UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

March 24, 2010

MEMORANDUM

SUBJECT: Formation of Science Advisory Board (SAB) Trichloroethylene Review Panel

FROM: Marc Rigas, Ph.D. ***/SIGNED/***
Designated Federal Officer (DFO)
EPA Science Advisory Board Staff Office (1400F)

THRU: Anthony F. Maciorowski, Ph.D. ***/SIGNED/***
Deputy Director
EPA Science Advisory Board Staff Office (1400F)

TO: Vanessa Vu, Ph.D.
Director
EPA Science Advisory Board Staff Office (1400F)

This memorandum addresses the set of determinations that were necessary for forming the SAB Trichloroethylene Review Panel including:

(A) The type of review body that will be used to conduct the review, and the nature of the review;

(B) The types of expertise needed to address the general charge;

(C) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;

(D) How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502 apply to members of the Panel; and

(E) How individuals were selected for the Panel.

DETERMINATIONS:

(A) 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 SAB will provide independent advice through the chartered SAB on EPA's *Toxicological Review of Trichloroethylene in Support of Summary Information on the Integrated Risk Information System (IRIS),* External Review Draft.

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

On October 22, 2009, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 74, Number 203, Pages 54563 – 54564) that it was forming a panel to provide advice on EPA's assessment of the health risks from trichloroethylene. To form the panel, the SAB Staff Office sought public nominations of nationally and internationally recognized experts with specific experience and knowledge in one or more of the following areas: toxicokinetics, toxicology, carcinogenic modes of action, physiologically-based pharmacokinetic (PBPK) modeling, epidemiology, statistics, dose-response modeling, and risk assessment.

(C) 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) federal, state, and local government agencies, elected officials, and non-government organizations involved in the development or implementation of risk assessments or risk management decisions relating to the release of or exposure to trichloroethylene; and 2) those involved with the interests of private or public organizations that may be affected by policies or regulations developed on the basis of EPA's Toxicological Review of Trichloroethylene.

(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 SAB Trichloroethylene Review 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 SAB 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 private or public organizations facing regulatory decisions related to the release of or exposure to trichloroethylene.

(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 the *SAB Panel members will be participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations on the Agency's assessment of human exposure and toxicology of trichloroethylene, and such advice is expected to directly influence the Agency's guidance on risk assessment and risk management decisions involving trichloroethylene. *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)]

(D) How regulations concerning "appearance of a lack of impartiality ," pursuant to 5 C.F.R. § 2635.502, apply to members of the Committee

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 lack of impartiality. This evaluation included responses to EPA 3110-48 confidential financial disclosure forms and the following supplemental questions:

1. 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?

2. 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.

3. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.

4. 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.

(E) <u>How individuals were selected for the Panel</u>

On January 6, 2010 the SAB Staff Office posted a list of 44 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 January 26, 2010. The SAB Staff Office received three sets of comments on this list of candidates from the following members of the public: Mr. Jerome Ensminger, citizen; Mr. Michael Partain, citizen; Dr. Jennifer Sass, Natural Resources Defense Council.

The SAB Staff Office Director makes the final decision about who serves on the Trichloroethylene Review Panel, based on all relevant information identified by SAB staff and public comment. This includes a review of the member's confidential financial disclosure form (EPA Form 3110-48) and an evaluation of an appearance of a lack of impartiality. For the SAB Staff Office, a balanced 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 charge to the panel. 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; (e) skills working on advisory committees and panels; and, for the committee as a whole, (f) diversity of scientific expertise and viewpoints.

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

Trichloroethylene Review Panel Members

Dr. Deborah Cory-Slechta, University of Rochester (NY), Chair
Dr. Scott Bartell, University of California, Irvine (CA)
Dr. Aaron Blair, National Cancer Institute, National Institutes of Health (MD)
Dr. Anneclaire De Roos, University of Washington (WA)
Dr. Rodney Dietert, Cornell University (NY)
Dr. Claude Emond, University of Montreal (Canada)
Dr. Montserrat Fuentes, North Carolina State University (NC)
Dr. David Hoel, Medical University of South Carolina (SC)
Dr. Gunnar Johanson, Karolinska Institute (Sweden)
Dr. Deborah Keil, University of Nevada, Las Vegas (NV)
Dr. Jose Manautou, University of Connecticut (CT)
Dr. David McMillan, University of Nebraska Medical Center (NE)
Dr. Marion Miller, University of California Davis (CA)
Dr. Michael Pennell, The Ohio State University (OH)
Dr. Kenneth Portier, American Cancer Society Home Office (FL)
Dr. Gloria Post, New Jersey Department of Environmental Protection (NJ)
Dr. Gary Rankin, Marhsall University (WV)
Dr. Ivan Rusyn, University of North Carolina at Chapel Hill (NC)
Dr. Ornella Selmin, University of Arizona (AZ)
Dr. Brian Thrall, Pacific Northwest National Laboratories (WA)
Dr. John Vena, University of Georgia (GA)
Dr. Virginia Weaver, Johns Hopkins University (MD)

Concurred,

_____***/SIGNED/***_____ ___**MARCH 25, 2010**_____
Vanessa Vu, Ph.D. Date
Staff Director
EPA Science Advisory Board (1400F)

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