

**Summary Minutes of the  
U.S. Environmental Protection Agency  
Science Advisory Board  
Chemical Assessment Advisory Committee Augmented for the Review of the Draft IRIS  
Ammonia Assessment (CAAC-Ammonia Panel)  
Teleconference  
June 4, 2014**

**CAAC-Ammonia Panel Members:**

Dr. Michael Dourson, CHAIR  
Dr. Daniel Acosta  
Dr. Henry Anderson  
Dr. Scott Bartell  
Dr. Arthur Cooper  
Dr. David Eastmond  
Dr. William Michael Foster  
Dr. Russ Hauser  
Dr. Abby A. Li  
Dr. Jacob McDonald  
Dr. Maria Morandi  
Dr. Victoria Persky  
Dr. Richard Pleus  
Dr. Kenneth Ramos  
Dr. Alan Stern  
Dr. I. David Weiner

**Purpose:** To allow panel members to learn about the development of the agency's draft Integrated Risk Information System (IRIS) *Toxicological Review of Ammonia* (August 2013 Revised External Review Draft), to learn about the Health and Environment Research Online (HERO) database and to discuss the charge questions.

**Attendees:** see Appendix 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/3DBA2DA9C994064185257C980064D2CA?OpenDocument>

- Agenda
- Federal Register Notice
- Agency Briefing Material
  - Health and Environmental Research Online powerpoint slides
  - Overview of the Draft IRIS Assessment of Ammonia powerpoint slides
- Presentation by Registered Public Speaker
  - Statement by Dr. Nancy Beck of the American Chemistry Council
  - Statement by Mr. Roger Stacy on behalf of The Fertilizer Institute
  - Submission by Mr. Kevin Bromberg of the U.S. Small Business Administration

- Public comment submitted to the SAB Staff Office
  - Center for Advancing Risk Assessment Science and Policy (CARASP) Comments to EPA on the draft IRIS Ammonia Assessment dated August 6, 2012
  - Comments on the IRIS Program submitted to the NRC by the American Chemistry Council and Center for Advancing Risk Assessment Science and Policy dated January 30, 2013
  - Letter submitted to the SAB Chemical Assessment Advisory Committee by the American Chemistry Council and the Center for Advancing Risk Assessment Science and Policy June 24, dated August 20, 2013.

### **Meeting Summary:**

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

### **Wednesday June 4, 2014**

#### Opening Remarks

Dr. Shallal convened the meeting and called the roll. All CAAC-Ammonia panel members were present except Drs. Acosta, Bartell, Foster, Persky and Pleus. Dr. Shallal explained that the SAB CAAC-Ammonia 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.

She then reminded all participants that the meeting materials were available on the SAB website. Mr. Christopher Zarba, the Director of the SAB Staff Office, welcomed and thanked panel members for their willingness to serve on this panel. Dr. Shallal then turned the meeting over to Dr. Dourson, Chair of the CAAC-Ammonia Review Panel.

Dr. Dourson reviewed the agenda and then invited the EPA representatives to begin their presentations. Dr. Kenneth Olden Director of EPA's National Center for Environmental Assessment (NCEA) was unable to attend and Dr. Cogliano, Acting Director of the EPA's IRIS Program, provided some opening remarks on his behalf. He stressed the commitment of the IRIS program to be more transparent and engage in meaningful dialogue with stakeholders at multiple intervals during the development of the IRIS assessments. He explained that the IRIS Toxicological Review of Ammonia was released in 2012 and then revised and re-released in August 2013. The document had been modified to incorporate some of the new enhancements but does not completely reflect the current format of IRIS assessments. He referenced the latest NRC report on the IRIS program that commends the EPA for the changes made thus far but the group also recommended further changes.

The next speaker was Ms. Debra Walsh, Acting Deputy Director of EPA NCEA. She presented an overview of the Health and Environment Research Online (HERO) database. The database allows readers to access references that are cited in the assessments. She explained the steps for creating a user account in HEROnet. Members of the review panel, she said, are able to access a full copy of all studies cited in the assessment; whereas, members of the public are able to access only non-copyrighted materials, including the citation and abstract.

Ms. Susan Rieth of the NCEA IRIS Program then presented an overview of the IRIS Toxicological Review of Ammonia. She talked about the new format of the IRIS assessments and other changes that will be included in future assessments. She then reminded the panel that the Ammonia assessment focused on the risks associated with gaseous ammonia and ammonium hydroxide (ammonia dissolved in water). Studies using ammonium salts were not considered. She explained the strategy for selecting gathering and evaluating relevant studies. Ms. Rieth also summarized the conclusions presented in the Ammonia assessment, including the studies that were used in the assessment, the selection of the most sensitive endpoints, the derivation of an RfC, and the rationale for not deriving an RfD and cancer slope factor.

Ms. Reith was questioned by panel members regarding the lack of an RfD derivation. She stated that studies using chronic doses were not available. She also noted that the data was heterogeneous and not amenable to Benchmark Dose (BMD) modeling.

Dr. Dourson thanked the EPA presenters and asked members of the public that had registered to provide comments to the panel to begin their presentations. Three individuals had registered to present oral comments at the meeting (see Appendix B).

Mr. Roger Stacy of Agrium, Inc. presented on behalf of The Fertilizer Institute (presentation posted on the SAB website). He stated the 2011 NAS recommendations have not been fully implemented and that a clear and transparent rationale for dismissing public comments on the draft ammonia assessment was not provided. In addition, he suggested that the panel should rely on the findings of the Committee on Acute Exposure Guideline Levels (AEGL) which in 2008 selected an AEGL-1 of 30 ppm as a point of departure for the derivation of the RfC.

Some panel members stated that the AEGL values are intended for the general population and may not account for susceptible population (e.g., children and elderly). Furthermore, panel members stated that the ammonia AEGL was based on irritation which is an acute effect and not lung function, the endpoint selected by EPA according to the draft assessment.

Mr Kevin Bromberg of the U.S. Small Business Administration then addressed the panel. He suggested modifications (available on the SAB website) to the panel's charge questions. He also requested that more time be allotted to registered public speakers.

Dr. Nancy Beck of the American Chemistry Council was the next speaker (presentation posted on the SAB website). She stated that EPA had not implemented the 2011 NAS recommendations. She also noted that the format of the IRIS assessment had changed and a large portion of the supporting information had been placed in a supplemental document. She also contended that a robust systematic review had not been conducted for the assessment of ammonia. She then encouraged panel members to suggest a strategy for ensuring the recommendations from the public and peer reviewers are appropriately addressed. Finally, she asked panel members to provide clarification regarding the effect of endogenous production of ammonia on the systemic level of ammonia.

Dr. Dourson thanked the public commenters and turned to the next agenda item, the discussion of the charge questions. Panel members discussed the charge and offered edits that were intended to clarify the questions. The panel also discussed suggested modifications offered by public commenters and



## Appendix A List of Attendees

Ravi Subramaniam  
Richard Windsor, Apple  
Ted Berner  
Debra Walsh  
Pat Rizzuto  
P White  
Jesus Peralta  
Bob Fensterheim  
Jim Kim  
Maria Hegstad (Inside EPA)  
Mary Ross  
Wade Foster  
Norman Birchfield  
Jacqueline Sibblies  
YS Lin  
Sury Vulimiri  
Nancy B  
Ted Berner  
Kacee Deener  
James Weaver  
Jinot, EPA  
Allen Davis  
Roger Stacy  
Kevin Bromberg  
Kimberly Wise  
Dahnish Shams  
Robert Fensterheim  
Resha Putzrath  
Debra Walsh  
Audrey Galizia  
Maureen Johnson

Appendix B

**U.S. Environmental Protection Agency  
Science Advisory Board  
Chemical Assessment Advisory Committee (CAAC)  
Augmented for the Review of the EPA's Draft IRIS Ammonia Assessment  
June 2, 2014 Teleconference**

List of Registered Speakers\*

- 1- Mr. Wade Foster, The Fertilizer Institute (WITHDREW)
- 2- Mr. Roger Stacy, Agrium Inc.
- 3- Dr. Kimberly Wise, American Chemistry Council (WITHDREW)
- 4- Mr. Kevin Bromberg, Small Business Administration
- 5- Dr. Nancy Beck, American Chemistry Council

\*The SAB Staff Office previously announced (79 FR 16326-16327) that requests to provide oral statements to the CAAC-Ammonia Panel were to be received in the SAB Staff Office by May 27, 2014. The registered speakers will present their statement in the order in which the Staff Office received requests.