

**U.S. Environmental Protection Agency  
Science Advisory Board  
Chemical Assessment Advisory Committee (CAAC)**

**Public Meeting  
September 27-28, 2017**

**Minutes of the Meeting**

**Location:** Residence Inn Arlington Capital View, 2850 S Potomac Ave, Arlington, VA 22202.

**Purpose:**

The SAB CAAC will receive a briefing from the EPA's NCEA on the content and presentation of draft assessment products that represent an update to the IRIS enhancements of 2013. These materials are expected to add transparency and increase throughput and responsiveness to Agency needs.

**Participants:**

**CAAC Members:**

Attended in-person

Kenneth Ramos  
Henry Anderson  
Hugh Barton  
James Bruckner  
Karen Chou  
Deborah Cory-Slechta  
Joanne English  
Abby Li  
Melanie Marty  
Maria Morandi  
Victoria Persky  
Lorenz Rhomberg  
Alan Stern

Attended via teleconference

Stephen Roberts  
Alison Cullen  
Cynthia Harris  
Tamara James-Todd  
Isaac Pessah  
Tiffany Bredfeldt

**SAB Staff:**

Mr. Christopher Zarba, Director, SAB Staff Office  
Dr. Sue Shallal, SAB Staff Office

**Other Attendees:** See Attachment A.

## **Meeting Materials and Meeting Webpage:**

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

<https://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/b993d2c54053cd9a8525817d005fd1e2!OpenDocument&Date=2017-09-27>

### Agenda

#### Federal Register Notice

#### Chemical Assessment Advisory Committee Roster

#### Agency Briefing Materials:

- Draft IRIS Assessment Plan for Chloroform
- Draft IRIS Assessment Plan for Ethylbenzene
- Draft IRIS Assessment Plan for Nitrates/Nitrites
- IRIS Assessment Plan for Chloroform Presentation. Ted Berner
- IRIS Assessment Plan for Ethylbenzene Presentation. Paul Reinhart, Ph.D.
- IRIS Assessment Plan for Nitrate-Nitrite presentation. Larissa Pardo and Jenny Li, PhD.
- IRIS Assessment Plans - Background and Overview.
- IRIS Today-An Update on Progress presented by Tina Bahadori, Ph.D. and NCEA Staff.

#### Committee-Developed or Provided Background Material

- Citations provided by Dr. Alison Cullen

#### List of public speakers

- List of Registered Speakers

#### Presentation by Registered Public Speaker

- Presentation by Dr. George Cruzan of Tox works on behalf of the Styrene Information and Research Center.
- Presentation by Dr. Neeraja Erraguntla on behalf of the American Chemistry Council (ACC).

## **Meeting Summary:**

The meeting was held on September 27-28, 2017. The discussion followed the topics as presented in the meeting agenda.

## **Wednesday September 27, 2017**

### **Opening of Public Meeting:**

Dr. Suhair Shallal, the Designated Federal Officer (DFO), convened the meeting with a statement reminding the audience that the SAB Chemical Assessment Advisory Committee (hereafter referred to as the CAAC), operates under the Federal Advisory Committee Act (FACA). Under FACA, Dr. Shallal noted that committee meetings are held in public with advanced notice given in the Federal Register. The SAB consists entirely of special government

employees appointed by EPA to their positions. As special government employees, all the members are subject to all applicable ethics laws and implementing regulations.

Dr. Shallal stated that for this SAB advisory activity, no conflict of interest or loss of impartiality issues were identified for any committee member as this was only a briefing. No advice was being provided to the EPA. She then reminded all participants that the meeting materials were available on the SAB website. She then called the roll (see Committee Roster denoting attendance) and turned to Mr. Christopher Zarba, Director of the SAB Staff Office, who welcomed and thanked members for their participation. Dr. Kenneth Ramos, Chair of the CAAC, followed by offering welcoming remarks and inviting committee members to introduce themselves. He then reviewed the meeting agenda and invited the EPA representatives to begin their presentations.

#### **EPA Presentations:**

Dr. Tina Bahadori, Director of the EPA National Center for Environmental Assessment (NCEA), began the EPA presentation and provided background information about the IRIS Program. She described the initiatives underway in response to the NAS recommendations. She noted that they had developed new approaches for conducting systematic reviews of the studies used in IRIS Toxicological Reviews. Dr. Kris Thayer, IRIS Program Director, and Dr. Andrew Kraft then presented the systematic review approach being adopted by the IRIS Program. They explained in detail the steps for completing such a review. Other EPA presenters included, Dr. Jason Fritz, Dr. Michele Taylor, Dr. Xabier Arzuaga, Dr. Beth Radke and Dr. Barbara Glenn. Each presenter focused on one aspect of the systematic review process. They described the problem formulation and scoping step or IRIS Assessment Plan (IAP) and then provided a demonstration of the study evaluation, and synthesis and integration steps using various automation tools (e.g., SWIFT and HAWC).

Committee members asked clarifying questions and voiced concerns about discerning between and managing large numbers of pertinent and irrelevant studies. In response, EPA representatives clarified the purpose of the IAP was to limit the scope of the study search. They noted that public input would also can aid in gathering information and determining if the correct data is being used. They explained that the EPA will look to other authoritative bodies (e.g., ASTDR, IARC, etc.) to understand the areas of concern where time and resources should be devoted to conduct a credible search. An effective way to get others to accept these approaches, committee members suggested, is using previously reviewed chemicals as case studies to determine if the new methods work appropriately to screen the right studies for use in risk assessment.

#### **Public Comments:**

Dr. Ramos thanked the EPA presenters and turned the meeting over to Dr. Shallal for the facilitation of public comments. There was one speaker, Dr. Neeraja Erraguntla of the American Chemistry Council, who registered to present oral comments. Dr. Shallal invited Dr. Erraguntla to present her statement (statement is available on the meeting webpage).

#### **Committee discussion:**

After a lunch break, the Committee returned and offered their impressions of the EPA's proposed approach for systematic review. Committee members stressed the importance of IRIS

assessments for State agencies. They expressed concern that the more sophisticated and comprehensive systematic review being proposed by EPA would be resource intensive and diminish the value of the more rapid and less complex chemical assessments conducted by state scientists. EPA representatives clarified that not all assessments would require the same level of effort and that more streamlined procedures could be followed in many instances.

Committee members cautioned that transparency will not necessarily alleviate controversy. They also suggested that the EPA could use weight of the evidence (WOE) for categorization. Biological plausibility and read across from other chemicals when deriving a reference value were also important considerations. EPA representatives also indicated that they would like to pursue efforts to modularize the IRIS process where not all the information needs to be available before an IRIS assessment can be released, e.g., reference values may be published before issues about a cancer slope factor are resolved. Committee members agreed that this approach would be useful especially for states that rely on IRIS assessment values.

The last speaker for the day was Dr. Jason Fritz. He discussed the utility of IAPs within the IRIS process. He noted that IAPs are developed with partners within the EPA, states and the public. He explained that IAPs describe what will be examined and not how. He made committee members aware of the three IAP case studies that would be presented on the following date – Chloroform, Nitrates/Nitrites and Ethylbenzene.

The meeting recessed at approximately 5:00 p.m. until the following morning.

#### **Thursday, September 28, 2017, 2017**

Dr. Shallal reconvened the meeting at 9:00 am. She turned the meeting over to the Chair, Dr. Kenneth Ramos. Dr. Ramos began by providing a short summary of the previous day's discussions. He noted that the Committee supported the idea of creating modules within an IRIS assessment where not all risk values needed to be derived or all issues/controversies resolved before a portion of the assessment could be published. He also conveyed the support of the committee for the IAP approach that provides an opportunity for more public engagement early in the process.

Committee members expressed their thoughts on the importance of making sure that all materials- the studies, the evaluation of the studies, and the methodologies used- are accessible by the public. They also stressed that states should be allowed to develop less complex assessments to meet their needs. They supported the notion of having the materials available for future use, noting that should additional information be generated, it can easily be integrated.

#### **EPA Presentations:**

Dr. Ramos then called on Mr. Berner, Ms. Pardo and Dr. Reinhart to provide the briefing on the Chloroform, Nitrate/Nitrite and Ethylbenzene IAPs, respectively. They each explained the structure, content and use of the IAP. They said that the IAPs included a brief description of the physical properties of chemical under consideration, the current reference values, the known routes of exposure and the shortcomings of the current assessment. The IAP also discusses the

scope and problem formulation for each assessment. A table outlining the interactions with EPA offices that have requested the updated information and their statutory requirement is also included. They then explained that each IAP contains a PECO (Populations, Exposure, Comparators, and outcomes) statement. A PECO framework is used to focus the research questions, search terms, and inclusion/exclusion criteria in a systematic review.

CAAC members asked clarifying questions to gain a better understanding of the purpose of the IAPs and offered comments on how to improve them. They suggested that more information on exposure may help to focus the assessments. They also noted that using information from other authoritative bodies may help with the collection and consideration of available studies but may also miss some important data. Members remarked that probabilistic approaches may help with evaluating the risks from exposure at different life stages.

Members supported the use of IAPs recognizing they can be a valuable tool for communication. The early input received through public engagement will help to focus and direct the use of resources, they deduced. Creating databases of reviewed studies will be a very important and beneficial step for future updates, as well as, allowing the public access to the background materials used in the assessment. Members, however, agreed that while the new process for developing IRIS assessments may increase transparency and flexibility, it will not necessarily alleviate controversy.

**Public Comments:**

When the EPA presentation on the Ethylbenzene IAP concluded, Dr. Ramos thanked the EPA presenter and turned the meeting over to Dr. Shallal for the facilitation of public comments. There was one speaker, Dr. George Cruzan of Tox works, who registered to present oral comments. Dr. Shallal invited Dr. Cruzan to present his statement on behalf of the Styrene Information and Research Center (statement is available on the meeting webpage).

**CAAC member discussion:**

After a short break, CAAC members shared some final thoughts. They asked EPA representative about the time and resources required to conduct an IRIS assessment using the new systematic review protocols. Members also wondered how new information about polymorphisms and gender differences will be incorporated into new assessments to illuminate concerns that may exist for susceptible populations.

EPA representatives responded that they are currently training staff in the use of the new tools and methods for conducting systematic review. They noted that as more staff are trained and become better acquainted with the processes, the faster and easier the evaluations will become. This will in turn lead to a more efficient and less resource intensive effort. In terms of incorporating new information on polymorphisms, there are papers being written to examine how this data can be included.

CAAC members stressed the importance of IRIS assessments for environmental programs at the state level and agreed that a modular step-wise approach would be helpful. Members supported the idea of completing a partial assessment with the information currently available and deferring other parts for the future. Members also encouraged EPA to acknowledge when there are

unresolved issues and if there are divergent opinions. Before the session ended, Dr. Shallal stated she had received an email from Dr. Bredfeldt who was participating via teleconference. She read her email for the record (email available on the meeting webpage).

In closing, Dr. Ramos urged EPA representatives to embrace three concepts; they are: 1) Partnership, 2) Consultation, and 3) Engagement. In order to increase the likelihood of successfully implementing the EPA's new proposed paradigm for developing IRIS assessments, he said EPA should seek *partnership* with the risk assessment community on how to address the complex issues that may arise; *consultation* with stakeholders outside of EPA and within the EPA to determine the scope of the assessments; and *engagement* with the public so they can gain confidence and trust in the assessments. He then thanked all the presenters and the CAAC members for their participation.

**Meeting Adjournment:**

Dr. Ramos turned the meeting back over to the DFO, Dr. Shallal. She thanked everyone for their attendance and adjourned the meeting at approximately 2:00 pm.

On Behalf of the Committee,

Respectfully Submitted,

Certified as True,

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Suhair Shallal, Ph.D.  
Designated Federal Officer

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Kenneth Ramos, MD Ph.D.  
Chair, SAB Chemical Assessment Advisory  
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 committee 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.

Appendix A

Chemical Assessment Advisory Committee Meeting  
September 27-28, 2017  
Public Attendees

<b>NAME</b>	<b>ORGANIZATION</b>
Pat Rizzuto	Bloomberg BNA
Mark Gibson	ACC
Peter De La Cruz	Keller & Heckman
George Woodall	EPA
Jack Synder	SIRC
George Guzon	ToxWorks
Dahnish Shams	EPA
Ted Berner	EPA
Melanie Yang	EPA
John Bucher	NIEHS
Andrew Hotchkiss	EPA
Susan Rieth	EPA
Vincent Cogliano	EPA
Roman Mesencer	EPA
James Avery	EPA
Vicki Soto	EPA
Jason Fritz	EPA
Elizabeth Radke	EPA
Rebecca Nachman	EPA
Victor Morozou	EPA
Andrew Kraft	EPA
Barbara Soarer	EPA
Emma Lovioe	EPA
Kathleen Raffaele	EPA
Antonio Yaquiar	EPA
Pat Casano	GE
Kelly Garcia	EPA
Karen Hogan	EPA
James Kim	OMB
Lou D'Amico	EPA
Maria Hegstad	Inside EPA
Catherine Gibbons	EPA
Samantha Jones	EPA
Cindy Walzale	MPS