

Summary Minutes
U.S. Environmental Protection Agency
Science Advisory Board
Perchlorate Advisory Panel

Panel Members: See Panel Roster¹

Date and Time: Wednesday December 5, 2012, 1:00 PM - 5:30 PM
Friday, December 7, 2012 1:00 PM - 5:30 PM

Location: Meeting conducted by teleconference

Purpose: To discuss substantive comments on the panel's draft report (11/9/2012) *Draft (11/9/2012) Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate* regarding EPA's draft white paper *Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop a Maximum Contaminant Level Goal (MCLG) for Perchlorate*

Attendees:

Panel Chair: Dr. Stephen M. Roberts

Panel Members:	Dr. Grant W. Anderson	Dr. Julie B. Herbstman
	Dr. Hugh A. Barton	Dr. David G. Hoel
	Dr. Claude Emond	Dr. Judy LaKind
	Dr. Jeffrey Fisher	Dr. Paul H. Lipkin
	Dr. Mary A. Fox	Dr. Jennifer Peck
	Dr. Wendy J. Heiger-Bernays	Dr. Joanne F. Rovet
		Dr. Cheryl R. Stein

SAB Staff Office: Mr. Thomas Carpenter, Designated Federal Officer

Others Present: See Attachment A

Meeting Materials: All meeting materials are available on the SAB Web site at the [Perchlorate Advisory Panel December 5 Meeting Page](#):

Convene Meeting

The meeting was announced in the Federal Register² and proceeded according to the agenda, as revised with discussions occurring via teleconference sessions, one on December 5 and one on December 7. Mr. Thomas Carpenter, Designated Federal Officer (DFO) for the Perchlorate Advisory Panel, convened the meeting at 1:00 p.m. on December 5, 2012. He stated that the EPA Science Advisory Board (SAB) was a chartered federal advisory committee and he reviewed Federal Advisory Committee Act (FACA) requirements. He noted that panel members are in compliance with government ethics requirements and have no conflict of interests or appearance of a loss of impartiality. Mr. Carpenter stated that as DFO, he would be present during the panel's business and deliberations. He informed participants that summary minutes of the meeting would be prepared by the DFO and certified as accurate by the Chair. He stated that the SAB Staff Office had convened an ad-hoc panel of experts to participate in the review of the

available data and information to support a Maximum Contaminant Level Goal for perchlorate. The panel will consider exposed individuals at different life stages, epidemiologic and biomonitoring data, and physiologically based pharmacokinetic (PBPK) analyses and develop a consensus advisory report for consideration by the Chartered SAB. Members provided preliminary comments and they are available on the SAB web page³. Mr. Carpenter noted that December 5th and 7th meeting dates were announced in the Federal Register notice. The meeting would proceed according to the Agenda and the Chair would decide if the panel would reconvene as necessary to complete its business.

Introduction of Members, Purpose of Meeting, and Review of the Agenda

Dr. Roberts stated that the teleconference was convened to review the *Draft (11/9/2012) Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate*,⁴ hereafter referred to as the Advisory Report, and provided a brief overview. The organization of the draft advisory report directly responds to the Charge⁵ to the SAB.

Dr. Roberts reviewed the meeting agenda⁶ and provided an overview of how the panel would conduct the teleconference to revise the draft Advisory Report. Dr. Roberts noted that public comments were posted on the SAB website and proceeded to introduce the registered speakers.

Public comments

Dr. Richard C. Pleus of InterTox Incorporated spoke on behalf of the Perchlorate Study Group. He highlighted key points from his written comments. He noted the document has improved since the last version and pointed to opportunities to improve the report by expanding on the dose response discussions, providing additional support for including infants as a sensitive life stage of concern, and what is considered an adverse effect.

Dr. Pamela Shubat, Chair, US EPA Children's Health Protection Advisory Committee also addressed the panel. Dr. Shubat provided an overview of the Children's Health Protection Advisory Committee's concern about developing a NPDWR for perchlorate. She noted that the process to evaluate perchlorate has been lengthy and urged the panel to consider interim approaches. She noted that MCLs are reviewed every six years as mandated by the Safe Drinking Water Act.

Written comments were provided by 6 individuals and they are posted on the SAB website for this meeting.

Mr. Tom Curtis, American Water Works Association
Dr. Kimberly Wise, American Chemistry Council
Dr. Gail Charnley, Health Risk Strategies
Mr. Hank Giclas, Western Growers Association
Ms. Patricia Nance, Toxicity Excellence in Risk Assessment
Dr. Richard C. Pleus, InterTox Incorporated
Dr. Lisa Corey, InterTox Incorporated

Discussion of Sensitive Life Stages

Drs. Anderson, Lipkin and Rovet were the lead discussants for this area and provided a summary of their respective reviews for the panel. Authors agreed that the majority of preliminary comments from panel members could be readily addressed. Members discussed proposals for consistent definitions for hypothyroxinemia and sensitive populations and life stages respectively.⁷ They noted that each of these issues are important cornerstones to the recommendations in the remaining Charge questions.

Members recognized that the definition of hypothyroxinemia was still unclear and discussed the proposal to use Moleti et al. (2011) as the primary reference for hypothyroxinemia, particularly in pregnant women. Members noted that definitions and quantitative levels for hypothyroxinemia vary slightly between the clinical and research literature. Similarly, there are differences in the descriptions and cutoffs used to describe hypothyroxinemia in human and animal studies. Members also noted that the numeric values describing ranges may vary in pregnant populations as compared to non-pregnant populations. Members noted that the Moleti study provides ranges and percentiles as boundaries to identify hypothyroxinemia rather than specific levels and therefore accounts for the variation among human populations. Members agreed to insert a definition based on Moleti in section 3.1.1 on Rationale for Considering Life Stages and to add studies that investigated neurodevelopmental outcomes for that population. Members agreed to draft language to describe hypothyroxinemia in the relevant current literature for discussion on December 7 and this draft text was posted it on the SAB website⁸ prior to the meeting. Members agreed to incorporate the new language noting that low “normal” levels of thyroid hormones have been shown to have long term adverse effects in fetuses and infants.

Members discussed the recommendation defining the sensitive life stages and changes that could better define the exposed populations and the exposure pathways. Members noted that the preliminary language distributed for the call was subtle and did not adequately address the affected life stages – fetuses and infants exposed through maternal exposure in pregnancy, breast feeding, or bottle feeding scenarios. Members also noted that bottle-fed infants were not addressed in the recommendation. Members agreed to draft language to describe the sensitive life stages and populations exposed to perchlorate that may affect the sensitive life stage. This language would be discussed on December 7th and posted it on the SAB website⁹ prior to the meeting. Members provided editorial changes to the recommendation and agreed that it should be incorporated in the report.

One member pointed out that current research is evolving to identify developmental changes through different biomarkers for low dose exposures. The member noted that molecular effects have not been directly linked to functional effects. The member believed that identifying this potential use was important advice to provide to EPA. Members of the panel agreed that it is appropriate to inform EPA of the new research areas and that the report should be explicit that these new biomarkers (i.e., gene expression, molecular effects) are pre-cursors to adverse effects that may be valuable in future studies.

Discussion of PBPK Modeling

Drs. Barton, Fisher, and Emond were the lead authors for this section. They noted that the comments on the section are editorial or clarifying and believed comments could be addressed

readily. Authors also agreed to incorporate changes in other sections as appropriate to provide continuity in the report. Dr. Roberts asked if the panel members had comments that had not yet been addressed in the report. Hearing no concerns the panel moved to the next agenda item.

Discussion of Epidemiological Studies

Dr. Herbstman, Hoel, Peck and Stein were the lead authors for this section of the report and believed that most of the preliminary comments from members could be addressed readily. One of the public comment suggestions was to provide advice on improvements to future epidemiological studies and the information needed. Members noted that information is included in Appendix B of the panel's draft report and could be incorporated by reference in the main body of the report or brought forward.

Another member suggested adding to the discussion of thyroid antibodies to provide additional background on their in function in thyroid homeostasis and use in epidemiological studies. Members discussed draft language posted on the SAB website¹⁰ and agreed to incorporate it in the report.

Discussion of Integrating Information

Drs. Heiger-Bernays, Fox, and LaKind were the lead authors for this section. They noted that changes in the previous sections would need to be addressed in this section. Members believed that most of the changes requested in the preliminary comments could be readily addressed. Members discussed the use of pooled analyses based on previously collected epidemiological and biomonitoring data and expressed several concerns. Members believed that too much emphasis was being placed on pooled analyses as a next step to integrating information because the analyses are time consuming and require cautious interpretation of the cross sectional data. Other members expressed concern that the discussion on pooled analyses in the report was too definitive. Members noted that there is value in the epidemiological data and potential analyses on the existing data set should not be omitted from the report. Members noted that the current presentation of next steps in Table 1 (p.29) seems to contradict the recommendations in Figure 2 and accompanying text. Members agreed to convert the analyses listed as next steps in Table 1 to text that better describes the potential options to support the PBPK-PPD model recommendation and the estimated timeframes to complete the analysis.

Members noted that the discussion on sensitive life stage needs to be incorporated into the discussion of estimating reduction in adverse health effects. Members noted that providing advice on this topic is dependent upon which option the Agency selects to develop the MCLG. Once the Agency selects an option (i.e., IUI or thyroid hormone levels), model prediction could be used to estimate reductions. Panel members agreed to provide generic advice and considerations the Agency will need to consider once they have selected an option(s).

Discussion of Executive Summary and the Letter to the Administrator

Members agreed that the key issues and recommendations were captured in the Executive Summary and the Letter to the Administrator. Dr. Roberts and the DFO will update the Executive Summary and Letter to the Administrator based on agreed changes in other sections of the report.

Discussion of Next Steps

Dr. Roberts reviewed the points that panel members identified as key issues and asked the panel for any additional thoughts. Panel members agreed that the key issues were identified and did not identify any additional issues or comments. Dr. Roberts asked the DFO to summarize the next step for panel members to develop the Advisory Report.

Mr. Carpenter stated that writing teams would edit sections of the draft Advisory Report based on comments provided, discussed and agreed upon by the panel. The DFO and Chair would develop a new version of the report and send it to the panel by January 5. Panel members will review the revised draft and send final comments of concurrence to the DFO.

Dr. Roberts asked the panel for any questions or clarifications. Hearing no requests from the panel, he then called upon the DFO to adjourn the meeting.

The Designated Federal Officer adjourned the meeting at 4:15 p.m.

Respectfully Submitted:

Certified as Accurate:

/Signed/

/Signed/

Mr. Thomas Carpenter
SAB DFO

Dr. Stephen Roberts
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 not to rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

Materials Cited

The following meeting materials are available on the [SAB Web site](http://www.epa.gov/sab), <http://www.epa.gov/sab>. The materials cited below are available at the [Perchlorate Advisory Panel December 5 and 7, 2012 meeting page](#) :

¹Roster SAB Perchlorate Advisory Panel

²Federal Register Notice Announcing the Meeting (Vol 77 Number 203, Pages 64335-64336)

³Comments from Members of the SAB Perchlorate Advisory Panel on the draft (11/9/2012) report

⁴[Draft \(11/9/2012\) Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate](#)

⁵Charge to the SAB

⁶Meeting Agenda

⁷Preliminary points for discussion on December 5, 2012 SAB Perchlorate Advisory Panel Draft (11/9/12) Report

⁸Preliminary draft language from members for discussion on December 7, 2012.

⁹Ibid.

¹⁰Ibid

Attachment A
Members of the Public Who Requested Call-in Information for the
Perchlorate Advisory Panel Teleconference¹
December 5 and 7, 2012

Ms. Michelle Babin, Ketchum Inc.
Dr. Nancy Beck, American Chemistry Council
Mr. Bob Benson U.S. EPA
Mr. Doug Brune, U.S. EPA
Mr. Scott Biernat, Association of Metropolitan Water Agencies
Ms. Sarah Bresolin, Assistant Chief Counsel, SBA Office of Advocacy
Mr. Kevin Bromberg, Small Business Administration
Mr. Eric G. Burneson, U.S. Environmental Protection Agency
Mr. Robert Cantilli, US EPA
Ms. Jennifer L. Carr, Nevada Division of Environmental Protection
Gail Charnley, PhD, HealthRisk Strategies
T. Matthew Cho, Ph.D, Navy and Marine Corps Public Health Center
Mr. Ken Clark, Boulder Public Works/ Utilities
Cindy Christian, DEC Drinking Water Program, Alaska
Dr. Perry Cohn, New Jersey Dept of Health
Mr. Lon A. Couillard, Milwaukee Water Works
Dr. Lisa Corey, InterTox
Ms. Sue Dempsey, Nebraska Department of Health & Human Services
Casey Deitrich, CQ Transcriptions
Dr. Elizabeth Doyle, US EPA
Dr. Eve Feinblatt-Meleze, INRA-Méthodologies d'Analyse des Risques Alimentaires, France
Dr. Michael Firestone, US EPA
Donna Fries, Miami-Dade Water & Sewer Department
Mr. Hank Giclas, Western Growers Association
Mr. Malcolm Garg, Army Environmental Programs
Mr. John T. Allan, American Frozen Food Institute
Maria Hegstad, Managing Editor, Risk Policy Report
Mr. Bob Hirst, International Bottled Water Association
Dr. Bob Howd, ToxServices
Dr. Ann Marie Gebhart, ToxServices
Dr. Mary E. Gilbert, US EPA
Ms. Susan Goldhaber, ToxServices
Ms. Jessica C. Godreau, North Carolina Public Water Supply Section
Ms. Anna Fan, California Environmental Protection Agency
Ms. Jeanene P Hanley, Arizona Department of Administration,
Ms. Ann Johnson, U.S. EPA
Dr. Elaine Kahn, California Environmental Protection Agency
Mr. Chris Knight, Pesticide & Chemical Policy
Mr. Larry Ladd, Rancho Cordoba, California
Mr. Jason Leuck, Lockheed Martin Corporation
Dr. Bruce Macler, U.S. EPA

¹ Based on members of the public requesting the teleconference dial in information

Mr. James McCauley, Lower Brule Rural Water System
Lt. Cmdr. Eva McLannan, U.S. Public Health Service
Ms. Patricia McNulty, MEYERS NAVE
Dr. William Mendez, ICF Inc.
Dr. Anita K. Meyer, U.S. Army Corps of Engineers
Dr. Kevin Morley, American water Works Association
Mr. Tom Neltner
Mr. Eric Newman, KP Public Affairs
Mr. Darrell Osterhoudt, Association of State Drinking Water Administrators
Mr. Daniel Olson, US EPA
Mary F. Ostrowski, American Chemistry Council
Dr. Richard Pleus, InterTox
Ms. Deborah Proctor, Tox Strategies
Dr. Gloria B. Post, New Jersey Department of Environmental Protection
Ms. Barbara Pugh, ARCADIS U.S., Inc.
Dr. Resha Putzrath, Navy and Marine Corps Public Health Center
Dr. Santhini Ramasany, U.S. Environmental Protection Agency
Mr. Andrew Rak, Noblis, Inc.
John F. Reichard, PhD., Toxicology Excellence for Risk Assessment (*TERA*)
Ms. Rebecca Rehr, U.S. EPA
David Rexing, Southern Nevada Water Authority
Mr. Charles Robinette, West Virginia Department of Health and Human Resource
Ms. Peggy Roefer, Southern Nevada Water Authority
Mr. Jim Rollins, Policy Navigation Group
Mr. Bill Romanelli
Ms. Meredith Russell, U.S. Environmental Protection Agency
Ms. Marcia A. St. Martin, Sewerage & Water Board of New Orleans
Ms. Mina Suh, ToxStrategies
Mr. Paul M. Schlosser, U.S. EPA
Mr. James Strock, Serve to Lead Inc.
Melissa Swerdlow, MPH, Colorado Department of Public Health and Environment
Ms. Yvonne Walker, Navy and Marine Corps Public Health Center
Ms. Patrica Ware, Daily Environment Report BNA
Linda S. Wennerberg, Ph.D., NASA
Kimberly Wise, Ph.D., American Chemistry Council
Mr. Clint Woods, House Committee on Science, Space, and Technology