

**Summary Minutes of the United States Environmental Protection Agency (U.S. EPA)
Science Advisory Board (SAB) Teleconference
June 16, 2010**

Chartered SAB Members: See Roster provided in Attachment A.

Date and Time: June 16, 2010, 11:00 a.m.- 2:00 p.m. Eastern Time

Location: By Teleconference

Purpose: to conduct quality reviews of two draft SAB reports and discuss a draft report on EPA's strategic research directions.

SAB Participants:

Dr. Deborah Swackhamer, Chair	Dr. Cecil Lue-Hing
Dr. Timothy Buckley	Dr. L.D. McMullen
Dr. George Daston	Dr. Judith Meyer
Dr. Costel Denson	Dr. Jana Milford
Dr. Otto Doering	Dr. Christine Moe
Dr. David Dzombak	Dr. Eileen Murphy
Dr. Taylor Eighmy	Dr. Duncan Patten
Dr. Elaine Faustman	Dr. Steven Roberts
Dr. John Giesy	Dr. Joan Rose
Dr. Rogene Henderson	Dr. James Sanders
Dr. Bernd Kahn	Dr. Jerald Schnoor
Dr. Nancy Kim	Dr. Paige Tolbert
Dr. Catherine Kling	Dr. Thomas Wallsten
Dr. Kai Lee	Dr. Robert Watts

SAB Staff Office Participants

Dr. Angela Nugent, Designated Federal Officer (DFO)
Dr. Vanessa Vu, Director
Mr. Edward Hanlon
Dr. Suhair Shallal

Meeting Summary:

The teleconference discussion at the meeting followed the issues and sequence as presented in the agenda (Attachment B).

1. Convene Teleconference

Dr. Angela Nugent, SAB DFO, convened the teleconference and welcomed the group. She noted that written public comments on the two draft documents to be quality reviewed had

been received and posted on the SAB Web site and that members of the public had requested to make oral public statements on those two draft documents. She noted that representatives of the Agency not listed on the agenda and members of the public participating in the call would be listed in the minutes of the meeting (Attachment D). Compilations of member comments on the two draft reports for quality review are included in Attachments E and F. Written public comments received were posted prior to the teleconference and were available on the SAB Web site, <http://www.epa.gov/sab>, and specifically .at the following URL: <http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/0f2fd0392bea0d11852577130041deee!OpenDocument&Date=2010-06-16>

2. Purpose and Review of the Agenda

The SAB Chair, Dr. Deborah Swackhamer reviewed the purpose of the teleconference: to discuss a draft report on EPA's strategic research directions prepared by the full chartered SAB and to conduct quality reviews of two draft SAB reports prepared by an SAB subcommittee and SAB work group. She noted that the chartered SAB must review and approve all SAB reports before they are transmitted to the EPA Administrator.

3. Quality Review of the Advisory on EPA's Research Scoping Document Related to Hydraulic Fracturing (5/19/2010 Draft)

The first item on the agenda was a discussion of the SAB Environmental Engineering Advisory Committee's draft report reviewing a draft EPA Office of Research and Development (ORD) draft report entitled "Scoping Materials for Initial Design of EPA Hydraulic Fracturing Research Study." Dr. Swackhamer introduced Dr. David A. Dzombak, Chair of the Environmental Engineering Advisory Committee, which reviewed ORD's draft report. In its draft report, ORD described planned research strategies to address public health and environmental protection issues regarding hydraulic fracturing performed for extraction of natural gas from geologic formations.

Dr. Swackhamer next introduced Dr. Kevin Teichman, ORD's Deputy Assistant Administrator for Science, who had requested an opportunity to speak. He commended the SAB Environmental Engineering Advisory Committee for holding an open meeting on April 7-8, 2010 that gave the public opportunity to air many different opinions and perspectives. Dr. Teichman also thanked the committee for its draft report and asked several questions. He noted that the draft report called for ORD to conduct case studies. Given available resources for Fiscal Year 2010, he asked whether the committee could advise ORD on ways to "leverage hydraulic fracturing sites" so that ORD could include as many case studies as possible, since hydraulic fracturing efforts vary across the United States. Dr. Dzombak responded that the committee did not want to be prescriptive; partnering with other federal agencies and organizations would make sense, however, and the committee would not object to that approach. Dr. Teichman stated that ORD would "leverage dollars as best we can." ORD will work at sites that already exist and conduct research in ways that nongovernmental organizations feel are open and transparent.

Dr. Teichman asked Dr. Dzombak to clarify whether the committee's recommendation to form a balanced advisory group of stakeholders and engage with them early and throughout the

process of developing the hydrofracturing study would involve formation of a federal advisory committee. Dr. Dzombak responded that the committee did not contain legal experts on advisory committees. The committee advises ORD to take appropriate steps to engage stakeholders in a meaningful way early and throughout the process. The committee advises ORD to think carefully "up front" about ORD's objectives for a stakeholders' process and make those objectives clear when any stakeholders group is put together.

Dr. Swackhamer introduced two oral public commenters. Ms. Natalie Joubert from the Consumer Energy Alliance noted that she had submitted written comments and highlighted several points in her remarks. She stated that the 2010 appropriation conference report called for a study of the relationship between hydraulic fracturing and drinking water, a narrower focus than recommended by the SAB draft report. The SAB's draft report identifies additional areas for study that would explore interrelationships between ecosystems and health. Given the limited time and limited resources and the statutory mandate, she asked the committee to consider restricting the study to effects on drinking water and cumulative exposures. She also asked that the committee more narrowly define the research boundaries for ORD's study, especially given its recommendation that ORD should use a life-cycle framework.

Ms. Sarah Eckel from the Citizens Campaign for the Environment spoke next and emphasized that ORD's study should focus on current and future drinking water, recreation, and fishing. She called on ORD's study to use a comprehensive life-cycle framework that would support an economic assessment. She stated that the study be designed to address potentially broad effects around the wellheads that would be studied. She called for case studies of different geological formations and different kinds of hydrofracturing processes. She supported the SAB committee's recommendation that ORD study different phases of the hydrofracturing process, from drilling to waste disposal. She also called for a broad and diverse advisory group that would have public meetings in different parts of the country.

SAB members had no questions for the oral commenters.

Dr. Deborah Swackhamer, the SAB Chair, then reminded SAB members of their charge when conducting a quality review. She reviewed the four questions that are the responsibility of the chartered SAB when conducting a quality review:

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the body of the Committee's report supports the conclusions drawn or recommendations provided.

Dr. Swackhamer recognized the lead reviewers, Drs. Taylor Eighmy, Joan Rose, and Jerald Schnoor, to provide a brief summary of their comments. Comments included the following points:

- The committee might recommend that EPA build on research conducted by the U.S. Geological Survey on fractured bedrock

- The committee might emphasize that although EPA's study is short-term in focus, there are also questions about the long-term impact of hydro fracturing as well.
- The committee should more clearly distinguish between use of a life-cycle framework and development of a full life-cycle assessment and explain why a full life-cycle assessment cannot be done.
- The research topic areas and approaches recommended by the committee are appropriate, especially geographic information systems (GIS) to organize information on the many different wells in the United States and previous Environmental Impact Statements.
- It is appropriate to use a GIS-based approach to find where drilling for coal and natural gas may be co-located with drinking water aquifers
- The report should advise ORD to consider worst case scenarios vis a vis drinking water and public health.

Dr. Dzombak made the following responses to the oral commenters and lead reviewers. He noted that Environmental Engineering Advisory Committee supports a broad view of the scope. Drinking water resources can incorporate many different kinds of sources that depend on ecosystem health. The committee included experts in life-cycle assessment who agreed that it is appropriate for ORD to consider the whole life-cycle involved in hydrofracturing. Formal life-cycle analysis, however, would require data that does not currently exist. Use of a life-cycle framework can guide ORD's future research. Dr. Dzombak noted that the draft report inadvertently omitted mention of the U.S. Geological Survey. The revised report will identify that important partner. He also noted that the committee concurs with the use of GIS tools to identify co-occurrences of water resources and hydrofracturing efforts. The committee recommends site-specific case studies and GIS mapping to help EPA consider large-scale environmental impacts of hydrofracturing.

Other SAB members also provided comments. One member agreed that it was not appropriate to recommend that EPA conduct cost-benefit analysis as part of its study. She recommended, however, that the committee encourage ORD to confer with economists and anticipate the future needs of such analysis so that needed scientific data would be available in the future to support economic analysis. The SAB chair asked the committee to shorten the letter to the Administrator to no more than two pages and develop an executive summary for the report.

Dr. Swackhamer asked for a motion to dispose of the draft report. A motion was made and seconded to accept the report, conditional on changes being made by the Chair and DFO to address the quality review comments of members of the chartered SAB that were satisfactory to the Chair of the chartered SAB. There was universal approval with no members abstaining.

4. Discussion of the Draft Report Office of Research and Development Strategic Research Directions and Integrated Transdisciplinary Research

Dr. Swackhamer introduced the draft letter, developed to provide interim advice to EPA's Office of Research and Development after the chartered SAB's meetings on November 7-9, 2009 and April 5-6, 2010 on ORD's strategic research vision. She noted that the current draft letter

intended to provide a focused, short letter to the Administrator that provides a response to ORD's charge questions and some additional comment on integrated transdisciplinary research.

Dr. Kevin Teichman, ORD's Deputy Assistant Administrator for Science, complimented the letter and offered several comments as possible points of clarification. He asked for a description of the additional "detailed information" the SAB requires before it can respond to charge questions regarding ORD's entire research portfolio. Dr. Swackhamer responded that the SAB had discussed new approaches during its Administrative retreat for providing advice to ORD on strategic research directions. She asked Dr. Vanessa Vu, SAB Staff Office Director, to follow up with Dr. Teichman on those new ideas. Dr. Teichman asked that any new process allow adequate time for ORD to prepare for future meeting and for the SAB to address charge questions.

Dr. Teichman suggested that the SAB might include tribes as well as states in its recommendation that "a more systematic process is needed for states" to communicate research needs to EPA. He also invited the SAB to offer comments on the suitability of the Environmental Council of the States to serve as such a mechanism. He also asked whether the SAB would like to expand the text on page 3, lines 32, to recommend that EPA adopt a systems approach to planning policy, as well as research. He welcomed the SAB's descriptions of the biofuel and ecosystems services research programs as examples of the use of systems approaches in research planning. He suggested that the SAB might add regional offices to the list of organizations to involve in discussions about future research visions on page 4, line 31.

SAB members discussed the draft letter briefly. Two members spoke of the need to include some additional brief language concerning the need for ORD to leverage non-ORD science programs. Dr. Timothy Buckley committed to provide brief draft language. Dr. Vanessa Vu suggested that the letter characterize itself as an "interim report."

Dr. Swackhamer asked for a motion to dispose of the draft report. A motion was made and seconded to accept the report, conditional on changes being made that reflected the SAB's discussion. There was universal approval with no members abstaining.

5. Quality Review of the SAB's Review Comments on EPA's draft Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the IRIS (5-13-10 Draft)

The SAB Chair noted that the SAB Work Group was given a focused charge for this report. In response to a request from the EPA Administrator, ORD asked the SAB to comment on a limited set of charge questions related to ORD's revised cancer assessment for inorganic arsenic. ORD asked the SAB to comment on EPA's interpretation and implementation of key SAB recommendations made in 2007, when the SAB reviewed a 2005 draft arsenic cancer assessment. She also noted that when the SAB planned this teleconference, it did not anticipate the large number of requests for oral public comments that have been received. Dr. Swackhamer also noted that although SAB provides important independent advice to EPA; EPA is responsible for its science assessments and regulatory decisions. Dr. Swackhamer also noted that the teleconference agenda had been adjusted for the chartered SAB to hear these oral comments. Given the time constraints of the teleconference, the chartered SAB would use the remaining

time after public comments to discuss general issues and next steps related to the quality review of the SAB Work Group's draft arsenic report and would likely not make a final decision on the quality review during the call.

Dr. Elaine Faustman, Chair of the Work Group of the Chartered SAB for the Arsenic Cancer Review, provided brief contextual background on the report. She noted that the Work Group focused EPA's response to several key recommendations made by the SAB in 2007. The group focused on the Agency's response to SAB recommendations concerning choice and use of epidemiological data, use and evaluation of dose-response modeling, sensitivity analysis of the exposure assumptions used for the assessment. She thanked members of the Work Group. She reported that, in general, the Work Group found EPA to be responsive to the 2007 recommendations and requested clarification in several areas, detailed in the draft Work Group Report.

Dr. Swackhamer introduced ten individuals who had requested public comment. She noted that each speaker had three minutes for comment, as stipulated in the Federal Register Notice announcing the quality review teleconference.

Mr. Kevin Bromberg from the U.S. Small Business Administration stated that the SAB Work Group effort was rushed, limited by a narrow set of charges, and did a "poor job." He recommended that the SAB terminate the Work Group's effort and undertake a full peer review of EPA risk assessment. He asked the SAB to respond to public comment on this advisory activity. He noted that five members from the SAB's 2007 panel had filed critical comments that deserved special attention. He also asked that the EPA review incorporate the results of significant new scientific research underway.

Dr. Steven H. Lamm from Consultants in Epidemiology & Occupational Health stated that he had reviewed ORD's draft toxicological review and found it incomplete and inaccurate. EPA's analytic modeling did not allow for the confounding factor of other organic substances in the water likely to be significant for bladder cancer. He also noted that 1) EPA did not consider the defining characteristics of arsenic poisoning; 2) EPA's linear no-threshold approach did not consider geographic variability; and 4) EPA relied on the results of a West Taiwanese study that has been discounted.

Dr. Barbara D. Beck from Gradient Corporation presented oral comments on behalf of the Organic Arsenical Products Task Force. She asked that the minutes refer to her written and oral comments provided at the SAB Work Group meeting on April 6, 2010. She noted that the Work Group's narrow focus had resulted in her concerns being "given short shrift or ignored." She commented that the Work Group responded to charge question D2 (choice of a dose-response model) in only a limited manner. The Work Group draft report did not discuss dose-response model selection, especially based on EPA's cancer risk assessment guidelines. She also noted that some concerns of the SAB 2007 Panel had not been addressed, specifically the integrated analysis of *in vivo* and *in vitro* studies. EPA simply listed the studies without interpreting them or conducting an integrated analysis. Dr. Beck noted that such an analysis could shed light on the arsenic mode of action. She asked that the SAB's 2007 letter be provided to the chartered SAB for the quality review. Given the significance of the Toxicological

Assessment for risk assessment and risk management, the SAB should consider the science issues underlying this analysis.

Dr. Lorenz R. Rhomberg from Gradient Corporation presented comments on behalf of the North American Metals Council. He asked that the minutes refer to his written and oral comments provided at the SAB Work Group meeting on April 6, 2010. In those comments, he noted that EPA's current draft Toxicological Assessment did not address the recommendations of the 2007 SAB panel and he stated that the Work Group did not heed his own opinion. The SAB 2007 report asked EPA to consider the impact of an outside reference population (different from Taiwan) on the shape of the dose-response curve shape to identify possible bias. The current Agency draft Toxicological Assessment does not include a reference population and "falsely uses linearity." This issue should be addressed for the credibility of EPA and the SAB. He also noted that the 2007 SAB report called for EPA to conduct an integrative analysis across many low dose studies. Many of those studies show that low arsenic doses do not elevate risk. EPA's draft Toxicological Analysis does not address recently published meta analyses. It also does not address whether there is any study preferable to the Taiwanese study, given the disconnect between the results of that study and toxicological data on low-dose cancer risk.

Dr. Samuel M. Cohen from the University of Nebraska Medical Center spoke about his research on bladder cancer and the mode of action for arsenic. He stated that the science of cytotoxicity and regeneration for bladder and skin cancer related to inorganic and organic arsenic is consistent. "Everything we know about inorganic and organic arsenic points to a non-linear mode of action." He stated that these scientific findings were discussed by the 2007 SAB arsenic report but not addressed by the SAB Work Group's current draft report. He stated that it was inappropriate for EPA to fall back on non-linear mode of action.

Mr. Patrick Quinn from The Accord Group presented comments on behalf of Osmose, Inc., a firm concerned with wood treatment technology. He noted that there was a strong public and political interest in EPA's assessment because inorganic arsenic is found in food and drinking water. He noted that the assessment would affect the drinking water maximum contaminant level, Superfund clean-ups, and requirements under the Resource Conservation and Recovery Act. He noted that no SAB panel has been asked to review ORD's draft Toxicological Assessment in terms of its inputs and analysis. He observed that the SAB Work Group "probably did a good job" on its narrow charge, but the right approach would be to reexamine the cancer assessment with the right panel properly charged to do the right analysis.

Ms. Lynn L. Bergeson from Bergeson & Campbell, P.C. presented comments on behalf of Luxembourg Industries Ltd. She noted that the SAB's public participation procedures were limited. She stated that the SAB Work Group "excluded comments" from stakeholders. Stakeholders complained that the narrow charge frustrated actual full and fair consideration of the recommendations from the 2007 panel. She reported that the ORD Assistant Administrator, Dr. Paul Anastas, had informed stakeholders that the SAB was not constrained by narrow charge questions, but the SAB Work Group did not provide advice outside very narrow charge questions. She called on the SAB not to "abandon independence and yield to a program office." The SAB must be independent to ensure its credibility. She urged the SAB to terminate the current review. She also noted that the Organic Arsenical Products Task Force and the Wood

Preservative Science Council sent to EPA a request for a formal correction of information under the Information Quality Act to address issues in the draft ORD Toxicological Assessment.

Dr. Joyce S. Tsuji from Exponent presented comments on behalf of the Wood Preservative Science Council. She identified herself as the author of a recent meta-analysis of arsenic toxicology studies. She noted that there has been no independent peer review of EPA's calculated cancer slope factors. She also noted that the SAB Work Group did not receive detailed written public comments before its April meeting. The Work Group's draft report indicates deficiencies in EPA's draft Toxicological Assessment. She expressed concern that EPA's assessment lacked toxicological studies published since 2007 and a synthesis of recent research. She stated that EPA's document was not consistent with the results from this recent research. She expressed the view that the Work Group provided only criticisms of minor issues in EPA's draft document and did not address the major issues that deserved attention.

Ms. Jane C. Luxton from Pepper Hamilton LLP presented comments on behalf of Rio Tinto. Ms. Luxton asked members of the chartered SAB to take note of the comments provided by Drs. Bill Adams and Justin Teegardin, who had served on a past SAB subcommittee and panel. She expressed their view that EPA's report does not meet criteria for quality and relevance because the literature review does not address studies published since 2007 and excludes work funded by Dr. Samuel Cohen and EPA-funded work close to completion. She noted that Dr. Teegardin's letter included a critique of the Work Group's draft report from three members of the SAB Arsenic Review Panel, which authored the SAB's 2007 arsenic report.

Mr. William Herz from the Fertilizer Institute noted that many fertilizers are mined materials, such as potash, which include trace amounts of arsenic. EPA's decision on an arsenic standard will affect "dozens of standards incorporating arsenic" that will have a major impact on the fertilizer industry, other industries, and municipalities. He asked that the SAB convene a panel on the "larger issues" identified by public commenters. EPA has not addressed recent key scientific literature, has used an out-dated reference population, and overlooked significant confounders, such as Blackfoot disease and occupational exposures.

After the public comments, the SAB Chair asked chartered SAB members if they had questions for any of the public commenters. Dr. Faustman asked Dr. Cohen if his study has been published yet. Dr. Cohen responded that it had not yet been published.

Chartered SAB Discussion

Dr. Swackhamer introduced the lead reviewers' comments. She reiterated that the lead reviewers and SAB members generally were asked to address four questions when conducting a quality review:

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and

4. whether the body of the Committee's report supports the conclusions drawn or recommendations provided.

Dr. Swackhamer noted that three of the four chartered SAB lead reviewers, Drs. Jeffrey Griffiths, Jonathan Samet and Steven Heeringa, had provided written comments but were unable to participate in the call.

The fourth lead reviewer, Dr. Paige Tolbert, was present and made the following points. She noted that the Work Group had adequately addressed the specific charge questions posed to them. Specifically, in regard to Work Group Charge Question #1, the Work Group was well justified in concluding that EPA had been responsive to the SAB 2007 recommendations in evaluating the published epidemiology studies and in concurring with the choice of the Taiwanese dataset as the most appropriate data to use in the risk assessment. In regards to Work Group Charge Question # 2, whether EPA was responsive to the 2007 SAB review in performing requested sensitivity analyses of the dose-response modeling, Dr. Tolbert found that the Work Group's response was adequate. She agreed with the Work Group's assessment that EPA was responsive in performing sensitivity analyses and that EPA was justified in its use of a linear low-dose extrapolation in its risk assessment. In regard to Work Group Charge Question #3, Dr. Tolbert agreed with the Work Group's conclusion that EPA's review of the epidemiology literature could have been more systematic and synthetic and thereby more responsive to recommendations in the 2007 SAB review.

Dr. Tolbert offered a few suggestions for revisions to the Work Group's draft report. She suggested that the Work Group draft report not recommend that EPA provide "power calculations" for all studies, but instead examine relevant risk assessments for increases in exposures and related confidence intervals. The width of that confidence interval can serve as a measure of the robustness of findings. She recommended that the draft Work Group report recommend that EPA comment on the relative strength of the bias of exposure studies, rather than just discuss the "bias toward the null" of different calculations of exposure. She also suggested that the draft report ask EPA to identify and assess any studies published since 2007 that would materially change conclusions in its assessment. She noted that, given the extensive public comments received, EPA will give this recommendation due consideration.

Dr. Swackhamer asked Dr. Faustman to respond to lead reviewer comments. Dr. Faustman noted that reviewers had asked for clarification of language and revision of the language that called for power calculations. The Work Group's intent was to call for appropriate use of *post-hoc* analysis. The Work Group intended that EPA provide more discussion about the robustness of the studies being considered so that the draft Toxicological Analysis would be more transparent. She welcomed Dr. Tolbert's suggestion for recommendations about studies published after 2007. Dr. Faustman noted that other SAB members had called for an executive summary and a substantive discussion of the Work Group's "bottom line" in the letter to the Administrator. The Work Group lead writers could each develop appropriate text to address those comments.

An SAB member asked whether the Work Group considered going beyond their narrow charge and addressing some of the issues raised by public commenters. Dr. Faustman responded that the Work Group was constituted to address a narrow charge and that the expertise of the

group was not appropriate for a full review of EPA's Toxicological Assessment. Dr. Swackhamer noted that it within the purview of the SAB to consider science issues beyond its narrow charge and asked whether the Work Group explicitly considered whether to "go beyond the charge questions." Dr. Faustman responded that the Work Group did go beyond the charge in discussing research needed to fill critical data needs, but that the group generally wanted to stay within the charge. A Work Group member noted that one area where the Work Group went beyond the charge was to recommend that EPA "do a reality check on its analysis." He generally agreed that the group viewed its role as a "limited effort to tie up loose ends" for a document long in development.

Dr. Swackhamer noted that it is important for the SAB report to describe very explicitly the limited scope of the review, given the context of EPA's arsenic efforts. Dr. Faustman agreed. Dr. Swackhamer noted that the chartered SAB required additional time to hold a full quality review of the Work Group's draft document and stated that a follow-up teleconference would be scheduled. She asked Dr. Faustman and the work group to revise the draft report in response to comments received from lead reviewers and chartered SAB members and to consider comments received from the public. Dr. Faustman asked for time before the teleconference ended to note that the arsenic review raised many questions about risk management implications. She suggested that those questions and other interdisciplinary questions suggest that arsenic would benefit from an integrated transdisciplinary research effort.

Adjourn the Teleconference

The Designated Federal Officer adjourned the teleconference at 2:00 p.m.

Respectfully Submitted:

Certified as True:

_____/Signed/_____

_____/Signed/_____

Dr. Angela Nugent
SAB DFO

Dr. Deborah L. Swackhamer
SAB Chair

ATTACHMENTS

- Attachment A: Chartered SAB Roster
- Attachment B: Agenda
- Attachment C: FR Notice
- Attachment D: Members of the Public and EPA Representatives who requested call-in information or asked to be identified as participating in the teleconference.
- Attachment E: Comments from Members of the Chartered SAB on *Advisory on EPA's Research Scoping Document Related to Hydraulic Fracturing (5/19/2010 Draft)*
- Attachment F: Comments from Members of the Chartered SAB on *SAB's Review Comments on EPA's draft Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the IRIS (5-13-10 Draft)*

Attachment A
Roster
U.S. Environmental Protection Agency
Science Advisory Board

CHAIR

Dr. Deborah L. Swackhamer, Professor and Charles M. Denny, Jr., Chair in Science, Technology and Public Policy and Co-Director of the Water Resources Center, Hubert H. Humphrey Institute of Public Affairs, University of Minnesota, St. Paul, MN

SAB MEMBERS

Dr. David T. Allen, Professor, Department of Chemical Engineering, University of Texas, Austin, TX

Dr. Claudia Benitez-Nelson, Associate Professor, Department of Earth and Ocean Sciences and Marine Science Program, University of South Carolina, Columbia, SC

Dr. Timothy Buckley, Associate Professor and Chair, Division of Environmental Health Sciences, College of Public Health, The Ohio State University, Columbus, OH

Dr. Thomas Burke, Professor, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Dr. Deborah Cory-Slechta, Professor, Department of Environmental Medicine, School of Medicine and Dentistry, University of Rochester, Rochester, NY

Dr. Terry Daniel, Professor of Psychology and Natural Resources, Department of Psychology, School of Natural Resources, University of Arizona, Tucson, AZ

Dr. George Daston, Victor Mills Society Research Fellow, Product Safety and Regulatory Affairs, Procter & Gamble, Cincinnati, OH

Dr. Costel Denson, Managing Member, Costech Technologies, LLC, Newark, DE

Dr. Otto C. Doering III, Professor, Department of Agricultural Economics, Purdue University, W. Lafayette, IN

Dr. David A. Dzombak, Walter J. Blenko Sr. Professor, Department of Civil and Environmental Engineering, College of Engineering, Carnegie Mellon University, Pittsburgh, PA

Dr. T. Taylor Eighmy, Vice President for Research, Office of the Vice President for Research, Texas Tech University, Lubbock, TX

Dr. Elaine Faustman, Professor, Department of Environmental and Occupational Health

Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

Dr. John P. Giesy, Professor and Canada Research Chair, Veterinary Biomedical Sciences and Toxicology Centre, University of Saskatchewan, Saskatoon, Saskatchewan, Canada

Dr. Jeffrey Griffiths, Associate Professor, Department of Public Health and Community Medicine, School of Medicine, Tufts University, Boston, MA

Dr. James K. Hammitt, Professor, Center for Risk Analysis, Harvard University, Boston, MA

Dr. Rogene Henderson, Senior Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Bernd Kahn, Professor Emeritus and Associate Director, Environmental Radiation Center, School of Mechanical Engineering, Georgia Institute of Technology, Atlanta, GA

Dr. Agnes Kane, Professor and Chair, Department of Pathology and Laboratory Medicine, Brown University, Providence, RI

Dr. Nancy K. Kim, Senior Executive, New York State Department of Health, Troy, NY

Dr. Catherine Kling, Professor, Department of Economics, Iowa State University, Ames, IA

Dr. Kai Lee, Program Officer, Conservation and Science Program, David & Lucile Packard Foundation, Los Altos, CA

Dr. Cecil Lue-Hing, President, Cecil Lue-Hing & Assoc. Inc., Burr Ridge, IL

Dr. Floyd Malveaux, Executive Director, Merck Childhood Asthma Network, Inc., Washington, DC

Dr. Lee D. McMullen, Water Resources Practice Leader, Snyder & Associates, Inc., Ankeny, IA

Dr. Judith L. Meyer, Distinguished Research Professor Emeritus, Odum School of Ecology, University of Georgia, Lopez Island, WA

Dr. Jana Milford, Professor, Department of Mechanical Engineering, University of Colorado, Boulder, CO

Dr. Christine Moe, Eugene J. Gangarosa Professor, Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, GA

Dr. Eileen Murphy, Manager, Division of Water Supply, New Jersey Department of Environmental Protection, Trenton, NJ

Dr. Duncan Patten, Research Professor , Department of Land Resources and Environmental Sciences, Montana State University, Bozeman, MT

Dr. Stephen Polasky, Fesler-Lampert Professor of Ecological/Environmental Economics, Department of Applied Economics, University of Minnesota, St. Paul, MN

Dr. Stephen M. Roberts, Professor, Department of Physiological Sciences, Director, Center for Environmental and Human Toxicology, University of Florida, Gainesville, FL

Dr. Amanda Rodewald, Associate Professor, School of Environment and Natural Resources, The Ohio State University, Columbus, OH

Dr. Joan B. Rose, Professor and Homer Nowlin Chair for Water Research, Department of Fisheries and Wildlife, Michigan State University, East Lansing, MI

Dr. Jonathan M. Samet, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, University of Southern California, Los Angeles, CA

Dr. James Sanders, Director and Professor, Skidaway Institute of Oceanography, Savannah, GA

Dr. Jerald Schnoor, Allen S. Henry Chair Professor, Department of Civil and Environmental Engineering, Co-Director, Center for Global and Regional Environmental Research, University of Iowa, Iowa City, IA

Dr. Kathleen Segerson, Professor, Department of Economics, University of Connecticut, Storrs, CT

Dr. V. Kerry Smith, W.P. Carey Professor of Economics , Department of Economics , W.P Carey School of Business , Arizona State University, Tempe, AZ

Dr. Herman Taylor, Professor, School of Medicine, University of Mississippi Medical Center, Jackson, MS

Dr. Barton H. (Buzz) Thompson, Jr., Robert E. Paradise Professor of Natural Resources Law at the Stanford Law School and Perry L. McCarty Director, Woods Institute for the Environment, Stanford University, Stanford, CA

Dr. Paige Tolbert, Professor and Chair, Department of Environmental Health, Rollins School of Public Health, Emory University, Atlanta, GA

Dr. Thomas S. Wallsten, Professor and Chair, Department of Psychology, University of Maryland, College Park, MD

Dr. Robert Watts, Professor of Mechanical Engineering Emeritus, Tulane University,
Annapolis, MD

SCIENCE ADVISORY BOARD STAFF

Dr. Angela Nugent, Designated Federal Officer, 1200 Pennsylvania Avenue, NW
1400F, Washington, DC, Phone: 202-343-9981, Fax: 202-233-0643, (nugent.angela@epa.gov)

**Attachment B
Meeting Agenda
U.S. Environmental Protection Agency
Science Advisory Board (SAB)
Teleconference
Agenda**

June 16, 2010, 11:00 a.m. to 2:00 p.m. Eastern Time

Purpose: to conduct quality reviews of two draft SAB reports and discuss a draft report on EPA's strategic research directions.

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| 11:00 am. | Convene the Teleconference | Dr. Angela Nugent
<i>Designated Federal Officer
EPA SAB</i> |
| 11:05 a.m. | Purpose and Review of the Agenda | Dr. Deborah L. Swackhamer
<i>Chair
EPA SAB</i> |
| 11:10 a.m. | Quality Review of the Advisory on EPA's Research Scoping Document Related to Hydraulic Fracturing (5/19/2010 Draft) | |
| 11:10 a.m. | Public Comments | TBA |
| 11:25 p.m. | Chartered SAB Discussion | Dr. David A. Dzombak
<i>Chair, Environmental
Engineering Advisory Committee
Chartered SAB Members</i> |
| 12:00 p.m. | Discussion of the Draft Report <i>Office of Research and Development Strategic Research Directions and Integrated Transdisciplinary Research</i> | Dr. Deborah L. Swackhamer
Chartered SAB Members |
| 1:00 p.m. | Quality Review of the SAB's Review Comments on EPA's draft Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the IRIS (5-13-10 Draft) | |
| 1:00 p.m. | Public Comments | TBA |
| 1:15 p.m. | Chartered SAB Discussion | Dr. Elaine Faustman
<i>Chair, Work Group of the
Chartered SAB for the Arsenic
Cancer Review
Chartered SAB Members</i> |
| 2:00 p.m. | Adjourn the Teleconference | The DFO |

Attachment C
FR Announcement

[Federal Register: May 17, 2010 (Volume 75, Number 94)]
[Notices]
[Page 27553-27554]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr17my10-60]

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9152-3]

Science Advisory Board Staff Office; Notification of a Public
Teleconference of the Chartered Science Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the chartered SAB on June 16, 2010 to conduct quality reviews of two draft SAB reports. In addition, the SAB will discuss its draft report on EPA's strategic research directions.

DATES: The public teleconference will be held on June 16, 2010 from 11 a.m. to 2 p.m. (Eastern Daylight Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning this public teleconference should contact Dr. Angela Nugent, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9981; fax (202) 233-0643; or e-mail at nugent.angela@epa.gov. General information concerning the EPA Science Advisory Board can be found on the SAB Web site at <http://www.epa.gov/sab>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2, notice is hereby given that the EPA Science Advisory Board will hold a public teleconference to review three draft SAB reports: (1) The SAB Environmental Engineering Committee Hydraulic Fracturing Research Plan Review; (2) the report from the SAB Work Group to Lead the Review of the Arsenic Cancer Assessment; and (3) the chartered SAB's draft report on Strategic Research Directions and Integrated Transdisciplinary Research. The SAB was established pursuant to 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical

basis for Agency positions and regulations. The SAB is a Federal Advisory Committee under FACA. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: (1) Advisory on EPA's Proposed Hydraulic Fracturing Research Plan Review. In its Fiscal Year 2010 Appropriation Conference Committee Directive to EPA, the U.S. House of Representatives approved a provision that urges EPA to assess the potential risks to drinking water posed by hydraulic fracturing of formations including coalbeds and shale for extraction of natural gas. Hydraulic fracturing generates vertical and horizontal fractures in underground geologic formations to facilitate extraction of gas (or oil) from the subsurface.

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To meet the Congressional request, EPA's Office of Research and Development (ORD) developed a draft research plan. This plan described an approach to gather existing data and information including a stakeholder input process; to catalog potential risks to drinking water supplies from hydraulic fracturing; to identify data gaps; and to develop research questions, research needs, and research products. ORD requested SAB advice regarding the planned research. The SAB Environmental Engineering Committee discussed its advice on April 7-8, 2010 (75 FR 9205-9206). Background information about this advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Hydraulic%20Fracturing?OpenDocument.

(2) Review of the Arsenic Cancer Assessment: EPA is currently in the process of updating the 1988 IRIS cancer assessment for inorganic arsenic. The EPA evaluated and implemented the National Research Council recommendations in their report titled Arsenic in Drinking Water: 2001 Update and in 2005 requested the SAB review the Agency's draft cancer assessment for inorganic arsenic. The SAB review report (Advisory on EPA's Assessments of Carcinogenic Effects of Organic and Inorganic Arsenic: A Report of the US EPA Science Advisory Board, EPA-SAB-07-008) was finalized in 2007.

EPA's Office of Research Development has recently completed a 2010 draft titled: ``Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the Integrated Risk Information System (IRIS)'. ORD requested that the SAB evaluate and comment on EPA's interpretation and implementation of the key SAB (2007) recommendations. ORD requested a review focusing in three areas of the draft cancer assessment of inorganic arsenic: Evaluation of epidemiological literature; dose-response modeling approaches; and the sensitivity analysis of the exposure assumptions used in the risk assessment.

A work group of the chartered SAB discussed its review on April 6-7, 2010 (75 FR 9205-9206). Background information about this advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Rev%20Tox%20Review%20Inorg%20Arsenic?OpenDocument.

(3) Chartered SAB's draft report on strategic research directions and integrated transdisciplinary research: Since 2007 EPA's ORD has requested SAB advice on strategic research directions. ORD requested advice on the overall strategic direction of the program in relation to EPA's overall mission and components of EPA's research program. The draft report was developed after SAB discussions with ORD about strategic research directions on November 9-10, 2009 (74 FR 52805-

52806) and April 5-6, 2010 (75 FR 11883-11884).

Background information about this advisory activity can be found on the SAB Web site at http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Research%20Directions?OpenDocument.

Availability of Meeting Materials: The agenda and other materials in support of the teleconference will be placed on the SAB Web site at <http://www.epa.gov/sab> in advance of the teleconference.

Procedures for Providing Public Input: Public comment for consideration by EPA's Federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a Federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a Federal advisory committee to consider as it develops advice for EPA. They should send their comments directly to the Designated Federal Officer for the relevant advisory committee. Oral Statements: In general, individuals or groups requesting time to make an oral presentation at a public SAB teleconference will be limited to three minutes, with no more than one-half hour for all speakers. Those interested in being placed on the public speakers list should contact Dr. Nugent at the contact information provided above by June 9, 2010. Written Statements: Written statements should be received in the SAB Staff Office by June 9, 2010. Written statements should be supplied to the DFO via e-mail to nugent.angela@epa.gov (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format). Submitters are asked to provide versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Angela Nugent at (202) 343-9981 or nugent.angela@epa.gov. To request accommodation of a disability, please contact her preferably at least 10 days prior to the teleconference, to give EPA as much time as possible to process your request.

Dated: May 10, 2010.

Anthony Maciorowski,
Deputy Director, EPA Science Advisory Board Staff Office.
[FR Doc. 2010-11691 Filed 5-14-10; 8:45 am]
BILLING CODE 6560-50-P

Attachment D: Members of the Public and EPA Representatives who requested call-in information or asked to be identified as participating in the teleconference

Matthew J. Armstrong Bracewell & Giuliani LLP	Dr. Samuel M. Cohen University of Nebraska Medical Center
Barbara D. Beck Gradient	Julie K. Conroy Colorado Department of Public Health and Environment
Nancy B. Beck Office of Management and Budget	George Deeley Shell Upstream Americas
Norman Birchfeld EPA	Natenna Dobson U.S. Department of Energy
Lynn L. Bergeson Bergeson & Campbell, P.C.	Kevin Easley U.S. Department of Energy
Judy Blanchard Chevron	Sarah Eckel Citizens Campaign for the Environment
Kevin Bromberg U.S. Small Business Administration	Michal Eldan Luxembourg-Pamol, Inc.
Tawny A. Bridgeford National Mining Association	Sara Everitt Chevron
Judsen Bruzgul US Environmental Protection Agency	Lynn Flowers Acting Associate Director for Health
Liz Buckley Pesticide & Toxic Chemical News	Lee Fuller
Jay Close Chevron	Suzannah Glidden Croton Watershed Clean Water Coalition, Inc.
Craig Arthur Brown Questar Market Resources	Helen Goeden
Erica Michaels Brown Association of Metropolitan Water Agencies	Natalie Joubert Consumer Energy Alliance
Angie Burckhalter Oklahoma Independent Petroleum Association	Judy Hauswirth
Sharan Campleman Electric Power Research Institute	Armando Herald, E.I.T. Water Quality Control Division Denver, CO

William C. Herz The Fertilizer Institute	Denise Moyer BP
Bill Hochheiser ALL Consulting	Jennifer Peters Clean Water Network
John Horton Osmose, Inc.	Patrick Quinn The Accord Group
Suzanne P. Holland, PE Chevron North America EP	Marian H. Rose Croton Watershed Clean Water Coalition, Inc.
Carliane D. Johnson SeaJay Environmental LLC	Pat Rizzuto BNA, Inc.
Debra A. Kaden DakTox, LLC	Reeder L. Sams II U.S. Environmental Protection Agency
Alan Kovski BNA	Robert Sandilos Chevron
Katharine Kurtz Navy and Marine Corps Public Health Center	J. Barton Seitz Baker Botts LLP
Steven H. Lamm, MD Consultants in Epidemiology & Occupational Health	Shirley S.-H. Tao Food and Drug Administration
Yvette W Lowney Exponent	Kevin Teichman U.S. Environmental Protection Agency
Jane C. Luxton Pepper Hamilton LLP Jennifer E. Lynette U.S. Environmental Protection Agency	Joyce S. Tsuji Exponent
Stephanie R. Meadows American Petroleum Institute	Robert Vagnetti U.S. Department of Energy
Charles B. Moldenhauer Morgan, Lewis & Bockius LLP	John Vandenberg ORD/NCEA
Bob Moran Halliburton	Asha Venkataraman Van Ness Feldman, P.C.
	Brian Woodard Devon Energy Corporation

Attachment E

Comments from Members of the Chartered SAB on *Advisory on EPA's Research Scoping Document Related to Hydraulic Fracturing (5/19/2010 Draft)*

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Comments from Lead Reviewers

Comments from Dr. Taylor Eighmy

Review of Advisory on EPA's Research Scoping Document Related to Hydraulic Fracturing

Taylor Eighmy
June 8th, 2010

EPA has developed scoping materials for the initial design of a hydraulic fracturing research study. The study is in response to a request from Congress to carry out a study on the relationship between hydraulic fracturing and drinking water. The scoping materials are designed to frame the research questions and the focus of the framing is on the characterization of the hydraulic fracturing lifecycle, potential relationships to drinking water resources, and potential health and environmental risks. In their scoping, EPA also describes their approach for compiling background data and information, provides potential elements for the research study, and offers an approach for transparent stakeholder involvement.

In seeking input from the SAB EEC, four charge questions were provided around three broadly framed issues around the proposed scope of the study, the proposed research topics, and the stakeholder process:

1. (Under the Proposed Scope of the Study): #1---*What recommendations does the SAB EEC have regarding this question of scope?*
2. (Under the Proposed Research Topics): #2a---*What recommendations does the SAB EEC have regarding these proposed research categories and related questions in the scoping paper?*
3. (Under the Proposed Research Topics): #2b---*What process does the SAB EEC suggest for prioritizing research needs given the Congressional request and a desire by the Agency to complete initial research products by the end of calendar year 2012?*
4. (Under stakeholder Process) #3---*What advice does the SAB EEC offer for designing a stakeholder process that provides for balanced input in developing a sound scientific approach for the overall research strategy?*

Quality Review Questions:

1. Whether the Original Charge Questions to the SAB were Adequately Addressed:

The four charge questions were adequately addressed.

The four charge questions posed reflect the appropriate focus on the three broadly framed issues around the proposed scope of the study, the proposed research topics, and the stakeholder process.

The response to charge question 1 around scope includes helpful recommendations around focused, short-term research goals and broad, long-term research needs. Specific recommendations for short-term research goals include focusing on sources and pathways of potential impacts to drinking water. Recommendations for long-term research needs include a focus on impacts to water resources and aquatic ecosystems. The response also discusses the need for a larger scale of analysis, the utility of an initial informal lifecycle framework without economic analyses, and the observation that the research plan will be relevant to policy formulation. Finally, the response appropriately emphasizes that the scope should focus--- as appropriate--- to issues of hydraulic fracturing and not so broadly on the oil and gas production activities.

The response to charge question 2a around the three research categories (characterization of the hydraulic fracturing lifecycle, potential relationships to drinking water sources, potential health and environmental risks) includes useful recommendations around life cycle components, focus, boundary definition, scale (e.g., functional unit), time horizon and metrics, focus on drinking water impacts, prioritization, use of case studies, and data needs on occurrence, volume, composition, treatability of fluids (fracturing fluids, flowback water, produced water), sources and pathways for exposure, secondary effects (e.g., biogeochemical), use of GIS for exposure assessments, and opportunities to leverage informational needs from related groundwater and hydrogeologic research.

The response to charge question 2b around prioritization very appropriately discusses compilation of existing information and how that can inform priorities and also encourages the use of risk-based prioritization. The response includes a number of additional fundamental questions to address--- these are good questions. One additional fundamental question to consider is the scale- and magnitude-dependent long-term consequences of bore hole drilling, aquitard penetration, hydraulic fracturing, and post-fracturing solute communication between geologic formations (e.g., shales) and overlying aquifers, especially around transport of methane and TDS.

The response to charge question 3 around transparent stakeholder processes addresses the need for advisory groups. One additional thought here--- the USGS has had a number of research programs tied to fractured bedrock biogeochemistry, solute transport in fractures, borehole-fracture reactive transport, etc. and that might be useful knowledge partnership to develop.

2. Technical Errors or Omissions in the Report or Issues That Are Inadequately Dealt With

I found no technical errors or omissions.

3. Whether the Report is Clear and Logical

The report is clear and logical.

4. Whether the Conclusions Drawn or Recommendations Provided Are Supported by the Report

The recommendations offered to the EPA by this advisory around their scoping of their research are fully supported.

Comments from Dr. Joan Rose

ADDRESS the following:

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

SAB was charged with a review of the following:

1. Scope of the Research Program
2. Proposed research categories and topics areas
3. Design of a stakeholder process.

The report of the SAB is very well written, all three charges were addressed and the report is clear. This is not my area of expertise but from the general science view there are no obvious errors and it does not seem that there are any grave omissions. Some further discussion and clarifications may improve and strengthen the recommendations.

Scope of the Research

The SAB review identified that there would be short term and long term goals and it seems that given the desire that research products are going to be forthcoming by 2012, it is reasonable to suggest that the road map should focus on the short term goals. Research on the impact of the hydraulic fracturing process on drinking water and public health was suggested as the focus in the short term. The technique of hydraulic fracturing used to recover oil and gas has been used for decades and it appears only recently that events regarding contamination of ground water have suggested a public health risk and that a research program is warranted.

The SAB reviewers have suggested that a Life cycle frame work but not a detailed life cycle assessment could provide a road map for knowledge gaps and research direction. However it is not clear why a full life-cycle assessment could not be undertaken (particularly when it is suggested later in the report in regard to topics that in depth case studies could be part of the research projects). How would one clearly delineate between a LCA framework and a LCA? Thus, the report should clarify why a full LCA should not be done. In addition, on Line 43, page 16, the report discusses how a LCA is useful and the authors may want to use a different abbreviation if they believe only a framework is needed so there is no confusion. The authors also state that details on occurrence, volume, and composition of source fluids, flow back water and produced water are needed. Is the best way to accomplish this through a LCA?

It is also not clear why in the first two years that research on ecosystem protection could not be addressed simultaneously. It seems that the flow back waters and the types of chemical impacting both natural and wastewater ecosystems could be part of the suggested literature review. It may be that various types of EIS that were undertaken (for example from oil shale extraction operations in the 1980s) could provide information that would be useful in this regard.

Proposed research categories and topics areas

The idea of setting up monitoring plans and the use of GIS and mapping seem to be incredibly important in the early stages and perhaps that can be emphasized more.

What about an inventory along with the literature review?

How many operations are there? Where are they located? What is the duration/ or life of some of the operations?

It seems that characterization of the pathways would be very site specific and that in order to choose the pilot case-studies that a broad view of the hydraulic fracturing activities in location and time be better understood.

Design of a stakeholder process

These case studies would lend themselves to piloting how to bring in the stakeholders. The states and oil and gas industry scientists and leaders would need to be brought into the process early on. I think that may be where much of the data and grey literature will be found. In regard to Stakeholders, it seems that the USGS would also be seen as government partners. Multidisciplinary science perspectives should be brought to the table, (eg. fluid mechanics and experts in porous medium flow).

Comments from Dr. Jerald Schnoor

I have reviewed the SAB EEC advisory on EPA's research scoping document related to hydraulic fracturing and drinking water. I believe the committee has done a good job of responding to the charge questions. The report is succinct, well written, and interesting reading.

The Charge Questions to the committee were the following:

Charge Question 1: What recommendation does the SAB EEC have regarding this question of scope? Should it be narrowly or broadly focused taking into account water resources and related public health and environmental issues over the lifecycle of hydraulic fracturing?

The Committee recommended that the research approach be broken into a short term program designed to study the sources, pathways, and potential impacts of hydraulic fracturing on water resources, especially drinking water resources; and a long term portion that focuses more generally on aquatic ecosystems and their ability to support fishing and recreation. A lifecycle framework was suggested.

Charge Question 2A: What recommendations does the SAB EEC have regarding these (below) proposed research categories and the related questions in the scoping paper?

- Characterization of the Hydraulic Fracturing Lifecycle
- Potential Relationships to Drinking Water Resources
- Potential Health and Environmental Risks

The Committee provided some good suggestions for EPA to consider for these research categories. One problem with hydraulic fracturing is it's impossible to know the details of the stratigraphy at depth and what the fracturing process actually does to the sub-surface structure and properties. We don't know what the extent of fracturing is going to be, the aperture openings, or the inter-connectedness between fractures that allows fracturing fluids to contaminate adjacent aquifers that are hydraulically connected to the shale formation.

The EEC Committee provided valuable suggestions as to the need for case studies by EPA ORD. However, the suggestion of 5-10 seemed somewhat arbitrary, although based on the "full range of regional variability". But later in the report, the EEC Committee suggests a GIS-based approach to find where major shale basins are co-located with major drinking water sources, and that seems like the best idea to determine the number of case studies necessary. For example, the Delaware River Basin's headwaters are underlain by the Marcellus Shale, a major gas reservoir, and five million people use groundwater and surface water for drinking water supply there (Kargbo, Wilhelm, and Campbell, *Environ. Sci. Technol.*, DOI: 10.1021/es903811p).

The above ground wastewater is a major issue that the EEC Committee has adroitly identified as one of high priority for EPA ORD. BMPs should be identified including how to dispose of brine reject waters following treatment, or solid salt products in some cases.

Regarding the relationship to drinking water resources and potential health risks, the committee suggests a life cycle approach, and it is incumbent on the EPA ORD to consider what constituents in fracturing fluids are too toxic to be used. Unfortunately, the Safe Drinking Water Act excludes the regulation of hydraulic fracturing by the U. S. Environmental Protection Agency (Kargbo, Wilhelm, and Campbell, *Environ. Sci. Technol.*, DOI: 10.1021/es903811p). This means that the ORD research program should be especially clear on the issue of identifying the most toxic chemicals that should not be part of proprietary formulations. For example in the Pavillion, Wyoming, shale development, EPA tested more than three dozen municipal and private water wells and found traces of 2-butoxyethanol, a foaming agent which is quite toxic (Hess, *C&EN*, May 31, 2010, pp. 42-45).

Charge Question 2B: What process does the SAB EEC suggest for prioritizing research needs given the Congressional request and a desire by the Agency to complete initial research products by the end of calendar year 2012?

I liked the “Fundamental Questions” laid out by the EEC Committee in this section of the report. I assume that the question on the “fate and transport of injected constituents” includes the necessity of identifying the variety of chemical in hydraulic fracturing fluids.

Within the Life Cycle framework suggested by the EEC Committee, the EPA ORD should identify the major threats to drinking water from hydraulic fracturing of shale in natural gas wells. For example, if Total Dissolved Solids (TDS), radium-226, and 2-butoxyethanol are the most hazardous contaminants associated with these operations, it would help to set research priorities for Agency completion in the near term (by the end of 2012). The EEC report fails to mention the risk from naturally occurring radionuclides, and that seems to be an important hazard based on the propensity for radium in shale formations.

Following the recent disaster of the Deepwater Horizon oil well explosion and oil spill, we are reminded of the need for worst case planning and technology development. One theme could be for the Agency to develop a Worst Case condition for natural gas development in shale formations. If the worst case happens, do we have technology to mitigate or abate it promptly?

Charge Question 3: What advice does the SAB EEC offer for designing a stakeholder process that provides for balanced input in developing a sound scientific approach for the overall research strategy?

This is an excellent section of the report which details some partnering opportunities. I would only add that EPA ORD should co-locate their research with the oil and gas development companies as suggested in the report, but the Agency must keep clear its regulatory mandate in terms of licensing these operations in conjunction with the states.

SAB Review Questions:

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed:

Yes, the charge questions have been adequately addressed.

2. Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report:

There are no errors that I found. I would add that a Worst Case scenario should be envisioned by EPA ORD in its first work product, and they should prioritize the greatest risks to drinking water. This would be highly responsive to Congress.

3. Whether the Committee's report is clear and logical:

Yes, the Committee's report is clear and logical.

4. Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report:

Yes, the report does a nice job of providing logical recommendations from the points made.

Comments from other SAB Members

Comments from Dr. George Daston

I thought the hydraulic fracturing recommendations were clear and well considered. The only point that I thought was missing was a recommendation to develop a public communication plan to explain the research prioritization and the research outcomes as they become available. Perhaps this can be something that the stakeholder group is tasked to develop, but it should be a reco here. This issue has captured a lot of attention nationally. I've even seen signs about it in southwestern Ohio, where this is not a local issue.

Comments from Dr. Otto Doering

I believe that the charge questions were well addressed. I would add one notion here with respect to the stakeholder/advisory group. My view is that this group can be extremely important in the EPA gaining adequate knowledge in this area and that its' composition may be critically important. Stakeholders are one thing - those with useful knowledge may be outside a group so defined. The draft committee report does indicate the importance of this group. Do we need to say a bit more about the range of expertise needed?

I strongly endorse the notion of performing in depth case studies.

I did not find technical errors or omissions.

The report appears to be clear and logical.

I believe that the conclusions/recommendations are supported

Comments from Dr. Rogene Henderson

This report is outside my field, so I can make only general comments.

1. The report outline is based on the charge questions. Each charge question has been addressed.
2. I am not knowledgeable on this process and so am not capable of detecting any technical errors.
3. The one part of the report that I felt competent to comment on was the answer to Charge Question #3 related to stakeholder involvement. I suggest one minor change to clarify the bottom line in this section. One sentence (page 22, line 41) says the stakeholders should be involved throughout the research process. Another sentence (page 22, lines 29-30) says the stakeholders could be involved in the transition from research results to policy setting. Another sentence (page 22, line 38) says the EP should plan the goals and objectives and then involve stakeholders. I think somewhere in the first part of this section, it needs to be made clear that stakeholders should be involved in the whole process, from planning, to research to transition from research results to policy. I think that is what was meant, but it is not clear.
4. The conclusions seem to be supported by the body of the report.

Comments from Dr. Bernd Kahn

The report addresses the charge questions, appears to have no technical errors or omissions, is clear and logical, and its conclusions are clear. The only possible problem that occurs to me is that the letter to the Administrator is far too detailed and could well be reduced in length about two-fold.

Comments from Dr. Nancy Kim

Comments on the Chair's Transmittal letter

1. On page 2, line 31 the following statement is made, "As a priority, the Committee believes ORD should develop a risk-based research prioritization approach." On page 3, line 12, the following sentences occur. "Regarding potential health and environmental risks associated with hydraulic fracturing, the Committee believes that such potential risks can only be assessed after sources and pathways of possible exposure are much better understood. Several activities must occur before such potential risks are assessed, including: a) characterization of the composition and variability of the source fluids, flowback water and produced water that is co-mingled with the flowback water...(followed by a list of 4 other specific issues).

At first glance it seems as though it would be difficult to come up with a risk-based research prioritization approach if the risks can't be assessed until after the 5 specific issues are completed. Additional language is needed to clarify what is meant. For example, if the sentence on page 2 refers to a preliminary risk-based prioritization approach is meant, words like preliminary could be added. The sentence on page 3 could be revised to say that the potential risks can only be well characterized after sources...

This would be one way to handle the sentences, but the committee is in a better position to revise the language, based on its discussions.

This same problem occurs within the body of the report.

2. On page 3, line 30. It isn't clear what the word characteristics refers to. Perhaps some examples could be added, e.g. chemical/physical properties?

The same problem occurs in the body of the report.

Report

1. I recommend defining the terms short-term and long-term early in the report. The report uses these terms frequently and I assumed that short-term meant before the 2012 deadline and long-term meant afterwards. On page 17, line 41, the committee defines short term within one to three years and long term five to ten years or longer. It would help to move this up front. ORD might appreciate having the break point be 2012, but that may not fit the committee's discussion.
2. On page 19, line 28. The committee recommends assessing possible synergistic effects. Although I don't disagree with the concept, it is a very difficult thing for ORD or anyone to accomplish with complex mixtures. Could the committee add some language to give further guidance about how ORD should accomplish this, how much effort should go into it, give some discretion to ORD, etc?
3. On page 20, line 1 the report states, "...an initial analysis should be conducted that identifies the exposure routes likely to pose the greatest human health risk." Perhaps this language would help with my first comment on the letter.
4. On page 20, line 10. The end of the paragraph mentions using GIS mapping techniques for looking at spatial associations between hydraulic fracturing activities and human

diseases. I have many reservations about this recommendation. First, if this is going to be done, CDC should be heavily involved. Secondly, looking for associations between locations and diseases without knowing anything about whether or not exposure is actually occurring, to what, what type of health effects it may cause, what exposure routes, what level of exposure, correcting for other risk factors, etc., could identify a number of spurious “clusters” that some health agency will have to address and the likelihood that they will be caused by some exposure related to hydraulic fracturing activities (especially if EPA does a good job of limiting contamination and exposure) could be low, if any. I am not convinced that this is a good way to spend limited research dollars. I do support mapping the hydraulic fracturing activities, using these data to identify means of carrying out activities to monitor exposure and, if exposure occurs and it is appropriate, to monitor health status.

5. On page 21, lines 11 and 15. These are examples of two areas in the report that relate to my 2nd and 1st comment on the letter.
6. Did the committee consider making any recommendation about the need for thinking about research to develop or identify actions that should or could be taken with any accidental releases? This comment is related to the oil problems in the Gulf of Mexico.

Charge questions.

I believe that the committee has adequately addressed the charge questions. My comments point out some places where I think additional clarity could be added and where a couple of technical issues concern me.

Minor comments

1. page 12, line 11. The sentence states “the following charge,” but the charge isn’t given until the bottom of page 13. How about removing the word following?
2. Page 18, line 15. Period should be after the parentheses.

Comments from Dr. Cecil Lue-Hing

In its charge to the SAB, the EPA on behalf of ORD requested that the Committee, review the Scoping Document, and provide comments on the following three areas:

1. Scope of the research program
2. Proposed research categories and topic areas, and process for prioritizing research needs given the Congressional request and a desire by the Agency to complete initial research products by the end of calendar year 2012; and
3. Design of a stakeholder process that provides for balanced input

General comments

The EEC has satisfactorily addressed the charge questions posed by the EPA, and has offered some very meaningful recommendations in each of the three charge areas. While some of these recommendations, may, on their face appear to be commonsensical, they are nonetheless important. A few select examples:

- Be hydraulic fracture specific, and avoid the temptation of expanding the project to include environmental concerns that are common to all oil and gas production activities
- The need to recognize the usefulness of lifecycle assessment, but also to understand that it does not necessarily need to be undertaken in this case
- EPA should partner with industry who develop and operate the wellsites while EPA conduct research at the sites. This partnering would promote transparency, and avoid the need for scale-up of research data.
- EPA should partner with DOE on risk assessment approaches pertaining to geologic sequestration of carbon dioxide.

Other comments

The following comment may be added with respect to caution:

- Since the behavior of hydraulic fractures in geologic formations once created, is not well understood, e.g., do they have the ability to heal naturally, the EPA should plan for the potential of a very long term involvement.

Summary

I approve the report as is.

Comments from Dr. L.D. McMullen

I have the following comments:

A. Letter to the Administrator

1. It seems to me that the letter is a little long. While the content of the letter is good, the points could be more summarized with a letter that is more in 2 to 2 ½ page length.

B. Report

1. I found the report a little hard to follow in places. It seemed to be a collection of thoughts and/or ideas put together without some connection language. In most cases an introductory paragraph may help. For example, the response to Charge Question 1 on Page 15, the first paragraph is the approach, the second paragraph is systems perspective, then life cycle framework, etc. If the second paragraph in this section outlined the issues, the reader would know how each section tied together.
2. I didn't understand A. Background and the B. EPA's charge to the Committee – Background. It seemed to me that A at the top of page 12 could be included in Part B Background on page 13.
3. Part C at line 27 on page 14. I don't think we need the first paragraph. The reader has just completed reading the questions above.
4. Page 15, line 3 states “The committee identified a hierarchy of issues....” It may be of value to include a list of those issues.
5. Page 17, line 28 states “As discussed under Charge Question 2B...”. Since this is the first time this issue appears, address it here and reference it back to this point when Charge Question 2B is discussed.
6. Page 18, line 2 “research programs.” An example here would be of value.
7. On page 18, the first paragraph has a discussion of case studies. It seemed to me that it was implied that new hydraulic fracturing systems be studied in partnership with industry. I am a strong supporter of case studies, but with deeper groundwater systems it may take many years before we know how they react to fracturing. While it may not be ideal, existing sites may provide similar valuable information. I may be reading more into this paragraph than what the committee intended.
8. I did not feel that we addressed Charge Question 2B. We talk about a risk-based research prioritization approach, but I think we need to give a little more detail to what we are thinking would be appropriate. We list a series of questions but don't indicate how that would guide the prioritization.

Charge Question 3 is extremely important. It seems that we may want to suggest that prior to developing a stakeholder group that EPA decides what it desires from a stakeholder process. Then bring together a small group of experts in participatory research to develop a process that

will accomplish the results EPA desires. Then would be the time for team selection. While EPA has some expertise, this is an issue that requires some expert guidance.

Comments from Dr. Jana Milford

We ask SAB members' specifically to address the four quality review questions below from the vantage point of your own expertise:

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

Yes.

2. whether there are any technical errors or omissions in the Report or issues that are inadequately dealt with in the Committee's report;

I realize EPA's effort and correspondingly the SAB review were meant to be focused on the potential impact of hydraulic fracturing on drinking water. While this should clearly be the focus of the advisory, I wondered if the Committee's report should at least acknowledge the potential for other environmental impacts and human exposure routes for contaminants associated with hydraulic fracturing, such as air emissions and occupational exposures to fracturing fluids or wastes.

3. whether the Committee's report is clear and logical; and

Yes.

4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Yes.

Comments from Dr. Judith Meyer

Meyer Quality Review of Hydraulic Fracturing Advisory

5. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

YES. I think the committee has made the appropriate recommendation that ORD needs to think beyond impacts on drinking water. That is a reasonable short term research goal, but considering impacts on aquatic ecosystems is also needed.

6. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

p. 22, lines 26-27: I was surprised that academia was not listed as one of the possible sources for experts for this advisory group. Surely there are professors who know something about this!

If the committee is recommending 5-10 case studies, are they suggesting a similar number of stakeholder groups? Or one national group? If so, did the committee consider representation from the areas represented by the various case studies? I think some mention is needed of how the stakeholder process and case study approach can be meshed. Some mention of interactions with communities at case study sites is made on p. 23, line 24, but I think some more specific attention is needed as to how these two aspects of the program could be better linked.

The last sentence of the report is directing ORD to interact with other federal agencies – which ones? As written, the directive is what Congress told them they had to do with no further guidance provided.

7. whether the Committee's report is clear and logical;

In general, YES with the following concerns as to structure of the report:

The Letter seems rather long. I question whether the paragraph starting on p. 2, line 36 is really needed in the Letter. At the very least it could be shortened. P. 3, lines 14-28 also seem very detailed for a Letter.

Where's the Executive Summary? Does the Letter supposedly replace this? I thought a Letter and an Executive Summary filled two different needs: the Letter a short communication to the Administrator that highlighted the main points, and the Executive Summary would provide a more technically detailed summary of the report's main points.

8. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

YES although the conclusions and recommendations are not singled out as such, but are presented as part of the general narrative.

Comments from Dr. Amanda Rodewald

The charge questions were well addressed, the report was technically correct, clear and logical. I found that the body of report supported the recommendations.

As an aside, I agree that careful and deliberate adherence to best social science practices for stakeholder involvement is especially important given that the hydraulic fracturing study has the potential to be particularly contentious as the movie, "Gasland" is currently in the national spotlight. I liked that the Committee highlighted the value of knowledge held by various stakeholder groups.

Comments from Dr. James Sanders

Were the original charge questions to SAB Committee adequately addressed?

Yes, the committee did a very good job of clearly and completely addressing the three charge questions.

Were there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

No. Not that are apparent to a non-expert

Was the Committee's report is clear and logical?

Yes. The report is brief and to the point, but easy to understand. I was impressed a the EEC's ability to simply address each of the charge questions, and felt that their answers were to the point and helpful.

Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes. My only comment has to do with the fundamental questions developed under 2B. I expect that the EEC does not feel that this listing of questions are the sum of what should be addressed, merely examples? That concept is implicit in the wording, but the EEC should consider being a bit more explicit here.

Otherwise, an easily followed and well thought report.

Comments from Dr. Gary Saylor, Liaison to the ORD Board of Scientific Counselors

BOSC recently provided SAB a copy of a case study workshop Decision Analysis (DA) report prepared for the Office of Research and Development. In discussion with the BOSC DFO it was concluded that the DA report had significance relevance to the Hydrofracture analysis that the SAB conducted for the Agency. Below are excerpts from the SAB report for which the DA report appears most relevant and the issues from the BOSC report that are significantly responsive to issues raised in the SAB report are underlined. If SAB finds utility in drawing on the results of the BOSC DA report, we are pleased to provide corroboration for the SAB analysis.

SAB was asked to comment on the following three areas of hydraulic fracturing:

- Scope of the research program;

SAB Draft Response: “

“In general, the Committee found ORD’s overall approach and scope for the hydraulic fracturing research plan and program appropriate and comprehensive.”

- Proposed research categories and topic areas, and process for prioritizing research needs given the Congressional request and a desire by the Agency to complete initial research products by the end of calendar year 2012;

SAB Draft Response:

“As a priority, the Committee believes ORD should develop a risk-based research prioritization approach that would provide the scientific knowledge necessary for characterizing the risk of human and ecological exposure to hydraulic fracturing fluids and products.”

“The ORD research plan provides several lists of possible specific research questions. The Committee recommends that ORD identify a few overarching, fundamental questions which can then be placed in order of priority before revising the research plan.”

- Design of a stakeholder process that provides for balanced input.

From SAB Draft Response:

“The Committee recommends developing a balanced, collaborative advisory group of stakeholders representing a broad range of perspectives. In addition to providing information to ORD, the stakeholder group would be engaged throughout the research process. ORD’s objectives and process for stakeholder engagement with the research should be carefully designed. One important objective for engagement with stakeholders should be to gain access to and leverage the existing knowledge base on hydraulic fracturing and its environmental impacts. There is a wealth of data and experience in industry, advocacy groups, state agencies, and other groups for ORD to draw upon in the research effort. It will also be important for ORD to engage with other federal agencies to share data, collaborate, leverage expertise, and align research priorities for optimal use of limited resources.”

From BOSC DA Report.

The following texts are from the BOSC DA Report. They address the second and third bullets, prioritization and stakeholders.

“Introduction

ORD is tasked with identifying and carrying out a diverse research agenda with the goal of protecting human health and the environment. Identifying and evaluating research priorities would benefit from more structured approaches as are offered through the use of decision analysis methods.”

“Recommendations

“Decision analysis” can be an intimidating term for some people. The emphasis should be on the process for making decisions, and the tools and approaches that allow key stakeholders to get involved and explicitly resolve potential differences and discrepancies. Influence diagrams and conceptual models are key tools for identifying relationships and linkages across components of a decision. Resource allocation with respect to identifying research priorities is a multi-objective, multi-stakeholder process that changes over time given new information, constraints, budgets, political priorities, and technical feasibility.”

“Use of decision analysis techniques to support research prioritization within ORD is feasible and recommended. The BOSC commends ORD on the initiative to provide a more transparent and accountable process for determining research priorities. Decision analysis techniques are a useful means of organizing and interpreting different kinds of information and data across stakeholders. There are many examples of models and techniques that can be used to support such an effort; indeed, the models may exceed our ability to use them effectively. The model or approach will not make the decision—it will merely inform the process by providing a framework for integrating data and stakeholder opinions, and provide a means for explicitly evaluating uncertainty. The tools, methods, approaches, and software available for incorporating decision analysis methods into the decision-making process have grown tremendously in the last 15 years, so much so that it is difficult, indeed unnecessarily prescriptive, to recommend one particular approach or piece of software. Approaches range from spreadsheet-based tools (see Case Study #3) to sophisticated pieces of software that facilitate web-based stakeholder elicitation tools linked to optimization engines (see Case Study #1).”

“Chicago Area Waterway System. Should the dams between the Chicago Area Waterway System be permanently closed to protect the Great Lakes against Asian Carp and other invasive species? There are benefits and limitations to consider in making this decision, and one way to evaluate the potential tradeoffs that might be made is through the use of multi-criteria decision analysis. In general, this process involves developing alternatives (there are other alternatives in addition to permanently closing the dams), developing criteria/objectives (to be maximized or minimized), and assigning weights to the criteria. Each of these steps requires a participatory process that includes all relevant stakeholders and agencies that have input to the decision. There are web-based software tools available for such a participatory process that allow for the application of rigorous methods in developing weights for each of the alternatives.”

“Gene-environment Interactions/Endocrine Disruptors/Pharmaceuticals. There is increasing emerging epidemiologic research on genetic/epigenetic alterations and disease outcomes, endocrine disruptors, and pharmaceuticals, but many unanswered questions remain. One approach to identifying what research to pursue would be to use a strategy similar to the one presented here for Case Study #1. This approach would use decision analytic tools to prioritize fruitful areas of research to pursue within a particular subject area.”

“Engage staff in the effort. Imposing a process on staff and personnel is unlikely to be successful. Any significant changes to management procedures and the way in which decisions are made require a “cultural” as well as logistical shift within ORD. Start to cultivate the culture internally such that EPA staff recognizes the utility and usefulness of these approaches in making decisions, rather than as an imposition of an external process. A key aspect to this is that decision analysis methods, regardless of the specific approach or piece of software being used, are fundamentally concerned with communication. From a transparent, formalized process for engaging stakeholders and engaging in a deliberative process to developing criteria with which to evaluate specific courses of action or to prioritize research, decision analysis requires communication across management and levels of responsibility.”

“Case Study Development and Conclusions

Based on the comments from the workshop participants, we devised a simple example for resource allocation for the ecological research program using ExpertChoice software¹. This software provides an intuitive web-based platform from which to include multiple stakeholders and to elicit stakeholder preferences in a consistent and transparent manner.”

“Use of influence diagrams. Influence diagrams represent an excellent first step to understanding determinants of a decision by developing a conceptual model of linkages and interrelationships across key aspects of the decision. Decision planners and analysts must communicate—as they are thinking about a research process—concerning the nature of the decision, the different elements, and how the linkages can be mapped. This allows analysts to better appreciate how their piece fits in, and what the specific uncertainties are that they face. Analysts and decision makers must agree on the completeness and complexity of the influence diagram. Different components emerge at different times, and will need to be added. Influence diagrams will assist in communicating decisions regarding funding and prioritization outward to interested stakeholders. In addition, influence diagrams ultimately allow analysts to capture complex mathematical relationships using decision analysis methods to identify preferred solutions and alternatives in a decision-making context.“

Comments from Dr. Paige Tolbert

I just wanted to convey that I was positively impressed by the Environmental Engineering Committee's draft report to EPA on the hydraulic fracturing research program. It is very well-written and appears to have given thoughtful treatment to the many questions relating to potential impacts of hydraulic fracturing.

Attachment F
Comments from Members of the Chartered SAB on SAB's Review Comments
on EPA's draft Toxicological Review of Inorganic Arsenic: In Support of the
Summary Information on the IRIS (5-13-10 Draft)

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Comments from lead reviewers

Comments from Dr. Jeffrey Griffiths

Review by Jeffrey K. Griffiths of the SAB's review of the "Toxicological Review of Inorganic Arsenic in Support of the Summary Information on the Integrated Risk Information System (IRIS)"

In my opinion, the original charge questions were adequately addressed; no technical errors or omissions exist; the report is admirably clear and logical; and the suggestions, conclusions, and recommendations are supported by the body of the report.

The draft letter to the Administrator is admirably short. My suggestion is to make it even more admirably short, by placing the most important paragraph, e.g. what the SAB recommends in response to the charge questions relating to arsenic, at the beginning of the letter. The letter could begin:

"Dear Administrator Jackson:

The EPA has asked the SAB to review the implementation of the 2007 SAB recommendations regarding arsenic toxicology. [skip to next to last paragraph of the cover letter:] The SAB recommends that , as the EPA proceeds with its revisions of the 2010 draft IRIS assessment, that more detailed information be included.... It is especially important that this IRIS assessment explain the rationale for critical choices in EPAs' cancer risk calculations...."

The history of the review and assessment process since the NRC panel report from 1999 and 2001 could be shortened or contained in the Background section of the report.

The EPA has asked the SAB to address questions relating to the 2007 SAB recommendations relating to:

- Evaluation of the epidemiological literature;
- Dose-response modeling approaches for human health outcomes; and
- The sensitivity of the risk analysis to the exposure assumptions used in the risk assessment.

In this Lead Reviewer assessment I will in general not word-smith but rather assess the coherence, validity, and soundness of the recommendations by the arsenic working group.

Charge 1.

By way of background, in 2003 the US EPA decided to update the Integrated Risk Information System (IRIS) assessment for arsenic, in response to a National Research Council (NRC) panel

report in 2001. In the 2001 NRC report, it was recommended that the assessment of cancer risks associated with arsenic exposure be focused on lung and bladder cancer rather than skin cancers. It is well accepted that inorganic arsenic exposure is linked to lung, bladder, and skin neoplasms as well as to vascular, hematologic, neurologic, and developmental disorders (IARC, 2004).¹ Some recent literature has also shown a relationship to metabolic diseases such as type 2 diabetes. This discussion is linked to the determination of 'cancerogenic' risk. During the period 2003 to 2005 the US EPA developed an update on arsenic and cancer risk. The draft Toxicological Review of Inorganic Arsenic dating to 2005 was then reviewed by the SAB, which issued a report to the EPA Administrator in June of 2007. Based upon that report, the IRIS was further refined and a 2010 draft was prepared for SAB review.

The first charge to the SAB was,

Please comment on the EPA's response to the recommendations and the conclusions of the SAB (2007) Arsenic panel regarding the evaluation of the epidemiological literature.

Overall, the SAB working group found that the EPA was responsive to the SAB recommendations. I concur.

The SAB discussed:

- The selection of critical studies for determination of carcinogenic risk. The work group agreed with the EPA that the most appropriate dataset remains the Taiwanese information developed by Wu 1989, Chen et al 1988, and Chen et al 1992. The work group found that the limitations of these studies, as well as their strengths, were "well presented."
- A Review and Evaluation of available human studies. The 2007 SAB report requested that a group of 8 issues be addressed in any review and evaluation (exposure misclassification, temporal variability in assigning prior arsenic levels from recent measurements, imputed exposure levels, the number of exposed persons at various estimated levels of waterborne arsenic, response / participation rates, estimated exposure variability, control selection in case-control studies, and the influences of these factors of the magnitude and statistical stability of cancer risk estimates). The SAB work group found that the draft 2010 IRIS document is responsive to these issues and that the EPA had done a thorough job of describing the strength and limitations of the literature.
- Evaluation of other published epidemiology studies using a uniform set of criteria. The work group found the EPA to have been responsive, however that additional clarification and documentation on how various study design factors were considered and weighted. It was noted that aspects of studies discussed in the part 4.1 narrative were not included in the summary table of Appendix B. The work group recommended that the review of the literature "needs to more clearly state the set of criteria that were used in evaluating the studies.....and that the table of studies (Appendix B) be reformatted to present the study summaries more clearly and in a more consistent fashion including pulling any essential information from references into text for clarity." **It would be my recommendation that since the Wu (1989), and two Chen et al studies (1988, 1992) remain the studies**

¹ IARC. 2004. Some Drinking-Water Disinfectants and Contaminants, Including Arsenic. IARC Monog Eval Carcinog Risks Hum 84:39-270.

considered the best available for carcinogenic risk assessment, the summary table of Appendix B should make it quite clear what the evaluation criteria are so that the strengths and weaknesses of the other published studies are transparently and clearly visible to the readers.

- Study power. The work group noted that many studies have limited power to detect associations between exposure and disease if one exists. A "negative" study may reflect limited study power rather than the absence of a relationship. This is particularly pertinent given the judgment that the Taiwanese studies remain important ones given their large population sizes and the large number of person-years of follow-up, which improve study power. The study group recommended that study power be commented upon in section 4.1 of the report as well as Appendix B, which makes eminent sense.
- Bias towards the null due to study limitations regarding exposure and confounders. The study group noted that different forms of bias in epidemiological studies can lead to an underestimation or overestimation of risk. For example, exposure misclassification tends to bias studies towards an underestimation of risk. They recommended the potential for underestimation or overestimation of risk be expanded in the discussion of the draft IRIS document. **It would be my recommendation that when possible, the potential for underestimation or overestimation of risk be included in the summaries of the other epidemiological studies reviewed in the 2010 IRIS document. This may improve transparency.**
- Consideration of epidemiology studies published after 2007. The working group recommended that the EPA consider including an appendix summarizing major new studies published since 2007. The charge to the working group regarded the assessment of studies work up to 2007 but not after. While this is a sensible recommendation which also improves transparency, and would display the responsiveness of the US EPA to new epidemiological data, **it would be my recommendation to pursue this on a parallel track rather than delay finalizing the draft 2010 IRIS assessment.**

Charge 2.

The working group was asked,

Please comment on the EPA's response to the SAB recommendations and conclusions regarding the approach to modeling inorganic arsenic cancer risks and the corresponding sensitivity analyses.

In response, the working group determined that the sensitivity analysis was response to the prior SAB review. I concur.

The draft panel report notes the specific models which were recommended and the presence of these models in the draft 2010 IRIS document. They panel recommended graphic presentations to improve the interpretation of the results, and agreed with the EPA that "none of the alternative models materially changed the estimated risk levels versus use of a linear model." Other sensitivity issues were dealt with (potential bias by the high-end exposures, exclusion of a reference population) in a scientifically sound fashion. The working group

recommended that the rationale from a 2005 review of the use of a reference population be included in the IRIS review along with a description of the reference population.

Consistent with the latter recommendation, the arsenic working group recommended a more detailed description of the underlying Taiwanese datasets, a discussion of the well water arsenic measurements and their variability, and the inclusion of additional information on how the variability of water arsenic measurement affects the risk assessment. Furthermore, the working group requested that the modeling data and parameters, and that additional sensitivity analyses regarding the reference population be considered. **In general, all of these recommendations relate to transparency and clarity and are reasonable.**

Finally, the issues of mode of action; a linear versus non-linear approach; and risk calculation were addressed. The panel concurred that given the current state of knowledge, a linear approach should be accepted. It suggested that the results of the IRIS analysis should be interpreted in light of existing population-wide information regarding lung and bladder cancer risk. **These recommendations are reasonable.**

The point was made that a discussion regarding the risk attributable to drinking water may not be appropriate for the IRIS (which includes multiple routes of exposure) and may belong in a document specific to that issue. (For example, see Smith et al 2009, which suggests that increased lung cancer risks are similar whether arsenic is ingested or inhaled).² **While there is intense interest regarding the risk from inorganic arsenic in drinking water, on reflection this recommendation is reasonable given the role of an IRIS.**

Charge 3. The working group was asked, **Please comment on EPA's sensitivity analyses and choice of the exposure assumptions use in modeling cancer risk as recommended by the SAB (2007) Arsenic panel.**

The working group felt that the EPA was partially responsive, and gave a detailed set of recommendations and examples to improve transparency of the exposure assumptions, and the rigor and transparency of the sensitivity analysis. **I concurred with this assessment of partial responsiveness and found the list of examples and recommendations to be comprehensive.** This list (in summary) relates to

- Better explanations regarding the results of the sensitivity analyses;
- Justifications for the drinking water consumption rate assumptions;
- A sensitivity analysis relating to gender specific water consumption;
- Water arsenic concentration assumptions;
- Water consumption by susceptible groups;
- More complete and graphical analyses; and
- The conduct of selected analyses where more than one exposure assumption is varied.

To this discussion I would note that the examples on how water intake may vary did not include ones relating to physical labor.

² Smith AH, et al J Exposure Science and Environ Epidemiology 19:343-348.

As to the exposure assumptions, the working group noted that in face-to-face meetings with the EPA, "much of the documentation addressing the scientific basis of the exposure assumptions was provided through separate documents which could be incorporated into the draft IRIS, and then listed several examples of issues which could be addressed and connected via this incorporation. **These examples were logical and reasonable ones, and the suggestion of incorporation of the "scientific basis of exposure assumptions" made sense.**

Final comments regarding a justification for limiting non-water exposure to consumption was requested. The EPA's assumption that only ingestion of food and water are important may at times be appropriate but other routes of exposure should be discussed. In the Smith et al reference provided above, for example, an occupational inhalation exposure was compared to an ingestion route of exposure. If indeed the suggestion is to be made that the IRIS document is one that relates to all relevant exposures, then this IRIS may be missing the boat when other routes of exposure exist.

Comments from Dr. Steve Heeringa

The SAB workgroup has done an excellent job in its review of the EPA document. Each of the charge questions is addressed thoroughly. The SAB report is clear when it supports the major positions of the IRIS document (e.g. the Taiwanese data of Wu (1989) and Chen et al. (1988,1992) as the best available data for determining population risk). The report is concise in making recommendations for additions to the report (graphical analyses), clarification of assumptions and weighting of criteria for assessment and transparency in exposition. In terms of the discussion of statistical methodology, I found no major technical errors in the report. Many of the recommendations made in the report for additional sensitivity analyses of clarification of data evaluation criteria are completely consistent with the original findings from the 2005 review. There are a few minor issues that I have with the wording of the report but these do not rise to the level of technical error.

As noted above, the report is clearly written. The justification in support of positions taking by EPA in the IRIS document and the argument for additional work or clarification of the report wording are logically presented.

The conclusions and recommendations in the committee's report are consistently defined and supported in the body of the report.

I had just a few minor points where the report might benefit from rewording or clarification. On Page 4, the first section opens with a request that EPA attempt to present power calculations for the many epidemiological studies that were reviewed (case/control and prospective cohort designs) . Post hoc, an assessment of the potential power to detect true differences in cancer incidence in the population may be difficult. Nevertheless, the recommendation of the subcommittee still has value since if the post hoc assessment suggests power to detect true population differences are all extremely low (e.g $<.5$) it suggests that on a case-by-case basis, null results from the epidemiological studies may be attributable to insufficient sample size. In the recommendation (Paragraph 2 on page 4), the report refers to a "...quantitative presentation or discussion of *relative* power". I recommend that the report drop the adjective "relative" since it implies that power of $(1-\beta_1)=.5$ for study 1 vs. $(1-\beta_2)=.25$ is an advantage for Study 1 when it fact Study 1 still provides at best an even chance of accepting the null when the alternative is true.

Page 4, the recommendation for additional discussion of bias. This recommendation could be made more specific. As written it invites a lengthy review of bias and confounding in case-control and cohort study designs. In the recent February 2010 FIFRA SAP review of epidemiological research and its role in risk assessment, "Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment", charge questions pertaining to misclassification and confounding generated a "textbook" response. The EPA might actually borrow a discussion from that report. Rather than incorporate a lengthy discussion, the SAB report might suggest that the IRIS document include a simple table that identifies potential biases (misclassification of exposure, misclassification of disease, omitting confounders, etc.) and the potential magnitude and direction of bias in inferences that are draw from the study data. A

simple summary could then relate these sources of bias to their potential in the data and methods used in the IRIS assessment.

Page 6, Recommendation re variability of well water arsenic concentrations. The fifth sentence might be rewritten to read “.. the variability of measurements *both within and across wells* within a given village ...” . This minor change would communicate a recommendation for estimation of the relative magnitude of the between and within well components of variance. As suggested in the remainder of this paragraph, this would lend some insight into the stability of well concentrations over time and the impact of assuming that a resident of a village always consumed water from the same well.

Page 7, paragraph 3, line 8 – Minor terminological issue. The term parameter variations is used to refer to non-water intake value (a parameter of the model) and the reference population (a source of data). Suggest separating out the reference population choice as in “.. parameter variations and choice of a reference population...”

Page 12, para 1, line 7. This is probably only my personal preference but the phrase “...EPA does a reasonable job...” is not specific in terms of evaluating their work. I suggest, dropping “Although EPA does a reasonable job of discussing these reports,” and just pick up with “ The current report lacks specific rationale...”.

Comments from Dr. Jonathan Samet

General Comments

In general, the draft SAB comments are satisfactory and thoughtfully and comprehensively address the charge questions from EPA. The Administrator will be provided with a clear assessment of the Agency's responsiveness to the prior comments from the SAB. My specific comments below, largely relate to portions of the draft dealing with methodological issues specific to the epidemiological aspects of the comments.

Page 2, "The limitations of the studies are well presented, particularly regarding the ecologic study design, ..."

Studies described as "ecological" are often considered to be inherently weaker than individual-level studies. It is correct that the study by Chen et al. is of ecological design; that is, exposure has been assigned at the population (village) level. However, exposure, i.e., concentration of As in drinking water is the same for all persons within a particular village, although dose varies among individuals.

Page 4, first paragraph:

This paragraph needs conceptual "tightening" in discussing considerations of power. The first sentence should be rewritten as follows: "The power of an epidemiological study is the probability of detecting an association of a specified strength between exposure and disease if one exists." Additionally, the term "negative study" should be avoided; I assume that "negative" means not achieving statistical significance.

Page 4, second paragraph:

Emphasis should be given to assessing the width of confidence intervals. It would be reasonable for the report to include a set of power curves for various sample sizes and effect sizes, but necessarily to calculate power for completed studies. Power calculations require an a priori assumption of effect size; do we know what effect to expect?

Page 4, fourth paragraph (Recommendation)

Emphasis should be given to estimating the quantitative consequences of any bias. While the existence of bias can usually be proposed with some certainty, the key issue is whether the quantitative consequences of bias are of sufficient magnitude to be of concern. Methods are available for this purpose (see, for example: Lash, Fox, and Fink: *Applying Quantitative Bias Analysis to Epidemiological Data*, Springer, 2009).

Page 5, Recommendation

Of course, there are always new studies, but guidance should be given as to what makes a study "major" and potentially pivotal, e.g., large sample size or effect estimate substantially different from that estimated by Chen et al.

Page 8, bottom of page

These considerations are quite general. The Agency should have a reasonable and standardized approach to describing the basis for assumptions.

Comments from Dr. Paige Tolbert

The following comments are provided in my role as discussant/quality reviewer of the SAB Inorganic Arsenic Cancer Review Work Group's Review Comments on EPA's Draft Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the Integrated Risk Information System.

In reviewing the report by the SAB Work Group, the discussants are asked to respond to the following Chartered SAB quality review questions:

- whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
- whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
- whether the Committee's report is clear and logical; and
- whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Quality Review Question #1: whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

Response:

The SAB Work Group has adequately addressed the original charge questions posed to them by EPA.

The following questions constitute the original charge questions to the SAB Work Group:

Work Group Charge Question #1. Please comment on EPA's response to the recommendations and the conclusions of the SAB (2007) Arsenic panel regarding the evaluation of the epidemiological literature.

Work Group Charge Question #2. Please comment on EPA's response to the SAB's recommendations and conclusions regarding the approach to modeling inorganic arsenic cancer risks and the corresponding sensitivity analyses.

Work Group Charge Question #3. Please comment on EPA's sensitivity analyses and choice of the exposure assumptions used in modeling cancer risk as recommended by the SAB (2007) Arsenic panel.

I will comment on the adequacy of the Work Group's response to each of these charge questions in turn.

Regarding Work Group Charge Question #1, the Work Group concluded that the EPA had been responsive to the SAB 2007 recommendations in evaluating the published epidemiology studies, and concurred with the choice of the Taiwanese dataset as the most appropriate data to use in the risk assessment. Further, the Work Group expressed some concern regarding EPA's presentation

of the review of the epidemiologic studies and provided specific recommendations regarding how the evaluation could be improved. The Work Group adequately addressed Charge Question #1. It is well-justified in finding that the EPA was responsive to the original SAB recommendations regarding review of the epidemiologic literature and in finding that the Taiwanese data continues to provide an appropriate basis for the risk models. The Work Group found that the draft IRIS report presents a comprehensive overview of the epidemiologic literature, and is responsive to the 2007 SAB recommendation that a specific set of issues (the eight items listed on page 3 of the Work Group draft report) be reviewed in evaluating the studies. Moreover, the Work Group is on target in indicating that the review of the epidemiologic literature needs additional work. As pointed out by the Work Group, EPA needs to more clearly state the criteria used in evaluating studies and present the review in a more systematic and synthetic way; this will make EPA's choices regarding data used in the risk models more transparent and compelling. While it is always difficult to extract a uniform set of descriptors from the various studies comprising the body of literature on a topic, the Work Group is correct in pointing out that Table B-1 needs further work. It does not consistently convey the most important information about each study, such as sample size (for each exposure grouping if available), the estimate of effect (e.g., RR) and associated estimate of stability of the estimate, and expected biases. Furthermore, the text evaluating the literature in Chapters 4 and 5 of the IRIS report needs additional synthesis summarizing the relative merits of the studies to increase transparency regarding the ultimate decision to rely on the Taiwan data. For instance, a qualitative judgment of the relative bias to the null resulting from lack of individual exposure estimates across different studies could be provided (e.g., might this be expected to be a greater bias where people drink more bottled water and have higher residential mobility?) Overall, this reviewer concurs with Work Group assessment in response to Work Group Charge Question #1, although several minor clarifications to the Work Group report are suggested in my response to Quality Review Question #2.

Regarding Work Group Charge Question #2, the Work Group found that EPA was responsive to the 2007 SAB review in performing requested sensitivity analyses of the dose-response modeling and concurred with the EPA rationale for choosing a linear low-dose extrapolation risk assessment approach. The Work Group agreed with EPA's assessment that for the most part the various sensitivity analyses performed did not materially change the estimated risk levels. For the one case where the sensitivity analyses yielded materially different risk estimates, i.e., the sensitivity analysis incorporating a reference population, the Work Group requested that additional information be incorporated into the IRIS report from the relevant 2005 issue paper and the Work Group suggested further analysis of this issue. The Work Group further requested additional description of the Taiwan data to make the IRIS report self-standing, and publishing the data and parameter tables used in its modeling analysis for greater transparency in the presentation. This reviewer finds that the Work Group response to Charge Question #2 is adequate. The reviewer agrees with the Work Group's assessment that EPA was responsive in performing sensitivity analyses and that EPA was justified in its use of a linear low-dose extrapolation in its risk assessment. As the Work Group emphasized, the linear model is the prudent choice given lack of compelling evidence of a threshold or other dose-response form. The Work Group request for further work and expansion of the IRIS report as described above is also well justified.

Regarding Work Group Charge Question #3, the Work Group found the EPA Draft IRIS report was partially responsive to the 2007 SAB review. With respect to the sensitivity analysis of the impact of drinking water consumption and non-water arsenic intake assumptions on the estimated cancer potency, the Work Group found the approach to be minimally adequate, and recommended that EPA expand its treatment of this issue with more explanation of the observed sensitivity to the non-water intake assumption, better justification of the default assumptions regarding drinking water consumption and non-water arsenic intake rates, more description of how village well measurements were used in the water concentration assumptions, more complete presentation of sensitivity results, possible consideration of sensitivity to selected sets of exposure assumptions, and explanation of the rationale for not including some of the analyses suggested by the 2007 SAB review. This reviewer finds the Work Group response to Charge Question #3 adequate. The Work Group provides the basis for the finding that the EPA report is minimally responsive, and provides detailed suggestions for how the EPA report could be improved to be more responsive to the original SAB input and to increase transparency.

Quality Review Question #2: whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report

Response:

This reviewer did not find technical errors, omissions or issues that are inadequately dealt with in the report. However, I suggest the following clarifications to improve the Work Group report:

- The Work Group report, as written, appears to recommend that power calculations for each study be added if possible (p. 4). While the relative power of the various studies is important to convey, this should not be done by presenting power calculations. Power calculations are useful in planning a study, but after the study is completed, the most informative presentation of epidemiologic findings that combines both the observed results and reflects the power of the study is the relative risk point estimates for a specified exposure comparison and the associated confidence intervals. Furthermore, systematic presentation of numbers of individuals in each exposure stratum provides the reader with a sense of relevant sample size within strata and the robustness of the exposure contrast. For instance, the required sample size will be larger for a smaller exposure range (e.g., the U.S. studies), since the expected magnitude of the RR for low-level exposure is lower. The recommendation regarding presentation of power should be refined and clarified in the Work Group report.
- p.2 of the Work Group report, add “Taiwan” to sentence: “The limitations of the *Taiwan* studies are well presented, particularly the ecologic study design...,” to clarify that the Work Group is referring to the Taiwan studies here, not the entire body of literature, referred to in the immediately preceding text.
- Delete “toward the null” in the heading “Bias *toward the null* due to study limitations regarding exposure and confounders” (p.4) – while exposure error generally leads to a bias to the null, uncontrolled confounding can bias results upward or downward.

- This reviewer has some concern about the Work Group recommendation to summarize major studies since 2007 (p.5). To make the judgment that selected studies are major and have a potential impact on the risk assessment would require careful deliberation of the body of new studies, which could lead to a substantial delay. A quick review highlighting important developments could be helpful, but doing this in a cursory way could lead to the process becoming mired in debate. The Work Group may want to revise the language regarding this suggestion to give EPA wide latitude in determining whether to pursue this option.

Quality Review Question #3: whether the Committee's report is clear and logical

Response:

As described above, this reviewer finds that the Work Group's report is clear and logical. Other than the minor clarifications outlined in response to Quality Review Question #2, above, the report effectively communicates the Work Group's assessment of the draft IRIS report with respect to EPA's charge questions.

Quality Review Question #4: whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report

Response:

The conclusions drawn and recommendations provided are supported by the body of the Work Group's report. As described in response to Quality Review Question #1, the Work Group provides ample rationale for its recommendations. Overall, the Work Group's conclusions and recommendations are scientifically sound and well-justified.

Comments from other SAB Members

Comments from Dr. Otto Doering

I believe that the charge questions were adequately addressed - the responses were highly specific to the questions asked.

I did not find technical omissions, but this is not my field.

I found it clear and logical.

I believe the recommendations given and questions asked by the review committee are well supported.

Comments from Dr. David Dzombak

1. Were the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed?

Yes.

2. Were there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

No

3. Is the Committee's report clear and logical?

For the most part, the report is clear and logical. There is one response from the committee to Charge Question 2, in the recommendation pertaining to the last subsection on "Explanation of the risk calculation" (top of page 8), which contains some contradictory statements. After making some recommendations in the beginning of the recommendation for additional analysis of some specific aspects of water contamination with inorganic arsenic, the section concludes with the statement that "this discussion is probably better suited for inclusion in other risk assessments and characterization documents developed by the Agency."

4. Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?

The conclusions and recommendations are well supported by the body of the Committee's report. The conclusions are summarized perhaps too briefly in the letter to the Administrator, i.e., in one paragraph at the end of the two-page letter. The preceding material in the letter is a long explanation of the history of the process to re-examine the EPA toxicological review of inorganic arsenic. The amount of space devoted in the letter to background information seems excessive compared to the very concise statement of findings and recommendations.

Comments from Dr. Rogene Henderson

Comments on SAB's Review Comments on EPA's draft Toxicological Review of Inorganic Arsenic

Rogene F. Henderson

1. The charge questions were adequately addressed.
2. I found no technical errors.
3. I thought the writing was exceptionally clear. Good job!
4. The conclusions were supported by the text.

There were some typos. The pages are not numbered, but I will try to indicate where corrections are needed.

First page of letter, next to last line: Dimethylarsinic acid should not be capitalized in the middle of the sentence. It should be written dimethylarsinic acid.

Second page of letter, last line of last large paragraph: "theses" should be "these"

Page 3 of report: There is an extra period about midway in the next to last paragraph.

Page 4 of report, middle of page: The phrase, "this flaw possibly lead to the underestimation of risk" should be "this flaw possibly led to an underestimation of risk."

REVISION ON 6/18/10

After hearing the public comments on this document on June 16, 2010, I am concerned that the subcommittee was not given broad enough charge questions to review the EPA draft document adequately. I do not think the SAB should approve the review of the document until this issue is examined in more detail.

Comments from Dr. Bernd Khan

The report addresses the charge questions but is difficult to review by one who does not know the subject in detail. Specifically, it would be helpful if the SAB report stated the pertinent information at the appropriate points of discussion. This might include some, but not all, of the following: the relation of As concentrations in lung and bladder relative to the steady-state As intake rate; the relation of lung and bladder cancer incidence to As concentration; the contribution of As in drinking water to total daily intake; the expected retention of inorganic As relative to various forms of organic As; and the expected magnitudes of these various organic forms relative to the inorganic form and the extent to which they transform in nature

The report is well written, with the following minor typos,

- p. i, 3rd line from bottom: delete skipped line
- p. ii, par. 2, last line: don't forget to insert date.
- p. ii, par. 3, l. 8: Insert 'as' after 'such'.
- p.3, par. 3, l. Delete second period.
- p.4, par. 3, l. 5: 'lead' should be 'leads'.

Comments from Dr. Cecil Lue-Hing

SAB. CLH Homework Review Notes. Inorganic Arsenic For June 15-16/2010 Meeting

Review of SAB's Work Group Report on EPA's draft assessment "Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the Integrated Risk Information System (IRS)" (EPA/635/R-10/001).

General Comments

The Genesis of the report under review dates back to 2005 when the SAB was first asked to review some EPA material on inorganic arsenic relative to, metabolism, mode of action, dose-response, and human relevance. The SAB submitted its review and recommendations to EPA in 2007 and has now been charged to determine how well EPA has responded to the 2007 SAB comments and recommendations.

The SAB has been asked to respond specifically to three charge questions – literature review, modeling generally, and sensitivity analyses regarding certain model assumptions.

Specific Comments

The SAB finds that the EPA has been generally responsive to the 2007 comments and recommendations on literature review, but found some deficiencies and offered recommendations to correct them.

As expected the most extensive discussions were directed at modeling and modeling assumptions.

One important issue in this debate was the EPA's choice of using a linear approach for arsenic associated cancer risks. The SAB took the EPA to task, the EPA defended and the SAB accepted the linear approach.

The next extensive discussion was directed at the selection, use, and impact of default assumptions on modeling outcomes.

Here the SAB acknowledged that EPA tried to be responsive to earlier (2007) recommendations, but there still remained several deficiencies including the need for better justified default assumptions in the risk assessment process.

Summary

The SAB has responded appropriately to the three charge questions posed by EPA, and has provided additional comments and recommendations to remedy deficiencies in the EPA document. Because risk assessment procedures are as much art as science, it is possible that this portion of the Arsenic document could require one more round of review.

I am very satisfied with the performance of the SAB's Work Group and support the submittal of their review work product.

Comments from Dr. L.D. Mc Mullen

I want to commend the committee for developing an excellent report. I found it easy to read and it was organized in a very logical style. I feel the original charge questions were adequately addressed and I did not find any technical errors or omissions. The recommendations followed the discussion contained in the body of the report.

I do believe that we may want to change the cover letter a little. The length seems to be correct; however, three-fourths of the letter is history and that we had a meeting. Only one paragraph gives the Administrator a summary of our recommendations. It seems to me that we could reduce the history to one paragraph and leave a page and a half for a summary of our recommendations.

Comments from Dr. Judith Meyer

Meyer Quality Review of Arsenic Advisory

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

YES

2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

No errors that I could detect.

- a. The absence of an Executive Summary is a significant omission. The Letter is almost entirely a history of the questions with only one short paragraph of what the committee recommended. The Letter definitely does not have the kind of information one would find in an Executive Summary. This report needs an Executive Summary!
- b. p. 5 recommendation at top: Can the committee provide a list of key references that EPA should be considering here? The recommendation seems very broad and could inappropriately delay this IRIS assessment. Are there some particularly relevant studies that have appeared since 2007 that the committee could cite?
- c. p. 13: I think the committee should be more forceful in its recommendation on distinguishing between organic and inorganic forms of arsenic. I think that is more than "helpful"; I would argue that it is essential, particularly when dealing with dietary intake.

3. whether the Committee's report is clear and logical;

Generally YES. HOWEVER the absence of line numbers in the document make it more difficult to provide specific comments.

- a. p. 1, paragraph 2 last sentence: move the parenthetical phrase after "The charge questions" so it is clear that this is in what is in the Attachment.
- b. p. 2, Response: It was not clear whether the comments on the strengths and limitations referred to the Taiwanese dataset or the other studies reviewed. Clarification needed.
- c. p. 4, first paragraph under Bias – Is one supposed to conclude that all the other studies suffered from the same flaw as the Chen study? The point that the committee is trying to make with this paragraph needs to be clarified.
- d. p. 8, first recommendation: Does the committee mean "Because there is tremendous interest in the contamination of water by iAs"? If so, change the sentence to that. I'm not sure what iA's water contamination means. Is the committee recommending that any of this discussion be in the IRIS document – or should all be in other documents?
- e. p. 10: I am unclear about what was not done for susceptible groups (children and pregnant women). Did they just not use different water consumption numbers for these populations? Or did they not do any analyses for these groups? If it is the latter, that seems to be a significant deficiency in the analysis that the committee should comment on.

4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

YES

Comments from Dr. Amanda Rodewald

The Committee clearly addressed the charge questions. The use of bulleted recommendations made the report especially easy to read. The report was clear and logical, and I did not notice any technical errors or omissions. The body of the report nicely elaborated on and supported the overarching recommendations made by the Committee.

Comments from Dr. James Sanders

Were the original charge questions to SAB Committee adequately addressed?

Yes, the committee did a very good job of clearly and completely addressing the three charge questions.

Were there any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report?

No.

Was the Committee's report clear and logical?

Yes. The report is brief and to the point, but easy to understand.

Were the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes. While brief, the responses to each charge question were clear, documented, and logical. The committee is to be commended for their clarity.