

**U.S. Environmental Protection Agency
Science Advisory Board
Dioxin Review Panel**

Summary Minutes

Date and Time: March 1, 2011, 1:00 – 4:00 p.m. (Eastern Time)

Location: By teleconference

Purpose: The purpose of the teleconference was to discuss the draft report, *SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* (draft dated 2/9/11)

Attendance:

Members of the EPA Science Advisory Board (SAB) Dioxin Review Panel:

Dr. Timothy Buckley (Chair)
Dr. Elaine Faustman
Dr. Scott Ferson
Dr. Jeffrey Fisher
Dr. Helen Hakansson
Dr. Russ Hauser
Dr. B. Paige Lawrence
Dr. Michael Luster
Dr. Paolo Mocarrelli
Dr. Victoria Persky
Dr. Sandra Petersen
Dr. Arnold Schechter
Dr. Allen Silverstone
Dr. Mitchell Small

SAB Staff:

Thomas Armitage, Designated Federal Officer
Diana Wong, Designated Federal Officer

EPA Representatives (individuals who requested access to the teleconference):

Stan Barone, EPA Office of Research and Development (ORD)
Norman Birchfield, EPA ORD
Becki Clark, EPA ORD
Vince Cogliano, EPA ORD

Kathleen Deener, EPA ORD
Julie Fitzpatrick, EPA ORD
Lynn Flowers, EPA ORD
Annette Gatchett, EPA ORD
Belinda Hawkins, EPA ORD
Audrey Hofer, EPA ORD
Glenn Rice, EPA ORD
Jeff Swartout, EPA ORD
Linda Teuschler, EPA ORD
Darrell Winner, EPA ORD

Public (individuals who requested access to the teleconference):

Craig S. Barrow, Craig Barrow Consulting
Nancy Beck, OMB
Robert Budinsky, Dow Chemical Company
Heather Burleigh-Flayer, PPG Industries, Inc.
Patricia Kablach Casano, General Electric Company
Kevin Connor, Arcadis, Inc.
John L. Festa
David Fischer, American Chemistry Council
M. Lindsay Ford, Parsons Behle & Latimer
Donald Hassig, NY Cancer Action
Maria Hegstad, Risk Policy Report
Stacy C. Hetz, FDA
Caarl Herbrandson, Minnesota Department of Health
Van P. Hilderbrand, Jr, Sullivan & Worcester, LLP
Laurie Holmes, American Forest and Paper Association
Sarah Irvin, Exponent
Katharine Kurtz, Navy and Marine Corps Public Health Center
Stephen Lester, Center for Health, Environment, and Justice
Yvette W. Lowney, Exponent
Sarah C.L. McLallen, American Chemistry Council
Clarence W. Murray, Center for Food Safety and Applied Nutrition
Olga Naidenko, Environmental Working Group
Resha Putzrath, Navy and Marine Corps
Natalie Paul, AECOM
Pat Rizzuto, BNA, Inc.
Mike Schade, Center for Health, Environment, and Justice
Jay B. Silkworth, GE Global Research Center
Thao Tran
Vera D. Wang, Navy and Marine Corps Public Health Center
Thomas Starr, TBS Associates
Daniele Staskal Wikoff, ToxStrategies, Inc.
Thomas Tripp

David Tundermann
Linda M. Wilson, New York State office of the Attorney General
Timothy C. Wolfson, Babst, Calland, Clements, and Zomnir, PC
Tsedash Zewdie, Massachusetts Department of Environmental Protection

Teleconference Summary:

Convene the meeting

Dr. Thomas Armitage, Designated Federal Officer (DFO) for the Dioxin Review Panel, convened the teleconference at 1:00 p.m. Eastern Time. He identified Panel members who were on the call. He stated that the EPA Science Advisory Board (SAB) is a chartered federal advisory committee and he reviewed Federal Advisory Committee Act (FACA) requirements. He stated that summary minutes of the teleconference would be prepared and certified by the Chair. He noted the Panel's compliance with ethics requirements. He stated that one Panel member, Dr. Paolo Mocarelli, had indicated that he would not participate in the discussion of the charge questions specifically pertaining to use of the Mocarelli et al. (2008) study (cited in the document, *EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments*) in deriving the reference dose for dioxin. Dr. Armitage indicated that meeting materials were available on the SAB web site and that they included: the Federal Register Notice announcing the meeting¹, meeting agenda,² and the Panel's draft report³. He also noted that six requests had been received from members of the public to provide oral comments,⁴ and that time had been provided on the agenda to hear these public comments. In addition, he noted that written public comments⁵ had been received, and that these had also been posted on the SAB website.

Review of Agenda and Purpose of the Meeting

Dr. Timothy Buckley, Chair of the Dioxin Review Panel, reviewed the teleconference objectives and agenda. He stated that the purpose of the call was to discuss the Panel's draft report, *SAB Review of EPA's Reanalysis of Key Issues related to Dioxin Toxicity and Response to NAS Comments*. He stated that the Panel would discuss any revisions needed in the draft report. He indicated that on the call the Panel would discuss the responses to charge questions 1-4 and the relevant parts of the executive summary and letter to the Administrator. He further indicated that on a second call to be held the following day, March 2nd, the Panel would discuss the responses to charge questions 5-6, the executive summary and letter to the Administrator. He noted that after the two teleconferences, the report would be revised as necessary and sent to Panel members for concurrence before it was transmitted to the chartered SAB for quality review and final approval.

EPA Remarks

Dr. Buckley introduced Ms. Rebecca Clark, Acting Director of EPA's National Center for Environmental Assessment, to provide EPA remarks to the Panel. Ms. Clark thanked the Panel for reviewing EPA's draft report. She indicated that the Agency had already begun work in response to some of the comments from the Panel, and she mentioned some Panel recommendations where more specificity would be helpful. She noted that it would be helpful if the Panel could identify additional toxicity studies of dioxin-like compounds that could be considered by EPA in the assessment. In addition, she noted that it would be helpful if the panel could suggest for EPA's consideration studies conducted using high-dose acute and low-dose chronic exposures in animals.

Dr. Buckley thanked Ms. Clark and indicated that the Panel would consider whether any additional studies could be suggested.

Public Comments

Dr. Buckley stated that six members of the public had registered to provide public comments. He noted that each individual had three minutes to present an oral statement. Dr. Buckley then asked the speakers to provide comments according to the order in which their requests to speak had been received by the SAB Staff Office.

Olga Naidenko of the Environmental Working Group commented on the Panel's draft report. She expressed agreement with the Panel's support for EPA's classification of TCDD as carcinogenic to humans. She commented that the draft letter to the EPA Administrator appeared to be skewed to the negative and did not seem to reflect some statements in the body of the report. She disagreed with the Panel's comments concerning major deficiencies in EPA's report. She commented that EPA had completed its work and should now be allowed to finalize the IRIS document for dioxin.

A Panel member asked the speaker to identify those parts of the letter with which she disagreed. The speaker responded that she disagreed with the statement in the letter indicating that there were major deficiencies in EPA's report

Stephen Lester of the Center for Health, Environment, and Justice expressed support for some findings and recommendations in the Panel's report. In particular, he agreed with the support for EPA's approaches to developing the oral slope factor, benchmark dose, and the use of whole blood as the dose metric. He also expressed support for statements in the report calling for EPA to move expeditiously to complete the dioxin assessment. He commented that parts of the report, particularly the letter to the Administrator were too negative and that some of the recommendations appeared to be unreasonable.

Donald Hassig of Cancer Action NY summarized his written comments. He expressed the opinion that some members of the Panel had potential conflicts of interest. He also expressed disagreement with the recommendations in the Panel's report concerning quantitative uncertainty analysis.

Daniele Staskal Wikoff of ToxStrategies presented comments on behalf of Tierra Solutions. She expressed agreement with statements in the Panel's draft report regarding deficiencies in the EPA document. She indicated that several statements in the Panel's report reflected policy decisions not science. She indicated that the Panel should consider the dissenting opinion offered by Dr. Karl Rozman. She noted that confounding factors should be considered in EPA's cancer risk assessment and indicated that a quantitative uncertainty analysis was essential.

Patricia Kablach Casano of General Electric Company noted that she had provided written comments. She indicated that the Panel's report should focus on science not policy. She discussed the chloroform drinking water standard as an example illustrating problems caused by ignoring science in favor of policy. She indicated that the Panel should reconsider its conclusion regarding use of all cancer mortality for assessing cancer risk. She commented that there were some contradictory statements in the Panel's report. She also commented that the Panel should state that recommendations in its report should be implemented by EPA.

David Fischer of the American Chemistry Council expressed agreement with some recommendations in the Panel's report. He commented that the draft report should be revised to address: the importance of the weight of evidence approach in selection of point of departure and dose-response assessment, the role of peak vs. average exposures in sperm effects, the dissenting opinion of Dr. Karl Rozman, the potential for co-exposures in the Cheng et al., 2006 study, and the need to conduct an uncertainty analysis.

The Chair thanked the speakers for their comments.

Panel Discussion

The Chair called for discussion of the responses to charge questions 1- 4 in the Panel's draft report. He asked members to raise any substantive issues that required discussion. He indicated that, if changes were needed in any of the responses to the charge questions, he would make assignments to Panel members to develop the revisions and send them to the DFO.

Discussion of the responses to charge question #1

The Panel discussed the responses to charge question 1. A member suggested that the three areas of deficiency that were identified in the letter to the Administrator could be combined into two areas. The Chair responded that this point should be discussed by the Panel, but first he wanted to discuss the responses to the charge questions in the body of the report.

A member asked whether any additional critical studies should be mentioned in the response to charge question #1. The Chair asked Panel members to suggest any studies

that should be mentioned. No specific studies were identified and the Chair indicated that he would consider whether specific studies cited in the report should be mentioned in this section. He noted that the Simon study cited in public comments could be mentioned in the report.

A member suggested that on page 12, lines 18-20, the discussion of critical elements 1 and 2 (nonlinear dose response and mode of action) could be combined into one critical element. The Chair agreed and, without objection from the Panel, indicated that he would revise the text.

A member noted that the response to charge question 1 indicated that EPA's report was clear, logical, and responsive to the NAS recommendations but this was inconsistent with some of the other recommendations in the Panel's report. The Chair suggested that this sentence be revised to state that EPA had developed a report that was clear, logical, and responsive to many but not all of the recommendations of the NAS. Panel members agreed and the Chair asked the DFO to incorporate this change.

A member noted that the Panel's responses to charge question 1 had indicated that negative studies should be discussed in more detail, and she asked whether any specific studies should be mentioned. Another member responded that Panel members had not listed specific studies in this section, but had indicated that a more balanced discussion of negative studies was needed. No additional specific studies were suggested by Panel members. The Chair asked whether Panel members had additional comments on the responses to charge question 1. There were no additional comments.

Discussion of the responses to charge question # 2

The Chair called for discussion of the responses to charge question 2. Several members indicated that they agreed with the text of the responses to charge question 2. A member commented that in some places the report referred to a "balanced" discussion and also used the term "in general." The member stated that it would be preferable to sharpen the report language by removing these terms. Other members agreed. The Chair indicated that he and the DFO would review the report to determine where it could be revised to address this comment. A member stated that in this regard both the letter to the Administrator and the report should be reviewed. There were no further comments on the responses to charge question 2.

Discussion of the responses to charge question # 3

The Chair next called for discussion of the response to charge question 3. Several members indicated that they were in agreement with the report text. The Panel discussed whether the language addressing the Hill coefficient needed clarification. No changes were suggested. A member questioned whether more specificity was needed in the sentence concerning clustering of mouse points of departure at the lowest doses. Dr. Fisher indicated that he did not think additional specificity was needed in this statement and no changes were suggested by Panel members. A member commented that animal

data on perinatal exposure might be mentioned in the response to question 3.5. Dr. Fisher noted, however, that this charge question pertained to human data so it was decided that no changes were needed in this section. The chair asked members if any other changes were needed in the responses to charge question 3. No additional changes were suggested.

Discussion of the responses to charge question # 4

The Panel next discussed the responses to charge question 4. Members noted that the tone of the language in the executive summary might be more negative than in the body of the report. A member indicated that the sentence on page 25, line 11 should be revised to remove the word “balanced” and indicate that a discussion addressing the strengths and weaknesses of the studies is needed. Dr. Faustman indicated that she would review text in the main body of the report and the executive summary to address this concern and send suggested changes to the DFO. The Panel discussed whether any specific studies could be suggested to provide a comparison of high-dose acute vs. low-dose chronic effects on similar endpoints for dioxin or dioxin-like chemicals. Drs. Luster, Silverstone, and Faustman indicated that they would consider whether additional studies could be suggested. The Panel discussed whether a relevant EPA guidance should be mentioned in the report to address this issue. Dr. Faustman noted that she would consider whether specific guidance could be mentioned and, if indicated, send revised text to the DFO. A member noted that it could be presumed that EPA was following its own guidance. The Panel also discussed report text calling for an integrated message in Section 4 of the EPA document. No specific changes in the report were suggested but Dr. Faustman noted that she would determine whether any reordering of the sentences was necessary and provide any revision to the DFO. Several panel members reiterated comments about the need to change the tone of some sentences in the letter to the administrator and the executive summary and suggested that sentences calling for a more “balanced discussion” be revised to indicate that a discussion addressing the strengths and weaknesses of the studies was needed. Dr. Faustman indicated that she would review these sentences and provide any changes to the DFO.

Additional comments

Dr. Buckley next indicated that he wanted to discuss Dr. Hauser’s comments on the responses to charge question 6 because Dr. Hauser would not be available for the call on March 2nd. Dr. Hauser commented that the response to charge question 6 listed some questions that could be answered by conducting an uncertainty analysis. Dr. Hauser indicated that these questions all seemed to be related to the issue of overstating risk. He commented that it was also necessary to consider the point that the EPA’s assessment may understate risk, and that questions related to understatement of risks should be included in the response to charge question 6. The Chair and other Panel members agreed. Dr. Small indicated that he would send revised text to the DFO to address this.

Dr. Buckley asked Panel members if there were additional comments on the responses to charge questions 1-4. There were no additional comments so the Dr. Buckley thanked

members for their comments and indicated that the Panel would hold another teleconference on the following day (March 2) to discuss the responses to charge questions 5 and 6, the executive summary, and letter to the Administrator. The DFO then stated that there were no other items on the agenda and adjourned the teleconference.

Respectfully Submitted:

Certified as True:

/Signed/

/Signed/

Dr. Thomas Armitage
Designated Federal Officer

Dr. Timothy Buckley, Chair
SAB Dioxin Review Panel

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

ATTACHMENT A: PANEL ROSTER

U.S. Environmental Protection Agency Science Advisory Board Dioxin Review Panel

CHAIR

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

MEMBERS

Dr. Harvey Clewell, Director of the Center for Human Health Assessment, The Hamner Institutes for Health Sciences, Research Triangle Park, NC

Dr. Louis Anthony (Tony) Cox, Jr., President, Cox Associates, Denver, CO

Dr. Elaine Faustman, Professor and Director, Institute for Risk Analysis and Risk Communication, School of Public Health, University of Washington, Seattle, WA

Dr. Scott Ferson, Senior Scientist, Applied Biomathematics, Setauket, NY

Dr. Jeffrey Fisher, Research Toxicologist, National Center for Toxicological Research, U.S. Food and Drug Administration, Jefferson, AR

Dr. Helen Håkansson, Professor of Toxicology, Unit of Environmental Health Risk Assessment, Institute of Environmental Medicine, Karolinska Institutet, Stockholm, Sweden

Dr. Russ Hauser, Frederick Lee Hisaw Professor, Department of Environmental Health, Harvard School of Public Health, Boston, MA

Dr. B. Paige Lawrence, Associate Professor, Departments of Environmental Medicine and Microbiology and Immunology, School of Medicine and Dentistry, University of Rochester School of Medicine and Dentistry, Rochester, NY

Dr. Michael I. Luster, Professor, Department of Community Medicine, West Virginia University Health Sciences Center, Morgantown, WV

Dr. Paolo Mocarelli, Professor of Clinical Biochemistry, Department of Clinical Laboratory, Hospital of Desio-Nuovo Monoblous, University of Milano Bicocca, 20033 Desio-Milano, Italy

Dr. Victoria Persky, Professor, Epidemiology and Biostatistics Program, School of Public Health, University of Illinois at Chicago, Chicago, IL

Dr. Sandra L. Petersen, Professor, Associate Graduate Dean, Department of Veterinary and Animal Sciences, College of Natural Sciences, University of Massachusetts-Amherst, Amherst, MA

Dr. Karl Rozman, Professor, Pharmacology, Toxicology and Therapeutics, The University of Kansas Medical Center, Kansas City, KS

Dr. Arnold Schecter, Professor, Environmental and Occupational Health Sciences, School of Public Health-Dallas Campus, University of Texas, Dallas, TX

Dr. Allen E. Silverstone, Professor, Department of Microbiology and Immunology, Health Science Center, SUNY Upstate Medical University, Syracuse, NY and Adjunct Professor of Environmental Medicine, University of Rochester School of Medicine and Dentistry, Rochester, NY.

Dr. Mitchell J. Small, The H. John Heinz III Professor of Environmental Engineering, Department of Civil & Environmental Engineering and Engineering & Public Policy, Carnegie Mellon University, Pittsburgh, PA

Dr. Anne Sweeney, Professor of Epidemiology, Department of Epidemiology and Biostatistics, School of Rural Public Health, Texas A&M Health Science Center, College Station, TX

Dr. Mary K. Walker, Professor, Division of Pharmaceutical Sciences, College of Pharmacy, University of New Mexico, Albuquerque, NM

SCIENCE ADVISORY BOARD STAFF

Dr. Thomas Armitage, Designated Federal Officer, U.S. Environmental Protection Agency, Washington, DC

Dr. Diana Wong, EPA Science Advisory Board, Science Advisory Board Staff Office, Washington, DC

Materials Cited

The following meeting materials are available on the SAB Dioxin Review Panel Web site, at the Meeting Page

<http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/2A487AA3750E94008525780D00597054?OpenDocument>

¹ Federal Register Notice

² Agenda

³ SAB Review of EPA's Reanalysis of key Issues Related to Dioxin Toxicity and Response to NAS Comments

⁴ List of Public Speakers

⁵ Public Comments received

- Comments from Donald L. Hassig
- Comments from g. Thomas Tripp
- Comments from Kenneth A. Mundt
- Comments from Kevin Connor and Brian Magee
- Comments from Mark Harris
- Comments from Olga V. Naidenko
- Comments from Patricia Kablach Casano
- Comments from Paul Noe and Robert Glowinski
- Comments from the Chlorine Chemistry Division of the American Chemistry Council
- Email comments from Sarah McLallen and DFO response
- Statement from David B. Fischer, on behalf of American Chemistry Council
- Statement from Patricia Kablach Casano