

## FINAL MINUTES

### MINUTES FROM THE EPA SCIENCE ADVISORY BOARD Ethylene Oxide Review Panel Public Teleconference December 8, 2006

**PURPOSE:** The Ethylene Oxide Review Panel of the EPA Science Advisory Board (SAB) met on December 8, 2006 via teleconference. The purpose of this teleconference was to offer an opportunity for panel members to learn more about the Agency's draft assessment entitled, *Evaluation of the Carcinogenicity of Ethylene Oxide*, its purpose and how the analysis was conducted. There was also an opportunity for panel members to ask questions regarding the assessment and the charge questions so that they may be better prepared to respond to them. The SAB Ethylene Oxide Review Panel is being asked to comment on the scientific soundness of this carcinogenicity assessment. Attachment A is the Federal Register notice announcing the meetings (71 FR 219, November 14, 2006). A meeting agenda is included as Attachment B.

**LOCATION:** By telephone only.

**DATE AND TIME:** December 8, 2006 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, James Klaunig, Ulrike Luderer, Mark Miller, Maria Morandi, A. Robert Schnatter, Ann Sweeney. 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; 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 1:12 PM after allowing time for panel members to dial in to the teleconference. She 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 also reminded the members of the panel and the audience that the background materials including the charge questions (Attachments F) are located on the SAB website.

Welcome - Dr. Roberts then reviewed the agenda and explained the purpose of the teleconference. He reminded panel members that he had assigned individuals as lead discussants for each of the charge questions. He stated that we will begin with presentations from the Agency and the panel members will be able to ask clarifying questions. Discussion of the charge questions would occur during the upcoming face-to-face meeting scheduled for January 18-19, 2007. He asked that panel members provide their preliminary comments in advance of that meeting by January 12, 2007.

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### **Agency Presentations**

Henry Kahn of the EPA National Center for Environmental Assessment presented some of the background regarding the EtO assessment (Attachment G).

He elaborated on the findings of the Agency's carcinogenicity evaluation. He also explained the evidence used in the evaluation and the conclusions reached in the draft evaluation. Some panel members then asked clarifying questions. He was followed by Jennifer Jinot who outlined the methods and models that were used to analyze the data. She explained how the cancer risk estimates were derived, as well as, the data sets, model assumptions, the adjustment factors and the uncertainties associated with the modeling. Panel members had the opportunity to ask clarifying questions through the presentation period and at the end of the entire presentation.

Dr. Roberts then introduced the public commenters. There were 5 individuals who had registered to present public oral comments. Dr. Shallal informed the teleconference participants that the public comments were available on the SAB website.

### **Public comments**

Public Comments were presented by Dr. Jane Teta, Principal Scientist with Exponent, (Attachment H) discussed the use of Union Carbide epidemiology data be included in the Agency's analysis. She was followed by Dr. William Snellings, of Dow Chemical Company and representing the Ethylene Oxide/Ethylene Glycols Panel of the American Chemistry Council (Attachment I), expressed concerns of the EO/EG Panel about the assessment. Mr. Joe Hadley (Attachment J) of the Ethylene Oxide Sterilization Association, Mr. Francis Dobscha (Attachment K) of AdvaMed and Mr. David Ludwig, Vice President and General Manager and an Officer of Balchem Corporation, (Attachment L) reviewed the importance of EtO used as a sterilant for medical devices. Panel members were also given an opportunity to ask questions.

Dr. Roberts thanked the public commenters. He then reminded panel members of their assignments and reiterated that all members may respond to any of the charge questions in addition to the ones they were assigned to.

Dr. Shallal reminded panel member to include her as a recipient on any correspondence with other panel members. All preliminary comments were to be sent to both Dr. Roberts and Dr. Shallal.

The meeting adjourned at approximately 4:00 PM.

Respectfully Submitted:

\_\_\_\_\_/s/\_\_\_\_\_  
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Dr. Suhair Shallal

Designated Federal Officer, EPA SAB EtO 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 hardcopy upon request

<u>Attachment A</u>	Federal Register notice (71 FR 219, November 14, 2006).
<u>Attachment B</u>	Meeting agenda- December 8, 2006
<u>Attachment C</u>	Consultative Panel roster
<u>Attachment D</u>	Biographical sketches
<u>Attachment E</u>	List of participants
<u>Attachment F</u>	Charge Questions
<u>Attachment G</u>	powerpoint presentation by Henry Kahn and Jennifer Jinot
<u>Attachment H</u>	Oral presentation by Dr. Jane Teta, Principal Scientist,Exponent
<u>Attachment I</u>	Dr. William Snellings, of Dow Chemical Company and the ACC Ethylene Oxide/Ethylene Glycols Panel
<u>Attachment J</u>	Mr. Joe Hadley, Ethylene Oxide Sterilization Association
<u>Attachment K</u>	Mr. Francis Dobscha, AdvaMed
<u>Attachment L</u>	Mr. David Ludwig, Vice-President and General Manager of ARC Specialty Products, Balchem Corporation