

**Summary Minutes of the
U.S. Environmental Protection Agency
Trichloroethylene Review Panel
Public Teleconference
June 24, 2010
12:30 – 4:30 pm, Eastern Time**

TCE Panel:

Dr. Deborah Cory-Slechta
Dr. Scott Bartell
Dr. Aaron Blair
Dr. Anneclaire De Roos
Dr. Rodney Dietert
Dr. Claude Emond
Dr. Montserrat Fuentes
Dr. David G. Hoel
Dr. Gunnar Johanson
Dr. Michael Pennell
Dr. Kenneth Portier
Dr. Gloria Post
Dr. Gary Rankin
Dr. Ivan Rusyn
Dr. Ornella Selmin
Dr. Brian Thrall
Dr. John Vena
Dr. Virginia Weaver

Purpose:

To discuss the Panel's draft responses to charge questions on the Toxicological Review of Trichloroethylene (October 2009).

Designated
Federal Officer:

Dr. Holly Stallworth, Designated Federal Officer

Other EPA Staff:

Ambuja Bale, Chao Chen, Cheryl Scott, Glinda Cooper, Jane Caldwell, Jennifer Jinot, John Fox, John Lipscomb, John Schaum, Kate Guyton, Marina Evans, Maureen Gwinn, Nagu Keshava, Rebecca Brown, Stan Barone, Susan Makris, Weihsueh Chiu

Public:

Maria Hegstad, Risk Policy Report
Kenneth G. Bogdan, NY Department of Health
Mitch Waxman, Arcadis Inc.
Nadia Rhazi, Government Accountability Office
Pat Rizzuto, Daily Environment Report
Catherine Curts, Navy Public Health

Mike Dourson, Toxicology Excellence in Risk Assessment
Paul Dugard, Halogenated Solvents Industry Association
Michael Kelsh, Exponent Health Sciences
James Bus, Dow Chemical
W. Caffey Norman III, Patton Boggs LLC

Webpage: The meeting agenda, public comments and draft report are all posted at:

<http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/6cdc83d5129a174f8525772d004d77c0!OpenDocument&Date=2010-06-24>

Meeting Summary

The discussion followed the issues, as presented in the meeting agenda.

THURSDAY, JUNE 24, 2010

Opening of Public Meeting

Dr. Stallworth convened the meeting and explained that Science Advisory Board operates under the Federal Advisory Committee Act.

Five public speakers presented comments on behalf of the Halogenated Solvents Industry Association (HSIA). Dr. Paul Dugard questioned EPA's application of the modified Hill criteria listed in EPA's Cancer Guidelines (2005). Dr. Michael Kelsh emphasized studies that did not find an association between TCE and cancer and questioned EPA's interpretation of the meta analyses. Dr. Michael Dourson criticized EPA's conclusions from the experimental animal data while suggesting that EPA should approach the dose response as a dual mode of action. Dr. James Bus stressed the findings of the 2006 National Academy of Sciences report on Camp Lejeune. Mr. W. Caffey Norman said that EPA should explain why it disagrees with the NAS. Mr. Norman also criticized EPA for not explaining which meta analysis is more likely to be more correct.

One panelist requested written comments from the three speakers who had not already submitted them (Kelsh, Bus and Norman). These three speakers promised to send their comments in to Dr. Stallworth who said she would share them with the Panel and post them on the SAB website.

With respect to charge question 1 on PBPK modeling, minor comments were offered to clarify the recommendation to provide better descriptions on the choice of prior distributions as well as the recommendation to provide some information on correlations among posterior medians for species-specific parameters. In reference to the recommendation to perform a local sensitivity analysis, one panelist also asked for a clarification on what was meant by "state parameters."

With respect to charge question 2 on meta analysis of cancer epidemiology, panelists agreed that the risk assessment should adopt the “non-Hodgkins lymphoma” term in place of lymphoma. Panelists discussed what was meant by “conservative” approaches in meta analysis and decided to strike that term. Panelists also discussed whether any advice should be given to recognize that higher associations found with cervical cancer vis-a-vis kidney cancer in the cohort studies in the meta analysis.

With respect to charge question 3 on hazard assessment, one panelist requested improved language to clarify what was actually a recommendation versus what was a statement. Dr. Stallworth said that SAB reports can have various levels of recommendations, ranging from specific statements like “we recommend” to statements that said “EPA might consider.” With respect to charge question 4, panelists discussed the wording regarding the effect of exposure misclassification on estimates of relative risk. Panelists discussed the extent to which the EPA draft risk assessment document should discuss or compare its findings and conclusions to those of the 2009 NAS Report on Camp Lejeune. It was generally agreed that it was not necessary to compare EPA conclusions to all the other reviews, particularly in view of the different criteria applied across reviews, different studies used across assessments and different scopes of each review and the fact that the current draft risk assessments carries out a meta-analysis that was not considered in the 2009 NAS review.

With respect to charge question 5, panelists discussed the conditions under which it is appropriate to assume linear extrapolation and when thresholds might be assumed. It was generally acknowledged that EPA had to follow its 2005 Guidelines. Some minor edits were offered to the text. On charge question 6, one panelist requested clarification on the statement saying the weight of evidence does not exclude the MOA for TCE-induced kidney tumors involving cytotoxicity and compensatory cell proliferation. Similarly, edits were offered to clarify the panel’s text on charge question 7. Panelists had no edits to suggest for charge question 8 on the dose-response assessment. On charge question 9, panelists said they were pleased with EPA’s dose-response assessment but were only commenting on EPA’s implementation and description of the analysis. On charge question 10, panelists decided to delete the paragraph that discussed the small impact of the use of Age-Dependent Adjustment Factors (ADAFs) in the final estimates of total cancer unit risk. Given that EPA had already provided an explanation of this low impact (that only one tumor type received the ADAF adjustment), it was decided that there was no need for the Panel to repeat what EPA had already said.

Dr. Cory-Slechta reminded panelists that research recommendations would be pulled out of charge questions 1 – 10 and exported to charge question 12. In addition, Dr. Cory-Slechta said that suggestions for line edits would be exported to a separate section. Dr. Stallworth reminded the panelists of next steps: that revised charge questions were due to her by July 14, 2010, that an Executive Summary and letter to the Administrator would be drafted and that a revised report would be posted in advance of the August 5, 2010 teleconference.

On Behalf of the Committee,
Respectfully Submitted,

Holly Stallworth, Ph.D. /s/
Designated Federal Officer

Certified as True:

Deborah Cory-Slechta, Ph.D. /s/
Chair, SAB Trichloroethylene Review Panel

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.