



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD
STAFF OFFICE**

July 13, 2017

MEMORANDIUM

SUBJECT: Addendum to the May 10, 2017 Memorandum: Formation of the Chemical Assessment Advisory Committee (CAAC) augmented for the review of the EPA's Draft tert-Butyl Alcohol (tBA) Toxicological Review and the EPA's Draft Ethyl Tertiary Butyl Ether (ETBE) Toxicological Review. (CAAC Augmented for the ETBE and tBA Review)

FROM: Shaunta Hill-Hammond, Ph.D. /s/
Designated Federal Officer
EPA Science Advisory Board Staff Office (1400R)

THRU: Wanda Bright /s/
Ethics Officer
EPA Science Advisory Board Staff Office (1400R)

TO: Christopher Zarba
Director and Deputy Ethics Official
EPA Science Advisory Board Staff Office (1400R)

On May 10, 2017, the Science Advisory Board (SAB) Staff Office Director signed a memorandum that announced to the public the members of the SAB's Chemical Assessment Advisory Committee (CAAC) augmented for the review of the tert-Butyl Alcohol (tBA) and Ethyl Tertiary Butyl Ether (ETBE) Toxicological Review. The memorandum provided a set of determinations that were necessary for forming the augmented committee, and described all relevant information considered in forming the augmented committee, including a review of the confidential financial disclosure forms and evaluation of an appearance of a lack of impartiality. Since May 10, 2017, the SAB Staff Office has received additional information regarding membership of the CAAC augmented for ETBE and tBA committee. Based on review of this additional information, the members of the SAB CAAC augmented for ETBE and tBA committee are as follows:

CAAC Augmented for the ETBE and tBA Review:

- Dr. Janice Chambers - Mississippi State University, **CHAIR**
- Dr. Hugh A. Barton - Pfizer, Inc.
- Dr. Janet Benson - Lovelace Biomedical
- Dr. Trish Berger - University of California, Davis
- Dr. James Bruckner - University of Georgia
- Dr. John Budroe - Office of Environmental Health Hazard Assessment, California
- Dr. Karen Chou - Michigan State University
- Dr. Harvey Clewell - Hammer Institutes for Health Sciences
- Dr. Deborah Cory-Slechta - University of Rochester
- Dr. Bevin Engelward - Massachusetts Institute of Technology
- Dr. Jeffrey Fisher - Food & Drug Administration
- Dr. William Foster - Independent Consultant
- Dr. Alan Hoberman - Charles River Laboratories
- Dr. Tamarra James-Todd - Harvard T.H. Chan School of Public Health
- Dr. Lawrence Lash - Wayne State University
- Dr. Issac Pessah - University of California at Davis
- Dr. Marvin Meistrich - University of Texas M. D. Anderson Cancer Center
- Dr. Maria Morandi - Independent Consultant
- Dr. Lorenz Rhomberg - Gradient
- Dr. Stephen M. Roberts - University of Florida
- Dr. Alan Stern - New Jersey Department of Environmental Protection/University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School

Concurred,

/s/
Christopher S. Zarba
Director and Deputy Ethics Official
EPA Science Advisory Board Staff Office (1400R)

7/13/17
Date



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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May 10, 2017

MEMORANDIUM

SUBJECT: Formation of the Chemical Assessment Advisory Committee (CAAC) augmented for the review of the EPA's Draft tert-Butyl Alcohol (tBA) Toxicological Review and the EPA's Draft Ethyl Tertiary Butyl Ether (ETBE) Toxicological Review. (CAAC Augmented for the ETBE and tBA Review)

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The National Center for Environmental Assessment (NCEA) in the EPA's Office of Research and Development (ORD) develops toxicological reviews/health assessments for various chemicals for EPA's Integrated Risk Information System (IRIS). NCEA has developed two draft IRIS toxicological reviews for the chemicals Ethyl Tertiary Butyl Ether (ETBE) and tert-Butyl Alcohol (tBA). The draft Toxicological Review of ETBE and the draft Toxicological Review of tBA were released in February 2017. NCEA has asked the Science Advisory Board (SAB) to peer review both draft toxicological reviews.

This memorandum addresses the set of determinations that were used in augmenting the Chemical Assessment Advisory Committee (CAAC) for the ETBE and tBA 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 loss of impartiality” pursuant to 5 C.F.R. § 2635.502 apply to members of the augmented committee;
5. Other considerations that might affect the objectivity of members of the augmented committee; and
6. How individuals were selected for the augmented committee.

DETERMINATIONS:

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

The CAAC, a standing committee of the SAB, will be augmented by subject matter experts to conduct a peer review of EPA’s Toxicological Review of Ethyl Tertiary Butyl Ether (ETBE) (External Review Draft – February 2017) and EPA’s Toxicological Review of tert-Butyl Alcohol (tert-Butanol) (External Review Draft - February 2017). The CAAC Augmented for the ETBE and tBA Review will provide independent advice to the EPA Administrator through the chartered SAB.

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

On October 27, 2016, the EPA SAB Staff Office announced in a Federal Register Notice (Volume 81, Number 208, Pages 74782-74783) that it was augmenting the CAAC with additional experts to review and provide independent expert advice through the Chartered SAB on the draft toxicological reviews for ETBE and tBA. To augment the CAAC, the SAB Staff Office sought public nomination of nationally and internationally recognized scientists in one or more of the following areas, with a particular focus on ETBE and tBA: toxicology, rat nephrotoxicity, liver toxicity, reproductive toxicity, cancer biology, physiologically-based pharmacokinetic (PBPK) modeling, toxicokinetics, and dose-response modeling of animal data.

3. Financial conflict of interest consideration, including identification of parties who are potentially interested in or may be affected by the topic 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 for these topics are organizations or industry sectors that may be affected by policies or regulations developed on the basis of EPA’s Toxicological Reviews of ETBE and tBA. These industry sectors include those involved in the manufacture and use, as well as activities associated with the storage, release and disposal of ETBE and tBA containing waste (e.g. petroleum refining, cosmetics and food flavoring). This includes groups such as Lyondell Basell, the American Chemistry Council, the Japanese Petroleum Energy Center (JPEC), Petroleum Association of Japan (PAJ), Methanol Institute, National Petroleum Refiners Association (NPRA), ExxonMobil, and the American Petroleum Institute, among others.

- 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 financial conflict of interest; however, the general provisions in the appearance of impartiality guidelines still apply and need to be considered.
- i. Does the general charge to the CAAC Augmented for the ETBE and tBA 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 specific party means a particular matter that is focused on the interests of a specific party [5 C.F.R. § 2640.102(m)].

The activity of the CAAC Augmented for the ETBE and tBA Review 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 ETBE and tBA toxicological reviews that may impact the manufacture and distribution of ETBE and tBA containing products, and the release or disposal of ETBE and tBA containing waste.

- 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 CAAC Augmented for the ETBE and tBA Review members will be *participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations through the chartered SAB on the Agency’s draft IRIS toxicological review of ETBE and the draft toxicological review of tBA. Such advice is expected to directly influence the Agency’s final assessment, *therefore, participation in this review also will be substantial*.

- iii. Will there be a direct and predictable effect on panel members’ financial interests? 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 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)(ii)]. The ethics regulations include an exemption allowing special government employees (SGEs) serving on federal advisory committees to participate in any particular matter of general applicability where the disqualifying financial interest arises from their non-Federal employment or non-Federal prospective employment, provided that the matter will not have a special or distinct effect on the employee or employer other than as part of a class [5 C.F.R. § 2640.203(g)]. (This exemption does not include the interests of an SGE arising from the ownership of stock in his employer or prospective employer.)

Prospective CAAC Augmented for the ETBE and tBA Review members were asked to submit EPA 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 CAAC Augmented for the ETBE and tBA Review members from their participation.*

4. How regulations concerning “appearance of a loss of impartiality” pursuant to 5 C.F.R. § 2635.502. apply to members of the Augmented CAAC.

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 were evaluated against the 5 C.F.R. 2635(a)(2) general requirements for considering an appearance of a loss of impartiality. This evaluation included information provided on the EPA Form 3110-48 confidential financial disclosure forms. *The SAB Staff Office has determined that the matter to be considered by the CAAC Augmented for the ETBE and tBA 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 Augmented CAAC.

Members of SAB committees and 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 candidates (including on the EPA Form 3110-48), and information independently gathered by SAB staff.

As part of a determination that committee 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 augmented committee. This evaluation includes responses provided by candidates to the following supplemental questions contained on Form 3110-48:

- (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 the ETBE and tBA 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 augmented committee.

6. How individuals were selected for the augmented committee.

On December 21, 2016, the SAB Staff Office posted a list of 47 candidates for the CAAC Augmented for the ETBE and tBA Review, 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 January 23, 2017. The SAB Staff Office received one comment from the public on this list of candidates from the following:

Marcy Banton of LyondellBasell. Received January 22, 2017

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, 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 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; (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 the ETBE and tBA Review are as follows:

CAAC Augmented for the ETBE and tBA Review:

- Dr. Janice Chambers - Mississippi State University, **CHAIR**
- Dr. Hugh A. Barton - Pfizer, Inc.
- Dr. Janet Benson – Lovelace Biomedical
- Dr. Trish Berger - University of California, Davis
- Dr. John Budroe - Office of Environmental Health Hazard Assessment, California
- Dr. Karen Chou - Michigan State University
- Dr. Harvey Clewell - Hammer Institutes for Health Sciences
- Dr. Deborah Cory-Slechta - University of Rochester
- Dr. Bevin Engelward - Massachusetts Institute of Technology
- Dr. Jeffrey Fisher - Food & Drug Administration
- Dr. William Michael Foster - Independent Consultant
- Dr. Alan Hoberman – Charles River Laboratories
- Dr. Tamarra James-Todd - Harvard T.H. Chan School of Public Health
- Dr. Lawrence Lash - Wayne State University
- Dr. Marvin Meistrich - University of Texas M. D. Anderson Cancer Center
- Dr. Maria Morandi - Independent Consultant
- Dr. James O'Callaghan - Centers for Disease Control and Prevention National Institute for Occupational Safety and Health
- Dr. Lorenz Rhomberg – Gradient
- Dr. Stephen M. Roberts - University of Florida
- Dr. Alan Stern - New Jersey Department of Environmental Protection/University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School

Concurred,

/s/
Christopher S. Zarba
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5/10/17
Date