

**MINUTES FROM THE EPA SCIENCE ADVISORY BOARD**  
**Perflouroctanoic Acid (PFOA) Draft Risk Assessment Review Panel**  
**Telephone Conference Meeting**  
**January 25, 2005**

**PURPOSE:** The Perflouroctanoic Acid (PFOA) Draft Risk Assessment Review Panel of the EPA Science Advisory Board (SAB) met via teleconference on January 25, 2005 to hear briefings from the Agency on the Draft Risk Assessment of Potential Human Health Effects Associated with PFOA and Its Salts. The purpose of the teleconference meeting was for the SAB PFOA Review Panel to consider available advisory and background materials, to identify additional information needs, to discuss the draft charge questions to the SAB and to plan for a face-to-face meeting. Although this teleconference meeting was open to the public, it was not subject to the open meeting provisions of the Federal Advisory Committee Act (FACA) since the meeting was held only to gather information (see Final Rule for Federal Advisory Committee Management, 41 CFR Part 102-3.160(a), dated July 19, 2001). Attachment A is the Federal Register notice announcing the teleconference (70 FR 8, January 12, 2005). A meeting agenda is included as Attachment B.

**LOCATION:** Participation in the teleconference was via phone only.

**DATE AND TIME:** January 25, 2005, 2:00 - 5:00 pm Eastern Time.

**PARTICIPANTS:** The following individuals participated in this meeting: PFOA Review Panel Members - Drs. Deborah Cory-Slechta (Chair), James Kehrer, Norman Drinkwater, James Klaunig, Ron Melnick, Ernest Abel, Thomas Zoeller, Steve Roberts, Mathew Longnecker, Michael Kamrin, Melvin Andersen, William Hayton, Frank Mink, George Corcoran, David Ozonoff, and Anne Sweeney. Dr. Buck-Louis was unable to participate. The PFOA Review Panel roster is included as Attachment C and a set of biographical sketches is included in Attachment D. SAB Staff - Dr. Vanessa Vu, SAB Staff Office Director and Dr. Sue Shallal, Designated Federal Officer (DFO); EPA Staff Presenters - Dr. Jennifer Seed of the EPA Office of Pollution Prevention and Toxics and Dr. Hugh Barton of the EPA Office of Research and Development (ORD); Other Participants - Approximately 30 other EPA Staff and members of the public listened in (Attachment E).

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

Convene the Meeting and Introductory Remarks – Dr. Suhair Shallal, Designated Federal Officer (DFO), opened the meeting at 2:08 pm and took a roll-call of the PFOA Review Panel members. She then asked other participants to introduce themselves. Dr. Shallal gave an overview of teleconference procedures and then outlined the purpose of this meeting, namely to provide the PFOA Review Panel with an overview of the review document in preparation for the February 22-23, 2005 formal peer review meeting. PFOA Review Panel Members were asked to limit discussion to areas of clarification rather than deliberating on the document, as this will take place at the February meeting. The format of this teleconference will be to use the Agency

powerpoint presentation (Attachment F) as a guide, so all participants should have it available in front of them in hard copy or on the SAB website.

Dr. Deborah Cory-Slechta, PFOA Review Panel Chair, welcomed members, the agency and the public to the meeting. She reviewed the agenda for the teleconference and reminded the participants that this meeting is intended to allow panel members to get background information and clarify the charge questions. She also reminded panel members that there was to be no deliberation on the draft PFOA risk assessment (RA) taking place during this teleconference. She then asked Dr. Jennifer Seed of EPA's OPPT to begin her presentation.

#### Overview of the draft PFOA Risk Assessment

Dr. Seed referred participants to the powerpoint presentation that she and Dr. Hugh Barton had prepared (Attachment F). She explained that the presentation was written around the charge questions, which consisted of 4 issues and 9 questions. She summarized the development of the current draft risk assessment for PFOA and its salts. Giving a brief overview of the PFOA's unique chemical properties, she noted that PFOA is found in the blood of members of the general population; however, no clear understanding of the exposure route and pathways currently exists. It is a commercially valuable chemical with numerous uses (elastomers, flame retardants, lubricants, architectural coatings, etc.).

She continued, explaining that there is a large database of information regarding PFOA and more studies are currently underway. The current draft PFOA risk assessment takes into consideration all studies that were available as of June 2004. She stated that OPPT hopes to revise their draft risk assessment and incorporate the recommendations of the SAB along with any new data that becomes available. The Agency is looking for advice regarding the use of the novel approaches and not necessarily the specific risk numbers.

Dr. Seed provided further information regarding the kinetics of PFOA, its half-life in different species and different genders, its postulated mode of action for carcinogenesis as a PPAR alpha agonist, and the various toxicological endpoints that were considered in the current draft risk assessment. Dr. Barton then discussed the issues related to charge questions 6, 7, 8 and 9. He explained the use of the term "margin of exposure" (MOE) in this risk assessment and how it was calculated. He also discussed the use of the one-compartment model and the data that was used to predict exposure values.

#### Panel Questions

After the presentation by Drs. Seed and Barton was completed, Dr. Cory-Slechta provided an opportunity for panel members to ask question for clarification.

Dr. Ron Melnick began the questioning by asking about the inclusion of the mammary tumor data in the current draft RA. Dr. Seed responded that the mammary tumor data was discussed in the section of the document dealing with the carcinogenic potential of PFOA but no MOE was calculated because the incidence of mammary tumors was within historical control values. Dr. Melnick was also interested in an explanation of the cancer descriptor used in the RA (i.e., "*suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential*"). Dr. Seed commented that they had used the descriptors in the interim

1999 EPA Guidelines for Carcinogen Risk Assessment in their draft RA. A newer version currently exists (2003); this version is slightly different and does not include the final part of the phrase “i.e., ....., not sufficient to assess.....”. Either version of the cancer guidelines may be used to respond to this charge question. It is most important to focus on the conclusion that PFOA data is “suggestive” of carcinogenic potential.

Dr. Andersen

Was the AUC calculated per day? ANS. Yes

Is there any human PK data? ANS. A study was conducted with retired workers to determine the decrease in their PFOA serum concentration over time.

Dr. Kehrer

Is the animal half-life and human half-life comparable? ANS. In calculating the human AUC, human blood levels of PFOA were assumed to be at steady-state with no half-life determination needed.

Dr. Sweeney

In the study looking at changes of PFOA level in blood of retirees, were both males and females included? ANS. The study had a small sample size, only 7 participants (2 females, 5 males).

Dr. Abel

Has there been any attempt to study the offspring of PFOA plant workers? Looking at birth weights or any developmental anomalies? ANS. No

Has there been any attempt to observe maternal behavior and/or clinical observations recorded for mothers of offspring in the animal studies? The developmental effects seen in the rat studies may be due to maternal effects (e.g., malaise, lack of milk, etc.). ANS. PFOA has a very short half-life in female rats and does not appear to cause any clinical effects in the mothers.

Dr. Hayton and Melnick requested some of the references used in the draft RA. It was suggested that any panel members may submit their request for references to Dr. Shallal. She will obtain those references from Dr. Seed and will provide them to the panel members.

### Public Comments

After the discussion period ended, Dr. Cory-Slechta asked Dr. Shallal to introduce the public commenters. Dr. Shallal indicated that there was only one public commenter, Dr. Timothy Kropp of the Environmental Working Group. He was given 3 minutes to make his presentation. Dr. Kropp said he had three issues to raise: 1- He stated that the EPA had focused on the tumor triad (liver, leydig cell and pancreatic acinar cell tumor) when they assessed the carcinogenic potential of PFOA. He believed that the EPA should also consider mammary cell tumors when assessing the carcinogenic potential of PFOA. 2- The tumor triad was discussed by the FIFRA SAP in 2004. The FIFRA Scientific Advisory Panel had concluded that the relevance of the hepatocarcinogenesis in infants and children is unknown and therefore cannot be discounted 3- The PFOA Review Panel consider the BMD approach. There is a precedent with the assessment of methyl-mercury by the NAS. A BMDL was calculated and an uncertainty factor was applied to derive a reference serum level for setting an MOE- similar to this RA.

## Discussion of the Charge Questions

The next topic on the agenda was the discussion of the charge questions (Attachment G); Dr. Cory-Slechta stated that she wanted everyone to have the opportunity to ask clarifying questions regarding these questions.

For Charge Question 1

Should the panel comment on the relevance of the PPAR alpha MOA for infants and children, as well as, adults? ANS. Yes

For Charge Question 2

What does “.....but not sufficient to assess human carcinogenic potential” mean?

(e.g., Is there not enough animal data? Not enough human data? The data is ambiguous?)

ANS. The Agency used the interim 1999 EPA Guidelines for Carcinogen Risk Assessment, as well as, the 2003 draft EPA Guidelines for Carcinogen Risk Assessment to select this descriptor. There is a detailed narrative that is associated with each descriptor in these documents to help explain what they mean. The 2003 version of the guidelines does not have this phrase (i.e., “.....but not sufficient to assess....”) added. Therefore focusing on the fact that the Agency has classified PFOA as a “suggestive” carcinogen and commenting on the appropriateness of this descriptor is the intent of this question.

For Issue 3, Question 3, Question 4 and Question 5, no one had any clarifying questions.

For Issue 4, Question 6 and Question 7, it was suggested that these questions should be reversed and Q7 would be answered before Q6.

For Charge Question 8

The panel has been asked to comment on modifying the default factor of 10 due to the use of a PK model, this does not involve intra-species extrapolation? How do you allocate pharmacokinetic and pharmacodynamic considerations?

ANS. It is not necessary to provide a numeric default value. The factors that should be considered in selecting an uncertainty/variability value is what we are interested in. If quantification is possible that would also be very helpful.

No one had any questions regarding Charge Question 9.

Dr. Cory-Slechta then went on to discuss the assignments to specific charge issues, not to specific charge questions. She explained that the assignments were made in consultation with the DFO and SAB Staff Office director based on panel member expertise. One individual in each group was identified as the lead discussant for each group and would be responsible for consolidating the group response. (Attachment )

## Discussion of the agenda for the face-to-face meeting

The February 22-23, 2005 face to face meeting agenda allows time for a short EPA overview and opportunity for panel members to ask further questions. Then time for public comments and

discussion of each of the charge issues.

Dr. Cory-Slechta inquired as to the number of registered public commenters expected to present at the public meeting and if there was enough time allocated for these presentations. Dr. Shallal informed the participants that the FR Notice states that individuals wishing to provide oral comments should request a timeslot 5 business days in advance of the meeting. The sooner requests are received the more likely that we can accommodate them.

#### Preparing for the face-to-face meeting

Dr. Cory-Slechta suggested that preliminary individual comments be sent to Dr Shallal one week in advance of the meeting (i.e., February 15, 2005). Dr. Shallal will distribute the comments to the appropriate lead discussant; they will then integrate the group comments into a single response. The integrated response should be sent to Dr. Shallal by February 18, 2005.

#### Other Issues

Some panel members inquired about travel and accommodations for the February 22-23, 2005 meeting. Dr. Shallal asked panel members to await the instructions on travel matters that will be sent by SAB staff or their designated representatives. If anyone does not receive this information by the end of the week they should contact Dr. Shallal.

Finally, as a reminder, Dr. Shallal instructed all panel members to conduct all their discussion and deliberations regarding the PFOA risk assessment in the public domain. All correspondence between panel members in reference to this review should also include Dr. Shallal as a recipient.

4. Meeting Adjournment – Dr. Shallal stated that she would send an e-mail to all panel members reminding them of the various deliverables and their due dates as agreed. Dr. Cory-Slechta adjourned the meeting at 4:25 pm.

Respectfully Submitted:

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

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

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Dr. Deborah Cory Slechta, Chair  
EPA SAB PFOA Review Panel

Attachments:

- A FR Notice; 69 FR 13829, March 24, 2004
- B Meeting Agenda
- C Panel Roster

- D Panel Bios
- E List of public participants
- F Agency powerpoint presentation
- G Charge Questions