



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

October 1, 2008

Memorandum

SUBJECT: Formation of the SAB Homeland Security Advisory Committee on Anthrax

FROM: Vivian A. Turner /S/
Designated Federal Officer (DFO)
Asbestos Advisory Committee
EPA Science Advisory Board Staff Office (1400F)

TO: Vanessa Vu, Ph.D.
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THRU: Anthony Maciorowski, Ph.D. /S/
Deputy Director
EPA Science Advisory Board Staff Office (1400F)

EPA's Office of Solid Waste and Emergency Response (OSWER) requested the Science Advisory Board (SAB) to provide consultative advice on Anthrax. This memorandum documents the process and steps taken to address OSWER's request to provide early independent scientific consultative advice on the Agency's proposed approach in developing an Anthrax Technical Assistance Document (TAD). This memorandum provides background information on this SAB activity and addresses:

- The expertise needed to address the charge;
- Conflict of Interest;
- Appearance of Lack of Impartiality;
- How individuals were selected to augment the Committee.

1) **Expertise Requested:**

The EPA Science Advisory Board (SAB) Staff Office requested in 73 FR no 61 (page 16679-80) the nomination of experts to augment the Homeland Security Advisory

Committee (HSAC). The request was for nominations of nationally and internationally recognized microbiologists with specialized expertise in bacteriology of aerobic gram positive rod endospore formers (i.e., *Bacillus anthracis*). It stated that individuals should possess extensive genomic and strain analysis and expertise in method development for Weapons of Mass Destruction emergency responders. As a result of that nomination, the SAB Staff Office posted a short list of 5 candidates, along with the link to the website listing the current HSAC Members, for public comment on August 18, 2008. The SAB Staff Office received no public comments on this short list or the names of the current Members.

2) 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.

Personal and Substantial Participation:

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 the Asbestos Committee **members will be participating personally in the matter**. Panel members will be providing the Agency with early advice and recommendations that is expected to include an assessment as to whether the proposed approach in developing the anthrax technical assistance document is scientifically sound and reasonable in providing guidance for emergency preparedness. Therefore, participation in this review will also be **substantial**.

Direct and Predictable Effect:

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)]

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)].

The HSAC’s activity in providing early consultative advice on the anthrax TAD 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 could be comprised of those who are associated or involved with the potentially interested or affected parties including: (1) Federal, State, regional and local remediation programs, State regulatory officials; (4) State and local health officials; (5) research universities; (6) environmental interest groups/non-Governmental organizations (NGOs); and (7) potentially responsible parties (PRP) and their contractors.

3) Appearance of a Lack of Impartiality Considerations:

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 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 evaluate any potential appearance of a lack of impartiality, the following four questions were posed to each prospective member of the HSAC Committee:

- 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 might be questioned?
- b) Have you had any previous involvement with the review document under consideration including authorship, collaboration with the authors or previous peer review functions? If so, please identify and describe that involvement.

- c) Have you ever served on any previous advisory panels or 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.

4) How individuals were selected for the final Committee:

Prospective advisory members were asked to submit a confidential financial disclosure form (EPA Form 3110-48, Confidential Financial Disclosure F for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency) which includes the response to the above four (4) questions. The Deputy Ethics Official of the Science Advisory Board has determined that there are no conflicts of interest or appearance of a lack of impartiality for the members of this Committee.

The SAB Staff Office Director, taking all factors into account, makes the final decision about the membership of the Committee. Specific criteria to be used in evaluating an individual Committee 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 Committee as a whole, (f) diversity of, and balance among, scientific expertise, viewpoints, *etc.*

On the basis of the above-specified criteria, the Members of the HSAC on Anthrax are as follow:

CHAIR

Dr. Baruch Fischhoff, Carnegie Mellon Institute, (PA)

HSAC MEMBERS

Dr. William Bellamy, CH2M Hill, (CO)

Dr. Vicki Bier, University of Wisconsin, (WI)

Dr. Mary Durfee, Michigan Technological Institute, (MI)

Dr. David S. Ensor, Research Technical Institute, (NC)

Dr. Lynda Knobeloch, Wisconsin Department of Family Services, (WI)

Dr. Paul J. Liroy, Robert Wood Johnson Medical School-UMDNJ & The Environmental and Occupational Health Sciences Institute (EOHSI) (NJ)

Dr. Lee D. McMullen, Snyder & Associates, (IA)

Dr. Royal Nadeau, The Eco-Strategies Group, (NJ)

Dr. W. Kip Viscusi, Vanderbilt University, (TN)

Dr. Daniel Walsh, New York State Department of Environmental Conservation, (NY)

Dr. Rae Zimmerman, New York University (NY)

CONSULTANTS

Dr. John Bartlett, The Johns Hopkins University School of Medicine, (MD)

Dr. Christina Egan, Wadsworth Center, New York State Department of Occupational Health, (NY)

Dr. Philip Hanna, University of Michigan Medical School (MI)

Dr. Denise Pettit, Virginia Division of Consolidated Laboratory Services, (VA)

Dr. James Rogers, Food Safety Inspection Service, USDA, (DC)

Concurred:

October 1, 2008

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

Date