

**Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Science Advisory Board (SAB)
Polycyclic Aromatic Hydrocarbon (PAH) Mixtures Review Panel
Public Teleconference of September 30, 2010**

Date and Time: Thursday, September 30, 2010, 1:00 PM – 5:00 PM ET

Location: Teleconference Only

Purpose: The purpose of the meeting was to review the Panel's draft report on EPA's draft technical document, *Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures*.

Participants: PAH Mixtures Review Panel (for full roster, see Attachment A)

Dr. Nancy Kim, Chair
Dr. Shantu Amin
Dr. Frederick Beland
Dr. James Chen
Dr. John DiGiovanni
Dr. Marilie Gammon
Dr. David Gaylor
Dr. Nicholas Geacintov
Dr. Chris Gennings
Dr. Joshua Hamilton
Dr. Edmond LaVoie
Dr. Aramandla Ramesh
Dr. Benjamin Rybicki
Dr. Paul Strickland
Dr. Emanuela Taioli

Mr. Aaron Yeow, Designated Federal Officer (DFO)
Dr. Lynn Flowers, EPA Office of Research and Development (ORD)
Other Attendees (See Attachment B)

Opening Remarks

Mr. Aaron Yeow, the DFO for the PAH Mixtures Review Panel, took roll and then opened the meeting. He noted that as required under the Federal Advisory Committee Act (FACA), the Committee's deliberations are held in public with advanced notice given in the Federal Register¹, and the meeting minutes will be made publicly available after the meeting. He noted that the Panel did not receive any requests from the public to present oral comments and did not receive any written public comments. He noted that the Panel members are in compliance with federal ethics regulations and conflict-of-interest laws that pertain to them. He turned the meeting over to Dr. Nancy Kim, Chair of the PAH Mixtures Review Panel.

Review of Agenda and Purpose of Meeting

Dr. Nancy Kim, Chair of the PAH Mixtures Review Panel, welcomed everyone and stated that the purpose of the meeting was to review the Panel's draft report² on EPA's draft technical document, *Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures*³. She went through the Agenda for the teleconference⁴ and with no public comments, she introduced Dr. Lynn Flowers from EPA's Office of Research and Development for EPA's comments.

EPA Comments

Dr. Lynn Flowers, Acting Associate Director for Health, National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), thanked the Panel for their time and effort in providing advice to the Agency. EPA appreciated the attention to detail that was reflected in the report, but asked the Panel to develop clear recommendations in the report, particularly with respect to rating the quality of studies, developing a weighting scheme, how to deal with tumor multiplicity data, and the handling of positive and non-positive studies.

With no further questions from the Panel, Dr. Kim proceeded on to the discussion of the Panel's response to the charge questions in the Panel's draft report.

Discussion of Responses to Charge Questions

Regarding the response to charge question 1, one Panel member thought that the goal of the development of the 12-15 complex mixtures for bioassay testing was to validate the RPF approach and not to replace the RPF approach. The Panel members stated that the goal was for both, and agreed to revise the report to indicate both goals.

For the response to charge question 4, there was discussion regarding EPA's handling of positive and non-positive studies. There was concern that EPA was throwing out data that did not have statistical significance, which would create unnecessary bias. It was agreed that a discussion of this concern would be added to the report, but that it was probably more suitable for the response to charge question 6.

For the response to charge question 6, there was considerable discussion on 6a. The Panel agreed that this response should convey the following issues: quality of individual studies, variability across studies due to differences in study characteristics, biological relevance of studies, and the issue of statistical significance. It was not clear to the Panel what the last paragraph (5th paragraph) of the draft report was trying to convey and the Panel agreed to delete it. The Panel also agreed to combine the 3rd and 4th paragraphs to reflect the discussion about the variability across studies. A paragraph on the biological relevance will be added and a discussion on statistical significance will also be added. The Panel agreed to delete the response to 6c because this will be reflected in the discussion of statistical significance that will be added to 6a. The Panel members agreed to delete the 3rd paragraph under the response to 6d and the first sentence of the last paragraph.

For the response to charge question 7a, the Panel did not want to make a strong recommendation on whether EPA should or should not calculate RPFs using studies with data characteristics that the Panel was concerned about. There was also discussion that the geometric mean might be more appropriate to use rather than the arithmetic mean when calculating the final RPFs. The Panel agreed that a discussion of the geometric mean will be added to the report. For the response to charge question 7b, there was considerable discussion on how to handle tumor multiplicity data. It was agreed that the 3rd paragraph will be revised to reflect the Panel's discussion on tumor multiplicity.

For charge question 8, it was agreed to merge the discussion of RPFs based on a single dose, especially at high doses (p.31, lines 32-33) with the response to charge question 6a.

Discussion of Executive Summary

Dr. Kim noted that the Executive Summary will be revised to reflect the changes that are made to the body of the report. The Panel members did not have any comments on the Executive Summary.

Discussion of Letter

Dr. Kim also noted that the Letter will be revised to reflect the changes made to the body of the report. The Panel members did not have any comments on the Letter.

Summary of Action Items

Dr. Kim went over the writing assignments and timetable for the finalization of the report.

With the business concluded, the Designated Federal Officer adjourned the meeting at 4:00 PM ET.

Respectfully Submitted:

/SIGNED/

Mr. Aaron Yeow
Designated Federal Officer
EPA SAB Staff Office

Certified as True:

/SIGNED/

Dr. Nancy K. Kim
Chair
PAH Mixtures Review Panel

Materials Cited

The following meeting materials are available on the SAB website: <http://www.epa.gov/sab>, at the [September 30, 2010 PAH Mixtures Review Panel Meeting page](#):

¹ Federal Register Notice Announcing the Meeting

² Draft (09/08/10) SAB Review of EPA's "Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures"

³ *Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures*

⁴ Agenda for September 30, 2010 Teleconference

ATTACHMENT A - ROSTER

U.S. Environmental Protection Agency Science Advisory Board Polycyclic Aromatic Hydrocarbon (PAH) Mixtures Review Panel

CHAIR

Dr. Nancy K. Kim, Senior Executive, Health Research, Inc., Troy, NY

MEMBERS

Dr. Shantu Amin, Professor, Department of Pharmacology, Penn State Hershey Cancer Institute, Penn State College of Medicine, Hershey, PA

Dr. Frederick Beland, Director, Division of Biochemical Toxicology, National Center for Toxicological Research, U.S. Food and Drug Administration, Jefferson, AR

Dr. James Chen, Senior Biomedical Research Service/Senior Mathematical Statistician, National Center for Toxicological Research, U.S. Food and Drug Administration, Jefferson, AR

Dr. John DiGiovanni, Professor and Coulter R. Sublett Chair in Pharmacy, Division of Pharmacology and Toxicology and Department of Nutritional Sciences, Dell Pediatric Research Institute, The University of Texas at Austin, Austin, TX

Dr. Marilie Gammon, Professor, Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. David Gaylor, President, Gaylor and Associates, LLC, Eureka Springs, AR

Dr. Nicholas Geacintov, Professor, Chemistry, New York University, New York, NY

Dr. Chris Gennings, Professor, Department of Biostatistics, Medical College of Virginia, Virginia Commonwealth University, Richmond, VA

Dr. Joshua Hamilton, Chief Academic and Scientific Officer; Senior Scientist, Bay Paul Center for Comparative Molecular Biology and Evolution, Marine Biological Laboratory (MBL), Woods Hole, MA

Dr. Edmond LaVoie, Professor and Chair, Department of Pharmaceutical Chemistry, College of Pharmacy, Rutgers, The State University of New Jersey, Piscataway, NJ

Dr. Aramandla Ramesh, Assistant Professor, Biochemistry and Cancer Biology, School of Medicine, Meharry Medical College, Nashville, TN

Dr. Benjamin Rybicki, Senior Scientist, Department of Research
Epidemiology and Biostatistics, Henry Ford Hospital, Detroit, MI

Dr. Paul Strickland, Professor, Environmental Health Sciences, Bloomberg School of Public
Health, Johns Hopkins University, Baltimore, MD

Dr. Emanuela Taioli, Professor, Department of Epidemiology and Biostatistics, School of
Public Health, State University of New York (SUNY) Downstate Medical Center, Brooklyn, NY

SCIENCE ADVISORY BOARD STAFF

Mr. Aaron Yeow, Designated Federal Officer, United States Environmental Protection Agency,
Washington, DC

ATTACHMENT B – Other Attendees
SAB PAH Mixtures Review Panel Teleconference
September 30, 2010

The following people either pre-registered for the teleconference or indicated that they were on the teleconference.

| Name | Affiliation |
|------------------------|--|
| Arietta, Daniel | Chevron Phillips Chemical |
| Arp, Earl | Asphalt Institute |
| Beck, Nancy | OMB |
| Brock, Samuel | Air Force |
| Carlson-Lynch, Heather | SRC, Inc. |
| Daughtrey, Wayne | ExxonMobile |
| Dicosmo, Bridget | Inside EPA |
| Gehlhaus, Martin | EPA |
| Goyak, Katy | ExxonMobil Biomedical Sciences, Inc |
| Hansen, Emily | Minnesota Department of Health |
| Herbrandson, Carl | Minnesota Department of Health |
| Keshava, Channa | EPA |
| Kurtz, Katharine | Navy |
| Lehuray, Anne | Pavement Coatings Technology Council |
| Maston, Scott | NIEHS/NTP |
| McClure, Peter | SRC, Inc. |
| Morris, Mark | Coopers Creek Chemical Corporation |
| Nesnow, Stephen | EPA |
| Phillips, Tracie | Texas Commission on Environmental Quality (TCEQ) |
| Pugh, Barbara | AMEC Earth and Environmental |
| Putzrath, Resha | Navy |
| Rider, Cynthia | NIEHS/NTP |
| Rohr, Annette | EPRI |
| Roper, Chad | AECOM |
| Ruiter, J. Bart | Dupont |
| Sande, Kate | Minnesota Department of Health |
| Stickney, Julie | SRC, Inc. |
| Teuschler, Linda | EPA |
| Vrahopoulou, Elisabeth | ExxonMobile |
| Wampler, Steve | AquAeTer, Inc. – Denver |
| Wang, Vera | Navy |
| Wilson, Linda | NY State |
| Wise, Kimberly | API |
| Zimmerman, Meegan | AECOM |