

**MINUTES FROM THE EPA SCIENCE ADVISORY BOARD**  
**SAB Exposure and Human Health Committee**  
**Public Meeting**  
**July 1-2, 2010**  
**The St. Regis, 923 16<sup>th</sup> and K ST. NW, Washington DC 20006**

**ATTENDANCE**

SAB EHC Members

Dr. Deborah Cory-Slechta  
Dr. Claude Emonde  
Dr. Alfred Franzblau  
Dr. Chris Jennings  
Dr. Robert Goble  
Dr. Cynthia Harris  
Dr. Russ Hauser  
Dr. Laurie Haws  
Dr. Darryl Hood  
Dr. Kristen Moysich  
Dr. David Ozonoff  
Dr. Gloria Post  
Dr. Virginia Rauh  
Dr. P. Barry Ryan  
Dr. John Vena  
Dr. Clifford Weisel  
Dr. Robert Wright  
Dr. Thomas Zoeller

SAB Staff Office

Dr. Sue Shallal, Designated Federal Officers (DFO)  
Dr. Vanessa Vu, Director

EPA Representatives

Dr. Peter Preuss  
Dr. Vicki Delarco  
Mr. William Jordan  
Dr. Kathryn Gallagher  
Dr. Edward Ohanian

Other Participants

See Attachment A for the list of other participants including other EPA personnel and members of the public who were present at the meeting or participated by phone

## MEETING MATERIALS

The following meeting materials were available prior to or during the July 1-2, 2010 meeting and were available on the general SAB Web site, <http://www.epa.gov/sab>, and specifically .at the following URL:

<http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/9c1d2472d2036f358525756e00522362!OpenDocument&Date=2010-07-01>

- FEDERAL REGISTER NOTICE
- MEETING AGENDA
- COMMITTEE ROSTER
- AGENCY BRIEFING MATERIAL
  - OPP Presentation by Dr. Vicki Dellarco and Mr. William Jordan. (PDF, 33 pp., 702,945 bytes)
  - ORD Presentation by Dr. Peter Preuss. (PDF, 29 pp., 990,583 bytes)
  - RAF Presentation by Dr. Edward Ohanian and Dr. Kathryn Gallagher. (PDF, 50 pp., 668,920 bytes)

## PURPOSE

To provide an opportunity for EPA representatives to brief the EHHC on ongoing and planned human health risk assessment activities. The briefings will serve as background information for the Committee to develop advice on the subject areas.

## LOCATION

The St Regis, 923 16th Streets, NW, Washington DC 20006

## DATE AND TIME

The meeting was held on July 1, 2010 from 9:00 a.m. to 5:00 p.m. (Eastern Time) and July 2, 2010 from 9:00 a.m. to 12:30 p.m. (Eastern Time).

## MEETING SUMMARY

The discussion generally followed the meeting agenda unless it was noted in the meeting summary below.

### July 1, 2010

#### Convene the Meeting and Introductory Remarks

Dr. Suhair Shallal, Designated Federal Officer (DFO), opened the meeting at 1:00 PM. She presented background information on the SAB committee formation process and informed the audience that the SAB operates under the rules and regulations of FACA that required all meetings where discussions and deliberations take place must be held in public. She stated that

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none of the committee members required waivers as they did not have any conflict of interest or lack of impartiality issues.

Dr. Vanessa Vu thanked the Chair and members of the SAB committee. She indicated that the EHHC had not met in some time and this is an opportunity to hear about EPA's ongoing and future health and exposure risk assessment initiatives.

### Review of Agenda

Dr. Cory-Slechta thanked the committee members for their participation in this meeting and she reviewed the Agenda. She then asked committee members to briefly introduce themselves. Afterwards, she asked EPA representatives to give their presentations and informed the committee members that they would have an opportunity to ask clarifying questions.

Agency Presentations (EPA's power point presentations are available on the SAB meeting web page identified above under "Meeting Materials").

Mr. William Jordan of EPA's Office of Pesticide Programs (OPP) was the first presenter. He explained EPA's regulatory mandates that govern the registration and re-registration of pesticides. He then described OPP's organizational structure and their federal and international partners. He continued with a description of the various policy and science initiatives that are currently underway. One initiative he mentioned is referred to as "21<sup>st</sup> Century Computational Toxicology". Dr. Vicki Delarco, also representing OPP, followed with a brief overview of this initiative which is based on the NRC 2007 "Toxicity Testing in the 21st Century: A Vision & Strategy" recommendations. She presented the benefits of the toxicity pathway-based paradigm. The benefits, she explained, include - 1) a broader coverage of chemicals, end points, life stages; 2) using mechanistic & dose information for risk assessment; 3) reducing the cost and time of testing, increasing efficiency and flexibility; and 4) using fewer animals.

The next presenters were Dr. Edward Ohanian, Chair of the Risk Assessment Forum (RAF) and Dr Kathryn Gallagher, Executive Director of the RAF; they described the organizational structure and the activities of the forum. Their presentation was divided into two parts; half was presented before the lunch break and the other half after lunch. They began the presentation by explaining that the mission of the RAF is to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment guidance. They provided an overview of the various oversight groups that make up the forum and the process by which RAF work products are developed. They gave further details regarding current and upcoming projects that the forum has underway. Current projects include, updating the Guidelines for Exposure Assessment, developing an Interagency Microbial Risk Assessment Guidance, and conducting an internal EPA Human Health Risk Assessment Colloquium (October 2010). Other projects being planned include, developing Computational Tools Training, Ecosystem Services, Strengthening Consideration of Ecological Effects in Decision-making, and establishing a Cross-EPA Ecological Risk Assessment Community of Practice.

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Dr. Peter Preuss, Director of EPA's National Center for Environmental Assessment (NCEA), followed with a presentation on the human health risk assessment activities that NCEA is engaged in. They include - IRIS and other priority health hazard assessments, State-of-the-science risk assessment models, methods, and guidance and Air Quality Integrated Science Assessments (ISA). He noted that the landscape of risk assessment is changing to an extent that significant modernization of risk assessment is necessary. These changes are driven largely by advances in understanding the gene environment; the important input and advice from expert science panels; and volumes of new test data from Europe. He explained the development of new methods and strategies to try to respond to the changing needs of risk assessment. One such strategy is known as NextGen; the goal of the NextGen strategy is to map a course forward, focusing on creating 1st approximation NextGen risk assessments, learning from these efforts and, then, refining the next versions based on this new knowledge. He concluded that it may take a decade before risk assessment can rely primarily on these new advances in science. It is necessary, however, to begin now to address needed changes

Committee members asked clarifying questions regarding the activities that EPA has underway. They asked about initiatives focused on reducing the reliance on uncertainty factors, the use of genomics data in risk assessment, and assessing the risk from exposures occurring at different life-stages. Agency representatives responded that there are a number of activities that attempt to address these issues, including the development of PBPK models to estimate internal doses, development of guidance on the use of genomics data, and new technologies such as the "virtual liver".

After the dialogue period ended, Dr. Cory-Slechta asked committee members to think about how they would like to proceed with giving advice to the Agency on improving human health and exposure assessment. The meeting was adjourned at approximately 5:00 PM.

### **July 2, 2010**

The meeting reconvened at 9:00 AM. Dr. Cory-Slechta began the meeting by asking committee members if they had any thoughts or ideas about how to proceed with giving advice to the Agency. She asked the members about the role they believed that the EHHC should play.

Committee members commented that the EHHC should be used to provide intellectual "push back" for the Agency's assessment and guidance documents. The EHHC could assist the Agency in determining if the best, most current science and technology was being implemented appropriately.

When asked how the EHHC had been used previously, Dr. Vu explained that historically two committees, the Integrated Human Exposure Committee (IHEC) and Environmental Health Committee (EHC), provided peer review and advice regarding the Agency's human health and exposure assessments and other documents. Recently, these two committees were merged to form the EHHC. These committees were well-suited to review and comment on documents that deal with general scientific issues, such as guidance documents, research strategies, etc. Recently, the Agency has been asking the SAB to review IRIS documents and other more

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chemical-specific assessments. Most of these reviews require the EHHC membership to be augmented with chemical-specific experts (e.g., Exposure guidelines required augmented EHHC, Microbial Risk Assessment augmented with DWC or other committee members).

Committee members continued to discuss the role of the EHHC and suggested that they should provide advice and recommendations to enhance the scientific under-pinning of the Agency's work products. Members suggested that the EHHC can provide an alternative prospective and ensure that elements, such as, environmental justice (EJ) issues, children's health, and new endpoints are not overlooked. Other members added that EHHC can also help the Agency identify emerging technologies to address – e.g., low dose extrapolation, early-life exposure, and chemical mixtures. Several members noted that there are other EPA advisory groups that provide advice to the Agency on some of these same issues. They include the National Environmental Justice Advisory Council (NEJAC), the Board of Scientific Counselors (BOSC), the Children's Health Protection Advisory Committee (CHPAC) and others. Other members pointed out that the Agency may gain insight on how to deal with these issues through collaborative efforts with other federal and international organizations.

At the conclusion of the meeting, the committee agreed that before meaningful advice could be rendered, more information was needed about the Agency's human health and exposure programs and initiatives. Dr. Shallal asked committee members to visit the EPA website to try to find further information on some of the topics and issues that were discussed, such as, environmental justice programs, international collaboration efforts, and environmental impacts on children, elderly and other susceptible populations. She also stated that she would send an e-mail requesting availability in order to determine the best time for another meeting.

Dr. Cory-Slechta thanked members for their participation. The meeting adjourned at approximately 12:15 PM.

Respectfully Submitted:

\_\_\_\_\_/s/  
Dr. Suhair Shallal  
Designated Federal Officer,  
EPA SAB Inorganic Arsenic Cancer Review Committee

I certify that these minutes are accurate to the best of my knowledge:

\_\_\_\_\_/s/  
Dr. Deborah Cory-Slechta  
Chair,  
EPA SAB Exposure and Human Health Committee

**ATTACHMENT A**

Other Participants

Julie Fitzpatrick	EPA
Pat Rizzuto	BNA
Norman Birchfield	EPA
Maria Hegstad	Inside EPA
Steve Via	AWWA
Kimberly Wise	API
Michael Broder	EPA

Participated via teleconference

Katharine Kurtz	NAVY
Julie Jolly	Lewis-Burke Associates LLC
Marian Olsen	EPA
Glenn Suter	EPA