



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July 11, 2014

MEMORANDUM

SUBJECT: Formation of the Chemical Assessment Advisory Committee (CAAC) Augmented for the Ethylene Oxide Review

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TO: Christopher S. Zarba
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EPA Science Advisory Board Staff Office (1400R)

The U.S. Environmental Protection Agency (EPA) requested the Science Advisory Board (SAB) to conduct a peer review of its draft *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide in Support of the Integrated Risk Information System (IRIS)*. The SAB was asked to evaluate the draft document with regard to its responsiveness to recommendations from a previous SAB panel, and to review and comment on the exposure-response modeling of certain epidemiologic data; the adequacy, transparency and clarity of the draft document; and other scientific issues related to the hazard identification and dose-response assessment for the inhalation carcinogenicity of ethylene oxide.

This memorandum addresses the set of determinations that were used in forming the CAAC Augmented for the Ethylene Oxide Review 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. 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. Other considerations that might affect the objectivity of members of the Panel; and
6. How individuals were selected for the Panel.

DETERMINATIONS:

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

The Chemical Assessment Advisory Committee (CAAC), a standing committee of the SAB, will be augmented by subject matter experts to conduct a peer review of the draft *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide in Support of the Integrated Risk Information System (IRIS)*. The CAAC Augmented for the Ethylene Oxide Review will provide independent advice to the agency through the Chartered SAB.

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

On August 28, 2013, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 78, Number 167, Pages 53144-53146) that it was augmenting the CAAC to review and provide independent expert advice, through the Chartered SAB, on EPA's draft *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*. To augment the CAAC, the SAB Staff Office sought public nominations of recognized experts with demonstrated expertise and research in one or more of the following areas: epidemiology, biostatistics, exposure-response modeling, genotoxicity, cancer biology, and risk assessment.

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 (or class of parties) whose financial interests may be affected by the matter to be reviewed: The principal interested and affected parties as a class for this topic are: organizations involved in processes that could be considered part of the life-cycle of the chemical (i.e., ethylene oxide) to be considered by the Augmented CAAC (including, but not limited to, manufacture, use, distribution, treatment and disposal).

(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 CAAC Augmented for the Ethylene Oxide Review 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 Augmented CAAC 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 regulatory decisions informed by the IRIS ethylene oxide carcinogenicity evaluation that may impact the manufacture, distribution, treatment or disposal of ethylene oxide.

(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 members of the Augmented CAAC will be participating personally in the matter*. Members will be providing the Agency with advice and recommendations on the Agency’s IRIS ethylene oxide inhalation carcinogenicity evaluation, and such advice is expected to directly influence the Agency’s guidance on risk assessment and risk management decisions involving ethylene oxide. *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)]. CAAC members and prospective additional experts were asked to submit 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 members of the CAAC Augmented for Ethylene Oxide Review.*

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 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 members of the Augmented CAAC 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. *The SAB Staff Office has determined that the matter to be considered by the CAAC Augmented for Ethylene Oxide Review 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 the public in response to the invitation for public comment on the candidates, information provided by candidates (including on the EPA Form 3110-48), and information independently gathered by SAB staff.

As part of a determination that panel 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 panel. 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 CAAC Augmented for Ethylene Oxide Review 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 Panel.

6. How individuals were selected for the Panel.

On April 2, 2014, the SAB Staff Office posted a list of 40 candidates for the Augmented CAAC, 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 April 23, 2014. The SAB Staff Office has received comments from the public on this list of candidates from the following:

- American Chemistry Council
- Environmental Defense Fund (EDF) and Natural Resources Defense Council (NRDC)

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, public comments, 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 breath 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 CAAC Augmented for Ethylene Oxide Review are as follows:

Dr. Peter S. Thorne, Chair, University of Iowa

Dr. Henry Anderson, Wisconsin Division of Public Health

Dr. James V. Bruckner, University of Georgia

Dr. William Michael Foster, Duke University Medical Center

Dr. Gary Ginsberg, Connecticut Department of Public Health

Dr. Cynthia M. Harris, Florida A&M University

Dr. Russ Hauser, Harvard University

Dr. Steven Heeringa, University of Michigan

Dr. Peter Infante, Peter F. Infante Consulting, LLC

Dr. Lawrence Lash, Wayne State University

Dr. Maria Morandi, Independent Consultant

Dr. Victoria Persky, University of Illinois at Chicago

Dr. Kenneth Ramos, Arizona Health Sciences Center

Dr. Stephen M. Roberts, University of Florida

Dr. Elizabeth A. (Lianne) Sheppard, University of Washington

Dr. Katherine S. Squibb, University of Maryland School of Medicine

Dr. Daniel Zelterman, Yale University

Dr. Yiliang Zhu, University of South Florida

Concurred,

/SIGNED/

July 11, 2014

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Date