

**U.S. Environmental Protection Agency  
Science Advisory Board  
Chemical Assessment Advisory Committee (CAAC)  
Augmented for the Review of *ETBE and tBA***

**Public Teleconference  
July 11, 2017  
1:00 p.m.– 4:00 p.m. Eastern Time**

**Minutes of the Meeting**

**Purpose:**

The purpose of the teleconference meeting was to learn about the development of the two EPA draft assessments: 1) Toxicological Review of Ethyl Tertiary Butyl Ether (ETBE) and 2) Toxicological Review for tert-Butyl Alcohol (tert-butanol or tBA), and to discuss the draft charge questions.

**Participants:**

**CAAC-ETBE/tBA Panel Members\*:**

Dr. Janice E. Chambers (CHAIR)	Dr. William Michael Foster
Dr. Hugh A. Barton	Dr. Tamarra James-Todd
Dr. Janet Benson	Dr. Lawrence Lash
Dr. Trish Berger	Dr. Marvin Meistrich
Dr. John Budroe	Dr. Maria Morandi
Dr. Karen Chou	Dr. Lorenz Rhomberg
Dr. Harvey Clewell	Dr. Stephen M. Roberts
Dr. Jeffrey Fisher	Dr. Alan Stern

\*See Roster for full Panel

**SAB Staff:**

Dr. Shaunta Hill-Hammond, Designated Federal Officer (DFO) for the CAAC-ETBE/tBA Panel  
Mr. Christopher Zarba, Director, SAB Staff Office  
Ms. Khanna Johnston, Acting Deputy Director, SAB Staff Office  
Dr. Sue Shallal, SAB Staff Office

**Other Attendees:** See Attachment A.

### **Meeting Materials and Meeting Webpage:**

The materials listed below may be found on the SAB meeting webpage at:

<https://yosemite.epa.gov/sab/sabproduct.nsf//MeetingCalBOARD/6C865796C767B0B58525813F00401A8B?OpenDocument>

- Agenda
- Federal Register Notice
- Agency Briefing Material:
  - EPA presentation by Janice S. Lee: Overview of the Draft IRIS Assessment of tert-Butyl Alcohol (tert-Butanol) July 11, 2017.
  - EPA presentation by Keith Salazar: Overview of the Draft IRIS Assessment of Ethyl Tertiary Butyl Ether (ETBE) July 11, 2017.
- Charge to the Committee:
  - Charge for IRIS Assessment for Ethyl Tertiary Butyl Ether (ETBE), dated June 2017.
  - Charge for IRIS Assessment for tert-Butyl Alcohol (tert-butanol), dated June 2017.
- Agency Review Documents:
  - Toxicological Review of tert-Butyl Alcohol (tert-Butanol) (External Review Draft – June 2017)
  - Supplemental Information for Toxicological Review of tert-Butyl Alcohol (tert-Butanol) (External Review Draft - June 2017)
  - Toxicological Review of Ethyl Tertiary Butyl Ether (External Review Draft - June 2017)
  - Supplemental Information for Toxicological Review of Ethyl Tertiary Butyl Ether (External Review Draft - June 2017)
- Public Comment from Fukumi Nishimaki on behalf of the Japan Petroleum Energy Center(JPEC) regarding the Toxicological Review of ETBE (June 2017 -External Review Draft).
- List of Registered Public Speakers
- CAAC-ETBE/tBA Panel Roster

### **Meeting Summary:**

The meeting occurred from 1:00 p.m. to 3:15 p.m. Eastern Time. The discussion followed the issues as presented in the meeting agenda.

### **Opening of Public Meeting:**

Dr. Shanta Hill-Hammond, Designated Federal Officer, convened the meeting with a statement reminding the audience that CAAC augmented committee for the review of ETBE and tBA

(hereafter referred to as the CAAC-ETBE/tBA Panel or Panel), operates under the Federal Advisory Committee Act (FACA). Under FACA, Dr. Hill-Hammond noted that the SAB's deliberations are held in public with advanced notice for meetings given in the Federal Register.

The SAB consists entirely of special government employees appointed by EPA to their positions. As government employees, all the members are subject to all applicable ethics laws and implementing regulations.

Dr. Hill-Hammond stated that for this SAB advisory activity, no conflict of interest or loss of impartiality issues were identified for any panel member. She then reminded all participants that the meeting materials were available on the SAB website. Mr. Christopher Zarba, the Director of the SAB Staff Office, welcomed and thanked members for their willingness to serve on the panel. Dr. Janice Chambers, Chair of the CAAC-ETBE/tBA Panel followed, offering welcoming remarks and completing roll-call of the CAAC-ETBE/tBA Panel. She then reviewed the meeting agenda and invited the EPA representatives to begin their presentations.

**EPA Presentations and Remarks:**

Dr. Keith Salazar and Dr. Janice Lee, of the EPA National Center for Environmental Assessment, presented background information detailing the development of the ETBE and tBA assessments, respectively. Their powerpoint presentations may be found on the SAB meeting webpage mentioned above. Dr. Salazar presented an overview of ETBE and Dr. Lee presented an overview of tBA. Each presentation included general information on the chemicals, the implementation of the 2011 and 2014 NRC recommendations in the assessments, an overview of the toxicological review conducted. The speakers also provided a summarization of the key/major public comments received for each chemical and the EPA's responses to those comments.

Following the EPA presentations, members of the Panel raised a few clarifying questions.

- a. (Dr. Rhomberg) Is there a way in which the ETBE results influenced tBA?  
EPA response: Yes, the ETBE assessment does cite/discuss tBA. Both documents acknowledge the other chemical with reference to the key text sections.
  
- b. (Dr. Barton) For tBA you mentioned "inadequate", what does inadequate mean?  
EPA response: The term is defined in the supplemental materials, section b2.1. The point is that the evidence overall is inadequate and there is not enough data for a quantitative assessment.
  
- c. (Dr. Meistrich) Was the drinking water study used because there was no inhalation study or due to a negative result?  
EPA response: No chronic inhalation studies were available. Only a sub chronic inhalation study was available. As a chronic drinking water study was available, it was used for the assessment and a model was used to extrapolate.

Dr. Chambers thanked the EPA presenters and turned the meeting over to Dr. Hill-Hammond for the facilitation of public comments.

**Public Comments:**

Two individuals had registered to present oral comments during the teleconference. Each speaker was invited by Dr. Hill-Hammond to begin their presentations. Dr. James Bus presented comments on behalf of LyondellBasell on the ETBE draft assessment. Comments were specific to the proposed cancer classification for ETBE and the low concern for human health impacts by inhalation and oral exposures. Dr. Marcy Banton presented comments on behalf of LyondellBasell on the tBA draft assessment. Similar comments were raised regarding the proposed cancer classification for tBA and the low human health risk by inhalation and oral exposures. Both commenters requested that the Panel review and consider comments previously submitted to the Agency for each assessment.

The Panel requested access to comments previously submitted to the Agency.

**Panel Discussion of the Charge Questions:**

Following public comments, Dr. Chambers led the review of the charge questions. Each charge question was presented by Dr. Chambers allowing for comments and clarifying questions by the assigned sub-group and then the full Panel.

Panel members were in agreement that the charge questions were clearly written. Revisions were suggested for charge questions 4b and 4c for both ETBE and tBA. The purpose of the revisions was to enhance the clarity of each questions. Drs. Stern and Barton offered to draft proposed text for the Panel's review. The revised charge questions are available on the SAB webpage.

Dr. Chambers then turned the meeting over to Dr. Hill-Hammond for the facilitation of clarifying public comments.

**Clarifying Public Comments:**

One clarifying comment was presented by Dr. Bus. He noted that the mode of action consideration should be specifically expanded to include evidence of nonlinear toxicokinetics relative to the expression of male rat liver tumors. He also noted that toxicokinetic behavior is always regarded as a key element of mode of action evaluations as expressed in mode of action framework analyses.

**Meeting Adjournment:**

Dr. Chambers asked Dr. Hill-Hammond to review the next steps for the Panel. Dr. Hill-Hammond noted that proposed changes for charge questions 4b and 4c would be drafted by the Panel and shared with the Agency for concurrence on the intent of the question. Proposed changes would then be shared with the Panel and posted to the SAB webpage associated with this advisory activity. Dr. Hill-Hammond also noted that she would work with the Agency to provide the Panel with the previously submitted public comments to the Agency. Finally, all meeting participants were thanked for their attendance and the teleconference meeting was adjourned.

On Behalf of the Committee,

Respectfully Submitted,

Certified as True,

/s/

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/s/

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Shaunta Hill-Hammond, Ph.D.  
Designated Federal Officer

Janice Chambers, Ph.D.  
Chair, CAAC-ETBE/tBA Panel

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings and approval by the Chartered SAB.

Appendix A

**List of Participants for the Chemical Assessment Advisory Committee (CAAC)  
Augmented for the Review of *ETBE and tBA* Public Teleconference**

<b>Name</b>	<b>Affiliation</b>
Janice Lee	EPA
Amanda Persad	EPA
Andrew Hotchkiss	EPA
John Vandenberg	EPA
Channa Keshava	EPA
James Avery	EPA
Kris Thayer	EPA
Jason Fritz	EPA
Vicki Soto	EPA
Keith Salazar	EPA
Lou D'Amico	EPA
Tina Bahadori	EPA
Cheryl Itkin	EPA
Thomas Carpenter	EPA

**Requests for Teleconference Call-In Information**

Susan Felter	Procter & Gamble
Andrew Pawlisz	Phillips 66
Linda Wilson	New York State Attorney General
Steffen Erler	SABIC
Virunya Bhat	NSF International
Bhaskar Gollapudi	Exponent