

**Summary Minutes of the
U.S. Environmental Protection Agency
Science Advisory Board
Quality Review Committee (QRC)
Public Teleconference Meeting
3:00 pm – 4:30 pm (Eastern Time)
August 23, 2004
Draft Report on EPA's 3MRA Modeling System**

Meeting Location: Room 3704 USEPA Woodies Building,
1025 F Street NW, Washington, DC 20004

PURPOSE: The Quality Review Committees (QRC) for the review of the draft Science Advisory Board Panel report on EPA's *Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Modeling System* met to conduct a public telephone conference review on August 23, 2004 from 3:00 – 4:30 pm. Attachment A is the Federal Register notice announcing the meeting (69 FR 48230, August 9, 2004). A meeting agenda is included as Attachment B and a Roster as Attachment C. Attachment D is the draft report reviewed by the QRC and Attachment E is the public sign in sheet for the meeting.

LOCATION: Participation in the teleconference was via phone for QRC members and in person by SAB Staff and some agency personnel.

DATE AND TIME: Monday, August 23, 2004. 3:00 pm – 4:30 pm Eastern Time.

PARTICIPANTS:

Review of the Draft Report

Review Panel – SAB 3MRA Panel

Chair - Dr. Thomas Theis, University of Illinois-Chicago

Designated Federal Officer (DFO) - Ms. Kathleen White, SAB Staff

Discussants - Drs. Gregory Biddinger, Michael McFarland, Robert Twiss, and Lauren Zeise

The following individuals participated in this meeting: QRC Chair: Dr. Dom Grasso; QRC Members: Drs. Gregory Biddinger, Michael McFarland, Robert Twiss, and Lauren Zeise. Review Panel Chair, Dr. Thomas Theis. SAB Staff: Mr. Tom Miller and Ms. Kathleen White; and EPA Staff: Stephen Kroner and Zubair Saleem (OSW), and Justin Babendreier (ORD). One member of the public observed the meeting, Ms. Nadine Weinberg (Arcadis).

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

3:00 pm Convene the Teleconference Call

Mr. Thomas Miller,
Designated Federal
Officer

Convene the Meeting and Introductory Remarks - Mr. Thomas Miller, QRC Designated Federal Officer (DFO) opened the meeting at 3:00 pm and took a roll-call of the members. Other persons on the call were then asked to introduce themselves. Mr. Miller gave an overview of teleconference procedures, outlined the purpose of the meeting, and noted the charge questions that QRC members are asked to use in evaluating the draft report. Mr. Miller noted that the meeting was being conducted consistent with FACA requirements but that the meeting being a substantive editorial review was actually a non-FACA meeting. He noted that the QRC's purpose was to review the report and make a recommendation to the Board for its disposition during the Board's public meeting which will be held on September 14, 2004.

3:05 pm Welcome

Dr. Domenico Grasso,
Chair QRC

Introduction of the Chair: Dr. Grasso then provided introductory comments noting that use of QRC's to review Draft SAB Committee Reports was directed by the SAB in its reorganization plan during 2003. The QRC looks at reports to see if they are clear and logical, responsive to the agency charge, contain technical errors, and whether the report's conclusions are supported by the body of the report. Dr. Grasso introduced Dr. Theis who led the SAB review of the EPA 3MRA Modeling System.

Introduction to the 3 MRA Modeling System Review: Dr. Theis introduced the topic by stating that the Panel recognized that this modeling system represented an Herculean effort on the part of the Agency. It is very complex. The system is now ready for its stated purpose, conducting assessments for national level exit criteria from RCRA subtitle C requirements for low risk hazardous wastes. The effort is commendable but it does have limits to its use in site-specific assessments. The Panel believes that Monte Carlo approaches in the model should now be expanded especially to the area of toxicity even though that is not yet acceptable EPA policy. They did caution on the uncertainty and variability of response issues relative to human health.

a) Dr. Robert Twiss stated that the Letter to the Administrator was well written and reflected the text of the report. His main comment was a question about whether the model is able to be "stretched" by outside users and used for a purpose not yet intended by EPA, i.e., site-specific assessments. His written comments are in Attachment F to these minutes.

Dr. Theis responded that the Agency recognized the possibility that some would use the modeling system to advance their case for removing low risk hazardous wastes from the requirements of RCRA Subtitle C hazardous waste disposal. EPA cautioned that the intent of the 3MRA was for national criteria and that it is not yet applicable to site-specific assessments. The Panel itself was more diverse in its thoughts on this issue noting that it was not clear yet if site-specific use of the system was appropriate. It did

feel that even if it was not yet thought to be appropriate for the system to be used for site-specific assessments, it is natural to believe that it will be applied in this way and that these attempts will ultimately foster the development of the model for at least its national application. Dr. Theis agreed to ensure that the issue is clearly articulated in the report so that this is understood by readers.

b) **Dr. Michael McFarland** stated that he too applauded the Panel's report and he seconded the expansion of Monte Carlo methods for toxicity assessments within the system. He fully supports the report, though he suggests that the letter to the Administrator be shortened. His written comments are in Attachment G to these minutes.

c) **Dr. Lauren Zeise** stated that the draft report was well done. However, she stated that for now our ability to do probabilistic analysis of chemical toxicity indices quantitatively is quite limited and a bit ahead of its time. She suggested that the difficulty in doing this should be discussed in the executive summary and the report. Doing this type of analysis should be stated as a goal for the future but not something that can be done immediately. She also asked for additional discussion on separating human variability in toxicity from uncertainty in the analysis. Her written comments are in Attachment H.

Dr. Theis asked for some specific citations to places in the report where the added discussion could be placed. Dr. Zeise suggested it would be appropriate on or around pages 19, 27, 30 and Appendix 2B and 2C3. Specifically, Dr. Zeise suggested that beefing up the discussion of the difficulty in doing this would be appropriate in the Appendices and acknowledging the difficulty in the executive summary, the body of the report (around p. 19) and in the letter to the Administrator would be important.

Dr. Theis agreed that he could note the complexity of doing this assessment and note the further development as a goal for the future. The phrase "to the extent possible" was agreed as a reasonable caveat in the letter and report while more might be added to the appendix.

d) **Dr. Gregory Biddinger** stated that his comments largely focused on the Letter to the Administrator. He stated that this was one of the best letters he had read because it included the Panel's understanding of the regulatory context within which the 3MRA system would be applied. If the letter is to be shortened, try not to lose this dimension. He noted that the directions regarding proceeding with use of the model were not too clear and that this should be considered as the letter is revised. He supported the Panel's advice on validation efforts.

Dr. Theis noted the Panel's spirited debate on application of the model now vs. later and that all concurred on using it now. They recognized that any complicated approach such as this is subject to further development and recognized that that would occur and they encouraged continual evaluation of the model with an eye toward its improvement. Dr. McFarland pointed out that the report does acknowledge that more than the results of the model's application are parts of the support needed for Agency decisions. So the model is not the only input. There are other sources of information and analysis. Dr. Theis

noted that the Agency made it clear to the Panel that this richness of decision support information was a normal part of EPA's decision processes.

Dr. Theis noted that he intended to make the letter to the Administrator shorter. QRC members discussed this issue. The current letter is a little more than two pages – much shorter than letters of the past that were much larger and often merely repeated a report's executive summary. Given the current desire for shorter more focused letters interpreting the issue for the Administrator and providing him with advice appropriate for his own use the current letter may not be too long. Members are concerned that more than one page may be too much. Others suggested that a letter with bold headlines for the main message in each paragraph could be an effective approach to revising the letter. Others suggested a one page letter with the Executive Summary attached would provide added detail should the Administrator wish to read more.

Dr. Theis stated that he will revise the letter and hope to keep it to one page. He will see if the headline idea works. He will send it back to his Panel members for a quick look to ensure they have no concerns with the revision. He suggested that the final letter might include what is now paragraph one, the succeeding four bullets, and then what is now the final closing paragraph. The other information is repeated in the Executive Summary.

Dr. Grasso then thanked the QRC members and the review Panel for their tremendous job. He believes it is one of the best SAB reports he has seen.

Conclusion of the QRC Review: Dr. Grasso called an end to the discussion and asked the DFO to poll the members for agreement with the motion that the report be forwarded to the full Board recommending approval pending the revisions noted by the QRC. Mr. Miller asked the members to vote when called upon. He then polled the members and all agreed to send the report forward with the expectation that the changes agreed to in this meeting be made.

Dr. Grasso adjourned the meeting.

Respectfully submitted

Certified as True

/ Signed /

/ Signed /

Thomas O. Miller
Designated Federal Officer

Dr. Domenico Grasso
Chair, ROE Quality Review Committee

Attachment F

Comments from Dr. Robert Twiss on 3 MRA. – 8/17/2004

Hello Tom and fellow panelists,

I am most certainly not an expert in RCRA or modeling, but I did read the documents pretty carefully, and am pleased to offer my very brief comments.

The Letter to the Administrator was in my opinion very well crafted, and reflected the extensive comments in the body of the text.

I fully support the panelist's interpretation of their charges: "Have we ...?" to mean: "... and if not, what do you recommend?"

The report itself was fairly "dense" to use their terminology, but it was readable, and the examples and figures were very helpful.

The authorship was done with great care, precision, and tact (as seen from my outsider's perspective).

A couple of specific points: The term: "site" appears sometimes to mean a data-entry point with real or simulated information; sometimes to mean an operating facility that is monitoring and running localized modeling, and sometimes, both.

Also, it was not clear to me if site-specific use of 3MRA was a good idea that would help build the system over time, or if at the same time, the panel was issuing a warning against use of the model for local problems (vs. nationwide estimation). There certainly were many good suggestions about improved use of the model. Is the report being too tactful in not hitting a more cautionary note in the summary and letter as to the uses to which the model might be put?

I am prepared to listen in on the conference call, and look forward to the perspectives that others will bring to the table.

Attachment G

Comments from Dr. Michael McFarland

Charge Questions for QRC

1. Were the original charge questions to the SAB Panel adequately addressed?
2. Were there any technical errors or omissions, or issues that are inadequately dealt within the Panel's report?
3. Was the Panel's report clear and logical?
4. Were the conclusions drawn or recommendations provided supported by the body of the Panel's report?

In general, the Panel's responses to the original charge questions were clear, focused and complete. The Panel provided full and sufficient scientific justification for its findings and recommendations regarding the development and anticipated use of the 3MRA model. While, in principle, the Panel endorsed the functionality and implementation of the 3MRA model, the Panel nevertheless cited a range of technical

concerns, which if adequately addressed by the Agency, have the potential of significantly improving the range and accuracy of the 3MRA modeling software.

The Panel provided a balanced and comprehensive scientific evaluation of the 3MRA model and its accompanying documentation. The Panel is commended for clearly identifying both the overarching benefits and strengths of the 3MRA model in supporting regulatory decision-making as well as for identifying potential deficiencies that could limit the model's range of application. The Panel's repeated emphasis on the need to establish a transparent and scientifically defensible approach to conduct model validation was appropriate.

The Panel provided a very clear and logical approach to addressing the specific Agency charge questions as well as in establishing a regulatory and technical context for the reader to understand: 1) the impetus for 3MRA model development, 2) its anticipated use in Agency decision-making and 3) the cross-Agency approach employed to capture and address stakeholder concerns including those furnished within the 1995 SAB report.

All of the conclusions drawn from the Panel's review of the 3MRA documentation were supported by sound scientific and technically defensible arguments. Moreover, the Panel's endorsement of the Agency's extensive use of peer review in establishing the scientific credibility of the 3MRA modules directly addressed the charge. While supporting the development and the Agency's intended use of the 3MRA model, the Panel clearly underscored the importance of continuously refining and improving the various components of the model as new scientific information became available. Because of the inherent limitations associated with 3MRA model validation, the Panel emphasized the need for the Agency to categorically state that current model output should be employed in conjunction with other tools and factors in setting regulatory standards.

Beyond its stated conclusions, the Panel generated a range of technical recommendations supporting more effective development and implementation of 3MRA. These recommendations included, but were not limited to, the following: 1) improve the transparency in model output to Agency decision-makers by expanded development and use of the Site Visualization Tool, 2) expand the number of input parameters whose values are represented by probability distributions (adoption of this recommendation would facilitate the ability to conduct more comprehensive sensitivity and uncertainty analyses), 3) broaden the range of potential exposure scenarios that can be evaluated by 3MRA including those that may occur at distances beyond two kilometers from a waste site, 4) validate that the 3MRA mass balance constraint is supportable when secondary sources of contamination are found to be significant, 5) develop and implement an adequate software user training program to minimize the generation of inconsistent and unsupported results, 6) modify and refine the process of binning risks and hazard quotient values so that model output

will be less susceptible to misinterpretation, 7) expand the use of the Monte Carlo methodology to include the probabilistic modeling of environmental effects, 8) complete the sensitivity analysis that supports the use of 3MRA in developing national risk assessments and 9) expand the range of exposure scenarios to include volatilization of groundwater contaminants into indoor air and dermal exposure. These recommendations as well as others found in the Panel's report, which were supported by extensive and clearly formulated scientific arguments, provide the Agency with clear direction for improving the accuracy, usability, functionality and applicability of 3MRA.

Attachment H

Dr. Lauren Zeise's Comments on the Draft SAB 3MRA report:
August 23, 2004

All, I look forward to the telephone call this afternoon. Please forgive my late response. I agree with the comments sent earlier, but for one concern pertaining to the discussion of probabilistic analysis of chemical toxicity indices. The degree to which such analyses can be done quantitatively is quite limited, and it seems a bit ahead of its time, with other parts of the agency attempting to develop policies in this regard. A broader discussion in the panel's report of what probabilistic assessment would entail if done with any degree of confidence would be useful. Some additional discussion would be useful on separating inherent human variability (in toxicity) from uncertainty in the analysis, and perhaps a discussion of some of the important factors that might be amenable to quantitation - e.g. variability due to pharmacokinetics, physiology, disease status, age at exposure. I think it could be addressed by a broadening of the discussion of the issue in the panel's review.