

**U.S. Environmental Protection Agency  
Science Advisory Board  
Chemical Assessment Advisory Committee Augmented for the Review of the Draft IRIS  
Benzo[a]pyrene Assessment (CAAC-Benzo[a]pyrene Panel)  
Public Teleconference  
August 21, 2015**

**Minutes of the Meeting**

**Purpose:** To review and discuss the Science Advisory Board Panel's draft report of the EPA's *Toxicological Review of Benzo[a]pyrene (External Review Draft – September 2014)*

**Meeting Participants:**

**CAAC-Benzo[a]pyrene Panel Members (See Roster):**

Dr. Elaine Faustman, CHAIR	Dr. Ed Levin
Dr. Scott Bartell	Dr. Abby Li
Dr. Annette Bunge	Dr. Maureen Lichtveld
Dr. Anna Choi	Dr. Barry McIntyre
Dr. John DiGiovanni	Dr. Bhagavatula Moorthy
Dr. Joanne English	Dr. Miriam Poirier
Dr. William Michael Foster	Dr. Kenneth Portier
Dr. Chris Gennings	Dr. Stephen Roberts
Dr. Helen Goeden	Dr. Richard Schlesinger
Dr. Sean Hays	Dr. Charles Vorhees
Dr. John Kissel	Dr. Christi Walter

**Other Attendees:** see Attachment A.

**Meeting Materials and Meeting Webpage:**

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

<https://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/7a1e0d1303797d9485257e6c0054e785!OpenDocument&Date=2015-08-21>

- Agenda
- Federal Register Notice
- Agency Comment
  - EPA Clarifications/Comments for the SAB Draft Peer Review Report on Benzo[a]pyrene
- Public comments submitted to the SAB Staff Office
  - Public Comments from Anne LeHurray, Pavement Coatings Technology Council, 8/17/15
  - Public Comments from Nancy Beck, American Chemistry Council, 8/14/15

**Meeting Summary:**

The discussion followed the general plan as presented in the meeting agenda.

### **Opening Remarks**

Dr. Wong convened the meeting and called the roll. All CAAC-BaP panel members were present except Drs. Baynes, Burchiel, Ramos, Stayner, and Stern. Dr. Wong explained that the SAB CAAC-BaP panel operates under the authority of the Federal Committee Advisory Act (FACA). 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. She stated that for this SAB advisory activity, no conflict of interest or loss of impartiality issues were identified for any panel member.

Dr. Wong then turned the meeting over to Dr. Faustman, Chair of the CAAC-BaP Review Panel. Dr. Faustman reviewed the agenda and then invited the EPA representatives to provide their comments.

### **EPA Clarifying Remarks**

Dr. Vincent Cogliano, Director of EPA's IRIS Program, provided some requests for clarifications and comments (posted on the meeting webpage) on the draft SAB report on the BaP assessment in the following areas:

- Forestomach toxicity as a hazard
- Cervical hyperplasia and inflammation as critical endpoints for the RfD
- Application of a database uncertainty factor of 3 for the proposed RfD
- Recommendations for the reproductive toxicity section
- Confusion with respect to the response to charge question 3a
- Allometric scaling for alimentary tract tumors for the derivation of oral slope factor
- Additional studies for quantitative consideration for the dermal slope factor

### **Public Comments**

Dr. Faustman thanked EPA for their comments and asked members of the public who had registered to provide comments to the panel to begin their presentations. Two individuals had registered to present oral comments at the meeting (see Attachment B).

Dr. Anne LeHuray of Pavement Coatings Technology Council provided comments (posted on the meeting webpage), noting that (1) the literature search should include keywords focused on epidemiology or other human exposure studies; (2) the draft hazard assessment should be revised using systematic review techniques; (3) she agreed that studies of therapeutic use of coal tar medications were not useful for slope factor derivation, but disagreed that they did not inform hazard identification; and (4) the existing evidence did not support classification of BaP as a human carcinogen.

Dr. Kimberly Wise of the American Chemistry Council's Center for Advancing Risk Assessment Science and Policy presented the comments provided by Dr. Nancy Beck of the American Chemistry Council (posted on the meeting webpage). She commented on three areas: (1) the quality of individual studies should be objectively evaluated and transparently presented;

(2) The mode of action for forestomach tumors may not necessarily occur via a mutagenic mode of action and questioned whether the application of age-dependent adjustment factors is appropriate; (3) Comments on the confidence of the RfD and RfC values would be useful.

#### **Panel Discussion of the Draft SAB Report:**

Dr. Faustman thanked the public commenters and turned to the next agenda item, the discussion of the draft report by sections.

#### **Section 3.1 Literature Search/study selection and evaluation**

The panel did not propose changes for this section.

#### **Section 3.2.1 Developmental Toxicity**

The panel agreed that there were significant exposure gaps in brain development from gestation to weaning that were not covered in available neurodevelopmental studies on BaP. These gaps should be considered by the EPA in the evaluation of BaP developmental neurotoxicity. Dr. Charles Vorhees and Ed Levin agreed to write a paragraph to identify the data gap in exposure. The panel would discuss the write up during the next public teleconference.

#### **Section 3.2.2 Reproductive Toxicity**

The panel discussed the cervical hyperplasia and inflammation endpoint in Gao et al. (2011) and agreed it was a good study and could be used as a critical endpoint. Dr. Barry McIntyre agreed to write a few sentences that cited literature that linked cervical inflammation with premature labor and questioned why EPA did not use this information. The write-up would be circulated to the team for consensus before submitting for discussion by the entire panel.

#### **Section 3.2.4 Cancer**

The panel agreed that there are mechanistic studies that support genotoxicity of BaP. The primary cancer mode of action for BaP is mutagenicity, not hyperplasia. Dr. Miriam Poirier agreed to write a paragraph to support mutagenesis as the principal mode of action for BaP, and that there is a definite dose-response relationship on DNA adducts formation. She will circulate the write up to her team for consensus and copy the DFO before submitting to the entire panel for discussion during the next public teleconference.

The issue of no skin tumors in therapeutic use of coal tar formulation on psoriasis patients was brought up in public comments. The DFO recommended that the panel defer discussion of the coal tar studies to the next conference call on September 2 when the dermal slope factor section will be discussed.

#### **Section 3.2.5. Other Types of Toxicity**

The panel agreed no change is needed for this section.

#### **Section 3.3.2. Inhalation Reference Concentration**

The lead writer commented that there were no comments from EPA or the public on this section. No changes to this section are warranted.

#### **Section 3.3.3. Oral Slope Factor for Cancer**

The panel discussed the issue of cross-species scaling and whether allometric scaling should be reconsidered. There is no solid guidance from EPA on the application of allometric scaling on alimentary tract tumors, and EPA should acknowledge this in the assessment. It was not SAB's intent not to use allometric scaling; the text should be revised in this section and in the executive summary.

Dr. Steve Roberts agreed to write a paragraph on allometric scaling, The discussion should be linked to the mode of action for BaP carcinogenicity. Steve would circulate the write-up to the team and copy the DFO before submitting to the entire panel for discussion during the next public teleconference.

#### **Section 3.3.4. Inhalation Unit Risk for Cancer**

The panel agreed no change is needed

#### **Section 3.3.6 Age-dependent Adjustment Factors for Cancer**

The panel agreed the proposed use of age-dependent factor was justified, and there was no chemical specific age-dependent adjustment factor for BaP. No change is needed.

#### **Section 3.4 Executive Summary**

The panel agreed no change is needed.

#### **Section 3.5 EPA's Response to Public Comments**

Dr. Ed Levin agreed to write a paragraph about the use of decreased anxiety as a critical effect to be inserted in the section on developmental neurotoxicity. The write-up will be circulated to the team and copied to the DFO before submitting to the entire panel for discussion during the next public teleconference on September 2.

#### **Brief Public Comments**

Dr. Mike Dourson, a chartered SAB member, commented that non-linear mode of action should be considered since hyperplasia is a mode of action for forestomach tumors.

Dr. Faustman turned the meeting over to the DFO, Dr. Wong, for a review of the next steps for the panel. Dr. Wong noted that she would be sending out an e-mail to panel members with homework assignments. These homework assignment would be posted on the SAB website for discussion during the next public teleconference, to be held on September 2, 2016, from 1:00 – 5:00 pm. Dr. Wong thanked all the participants and adjourned the teleconference around 3:30 pm.

On Behalf of the Committee,  
Respectfully Submitted,

\_\_\_\_\_/s/  
Diana Wong, Ph.D.  
Designated Federal Officer



### Attachment A. Other Attendees

List of persons who identified themselves on the teleconference or who had requested call-in-information for the meeting.

<b>Name</b>	<b>Affiliation</b>
Vince Cogliano	EPA
Samantha Jones	EPA
Kathleen Newhouse	EPA
Resha Putzrath	Navy and Marine Corps Public Health Center
Ann LeHuray	Pavement Coating Technology Council
Pat Rizzuto	Bloomberg BNA
Michael Dourson	TERA
David Reynolds	Inside EPA
Kimberley Wise	American Chemistry Council
Jim Kim	OPM
Julie LeMay	Gradient
Kimberly Wise	American Chemistry Council
Rayna Laiosa	PSEG
Alison Foley	Utility Solid Waste Group
Leeann Sinagoga	Tetrattech
Naseera Bland	EPA
Rich Kapuscinski	EPA
Michele Burgess	EPA
Chris Saranko	Geosyntec
Fred Reitman	Shell

Attachment B.  
**List of Public Speakers**

**U.S. Environmental Protection Agency  
Chemical Assessment Advisory Committee (CAAC) Augmented  
Benzo[a]pyrene Review Panel**

**August 21, 2015 Teleconference**

#	Speaker's Name	Organizational Affiliation(s)
1	Anne LeHuray	Pavement Coatings Technology Council
5	Kimberly Wise	American Chemistry Council