

**Summary Minutes of the  
U.S. Environmental Protection Agency  
Science Advisory Board  
Exposure and Human Health Committee and FIFRA SAP liaisons  
Teleconference  
September 24, 2012**

EHHC members: Dr. R. Thomas Zoeller, Chair  
Dr. Claude Emond  
Dr. Anna Fan  
Dr. Alfred Franzblau  
Dr. Maida Galvez  
Dr. Chris Gennings  
Dr. Gary Ginsberg  
Dr. Robert Goble  
Dr. Russ Hauser  
Dr. Laurie Haws  
Dr. Darryl Hood  
Dr. Gloria Post  
Dr. Barry Ryan  
Dr. John Vena  
Dr. Clifford Weisel  
Dr. Robert Wright

FIFRA SAP liaisons: Dr. Janice Chambers  
Dr. Daniel Schlenk

Purpose: To discuss the committee's draft report.

Designated Federal Officer: Dr. Suhair Shallal

Other EPA Staff: Tina Bahadori, Kevin Crofton, Gail Bentkover

Public: Rick Becker (ACC), Pat Rizzuto (BNA), Nancy Beck (ACC), Ann Claassen (Latham & Watkins LLP), Danielle Pfeiffer (ARCADIS U.S. Inc), Fran Kruszewski (American Cleaning Institute), Catharine Collar (AFCEE/TDV), Linda Wilson (NY State Office of the Attorney General), John Kephart (Investa), Chris Murray (GAO), Casey Deitrich (CQ Transcriptions), Paul Price (Dow Chemical Co.), Jennifer McPartland (EDF), Puneet Kollipara (Inside Washington Publ.), Wendy Hillwalker, Michael Dourson (TERA), Shaila Rao (Chemtura Corp.), Chris Knight (Pesticide and Chem Policy), Craig Rowlands (Dow Chemical Co.),

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/A4E524574FF64AA085257A5C00793652?OpenDocument>

- Agenda
- Federal Register Notice
- Committee Charge
- Roster
- Draft Report
- Committee-Developed Material
- Public Comments

### Meeting Summary

The discussion followed the plan presented in the meeting agenda.

### Opening Remarks

Dr. Shallal convened the meeting and read the names of committee members to confirm who was on the phone line. Drs. Fan-Cheuk, Fransblau, Moysich and Rauh did not participate in the teleconference. Dr. Shallal then explained that the Science Advisory Board operates under the Federal Advisory Committee Act and that no committee member had any conflict of interest or lack of impartiality issues. She informed participants that there had been a previous meeting of the committee held on May 30-31, 2012. Dr. Zoeller described the purpose of the meeting as an opportunity to discuss the draft report of the committee and the associated letter to the Administrator. He then reviewed the agenda and asked Dr. Kevin Crofton of EPA's Office of Research and Development (ORD) to present his comments.

### Agency Comments

Dr. Crofton thanked the committee for the recommendations in the report and highlighted areas where the agency had already begun to try to implement some of the advice. In the area of communications, both internally and externally, the agency has developed mechanisms for more interaction among the regions and the CompTox center, he said. There is also an ongoing collaboration with outside experts through the "Communities of Practice" effort. He also mentioned that the agency is addressing the need to incorporate more exposure information into the assessments as the committee recommended by developing more high-throughput exposure models. Efforts to account for metabolism of chemicals are also underway through the use of *in vitro* and *in silico* methods, as well as, conducting experiments in the presence or absence of S9 fractions. He concluded his remarks by mentioning that he needed to leave the teleconference early but the Dr. Tina Bahadori would be available throughout the teleconference to respond to any questions from committee members.

Dr. Zoeller thanked Dr Crofton and then asked Dr. Richard Becker of ACC, the only registered public speaker, to present his oral comments.

### Public Comments

Dr. Becker commended the committee on its report and suggested that they consider several additional recommendations. Those recommendations include the need to enhance scientific confidence in the assays and prediction models being used depending on their specific intended use,

e.g., a lesser degree of confidence may be acceptable for priority setting compared to the confidence required for hazard characterization. He agreed with the committee's recommendation to develop a Data Use Guidance. He noted it is needed not only for the assays themselves, but also for the prediction models and related tools, such as ToxPi. He added that there is a need for transparent data quality control / quality assurance programs for the Comptox databases. There is also a need to have the actual data available for external analysis, verification of prediction models, and for development of new and improved models. Finally, he suggested that there should be more transparency in the NexGen program.

Dr. Zoeller thanked Dr. Becker for his comments and asked him to provide them in written format (which he did). Dr. Zoeller asked committee members if they had any questions for the speakers. There were no questions; he then asked members if they had comments regarding the report and letter to the Administrator.

### Committee Discussion

It was noted that the agency was aware of the challenges in implementing the CompTox information into chemical assessments. Their focus is on "operationalizing" the Adverse Outcome Pathways (AOPs) [finding ways to use them]. Members suggested that the current use of this data occurs mainly when no other data is available. Identifying upstream events in the pathways would allow the prediction of disease. As suggested by the public speaker, defining and characterizing the data used for each application is necessary.

A member noted that AOPs are focused on animal models and the challenge is to include human disease as outcomes. Animal pathways may or may not be the same as animal pathways.

One committee member noted that multiple layers of replication are needed in order to have confidence in the results of assays. He stated that, in a random standard-design assay, there are usually many false positives. Agency representatives explained that the information is currently being used for prioritizing only. Acceptable data is therefore less stringent. The agency is using this method to understand the assays and to gain more confidence in their reliability. Furthermore, the assays should be seen as a group and not in isolation. There are 2 approaches being implemented, 1) looking for a series of events that would indicate a positive outcome, i.e., 16 assays that would show the same effect – redundancy and 2) repeating the same assay several times to ensure that you see a true result – duplication.

It was suggested that the Deep Water Horizon (DWH) event should be used as an example which indicates that a guidance document on how and when to use the data is needed. Others noted that it should be used as a learning opportunity to understand the usefulness of such data and how to use it in the future.

Committee also identified several areas within the report and letter that require further clarification or revision. These include, a) explaining the concerns surrounding the use of CompTox data for decision-making in the case of the DWH incident (p.7). b) clarifying what is meant by "...assays were not developed for examples of current health trends." ( p. 13 lines 4-5). c) The statements regarding communication and interactions amongst program offices and ORD should be consistent (see p.7 line 4 and p. 2). d) Since CompTox data usually does not include

exposure data, there should be an effort to distinguish between hazard and risk. e) Revise the sentence on p. 1 lines 37-39, by removing the term interaction and replacing it with co-occurrence or in combination. F) Also revised and clarify the sentence on p. 10 line 13.

Dr. Zoeller asked if anyone had any additional comments. A suggestion was made to ask committee members for their top 5 recommendations that should be included in the letter to the Administrator. Dr. Zoeller agreed and asked committee members to submit their recommendations along with their suggested edits to Dr. Shallal. Dr. Zoeller then asked Dr. Shallal to explain the next steps in the report writing process.

Dr. Shallal began by asking committee members to provide their suggested edits and their 5 recommendations to her by October 15. She explained that she will work with Dr. Zoeller to incorporate the member's comments into a revised version of the report and would re-send it to committee members for their concurrence during the week of October 29. Additional final edits would be made, if needed, after members review the revised report. The final draft report will then be transmitted to the chartered Board for their review and approval. After the Board's edits are incorporated, it will be finalized and sent to the Administrator. Before adjourning, she also reminded members to cc: her on any correspondence with others regarding the subject matter under review.

The teleconference adjourned at 4:00 pm

On Behalf of the Committee,  
Respectfully Submitted,

/s/  
Suhair Shallal, Ph.D.  
Designated Federal Officer

Certified as Accurate:

/s/  
R. Thomas Zoeller, Ph.D.  
Chair, SAB Exposure and Human Health Committee

**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 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.