

**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
March 4, 2015**

Minutes of the Meeting

Purpose: To receive a briefing on the EPA's *Toxicological Review of Benzo[a]pyrene (External Review Draft – September 2014)* and to discuss EPA's charge questions.

Meeting Participants:

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

Dr. Elaine Faustman, CHAIR	Dr. Maureen Lichtveld
Dr. Scott Bartell	Dr. Abby A. Li
Dr. Ronald Baynes	Dr. Barry McIntyre
Dr. Annette Bunge	Dr. Bhagavatula Moorthy
Dr. Scott Burchiel	Dr. Miriam Poirier
Dr. Anna Choi	Dr. Kenneth M. Portier
Dr. John DiGiovanni	Dr. Kenneth Ramos
Dr. Joanne English	Dr. Stephen M. Roberts
Dr. William Michael Foster	Dr. Richard Schlesinger
Dr. Chris Gennings	Dr. Leslie T. Stayner
Dr. Helen Goeden	Dr. Alan Stern
Dr. Sean Hays	Dr. Christi Walter
Dr. John Kissel	

Other Attendees: see Attachment A.

Meeting Materials and Meeting Webpage:

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

<http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/0CB61E4284A29B5285257DB2005D23D5?OpenDocument>

- Agenda
- Federal Register Notice
- Agency Briefing Material
 - Overview of the Draft IRIS Assessment of Benzo[a]pyrene
- Presentation by Registered Public Speaker
 - Oral Comments by Anne LeHuray, Pavement Coatings Technology Council
 - Oral Comments by Kimberly Wise, on behalf of the American Chemistry Council
 - Oral Comments by Nancy Beck, American Chemistry Council
 - Presentation by Brian Magee, on behalf of American Petroleum Institute, Asphalt Institute, and Pavement Coatings,

- Public Comments by Annettee Rohr, Electric Power Research Institute
- Public comments submitted to the SAB Staff Office
 - ACC and ARASP November 2013 Comments on the IRIS Toxicological Review of Benzo[a]pyrene, submitted by Dr. Nancy Beck
 - American Chemistry Council and Center for Advancing Risk Assessment Science and Policy Comments on Benzo[a]pyrene Assessment, submitted by Drs. Nancy Beck and Kimberly Wise
 - Public Comments by Patrick Beatty, American Petroleum Institute
 - Public Comments from Anne LeHuray, Pavement Coatings Technology Council
 - Public Comments from Brian Magee, on behalf of American Petroleum Institute, Asphalt Institute, and Pavement Coatings Technology Council
 - Public Comments from Kevin Bromberg, Small Business Administration

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. Levin and Vorhees. 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 begin their presentations.

EPA Presentations

Dr. Vincent Cogliano, Director of EPA's IRIS Program, provided some opening remarks. He explained that for hazard identification, charge questions are organized around toxicity studies that support analysis in a section. He also explained that there have been charge questions on the preamble in many places, e.g., in the draft Ammonia and Trimethylbenzene Assessments. Most CAAC members have served on other panels. There will be comprehensive revision of the preamble to produce a handbook.

The next speaker was Ms. Kathleen Newhouse, assessment manager of the Benzo[a]pyrene assessment. She gave an overview of the Draft IRIS Toxicological Review of Benzo[a]pyrene. Her presentation can be found posted on the meeting webpage shown above. The panel members then asked questions on the assessment.

Public Comments

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

Dr. Anne LeHuray of Pavement Coatings Technology Council commented that the literature search revealed primarily reports of adverse effects, while failing to identify literature on exposures not associated with adverse effects. Dr. LeHuray's comments can be found posted on the meeting webpage.

On behalf of the American Petroleum Institute, Asphalt Institute, and Pavement Coatings Technology Council, Dr. Brian Magee commented on two major issues regarding the proposed dermal slope factor (DSF) for BaP. First, the DSF predicts that most of the people exposed to coal tar ointments and shampoos throughout their lifetimes should have contracted skin cancer. But none of the people exposed to coal tar in over 20 studies has seen an increase in skin cancer. Second, he has conducted "real world" validation calculations concerning the DSF's prediction of skin cancer risk in the general population due to dermal contact with background soils. The result demonstrated that the DSF is fundamentally flawed because it predicts more than 160,000% of skin cancer in some cases. Dr. Magee's comments can be found posted on the meeting webpage.

Dr. Patrick Beatty of the American Petroleum Institute commented on a number of issues and requested the special attention of the panel members to the following: (1) Some credence should be given to the decades old experience with coal tar-containing shampoos and treatment for skin diseases like psoriasis, (2) the MOA for carcinogenicity is assumed to be based on mutagenicity with inadequate justification, and (3) EPA is inconsistent in the way it considers the validity of data from mixtures in the trimethylbenzenes assessment and the BaP assessment. No human is exposed to pure BaP, which is only encountered outside of the laboratory as a complex mixture. The entire toxicology assessment of BaP relies on complex mixtures of other PAHs. He questioned if such inconsistency is warranted and to what degree should mixture-based data be used.

Dr. Nancy Beck of the American Chemistry Council commented on five main points on the charge questions. (1) Many charge question have been written such that a "yes" or "no" response would be sufficient, (2) Charge question 5 regarding the handling of public comments should focus on whether the panel agrees with the substance of EPA's response, and not whether or not EPA provided a response, (3) there is no charge question on the revised structure and approach to the assessment in accordance with NRC's recommendations, (4) the charge question on literature search should focus on the need for clear criteria for study selection and evaluation, and (5) input from the panel on how the public can be more helpful would be appreciated. Dr. Beck's comments can be found on the meeting webpage.

Dr. Kimberly Wise of American Chemistry Council's Center for Advancing Risk Assessment Science and Policy commented that the draft BaP assessment does not appear to address all public comments, and the current conference call agenda does not clearly implement the EPA's Fiscal Year 2012 Initiatives to enhance public involvement in advisory activities. She commented that clarifying remarks from the public should be allowed at the end of the meeting. Dr. Wise's comments can be found on the meeting webpage.

Dr. Annette Rohn of the Electric Power Research Institute commented on a scientific issue that EPRI included in their comment to EPA on the draft BaP assessment, which is that of differing mutational signatures in human skin tumors versus experimental mouse skin PAH-induced skin tumors. Dr. Rohn's comments can be found on the meeting webpage.

Dr. Kevin Bromberg of the U.S. Small Business Administration commented on charge question 1 (literature search/study selection and evaluation) and charge question 5, and suggested changes to these two charge questions to follow the charge questions for the ammonia panel. Dr. Bromberg's comments can be found on the meeting webpage.

Panel Discussion of Charge Questions

Dr. Faustman thanked the public commenters and turned to the next agenda item, the discussion of the charge questions. Panel members discussed the charge, and agreed to use the language for the charge question on literature review that was included in the charge for the Ammonia assessment, and that the charge question on Cancer should be moved ahead of Other Types of Toxicity. The panel also offered other edits that were intended to clarify the questions. In addition, the panel discussed suggested modifications offered by public commenters. Modifications to the charge questions agreed to by the panel were noted in bold font in the final charge questions that can be accessed at the above noted URL.

Dr. Faustman turned the meeting over to the DFO. Dr. Wong reviewed the next steps for the panel. She noted that the revised charge questions will be posted on SAB webpage associated with this advisory activity in one week. She also noted that the panel was scheduled to meet on April 15-17, 2015 in Washington DC. Dr. Wong thanked all the participants and adjourned the meeting at 4:00 pm.

On Behalf of the Committee,
Respectfully Submitted,

_____/signed_____
Diana Wong, Ph.D.
Designated Federal Officer

Certified as Accurate:

_____/signed_____
Elaine Faustman, Ph.D.
Chair, SAB CAAC-Benzo[a]pyrene Review 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

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.

Attachment A. Other Attendees

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

Name	Affiliation
Vince Cogliano	EPA
Samantha Jones	EPA
Kathleen Newhouse	EPA
Lynn Flowers	EPA
Andrew Hotchkiss	EPA
Channa Keshava	EPA
Audrey Galizia	EPA
Andre Weaver	EPA
Jenny Li	EPA
Ted Berner	EPA
Andrew Kraft	EPA
Linda Phillips	EPA
Belinda Hawkins	EPA
Jennifer Jinot	EPA
Karen Hogan	EPA
Paul White	EPA
Margaret Pratt	EPA
Lyle Burgoon	EPA
Susan Rieth	EPA
Joe DeSantis	EPA
Gina Perovich	EPA
Resha Putzrath	Navy and Marine Corps Public Health Center
Yvette Lowney	Exponent
Pat Casano	GE
Barbara Pugh	Arcadis
Doug Covert	Hazardous Substance & Waste Management Research
Ann LeHuray	Pavement Coating Technology Council
Pamela Lamie	CDM Smith
Jim Kim	OPM
Julie LeMay	Gradient
Brian Magee	Arcadis
Patrick Beatty	American Petroleum Institute
Nancy Beck	American Chemistry Council
Kimberly Wise	American Chemistry Council
Daniella Pizzurro	Gradient
Haylie Choi	RegNet Environmental Services
Robert Fensterheim	RegNet Environmental Services
Maria Hegstad	Risk Policy Report

Alison Foley	On behalf of Utility Solid Waste Group
Anita K. Meyer	U.S. Army Corps of Engineers
Annette Rohr	Electric Power Research Institute
Kevin Bromberg	Small Business Administration
Thomas Utzinger	PSEG
Neeraja K. Erraguntla	Texas Commission on Environmental Quality
Joe Frasca	ExxonMobil Biomedical Sciences
Wayne Daughtrey	ExxonMobil Biomedical Sciences
Leeann Sinagoga	Tetra Tech

Attachment B.
List of Public Speakers

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

March 4, 2015 Teleconference

#	Speaker's Name	Organizational Affiliation(s)
1	Anne LeHuray	Pavement Coatings Technology Council
2	Brian Magee	On behalf of American Petroleum Institute, Asphalt Institute, and Pavement Coatings Technology Council
3.	Patrick Beatty	American Petroleum Institute
4.	Nancy Beck	American Chemistry Council
5	Kimberly Wise	Center for Advancing Risk Assessment Science and Policy
6	Annette Rohr	Electric Power Research Institute
7	Kevin Bromberg	Small Business Administration