

**U.S. Environmental Protection Agency
Science Advisory Board (SAB)
Chemical Assessment Advisory Committee (CAAC)
Augmented for the Review of Ethyl Tertiary Butyl Ether (ETBE)
and tert-Butyl Alcohol (tBA)**

**Public Teleconference
June 6, 2018**

Minutes

Purpose:

To discuss the draft report of the SAB CAAC ETBE/tBA Panel titled, “SAB Review of EPA’s Draft Toxicological Review of Ethyl Tertiary Butyl Ether and Draft Toxicological Review of tert-Butyl Alcohol (tert-Butanol or tBA), 02-21-18”.¹

Participants:

CAAC Augmented for ETBE/tBA Members (See Roster² for full committee):

Dr. Janice E. Chambers (CHAIR)	Dr. William Michael Foster
Dr. Hugh A. Barton	Dr. Alan Hoberman
Dr. Janet Benson	Dr. Maria Morandi
Dr. John Budroe	Dr. Isaac Pessah
Dr. Karen Chou	Dr. Lorenz Rhomberg
Dr. Harvey Clewell	Dr. Stephen M. Roberts
Dr. Jeffrey Fisher	Dr. Alan Stern

SAB Staff:

Dr. Shaunta Hill-Hammond, Designated Federal Officer for the CAAC Augmented for ETBE/tBA, Science Advisory Board (SAB) Staff Office
Dr. Sue Shallal, SAB Staff Office

Other Attendees: See Appendix A.

Teleconference Summary:

The draft SAB report was discussed in a public teleconference held on June 6, 2018. The discussion followed the topics as presented in the meeting agenda.³ This was the third teleconference convened to complete the review of the panel’s draft report; it is a continuation of the March 22 and 27, 2018 teleconferences.

Convening of the Public Teleconference:

Dr. Shaunta Hill-Hammond, the Designated Federal Officer (DFO), convened the teleconference with a statement informing the participants that the Chemical Assessment Advisory Committee (CAAC) augmented 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 given in the Federal Register.⁴ The SAB consists entirely of special government employees appointed by the U.S. EPA (hereafter referred to as the EPA or Agency) to their positions. As special 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. Dr. Hill-Hammond reminded all participants that the teleconference materials were available on the SAB website. Dr. Hill-Hammond then conducted a roll-call of the Panel and turned the teleconference over to Dr. Janice Chambers, Chair of the CAAC-ETBE/tBA Panel.

Dr. Chambers offered welcoming remarks to the Panel and reviewed the agenda highlighting the charge questions pending discussion. She reminded the participants that this was the third teleconference where the panel had an opportunity to discuss their draft report. She noted that the panel had already reviewed charge questions 1-3, 4a, and 4b and that the Panel would have discussions on the remaining charge questions (4c-e, 5 and 6). She then indicated that typographical errors and minor corrections as noted by the Panel would be addressed in the next report draft. Dr. Chambers reminded the Panel of the general correction to the report regarding the presentation of the key recommendations. Where the Panel presented no recommendations, the proposed change was to reflect this finding by stating: "The SAB has no specific recommendations at this time for this tier"; instead of "none". No objections were raised by the Panel. Dr. Chambers also indicated if no comments were raised on a particular section of the report by the Panel, then consensus with the draft text as presented in that section (including any minor typographical corrections made by the chair) would be implied.

Dr. Chambers then asked Dr. Hill-Hammond to proceed with the public comment period.

Public Comments:

Dr. Hill-Hammond noted that no requests were received by the SAB staff office. She also noted that the EPA would not be providing oral comments. The meeting was returned to Dr. Chambers for continuation.

Discussion of the Draft Report:

Dr. Chambers led the review of the draft report. The discussion proceeded as following: Dr. Chambers identified the report section and read the charge question. She then presented written comments⁵ received regarding the corresponding report section and proposed changes to address the comments. She also invited additional comments and questions from the Panel during the review of each section.

3.4 Hazard Identification and Dose–Response Assessment: Cancer

3.4.3.1 ETBE:

The Panel engaged in discussion regarding use of the phrases "highly unlikely" and "potentially misleading". The Panel decided that the words "unlikely" and "potentially" would be removed

and the word “misleading” would be changed to “non-instructive”. No further comments or changes were raised by the Panel.

3.4.3.2 tBA:

The Panel engaged in discussion regarding use of the phrase “highly unlikely”. The Panel decided that the word “unlikely” would be removed. The Panel also agreed to replace “could” with “should” in the tier 1 recommendations. No further comments or changes were raised by the Panel.

3.4.4.1. ETBE:

The Panel discussed the submitted comments. The Panel agreed to utilize the revision proposed by Dr. Budroe, excluding the proposed tier 1 recommendation. No further comments or changes were raised by the Panel.

3.4.4.2. tBA:

The Panel discussed the submitted comments. The Panel agreed to utilize the revision proposed by Dr. Budroe, excluding the proposed tier 1 recommendation. The Panel also agreed to include a tier 3 recommendation requesting that EPA consider using other models. No further comments or changes were raised by the Panel.

3.4.5.1. ETBE:

No comments or changes were raised by the Panel.

3.4.5.2. tBA:

The Panel discussed the submitted comments. The Panel agreed to utilize the revision proposed by Dr. Budroe, excluding the proposed tier 1 recommendation. No further comments or changes were raised by the Panel.

Break:

The Panel took a break at approximately 10:42 am. The teleconference resumed at 10:55 am and Dr. Hill-Hammond conducted a roll-call of the Panel before turning the teleconference back over to Dr. Chambers.

3.5 Questions on Susceptible Populations and Lifestages

3.5.1. ETBE:

The Panel discussed the submitted comments and agreed that a citation was needed to identify the review referenced on page 48 at line 32. The Panel also agreed to restructure the key recommendations by placing most of the background text into the introductory paragraphs. Dr. Alan Hoberman volunteered to restructure the section. No further comments or changes were raised by the Panel.

3.5.2. tBA:

The Panel discussed the submitted comment and agreed to restructure the key recommendations by placing most of the background text into the introductory paragraphs. The Panel also agreed

to add a tier 3 recommendation regarding inactive ALDH2*2 variants. Dr. Hoberman volunteered to restructure the section. No further comments or changes were raised by the Panel.

3.6 Questions on the Executive Summary

3.6.1. ETBE:

The Panel agreed to restructure the overall response so that it is concise and presents the key findings, including a clear statement of the final outcomes and the supporting decision points. Dr. Lorenz Rhomberg volunteered to rewrite the section addressing these points. The Panel also agreed that the listed tier 3 recommendation should be presented with its respective topic section in the report. Dr. Isaac Pessah volunteered to suggest the appropriate report section placement for the text. No further comments or changes were raised by the Panel.

3.6.2. tBA:

The Panel agreed to restructure the overall response so that it is concise and presents the key findings, including a clear statement of the final outcomes and the supporting decision points. Dr. Rhomberg volunteered to rewrite the section addressing these points. The Panel also agreed that the listed tier 3 recommendation should be presented with its respective topic section in the report. Dr. Pessah volunteered to suggest the appropriate report section placement for the text. No further comments or changes were raised by the Panel.

Break:

The Panel took a break at approximately 11:57 am. The teleconference resumed at 12:05 pm and Dr. Hill-Hammond conducted a roll-call of the Panel before turning the teleconference back over to Dr. Chambers.

Draft Report - Letter to the Administrator

The Panel agreed that reference to parameterization for the PBPK model should be deleted as it is not a tier 1 recommendation. The Panel also agreed to delete the word “highly” as was decided for sections 3.4.3.1 and 3.4.3.2 of the draft report. No further comments or changes were raised by the Panel.

Draft Report - Executive Summary

The Panel discussed the submitted comments. The Panel agreed that reference to parameterization for the PBPK model should be deleted as it is not a tier 1 recommendation. The Panel agreed to revise the summary presented for the dose metric section to address comments raised by the EPA.⁵ Dr. Harvey Clewell volunteered to provide the revision. The Panel noted that use of the phrase “meaningful and useful” should be changed to “instructive” on page 4. The Panel also agreed to revise the final sentence on page 5 in lines 36 – 38 by deleting the second clause. The Panel agreed to clarify statements regarding the kidney endpoint selection. Finally, the Panel agreed the cancer mode of action information presented should be revised to eliminate contradictory statements. No further comments or changes were raised by the Panel.

Clarifying Public Comments:

Dr. Hill-Hammond acknowledged receipt of one request for clarifying comments.⁶

Dr. James Bus of Exponent presented comments⁷ on behalf of LyondellBasell. His comments were specific to the consideration of alternative endpoints and the selection of multiple endpoints for deriving the inhalation reference concentration (RfC) and oral reference dose (RfD) values.

Teleconference Adjournment:

Dr. Chambers thanked the Panel for their efforts in completing the review of the draft report. Dr. Chambers asked Dr. Hill-Hammond to review the next steps for the Panel. Dr. Hill-Hammond asked Panel members currently tasked with providing revisions to the report to submit them by June 20, 2018. She then noted that the revised report would be made available to the Panel for concurrence ahead of the quality review with the chartered SAB. Finally, all teleconference participants were thanked for their attendance and the teleconference was adjourned at approximately 1:20 pm.

On Behalf of the Committee,
Respectfully Submitted,

Certified as True,

/s/

/s/

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

Janice Chambers, Ph.D.
Chair, Chemical Assessment Advisory
Committee Augmented for the ETBE/tBA
Review

NOTE AND DISCLAIMER: The minutes of this public teleconference reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the teleconference. 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.

Appendix A

List of Participants and Requests for Call-In Information for the Chemical Assessment Advisory Committee (CAAC) Augmented for the Review of *ETBE* and *tBA* Public Teleconference June 6, 2018

Name	Affiliation
Janice Lee	US EPA
Andre Weaver	US EPA
Paul Schlosser	US EPA
Kris Thayer	US EPA
James Avery	US EPA
Tina Bahadori	US EPA
Vicki Soto	US EPA
Kathleen Newhouse	US EPA
Channa Keshava	US EPA
Mary Ross	US EPA
Francie Diep	Pacific Standard
Johanna Congleton	US EPA
Randy Loftis	Undark
Sarah Gardner	Koch
James Bus	Exponent, Inc., on behalf of LyondellBasell
Samuel Cohen	University of Nebraska Medical Center
Michael Honeycutt	Texas Commission on Environmental Quality
Abby Li	Exponent, Inc., on behalf of LyondellBasell
Kevin Bromberg	US SBA Office of Advocacy
Lily Wang	US EPA
Maria Hegstad	Inside EPA
Allison Nyholm	Steptoe & Johnson
Erik Janus	Steptoe & Johnson
Jessica Ryman-Rasmussen	American Petroleum Institute
Diana Smirnova	Uponor, Inc.

Materials Cited

The following teleconference materials are available on the SAB webpage at:

<https://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/dcbc685c251c4f488525827200604327!OpenDocument&Date=2018-06-06>.

¹SAB Review of EPA's Draft Toxicological Review of Ethyl Tertiary Butyl Ether and Draft Toxicological Review of tert-Butyl Alcohol 02.21.18.

² Roster.

³ Agenda.

⁴ Federal Register Notice Announcing the Meeting.

⁵ Comments for Review by the SAB CAAC-ETBE/tBA Committee.

⁶ List of Registered Public Clarifying Commenters.

⁷ Clarifying Comments Submitted by James Bus on behalf of LyondellBasell.