



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

May 28, 2008

Memorandum

SUBJECT: Formation of the SAB Asbestos Committee

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

TO: Anthony Maciorowski, Ph.D.
Deputy Director
EPA Science Advisory Board (1400F)

THRU: Daniel Fort /Signed/
Ethics & FACA Policy Officer
EPA Science Advisory Board Staff Office (1400F)

This memorandum documents the process and steps taken to address the request EPA's Office of Solid Waste and Emergency Response (OSWER) to the SAB to provide independent scientific advice on the Agency's proposed approach for the estimation of cancer potency factors for inhalation exposure to asbestos. On August 22, 2006, the SAB announced in the Federal Register, the formation of the Asbestos Committee and solicited nominations for experts to be members of that Committee. Over the next two to three years, the Asbestos Committee will provide advice and recommendations to the EPA Administrator on the scientific and technical aspects of various asbestos related exposures. The initial task that is currently requested by OSWER specifically targets the approach for estimating carcinogenic potency of asbestos via the inhalation exposure route and does not venture into the risk assessment domain. 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 for the Committee.

1) Expertise Requested:

The EPA Science Advisory Board (SAB) Staff Office announced in 71 FR no 162 (pages 48926 – 48927) that it was forming an SAB committee to provide technical advice on the Agency’s proposed methodology to estimate potential cancer risk from inhalation exposure to asbestos mineral fibers. The SAB Staff Office requested nominations for nationally and internationally recognized non-EPA scientists with demonstrated clinical, research and applied scientific experience and expertise with respect to human health effects of asbestos and related minerals in the following areas: Clinical and pulmonary medicine, epidemiology, occupational and public health, pathology, inhalation toxicology; biology, mineralogy; environmental fate and transport, environmental sampling and detection methods, biostatistics, statistical modeling and risk assessment. As a result of that nomination, the SAB Staff Office posted a short list of 65 candidates for public comment on April 19, 2007. The SAB Staff Office received approximately twenty five (25) public comments on this short list.

On October 26, 2007, the SAB Staff Office requested in 72 FR no. 207, (pages 60844-60845), additional expertise in the formation of Asbestos Committee. The sought expertise included biostatistics, statistical, modeling, epidemiology, meta-analysis, Bayesian analysis and toxicology of inhaled particles. As a result of that nomination, the SAB Staff Office posted a short list of 13 candidates for public comment on January 18, 2008. The SAB Staff Office received two (2) public comments on this short list.

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 advice and recommendations that is expected to include an assessment as to whether the proposed multi-bin approach is scientifically sound and reasonable in accounting for

any differences in potency between differing mineral types and sizes of asbestos particles. 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 Asbestos Committee's activity in addressing the charge for the peer review of the draft proposed approach to estimation of cancer potency via inhalation 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 could be comprised of those who are associated or involved with the potentially interested or affected parties including: (1) State, regional and local air program (or remediation programs) agencies, and State regulatory officials; (4) State and local health officials; (5) research universities; (6) environmental interest groups/non-Governmental organizations (NGOs); (7) potentially responsible parties (PRP) and their contractors; and (8) various industry sectors such as manufacturers and users interested in or affected by asbestos.

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 five questions were posed to each prospective members of the Asbestos Committee:

- a) Have you had any direct involvement in the development of any EPA documents under review (whether as a consultant or under a contract/grant) for EPA or any other Government agency (including both Federal and state) since 2000? If so, please identify that involvement.
- b) Do you now or have you ever served on any previous advisory panels or committees that addressed the subject under review convened by EPA or any other Government agency (both Federal and state) within the last 2 years? If so, please identify those panels.
- c) Have you ever made any public statements (written or oral) on this matter? If so please identify the time, place and nature of your statements. Please include any statements made before any Government legislative committee (both Federal or state).
- d) Is there any reason that you might be unable to provide impartial advice concerning this matter or any other reason that your impartiality might be questioned?
- e) Have you made any public statements on this subject of review 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:

Perspective 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) in addition to response to the above five (5) questions. The Deputy Ethics Official of the Science Advisory Board, in consultation with the SAB Ethics and FACA Policy Officer, 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 Deputy Director, taking all factors into account, makes the final decision about the membership of the Asbestos 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 Asbestos Committee are as follow:

- Dr. Agnes Kane**, Brown University (RI) - **Chair**
- Dr. Ann Aust**, Independent Consultant (AZ)
- Dr. Louis Anthony Cox, Jr.**, Cox Associates (CO)
- Dr. Jeff Everitt**, GlaxoSmithkline Pharmaceutical R&D (NC)
- Dr. Murray Finkelstein**, University of Ontario (Canada)
- Dr. Andrew Gelman**, Columbia University (NY)
- Dr. George Guthrie**, Los Alamos National Laboratory (NM)
- Mr. John Harris**, LabCor Portland, Inc. (OR)
- Dr. Karl T. Kelsey**, Brown University (RI)
- Dr. Paul J. Liroy**, Robert Wood Johnson Medical School-UMDNJ & The Environmental and Occupational Health Sciences Institute (EOHSI) (NJ)
- Dr. Morton Lippmann**, New York University School of Medicine (NY)
- Dr. Gary Marsh**, University of Pittsburgh (PA)
- Dr. Gunter Oberdorster**, University of Rochester (NY)
- Dr. Luis Ortiz**, University of Pittsburgh (PA)
- Dr. Julian Peto**, London School of Hygiene and Tropical Medicine (London)
- Dr. Christopher Portier**, National Institute of Environmental Health Sciences (NC)
- Dr. Carol Rice**, University of Cincinnati (OH)
- Dr. Randal Southard**, University of California, Davis (CA)
- Dr. Leslie Stayner**, University of Illinois (IL)
- Dr. David Veblen**, Johns Hopkins University (MD)
- Dr. James Webber**, New York State Department of Health (NY)

Concurred:

_____/Signed/_____
Anthony Maciorowski, Ph.D.
Staff Deputy Director
EPA Science Advisory Board (1400F)

May 28, 2008

Date

Attachment: List of Commenters Responding to the Asbestos “Short Lists”

Attachment

Commenters Who Responded to the Asbestos “Short List” Dated April 19, 2007

Jennifer Sass
NRDC

C. Maynard
Private Citizen

William M. Connelly
Richardson, Patrick, Westbrook and Brickman, LLC

Jeffery Simon
Simon, Eddins & Greenstone, LLP

Jeffrey A. Healy, Esq.
Tucker Ellis & West LLP

Bill Walker & Richard Wiles
Environmental Working Group

Maggie VanNorman
Private Citizen

James Nevin
Brayton & Purcell Law, LLP

Aaron K Trippler
American Industrial Hygiene Association

John R. Bowman
American Association for Justice

Alberto Marchevsky, M.D.
Cedars-Sinai Medical Center

Christian Hartley
Richardson, Patrick, Westbrook & Brickman, LLC

Samantha Flores
Hissey, Kientz & Herron, P.L.L.C.

Carolin Shining
Private Citizen

Hugh F. Young, Jr.
Product Liability Advisory Council

Anna Knudson
Bergman & Frockt

Craig Brown
Private Citizen

Gary M. DiMuzio
DiMuzio Law Firm

Lynne M. Armstrong & Lawrence Fineran
National Association of Manufacturers

Victor E. Schwartz
Coalition for Litigation Justice, Inc and the U.S. Chamber of Commerce

Brooke T. Mossman
University of Vermont, College of Medicine

Robert E. Paul
Paul, Reich and Myers, PC.

John C. Childs
Georgia Pacific, LLC

William C. Ford
National Stone, Sand & Gravel Association

Mark Frickel
Private Citizen

Commenters Who Responded to the Asbestos “Short List” Dated January 18, 2008

William C. Ford
National Stone, Sand & Gravel Association

Thomas Bateson
US EPA