United States Environmental Protection Agency (U.S. EPA)
Science Advisory Board (SAB)/Board of Scientific Counselors (BOSC)
Teleconference for the Chemical Safety for Sustainability/Human Health Risk Assessment (HHRA) Research Breakout Group Focusing on HHRA Research
July 1, 2014
Meeting Minutes

Date and Time: July 1, 2014, 3:00 p.m. – 4:30 p.m. Eastern Time

Location: By telephone.

Purpose: To: (1) provide SAB and BOSC members with a briefing on the EPA Office of Research and Development's (ORD's) HHRA Program and ORD's initial thinking regarding its 2016-2019 Strategic Research Action Plan and (2) allow members to discuss ORD's charge to their committees and preparations for the SAB-BOSC face-to-face meeting on July 24–25, 2014.

Meeting Participants:

SAB/BOSC Members (See rosters for the SAB[1] and BOSC Executive Committees[2])

Dr. Edward Carney, Acting Chair
Dr. Michael Dourson
Dr. Lois Lehman-McKeeman
Dr. Gina Solomon
Dr. Ponisseril Somasunderan
Dr. John Vena

SAB Staff:

Dr. Angela Nugent, SAB Staff Office, Designated Federal Officer (DFO)
Dr. Suhair Shallal DFO for the Chemical Safety for Sustainability/Human Health Risk Assessment (HHRA) Research Breakout Group

Other Attendees:

Dr. John Vandenberg, National Program Director for Human Health Risk Assessment
Attachment A lists members of the public who requested the call-in information for this meeting.

Meeting Materials:

http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/fa98b4c312771f4885257cf200708eb4!OpenDocument&Date=2014-07-01

Meeting Summary:

Convene the meeting

Dr. Angela Nugent, Designated Federal Officer (DFO), formally opened the teleconference and noted that this federal advisory committee meeting of the SAB had been announced in the Federal Register on June 18, 2014 (79 FR 34738-34739). She noted that the meeting had been announced as a briefing/planning meeting so that members of the SAB and BOSC could prepare for a July 24-25, 2014 meeting in Washington, DC to develop advice for the EPA on strategic

research directions. The SAB and BOSC has established an SAB/BOSC Breakout Group to focus particularly on ORD's Chemical Safety for Sustainability/Human Health Risk Assessment (HHRA) research programs.

Dr. Nugent noted that the EPA SAB is an independent, expert federal advisory committee chartered under the authority of the Federal Advisory Committee Act (FACA). The SAB is empowered by law - the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA) - to provide advice to the EPA Administrator on scientific and technical issues that inform EPA's decisions. The BOSC is a separately chartered committee established to provide ORD with advice on technical and management issues associated with its research programs. The DFO noted that the Federal Register notice announcing the meeting had provided the public with an opportunity to provide written and oral comment. There were no advance requests for oral comment and no written comments submitted in advance of the meeting.

Goals and agenda for the meeting

Because Dr. Edward Carney, the acting Breakout Group Chair, joined the call late, SAB member Dr. Michael Dourson welcomed the group and briefly summarized the purpose, to prepare for more extensive discussions on July 24-25, 2014 about ORD's strategic plans for Human Health Risk Assessment research.

Presentation on the Human Health Risk Assessment Research Program

Dr. John Vandenberg, National Program Director for the HHRA Research Program, began his discussion by thanking members for their service. He said that he looked forward to their early input into the development of the HHRA Strategic Research Action Plan (StRAP) for 2016-2019. He gave a slide presentation[3] that: (1) showed how the program aligned with the EPA's strategic goals; (2) provided a problem statement and vision statement linked to EPA's priorities and mandates; (3) described how the research fits into the HHRA program, which also generates a variety of assessments to meet the EPA's needs; (4) gave an overview of resource trends; and (5) provided a conceptual model of how research would advance cumulative risk assessment for community and site-specific risk. He briefly described future research directions to advance: (1) exposure and dosimetry approaches; (2) understanding of dose/duration/response complexity; (3) applications and integration of new data, including data from ORD's Chemical Safety for Sustainability (CSS) program; (4) assessment development methods; and (5) methods for stakeholder engagement and risk assessment training

Informational questions from the Breakout Group members

Dr. Edward Carney, who had joined the call early during the HHRA presentation, moderated questions from breakout group members. Dr. Vandenberg provided the following information in response to questions.

- Although slide 20 shows data from the REACH program feeding into RapidTox Assessments, the EPA will need to evaluate the quality of REACH data differently from other data. Dr. Vandenberg did not yet know much role those data will play. REACH data may be most useful for screening activities.
- The draft HHRA StRAP to be released on July 2, 2014 should reflect international collaboration with organizations such as World Health Organization, and the European

Union REACH program. "Read across" methodology might be used towill help ORD identify early signals of potential effects, and chemicals of interest.

- EPA realizes that different hazard assessments may generate different potency conclusions for a given chemical. To deal with this problem, the EPA has a hierarchy of methods. Integrated Risk Information System (IRIS) assessments have priority over Provisional Peer-Reviewed Toxicity Values, for example, because IRIS assessments are more extensively peer reviewed and rely on a more extensive database.
- EPA's research and methods for dealing with mixtures and cumulative exposures address the different safety of chemicals, given the context where other chemicals are present. The draft StRAP will contain a discussion of this research area.
- ORD's EXPO Toolbox is a recent product, released in the fall of 2013.
- HHRA staff is involved with developing ORD's Homeland Security research program's provisional advisory levels.
- Dr. Vandenberg stated that he could not currently describe exactly how RapidTox Assessment works or would work. The HHRA program is considering inputs from CSS and other data sources, but have not yet conducted such an assessment. This kind of approach may be more appropriate for informing screening-level decisions, rather than other regulatory decisions that must be made by the Office of Air and Radiation or Office of Water. He welcomed advice that would inform directions for how such an approach, which would integrate many new kinds of data streams, could be used.
- In response to a comment about the importance of the Risk Assessment Training and Experience (RATE) program, Dr. Vandenberg acknowledged the importance of outreach to a wide community of risk assessments and working relationships with a large, diverse group of scientists.
- ORD's interest in cumulative risk, as depicted in slide 12, is important. Dr. Vandenberg sees the need for advancing this approach and welcomes advice. He suggested that a disease-focused approach may supplement the current chemical-by-chemical assessment approach used by the agency.
- The draft StRAP will provide an additional level of detail to engage SAB and BOSC members. The StRAP will identify key questions, research challenges, objectives, and potential products in each of the areas discussed in the presentation.
- The HHRA StRAP will contain cross-referencing to StRAPs for other ORD programs. The interplay and interaction between CSS and HHRA will be particularly important.
- The "feedback loop" from the HHRA to the CSS program would work in the following way. HHRA would be the consumer of CSS outputs and play a potentially important role in determining whether CSS data are useful and make sense. HHRA staff play an active role in CSS research planning. This kind of relationship also exists for the HHRA and the Air, Climate, and Energy research program and is detailed in the HHRA StRAP.
- The EPA has close working relationships with the National Institute of Environmental Health Sciences, Agency for Toxic Substances and Disease Registry, Centers for Disease Control, National Institute for Occupational Safety and Health, the Food and Drug Administration, state agencies, and the world health organization. ORD works closely with these other agencies and uses their data.

Discussion of ORD's Charge to the SAB and BOSC and preparations for the face-to-face meeting

Dr. Carney reviewed the HHRA charge questions relevant to the Breakout Group discussion on July 24, 2014. The relevant charge questions are 2a, 2b, 2c, 6a, 6b, and 6c. The DFO committed

to providing members with a link to the EPA strategic plan by July 11, 2014 along with other information that the SAB and BOSC chairs may determine will be useful for discussions.

Members asked several questions related to the charge questions. One member asked if the reference to "integration" in question 2c included integration outside the EPA. The group agreed that it should include integration outside the EPA. Another member asked how ORD's "Next Gen" exercise aligned with the HHRA draft StRAP. Dr. Vandenberg responded that the "Next Gen" report was being drafted and is part of the CSS program, although there was significant HHRA engagement.

A member noted that question 2b asks for the SAB/BOSC perspectives on the proposed research directions. She asked whether the SAB and BOSC should provide alternatives, if the SAB and BOSC perspectives find the draft StRAP inadequate. Dr. Carney encouraged members to provide as much clarity and specificity in their comments as possible. The DFO stated that she would consult the SAB and BOSC chairs on this point so that there would be consistency across the breakout groups.

The DFO requested members to send their preliminary written comments to her by July 21, 2014, so that they can be compiled and posted on the SAB website.

The DFO closed the meeting by thanking breakout group members, representatives of the agency, and members of the public for participating.

The teleconference was adjourned at 4:26 p.m.

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Respectfully Submitted, Certified as Accurate,

Dr. Angela Nugent
SAB Designated Federal Officer

Dr. Edward Carney
Acting Breakout Group Chair

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.

Attachment A: Members of the public attending the public teleconference:

Carol Braverman, EPA
Dan Costa, EPA
Casey Dietrich, CQ Transcriptions
Annette Guiseppi-Elie, DuPont Engineering, Corporate Remediation Group
Maria Hegstad, Inside EPA
Elaine Hubal, EPA
Julie Hyman, EPA
Annie Jarabek, EPA
Dale Johnson, SBC Global
James Johnson, EPA
Robert Kavlock, EPA
Jennifer McPartland, EDF
Paul Price, Dow
Linda Wilson, New York State

Materials Cited

The following meeting materials are available on the SAB Web site, http://www.epa.gov/sab, at the page for the July 1 2014 teleconference:
http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/fa98b4c312771f4885257cf200708eb4!OpenDocument&Date=2014-07-01

[1] Roster for the Chartered SAB
[2] Roster for the BOSC Executive Committee
[3] Human Health Risk Assessment Research Program, Presentation by John Vandenberg