

FINAL MINUTES

MINUTES FROM THE EPA SCIENCE ADVISORY BOARD Ethylene Oxide Review Panel Public Teleconference May 29, 2007

PURPOSE: The Ethylene Oxide Review Panel of the EPA Science Advisory Board (SAB) met on May 29, 2007 via teleconference. The purpose of this teleconference was to offer an opportunity for panel members to discuss and finalize the SAB draft report on the Agency's draft assessment entitled, *Evaluation of the Carcinogenicity of Ethylene Oxide*. The SAB Ethylene Oxide Review Panel was asked to comment on the scientific soundness of this carcinogenicity assessment. Attachment A is the Federal Register notice announcing the meeting (72 FR 79, April 25, 2007). A meeting agenda is included as Attachment B.

LOCATION: By telephone only.

DATE AND TIME: May 29, 2007 from 1:00 – 4:00 PM Eastern Time.

PARTICIPANTS: The following individuals participated in this meeting: SAB Committee and Board Members - Drs. Stephen Roberts (Chair), Steven Belinsky, Timothy Buckley, Norman Drinkwater, Montserrat Fuentes, Dale Hattis, Steven Heeringa, James Kehrer, Mark Miller, Maria Morandi, A. Robert Schnatter, Ann Sweeney. Drs. James Klaunig and Ulrike Luderer did not participate. The Review Panel roster is included as Attachment C and a set of biographical sketches is included in Attachment D. SAB Staff - Dr. Sue Shallal, Designated Federal Officers (DFO); EPA Presenters – Henry Kahn, Jennifer Jinot, Paul White, David Bussard, Bob Sanawane; Other Participants – Other EPA staff and members of the public listened in to the discussions. A partial list of names is attached (Attachment E).

MEETING SUMMARY: The meeting followed the agenda (Attachment B). A summary of the meeting follows.

Convene the Meeting and Introductory Remarks – Dr. Suhair Shallal, Designated Federal Officer (DFO), opened the meeting at 1:10 PM after allowing time for panel members to dial in to the teleconference. She read the names of panel members from roster (Attachment C) and asked that they respond if present. All panel members were able to participate in this teleconference except Dr. Luderer and Dr. Klaunig. Dr. Shallal informed the participants that Dr. Klaunig had not been able to participate in the January face-to-face meeting and was therefore not present during this teleconference. She also read the names of those individuals that had request the call-in information and asked others to send an e-mail to her indicating that they listened-in to the deliberations. Dr. Shallal then presented background information on the SAB panel formation process and informed the audience that the SAB operates under the rules and regulations of FACA where all meetings, during which discussions and deliberations take place, are held in public. She then handed the agenda and the meeting to Dr. Roberts.

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Welcome - Dr. Roberts thanked panel members for their participation and explained the purpose of the teleconference. He presented the guiding principles for preparation of the panel's report: 1) try to remain faithful to the discussion that took place during the face-to-face meeting; 2) respond to the Agency's questions; 3) any differences of opinion should be discussed and explained in a balanced manner in the report. He stated that we would begin with presentations from public commenters and then hear from Agency representatives. Some time will be provided for panel members to ask questions. He asked that panel members try to minimize re-discussing the areas where there was a difference of opinion. He then asked if anyone had any questions. He asked Dr. Shallal to introduce the public commenters.

Dr. Shallal introduced Dr. Snellings who was presenting on behalf of Mr. Bill Gulledge.

Public comments

Dr. Snellings was making the presentation on behalf of Mr. Bill Gulledge (see Attachment F). There were no questions for Dr. Snellings.

Dr. Jane Teta then presented her comments (see Attachment G). There were no questions for Dr. Teta.

Dr. Bob Sielken then made his presentation. (see Attachment H). There were no questions for Dr. Sielken.

Agency Comments

Comments by the Agency's representative then followed. Mr. Paul White presented his comments and asked that the panel take into consideration the amount of effort vs. the benefit derived from their suggested recommendations. Dr. Kahn offered several areas that required correction and/or clarification. Dr. Jinot tried to explain the use of a 70 year average vs. an 85 year cut-off as utilized in the Agency's analysis.

Dr. Roberts asked the Agency representatives to provide their comments in writing (Attachment H).

Dr. Heeringa and Dr. Hattis asked clarifying questions. Dr. Walker asked the Agency representatives to consider additional studies in their revised final assessment.

Discussion of the Draft Report

Comments on Charge Question 1

Dr. Buckley suggested that the panel provide an example on page 16 line 3 where there is a reference to additional analysis. He had no further comments.

Dr. Fuentes – agreed with Dr. Buckley and had no additional comments.

Dr. Hattis had no additional comments.

Dr. Kehrer had no additional comments.

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Dr. Miller had no additional comments.

Dr. Morandi also agreed that the type of analysis should be explained. She also noted that there were lots of recommendations given and they should be prioritized. She also believed that there appears to be a contradiction of strong evidence vs. a weak carcinogenicity associated with Ethylene Oxide.

Dr. Schnatter had no additional comments.

Dr. Sweeney suggested that the wording regarding strong evidence should be revised.

Dr. Belinsky had no additional comments.

Dr. Drinkwater noted that the comment on p 17 line 40 does not refer to a threshold but rather to a limit of detection. This comment should therefore be revised

Dr. Heeringa on page 15, line 30, the discussion regarding internal vs. external should be clarified.

Dr. Swenberg suggested that the discussion regarding the cancer descriptor should include ethylene data.

Dr. Walker added further information to the MOA/hazard ID sections. He provided background information and cited studies regarding the MOA for cancer in rodents.

Dr. Drinkwater suggested adding these references to the list for EPA to consider. Dr Walker will also provide a paragraph.

Dr. Roberts summarized the discussion, noting that the types of analysis should be explained (i.e., use of individual exposure data rather than grouped data to eliminate the bias created in the modeling) and inclusion of a discussion of errors and variables. Additionally, clarify the discussion of “strong” vs. “weak” throughout the report.

Comments on Charge Question 2

Dr. Buckley had no additional comments.

Dr. Fuentes had no additional comments.

Dr. Hattis commented that segmenting or bifurcating the model should be based on biological and / or mechanistic evidence. The reference to a threshold should be changed to non-detectable level (on page 38 line 31- repair mechanism implies a threshold is wrong).

Dr. Kehrer suggested that Question 2c, page 38 line 31, this paragraph should be revised to reflect the views of the panel.

Dr. Miller suggested that the paragraph on page 38 line 31 should be removed.

Dr. Morandi had no additional comments.

Dr. Schnatter commented that on page 34-35 the cancer LH grouping and “Males Only” section are OK. He stated that the heading “low dose extrapolation” should be changed to “occupational exposure”. He agreed with Dr. Hattis that segmenting the data is not appropriate

Dr. Sweeney suggested the fact that no data was available for prenatal exposure to assess gestational exposure should be included to clarify the need for a ADAF (age dependent adjustment factor).

Dr. Belinsky had no additional comments.

Dr. Drinkwater had no additional comments.

Dr. Heeringa agreed with Drs. Hattis and Schnatter that segmenting for low dose and occupational exposures should not be done. The original NIOSH data should be used and a log-linear dose response with a 15 year lag will not be necessary. The priority should be to use

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individual data modeling and then errors and variables and HWSE are secondary analyses. He also suggested that the corrections that were presented by the Agency should be made.

Dr. Swenberg suggested that the cancer guidelines should be followed where clarity for observable and extrapolated data is encouraged. He also asked if a 2-generation reproduction study was available which could provide data for early life exposure and help to inform the ADAF.

Dr. Walker had no additional comments.

Dr. Roberts asked if there was any panel member that advocated keeping the paragraph on page 38 line 31. There were no panel members that did advocate keeping this paragraph. The second issue that needs to be addressed is the one dealing with concerns about segmenting the analysis of occupational exposures. Finally, the heading should be revised as per Dr. Schnatter's suggestion

The panel then discussed the Executive Summary. Dr. Roberts prefaced this discussion by stating that panel members should assume that the changes made in the body of the report would be reflected in the Executive Summary. He asked if there are any additional changes needed.

Comments on the Executive Summary

Dr. Buckley had no additional comments.

Dr. Fuentes stated that on page 9 line 26, the reference to a "threshold" should be removed. The sentence on page 9 line 35-36 should also be removed.

Dr. Hattis agreed with Dr. Fuentes.

Dr. Kehrer had no additional comments.

Dr. Miller stated that on page 8 line 12, the discussion of "a critical issue....." should be deleted and more discussion of the precursor events is needed.

Dr. Morandi commented that the Executive Summary should reflect the changes from body of report.

Drs. Schnatter, Sweeney, Belinsky, Drinkwater and Heeringa had no additional comments.

Dr. Swenberg suggested that for Issue 1 the discussion of strong vs weak should be revised.

He noted that on page 9 lines 23-29, the discussion of the non-linear model is needed by without referring to a threshold.

Dr. Walker disagreed with the change suggested on page 8, "a critical issue....." should be kept. A discussion ensued between Drs. Miller and Walker and both agreed that the word "critical" would be dropped.

Dr. Shallal attempted to determine if Dr. Luderer was able to join the teleconference. She was not present on the teleconference

Dr. Roberts summarized the major items that required further revision. Panel members agreed to:

- 1- Clarify the strong vs weak
- 2- Discuss the type of analysis – i.e., HWSE
- 3- Add references
- 4- Change Issue 2D to be more responsive

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5- Delete the paragraph on page38 line31- add that there is no chemical specific data on prenatal/childhood exposure

6- Remove the word “critical” and “threshold”

Dr. Roberts asked all members participating in this teleconference if they would be satisfied with the report pending the changes outlined above. All panel members indicated that they would be satisfied.

Dr. Roberts outlined the next steps. Panel members were asked to submit specific suggestions on changes that are needed by June 8 to Dr. Shallal. She will then send the comments regarding Issue 1 to Dr. Drinkwater and Issue 2 to Dr. Heeringa. They will incorporate these changes and Dr. Roberts will make the changes to the Executive Summary. Dr. Roberts and Dr. Shallal will draft a letter to the Administrator. Both the letter and the revised report will be sent to panel members for their final approval.

Dr. Shallal added that the approved report will then be transmitted to the Board for their review either later this summer or during the pre-scheduled quarterly SAB meeting this fall.

Dr. Roberts thanked the panel for their review and continued efforts to finalize the report and asked Dr. Shallal to adjourn the meeting.

The meeting was adjourned at approximately 3:30 PM.

Respectfully Submitted:

/s/
Dr. Suhair Shallal
Designated Federal Officer,
EPA SAB PFOA Review Panel

I certify that these minutes are accurate to the best of my knowledge:

/s/
Dr. Stephen Roberts
Chair,
EPA SAB EtO Review Panel

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All attachments are available in hard copy upon request

<u>Attachment A</u>	Federal Register notice (72 FR 79, April 25, 2007)
<u>Attachment B</u>	Meeting agenda- May 29, 2007
<u>Attachment C</u>	Consultative Panel roster
<u>Attachment D</u>	Biographical sketches
<u>Attachment E</u>	List of participants
<u>Attachment F</u>	Comments by Dr. Snellings on behalf of Mr. Bill Gullledge
<u>Attachment G</u>	Comments by Dr. Jane Teta
<u>Attachment H</u>	Comments by Dr. Bob Sielken
<u>Attachment I</u>	Agency's Comments