed by the EPA Administrator.

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

Per the solicitations for nominees to form the SAB *Ad Hoc* AALM Review Panel that were published in the *Federal Register* on February 28, 2005 (see citation above), national and international experts were sought in one or more of the following six (6) expertise areas:

(a) Lead Exposure Pathway Assessment. Expertise in the physical and chemical properties of lead and the biogeochemical processes involved in the multimedia pathways leading to human exposure to lead. These pathways should include:

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

(b) Lead Uptake/Absorption. Expertise in the process of the human uptake and/or absorption of lead from oral and/or inhalation intake.

(c) Internal Biokinetic Distribution of Lead. Expertise on the human physiological processes concerning the distribution, mechanisms of transport, accumulation, concentrations at the organ/tissue level, residence times (or other measures of potential impact), and elimination of absorbed lead.

(d) Human Growth and Activity Patterns. Expertise on growth patterns and typical human activity patterns from prenatal to elderly, including recreational, occupational, leisurely, household activities. This would include knowledge of published studies and other modeling applications.

(e) Exposure and Risk Assessment Modeling. Experience in relating a lifetime of human exposure to a potential health outcome, and the quantification of risk related to this health outcome.

(f) Statistical Treatment of Data Input and Model Output, and Model Code. Expertise in assessing the quality of data typically used for model input or the quality of probabilistic input data sets generated by models; expertise in assessing the statistical interpretation and presentation of model outputs; and expertise in computer programming language, specifically, C++ using XML data format.

(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 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, and, in particular, regional risk assessors; (2) potentially responsible parties (PRP) and their contractors; and (3) State and local health officials.

(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 SAB *Ad Hoc* AALM 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 SAB *Ad Hoc* AALM Review Panel’s activity in addressing the general charge for the peer review of the Agency’s the “AALM Version 1.05 (External Review Draft)” 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.

The Special Government Employees (SGEs) who are to serve on the SAB *Ad Hoc* AALM Review Panel for this review are part of a group of people who could represent organizations that in the future might be regulated by EPA or seek grant or contract funding for projects in research areas identified by the Panel. *Thus, the matter does involve deliberation that focuses upon the interests of a distinct and identifiable group of people, that is, the community that may be subject to EPA regulations or receive grant or contract funding from the Agency related to the topics under review or consultation by the Panel.*

(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 *SAB Ad Hoc AALM 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 AALM is effective in predicting lead concentrations in body tissues and organs for a hypothetical individual, based on a simulated lifetime of lead exposure; and whether the AALM will be widely accepted and used in the risk assessment community as a tool for implementing the site-specific risk assessment process for childhood, older childhood and adult lead exposure. *Therefore, participation in this review will also be substantial.*

(iii) Will there be a direct and predictable effect on SAB *Ad Hoc* AALM 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)]

Each SAB *Ad Hoc* AALM Review Panel member could conceivably have financial links to the Agency in the form of existing or pending grants, cooperative agreements, contracts, or other funding. Furthermore, each of these individuals could submit proposals for such grants, cooperative agreements, contracts or other funding in the future.

In determining whether a member’s or candidates’ participation has a direct and predictable effect on their financial interest, the SAB Staff Office has evaluated the process for awarding grants and whether it could directly tie a person’s actions in this review to financial gain. In evaluating this factor, the requirement is that a person’s actions in participating in the matter must have a “close causal link” to their financial interest. Further, the link must be predictable, that is actual and not “speculative.” In the case of members of the SAB *Ad Hoc* AALM Review Panel, the “chain of causation” is attenuated and contingent upon the occurrence of events that are speculative. Thus, while Panel members may, in the course of this review, provide the Agency with advice and recommendations that is expected to include an assessment as to whether: (1) the AALM is effective in predicting lead concentrations in body tissues and organs for a hypothetical individual, based on a simulated lifetime of lead exposure; and (2) the All-Ages Lead Model will be widely accepted and used in the risk assessment community as a tool for implementing the site-specific risk assessment process for childhood, older childhood and adult lead, provision of this advice would have no direct correlation with an individual Panel member’s receipt of current or future grants, cooperative agreements, contracts, or other funding from the Agency.

Moreover, selection of grant recipients follows a complex two-stage process in which independent reviewers judge the scientific quality of a proposal and then Agency representatives judge the relevance of the proposal to answering major scientific questions within the subject area. Thus, actual selection of grant recipients is mediated by a chain of events that attenuates any direct linking of a grant to a panel member’s participation in this or subsequent SAB *Ad Hoc* AALM Review Panel reviews, consultations or other activities. Therefore, any effects from participating in this review would not be direct, nor would they be predictable. Accordingly, no conflict-of-interest as defined by 18 U.S.C. § 208 exists in association with grant holding by members of the SAB *Ad Hoc* AALM Review Panel.

Furthermore, because the procedures for awarding grants, cooperative agreements, contracts, or other funding differ, each specific situation has been evaluated to determine if a direct and predictable effect exists between an SAB *Ad Hoc* AALM Review Panel member’s participation and their financial interest. Finally, matters in which Panel members have grants, cooperative agreements, contracts or other funding from EPA that are for work that fits conceptually or specifically within the expected work of this Panel have been evaluated under the requirements for considering “appearance of impartiality” under 5 C.F.R. § 2635.502, as discussed below in Section (4).

The U.S. Office of Government Ethics requires that all Special Government Employees (SGEs) submit confidential financial disclosure statement on an annual basis. For members of EPA Federal advisory committees, this is the Confidential Financial Disclosure Form (EPA Form 3110-48). In addition, all members of the SAB and associated panels and subcommittees are required to update their EPA Form 3110-48 whenever there have been substantive changes, or whenever they are participating in an advisory activity.

As a result of a review of the Agency's Confidential Financial Disclosure Form (EPA Form 3110-48) provided by each prospective SAB Ad Hoc AALM Review Panel member, the SAB Ethics and Federal Advisory Committee Act (FACA) Policy Officer, in consultation with the EPA Alternate Agency Ethics Official, as necessary, has determined that there is no financial conflict-of-interest presented for the SAB Ad Hoc AALM Review Panel. In addition, the Panel's advice on the particular matter under review will not have a direct effect on the financial interest of SAB Ad Hoc AALM Review 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. § 2635.502(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.”

As noted above in Section (3)(b)(i), the SAB *Ad Hoc* AALM Review Panel's activity in addressing the general charge for the peer review of the “AALM Version 1.05 (External Review Draft)” qualifies 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. However, as also noted above in Section (3)(b)(iii), the chain of events for a grant is attenuated by certain factors that do not constitute a conflict of interest; thus, the criterion for “appearance of impartiality” at 5 C.F.R. § 2635.502(a) is not met. EPA grant, cooperative agreement, contracts or other funding may present a different situation, and each Panel member was evaluated to determine whether his or her financial interest in existing grants, cooperative agreements, contracts or other funding constitutes an “appearance of impartiality.”

Even though circumstances for some specific candidates for the SAB *Ad Hoc* AALM Review Panel may raise neither formal conflict-of-interest nor formal appearance concerns, each candidate has been preliminarily evaluated against the five 5 C.F.R. § 2635(a)(2) general requirements to ensure that lack of an appearance of impartiality issues do not preclude their

participation. Information used in this evaluation has come from Panel members' EPA 3110-48 forms and other staff research.

To further ascertain whether there is any potentially-disqualifying involvement with the specific topic of the SAB *Ad Hoc* AALM Review Panel's upcoming meeting(s) which might indicate the appearance of a lack of impartiality, the following five questions were posed to each of the prospective selectees for the SAB *Ad Hoc* AALM Review Panel with regard to the general 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 SAB *Ad Hoc* AALM 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) [or, in this instance, the "AALM Version 1.05 (External Review Draft)" itself] 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? 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 SAB Ad Hoc AALM Review Panel, the SAB's Deputy Ethics Official, in consultation with the SAB Ethics and FACA Policy Officer, has determined that there is no appearance of a lack of impartiality on the part of the selectees for the SAB Ad Hoc AALM Review Panel.

(5) How individuals were selected for the Panel.

As noted in Section (1) above, the SAB Staff Office announced the formation of the SAB *Ad Hoc* AALM Review Panel in the *Federal Register* (70 FR 9642) on February 28, 2005, and requested nominations for recognized, national and international experts it was seeking in one or more of the six scientific/technical expertise areas delineated in Section (2) above. The SAB Staff received 20 nominations or self-nominations for this *ad hoc* panel via the SAB Web site. In July 2005, the SAB Staff Office published a "Short List" of nineteen (19) technically-qualified candidates at URL: http://www.epa.gov/sab/panels/ad_hoc_aalm_rev_panel.htm, for the purpose of soliciting comments from the public. The makeup of the "Short List" reflected discussions among the SAB Staff Office Director, the Associate SAB Director for Science, and the DFO for this *ad hoc* 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 two (2) public comments on this Short List from individuals representing the following organizations (date):

- The Missouri Coalition for the Environment (August 24, 2005)
- Toxicology Excellence for Risk Assessment (TERA) (August 24, 2005)

From the “Short List” of nineteen 19 technically-qualified candidates, the SAB Staff Office Director selected a final SAB Ad Hoc AALM Review Panel of fourteen (14) individuals. The SAB Staff Office Director makes the final decision about who serves on the Panel during the “Panel Selection” phase. 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.

The following two (2) current members of the Science Advisory Board were selected as members of the SAB Ad Hoc All-Ages Lead Model Review Panel:

1. **Dr. Meryl Karol**, University of Pittsburgh (PA)
2. **Dr. Deborah Cory-Slechta**, University of Medicine and Dentistry of New Jersey and Rutgers State University (NJ)

Additionally, on the basis of the above-specified criteria, the following twelve (12) experts were selected as members of the SAB Ad Hoc AALM Review Panel:

1. **Dr. Mary Jean Brown**, U.S. Centers for Disease Control and Prevention (GA)
2. **Dr. Bruce Fowler**, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (GA)
3. **Dr. Philip Goodrum**, Syracuse Research Corporation (NY)
4. **Dr. Roberto Gwiazda**, University of California – Santa Cruz (CA)
5. **Mr. Sean Hays**, Summit Toxicology (CO)
6. **Dr. Marlin Mickle**, University of Pittsburgh (PA)
7. **Dr. Paul Mushak**, PB Associates, and Albert Einstein College of Medicine (NC & NY)
8. **Dr. Joel Pounds**, Battelle – Pacific Northwest National Laboratory (WA)
9. **Dr. Michael Rabinowitz**, Marine Biological Laboratory (MA)
10. **Dr. Joel Schwartz**, Harvard University School of Public Health (MA)
11. **Dr. Alan Stern**, New Jersey Dept. of Environmental Protection/University of Medicine & Dentistry of NJ-School of Public Health (NJ)
12. **Dr. Ian von Lindern**, TerraGraphics Environmental Engineering, Inc. (ID)

Concurred:

/s/ Vanessa Vu

October 11, 2005

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Date