

**United States Environmental Protection Agency (U.S. EPA) Science Advisory Board (SAB)
Quality Review Teleconference
December 15, 2010**

Summary Minutes

Date and Time December 15, 2010, 1:00-4:00 p.m. Eastern Time

Location: By teleconference

Purpose: To conduct a quality review of a draft SAB report, *Review of EPA's Draft Assessment entitled Toxicological review of Trichloroethylene (October 2009)*¹

Meeting Participants:

SAB Members

Dr. Deborah Swackhamer, Chair

Dr. David Allen

Dr. Ingrid Burke

Dr. Terry Daniel

Dr. George Daston

Dr. Costel Denson

Dr. David Dzombak

Dr. Elaine Faustman

Dr. John Gieseey

Dr. James Hammitt

Dr. Bernd Kahn

Dr. Agnes Kane

Dr. Nancy Kim

Dr. Kai Lee

Dr. Cecil Lue-Hing

Dr. Lee D. McMullen

Dr. Judith Meyer

Dr. Horace Moo-Young

Dr. Eileen Murphy

Dr. Duncan Patten

Dr. Stephen Roberts

Dr. James Sanders

Dr. Kathleen Segerson

Dr. Paige Tolbert

Dr. John Vena

Dr. Thomas Zoeller

Dr. Deborah Cory-Slechta, TCE
Panel Chair

Liaison Members

Dr. James Johnson

(EPA's National Advisory Council for Environmental Policy and Technology)

Dr. Pamela Shubat

(EPA's Children's Health Protection Advisory Committee)

Other Participants:

SAB Staff Office

Dr. Thomas Armitage, Designated Federal Officer (DFO)

Dr. Vanessa Vu, Director, SAB Staff Office

EPA

Dr. Weihsueh Chiu, EPA Office of Research and development

Other

Nancy Beck, Office of Management and Budget

Paul H. Dugard, Halogenated Solvents Industry Alliance

Maria Hegstad, Risk Policy Report

Katharine Kurtz, Navy and Marine Corps Public Health Center

Anita K. Meyer, U.S. Army Corps of Engineers

W. Caffey Norman, Patton Boggs LLP

Resha M. Putzrath, Navy and Marine Corps Public Health Center

Vera Wang, Navy and Marine Corps Public Health Center

Teleconference Summary:

Convene the meeting

Dr. Thomas Armitage, SAB DFO, convened the advisory meeting and welcomed the group. He noted that two individuals had requested time to provide oral public comments and that written comments had been provided to SAB members. He noted that all meeting materials were available on the SAB Web site including: the Federal Register notice announcing the meeting², meeting agenda³, public comments⁴, and members' preliminary quality review comments⁵.

Purpose of meeting and review of the agenda

Dr. Deborah Swackhamer, the SAB Chair, welcomed SAB members and reviewed the purpose of the meeting. She reminded SAB members that quality reviews focus on four questions:

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?
2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?
3. Is the Committee's report clear and logical?
4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Overview of draft Report

Dr. Deborah Cory-Slechta, Chair of the SAB Trichloroethylene Review Panel, briefly summarized the Panel's responses to EPA's twelve charge questions as presented in the executive summary of the Panel's draft report.

Public Comments

Dr. Swackhamer introduced two individuals who had requested time to provide public comments.

Mr. W. Caffey Norman from Patten Boggs, LLP presented comments on behalf of the Halogenated Solvents Industry Alliance, Inc. Mr. Norman referenced his written comments. He commented that the epidemiological data on TCE did not meet the threshold for classification as carcinogenic to humans and that the draft advice prepared by the SAB TCE Panel contradicted a 2009 National Academy of Sciences (NAS) report on contaminated water supplies at Camp Lejeune. In his comments, Mr. Caffey indicated that the classification of TCE as carcinogenic to humans could not be justified under EPA's 2005 Guidelines for Carcinogen risk Assessment. He commented on problems associated with the studies used to support EPA's assessment and noted that the epidemiological evidence indicating that TCE is a human carcinogen is neither convincing nor strong. He noted that a National Academy of Sciences report on contaminated water supplies at Camp Lajeune found no cancer outcomes that provided sufficient evidence of a causal relationship or an association between exposure to TCE and human cancer.

Dr. Paul Dugard from the Halogenated Solvents Industry Alliance, Inc. provided a summary of written comments submitted to the SAB. Dr. Dugard's comments addressed issues that related to the numerical outcomes of the TCE IRIS assessment – RfC, RfD, and unit risks for cancer. He focused on uncertainties and concerns associated with studies used to support EPA's TCE assessment. Dr. Dugard noted that there was substantial uncertainty associated with conflicting data regarding the extrapolation of kidney effects from rodents to humans, and that full evaluation of this was needed to make sure that reliable data were used. Dr. Dugard also commented that an epidemiological study used to calculate unit risk for human renal cancer with numerical estimates of exposure was not sufficiently robust, and that further concerns arise from estimates of unit risk based on animal data.

After public comments, the SAB Chair asked chartered SAB members if they had questions for the public commenters. Chartered SAB members had no questions.

Chartered SAB Discussion

Dr. Swackhamer identified the lead reviewers to begin the SAB discussion. She noted that all of the lead reviewers had provided written comments; however, Dr. Thomas Burke was not able to call-in. She stated that she would summarize Dr. Burke's comments.

Dr. George Daston highlighted his written comments. He commented that it would be useful to prioritize the research needs in the Panel's report. He questioned why the Panel

recommended excluding the kidney toxicity information from the RfD calculation. He also indicated that he did not think that additional discussion of the mechanistic role of immunotoxicity would add clarity to EPA's report given the uncertainty of available knowledge.

Dr. Eileen Murphy indicated that there were several sub-questions to Charge Question 4 (Cancer Hazard Assessment) and that the sub-questions concerning animal data and toxicokinetics were not fully addressed. She also raised concern about the Panel's recommendation that EPA include selected studies published after 2009.

Dr. Stephen Roberts indicated that he did not have any concerns about the Panel's report.

Dr. Swackhamer summarized the written comments of Dr. Thomas Burke. Dr. Swackhamer noted that Dr. Burke had found the Panel's report to be comprehensive and very well written.

Dr. Cory-Slechta then responded to the SAB lead reviewer comments. She indicated that reviewers' comments could be easily addressed. She said that while it would be desirable to prioritize research needs, the Panel did not do that. She indicated that the Panel did not recommend the use of the kidney toxicity data to derive the RfD, although the data provide qualitative support. She indicated that additions would be made to Charge Question 4 with regard to the importance of animal data and toxicokinetic information. She also indicated that the recommendation to consider some additional recent studies (published after the date of EPA's draft report) could be removed from the Panel's report.

Dr. Swackhamer then asked other chartered SAB members for comments. The SAB had further discussion on whether EPA should consider "ground breaking" studies published after the date of EPA's report. Also, one SAB member indicated that it would be useful to hear Dr. Cory-Slechta's response to public comments concerning inconsistency between the Panel's report and the NAS Camp Lajeune study. Dr. Cory-Slechta responded that the material reviewed by the Panel was different from what the NAS had reviewed.

Dr. Swackhamer asked whether any members had additional comments. There were no further comments so Dr. Swackhamer asked for a motion concerning approval of the draft report. A member moved that the draft report be approved subject to editorial changes and that the final report be reviewed by the Chair of the chartered Science Advisory Board. The move was seconded. There was no further discussion so the chair asked for a voice vote to approve the motion. The motion carried.

Dr. Swackhamer then thanked Dr. Cory-Slechta and members of the SAB Panel for submitting a very a good report. The Designated Federal Office then adjourned the meeting.

Respectfully Submitted:

Certified as True:

/Signed/

/Signed/

Dr. Thomas Armitage
SAB DFO

Dr. Deborah L. Swackhamer
SAB Chair

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

The following meeting materials are available on the SAB Web site,
<http://www.epa.gov/sab>, at the following address:
<http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/a60f87e98e51f46f852577b300518230!OpenDocument&Date=2010-12-15>

¹ Draft SAB Report entitled *Review of EPA's Draft Assessment entitled Toxicological review of Trichloroethylene (October 2009)*

² Federal Register Notice Announcing the Meeting

³ Agenda

⁴ Written Public Comments

- Comments from Faye Graul
- Comments from Paul H. Dugard
- Comments from W. Caffey Norman

⁵ Preliminary Quality Review Comments from Members of the Chartered SAB and Board Liaison Members