

**MINUTES FROM THE EPA SCIENCE ADVISORY BOARD
Risk and Technology Review (RTR) Methods Panel
Face-to-face meeting
July 28-29, 2009**

ATTENDANCE:

SAB Committee and Board Members

Dr. Jana Milford (Chair)
Dr. David Eastmond
Dr. Thomas Gentile
Dr. Gary Ginsberg
Dr. Judith Graham
Dr. Cynthia Harris¹
Dr. Abby Li
Dr. Randy Maddalena
Dr. John O'Donoghue
Dr. Loren Raun
Dr. Mark Rood
Dr. John Veranth
Dr. Chris Walcek
Dr. Allen Burton
Dr. Thomas LaPoint

SAB Staff

Dr. Sue Shallal, Designated Federal Officers (DFO)
Dr. Vanessa Vu, Director of the SAB Staff Office

EPA Presenters

Rosalina Rodriguez
Dave Guinnup
Ted Palma
Roy Smith

Other Participants – See Attachment A for the list of participants who sign-in at the meeting.

MEETING MATERIALS: The following meeting materials were available prior to the July 28-29, 2009 face-to-face meeting and were available on the general SAB Web site, <http://www.epa.gov/sab>, and specifically .at the following URL:
<http://yosemite.epa.gov/sab/sabproduct.nsf/MeetingCal/2F1F9450472CE7B8852575BB0067E104?OpenDocument>

¹ participated via teleconference at several times during the two day meeting

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- FEDERAL REGISTER NOTICE
- MEETING AGENDA
- WORK GROUP ROSTER
- CHARGE TO THE COMMITTEE
 - OAQPS Charge Questions. (PDF, 10 pp., 69,994 bytes)
- AGENCY BRIEFING MATERIAL
 - Agency Risk and Technology Reveiw (RTR) Presentation - SAB Briefing on Risk Assessment Methodologies. (PDF, 11 pp., 86,982 bytes)
 - Agency Risk and Technology Review (RTR) Presentation - Flowcharts. (PDF, 4 pp., 60,550 bytes)
- Public Comments
 - Comments from John F. Reagan of Lafarge Building Materials - Attachment 1. (PDF, 81 pp., 489,437 bytes)
 - Comments from John F. Reagan of Lafarge Building Materials - July 20, 2009 Letter. (PDF, 8 pp., 60,034 bytes)
 - Comments from Matthew A. Todd on behalf of the Residual Risk Coalition. (PDF, 4 pp., 87,358 bytes)

BACKGROUND: EPA's Office of Air Quality Planning and Standards (OAQPS) requested that the Science Advisory Board (SAB) review their draft methodologies for conducting Risk and Technology Review assessments (RTR assessments) as required by the Clean Air Act. These assessments evaluate the effects of industrial emissions of hazardous air pollutants (HAPs) on public health and the environment. The proposed methodologies are demonstrated through the use of two case studies, (1) petroleum refineries and (2) Portland cement manufacturing facilities. The Federal Register notice announcing the meetings (74 FR 110, June 10, 2009) and the meeting agenda are available on the meeting web page.

PURPOSE: To provide an opportunity for panel members to deliberate on the charge questions and to discuss their responses.

LOCATION: Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC 27703.

DATE AND TIME: July 28, 2009 from 9:00 AM to 5:00 PM and July 29, 2009 from 9:00 AM to 4:00 PM Eastern Time.

MEETING SUMMARY: The meeting followed the agenda. A summary of the meeting follows.

Tuesday July 28, 2009

Convene the Meeting and Introductory Remarks – Dr. Suhair Shallal, Designated Federal Officer (DFO), opened the meeting at 9:00 AM. 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 explained that this was the second meeting of the RTR Methods Review

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Panel; the first was held via teleconference on June 30, 2009. She also reminded the members of the panel and the audience that the background materials including the charge questions are available in the lobby outside the meeting room and on the SAB website.

Dr. Vanessa Vu, Director of the SAB Staff Office, welcomed the Panel members and thanked them for taking the time to participate in the RTR Methods review.

Welcome - Dr. Milford then reviewed the agenda and explained the purpose of the meeting was to deliberate on the charge questions. She also thanked the panel members for their participation and asked each member to introduce themselves briefly. She stated that the meeting would begin with presentations from the Agency and she asked panel members to reserve their clarifying questions until after the presentations were complete.

Presentations - Rosalina Rodriguez, Associate Director of the Health and Environmental Impacts Division within OAQPS thanked panel members and emphasized the importance of this review for the Agency. She was followed by Dave Guinnup of the EPA Office of Air and Radiation who presented some of the background regarding the RTR methodology. He explained the process by which various source categories would be assessed and focused on the two case studies: petroleum refining and Portland cement manufacturing. He was followed by Roy Smith who presented the proposed methodology for conducting dose-response assessments, both acute and chronic. He also explained the uncertainties associated with these assessments and the risk characterization process. The Agency presentations are available on the meeting web page.

Dr. Milford thanked the EPA representatives and asked if anyone had questions regarding the Agency's presentations. Panel asked several clarifying questions regarding the methodology and the risk assessment process.

Dr. Milford then informed the participants that no one had registered to present public oral comments.

Dr. Milford suggested that she would ask the rapporteur (listed in blue next to each charge question) to present their comments regarding their assigned charge question. Other team members/lead discussants (listed in red next to each charge question) would then be able to offer their comments and then other panel members would have the opportunity to add their contributions.

Charge Question 1A: *Mr. Gentile and Drs. Maddalena, Rood and Walcek*

A variety of factors were discussed including, incorrect usage of meteorological data, reliance on voluntary reporting by facilities and deficiency of NEI database.

Panel members voiced concerns regarding emissions data sources. Panel members stated that emissions data are one of the most critical inputs to a residual risk assessment. The NEI, which reports *estimates* of *actual* emissions, may not be the most appropriate.

There was a concern regarding underestimation of emissions. Panel members noted that EPA should start with facility-specific allowable emissions to directly assess the effectiveness of the current MACT standards.

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Panel members agreed that the evaluations and comparative analyses described in Appendixes A, L and P were informative and scientifically credible. It appears from the analysis that some self-reported facility-specific emissions data in the NEI may be incomplete or biased low.

Panel members felt that the EPA should expand its efforts to encourage and assist community representatives bring relevant information and concerns.

Panel members recommended expanding the assessment in Appendix L to include more randomly-selected refineries to better represent the distribution in error across facilities.

Panel members found the analysis in Appendix P to be particularly useful since it most directly compares results based on reported NEI emissions versus estimates based on MACT compliance or allowable emissions.

Charge Question 1B: *Mr. Gentile and Drs. Rood, Veranth, and Walcek*

Members of the Panel noted that estimating dioxin and furan emissions from Portland cement by modeling allowable emissions and also modeling the reported emissions would give a better estimate of risk. Differences in emissions may be found for wet kiln vs. dry kiln facilities.

Members of the Panel indicated that using the current source-specific National Emission Standard for Hazardous Air Pollutants (NESHAP) allowable emission rate in combination with each facility's maximum permitted production rate would provide a better estimate of risk. This would directly address the impact of the current emissions limits. The NESHAP compliance testing information for D/F emissions from each facility should be collected and critically evaluated.

Charge Question 1C: *Drs. Maddalena, Raun, Rood and Veranth*

Panel members recommended the proposed analysis of radionuclides not be formally included in the RTR assessment until further progress is made to quantify the isotope-specific radionuclide emissions and the associated risks.

With information on radionuclide content of feedstocks, screening material balance calculations should be performed to estimate isotope-specific radionuclide emissions.

Charge Question 2: *Mr. Gentile and Drs. Maddalena, Raun, and Walcek*

Panel members concluded that the Agency's dispersion modeling for primary HAPs is well developed and appropriate. The Panel members noted that the choice of meteorological data for performing risk assessments appears to have a significant impact on calculated risks.

There is a potentially a serious underestimation bias in the dispersion modeling due to the ambiguous treatment of "calm" periods that have no definable wind directions.

The choice of meteorological data has a significant impact on calculated risks; local data should be used where possible.

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It is possible that secondary HAP formation through atmospheric chemical reactions could be significant for some source categories. More sensitivity studies of secondary HAP formation are needed to rule out the necessity of including complex photochemical modeling for future HAP risk assessments.

The HEM-AERMOD system should be run twice with different sets of receptors: for census block centroids, and also specific locations of residences to see if there is a these are greater than the differences that are characterized by elevated buoyant emissions from smokestacks.

Charge Question 3A: *Drs. Ginsberg, Graham and O'Donoghue +Li*

Panel members found the Agency's analysis in Appendix O suggests that only a few HAPs which are lacking chronic dose-response values could be important in the chronic risk assessment.

The approach used in the RTR assessments was reasonable, but should not accept dose-response numbers at face value.

A table should be created, including all the chemicals under consideration and all of the eligible dose-response values, along with the source of the value, the year it was last updated, and a qualitative description of the effect.

A literature search should be performed to identify studies that may revise the value and the chemical should be considered for addition to the Integrated Risk Assessment System (IRIS) high priority revision list.

The preferred database for chronic dose-response data is and should be the IRIS database. How surrogates are chosen should be clarified.

Charge Question 3B: *Drs. Graham, Harris and O'Donoghue +Li*

Panel members supported the use of California Reference Exposure Levels (RELs) for the assessment of acute effects as a conservative and acceptable approach to characterize acute risks. EPA's decision not to use ATSDR acute Minimum Risk Levels (MRLs) is appropriate.

Panel members expressed concern with the use of the Acute Exposure Guidelines Limits (AEGs) and Emergency Response Planning Guidelines (ERPGs).

AEG-2 and ERPG-2 values should never be used in residual risk assessments because they represent levels that if exceeded could cause serious or irreversible health effects.

Spacecraft Maximum Allowable Concentrations (SMAC) for Selected Airborne Contaminants and American Conference of Governmental Industrial Hygienists Threshold Limit Values (ACGIH TLVs) could be considered, with adjustment values.

TLV values should only be used after thorough and critical evaluation.

All the acute values for a given chemical should be arrayed in a table that displays their similarities and differences. A clear rationale for the selection should be given. The value chosen should have undergone appropriate peer-review.

Charge Question 4A: *Drs. Ginsberg, Li and Raun*

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Panel members found that EPA's overall approach was reasonable as a *screening* approach for localized impacts.

Panel members expressed concern about the Agency's chronic inhalation exposure estimates because children's exposures were not adequately addressed.

For the chronic inhalation exposure estimates, the decision to omit daily behavior is justified. Panel members recommended that long-term migration should not be incorporated into the risk assessment. It does not add value to the risk assessment and introduces additional uncertainty.

Charge Question 4B: *Drs. Ginsberg, Li, Maddalena and Veranth*

Members of the Panel found that the Agency's screening approach was appropriate and will likely screen out sources that do not need a detailed site-specific multi-pathway analysis. Panel members suggested that EPA avoid using the term "*de minimis*" to describe the threshold emissions estimates it derives. The public may not understand a local source's contribution being characterized as *de minimis*.

Model results should be clearly presented to show 1) the relative fraction of the source's emissions that are deposited locally versus being transported to add to regional burdens, and 2) the relative contributions to total multi-pathway exposure from local and regional background sources.

Dr. Shallal adjourned the meeting at 5:30 PM and asked Panel members to reconvene at 9:00 AM to continue their deliberations.

Wednesday July 29, 2009

The Panel members reconvened at 9:00 AM. Dr. Milford explained how the meeting would be conducted. Discussion of Charge Questions 5, 6, and 7 would conclude by 12:00 noon and Panel members would then be asked to gather in their assigned charge question teams. Panel members would be asked to select the major recommendations they would like to highlight in the Executive Summary and the letter to the Administrator.

Charge Question 5: *Drs. Eastmond, Li and O'Donoghue*

The Panel members agreed there is a critical need for better data addressing short-term exposures to HAPs. Panel members also agreed that in the absence of chemical- and site-specific data, the use of the 10X screening assumption for petroleum refineries seems reasonable.

For petroleum refineries, Panel members also suggest that after the screening process, the chemicals of highest concern should be compared with the list of chemicals reported in the Houston area found in Appendix B, to ensure they are adequately represented.

Members of the Panel generally agreed that the 10X assumption could be used for other geographic areas but the actual releases would depend on the manufacturing processes involved.

Charge Question 6: *Drs. Burton and LaPoint*

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The Panel members found the ecological risk assessment (ERA) presented in Appendix J to be an impressive effort, but should be revised to better follow the Agency's ERA guidelines. Their concerns and issues with the ecological risk assessment were focused on conducting a ground-truthing ERA at a site such as Ravena Pond, or by a comparison of TRIM.FaTE predictions with more conventional ERA methods.

The members of the Panel suggested that EPA should further investigate the numerous peer-reviewed studies that are relevant to this process, many of which have focused on mercury and highly chlorinated compounds such as dioxins.

The members of the Panel also recommended that site-specific ERAs and other site characteristics may need to be considered.

Charge Question 7: *Drs. Eastmond, Burton, Graham, Harris and LaPoint*

The Panel members noted that the Agency's document summarized and provided justification and explanation for most of the results, including uncertainties.

A number of improvements were discussed.

- focus more on the need to communicate with decision makers as the primary audience

- the risk characterization sections should stand alone.

The Panel members recommended that EPA should develop a separate methods document that contains a full description (including uncertainties) of all of the common components of the source-specific risk assessments.

The risk characterization should clearly explain the limitations due to the Clean Air Act requirement for separate assessments by source category.

The Panel members recommended that the Agency perform a sensitivity analysis to

- identify the major uncertainties in both the human health and ecological risk assessments.

- explain them clearly in the risk characterization section and

- take steps to reduce them.

After the initial discussions and deliberations on the charge questions, panel members had the opportunity to gather in their respective assigned groups to identify and summarize their major recommendations.

Each of the groups returned to report on their conclusions:

Charge Question 1A

- NEI is not the best source of data

- Non-voluntary reporting rule is needed

- better characterization of uncertainties is needed

- allowable HAPS emissions should be included in the analysis

Charge Question 1B

- Dioxin and Furan are important

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-Use allowable emissions to calculate MIR (maximum individual risk)

Charge Question 1C

- analysis of radionuclides from cement factories
- more careful mass/balance material characterization should be done
- evaluate reasonableness of value, some are very high

Charge Question 2

- use 1 year instead of 5 year meteorological data
- risk from secondary HAP should be calculated (e.g., formaldehyde)
- deposition should be included
- use census blocks not just centroids
- use local meteorological data when possible
- rectify issue of calm periods in the model

Charge Question 3A

- quality of data used should be ascertained
- a table should be created
- IRIS values need to be updated
- data gaps should be highlighted
- issues of susceptible populations and children should be addressed (i.e., use uncertainty factors)

Charge Question 3B

- REL is acceptable
- AEGL1 values should be divided by 10
- NASA SMAC EGL (used for healthy adults)
- MRL with adjustment for 1 hour
- TLV/420 (chronic)
- Ratio of RD50 (acute)

Charge Question 4A

- children's issues – inhalation rates should be adjusted
- activity pattern omissions are justified
- migration should not be included because it adds to the uncertainty

Charge Question 4B

- TRIM model is an improvement
- partition between transported and deposited
- Application of TRIM not validating
- uncertainty associated with extrapolation should be acknowledged

Charge Question 5

- Better data is needed
- Clear justification of assumptions
- Risk drivers should be compared to Houston/Galveston
- target-organ specific hazard indices (TOSHI) to estimate likelihood of risk or as a screening tool

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Charge Question 6

- ERA is a good effort
- Improve the risk characterization
- Conceptual model needed
- Human endpoints/health effects are not necessarily protective for animals

Charge Question 7

- Communicate to decision makers
- Summarize risk
- Sensitivity analysis of major uncertainties
- TRIMFaTE needs better groundtruthing
- Describe the populations being protected

After the discussions were completed, Dr. Shallal explained that panel members may work within the charge question team to finalize their response. She reminded panel members to include her as a recipient on any correspondence with other panel members. All preliminary comments were due on August 21 and should be sent to both Dr. Milford and Dr. Shallal.

The meeting adjourned at approximately 4:00 PM.

Respectfully Submitted:

_____/s/
Dr. Suhair Shallal
Designated Federal Officer,
EPA SAB RTR Methods Review Panel

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

_____/s/
Dr. Jana Milford
Chair,
EPA SAB RTR Methods Review Panel

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ATTACHMENT A

Other Participants (names listed as they appear on sign-in sheets, excluding those listed as presenters)

July 28, 2010

Dave Guinnup	EPA
Elaine Manning	EPA
Ted Palma	EPA
Mark Morris	EPA
David Burch	ICF
Roy Smith	EPA
Rosalina Rodriguez	EPA
Darcie Smith	EC/R
Chris Holder	ICF
Sarah Mazur	EPA
Audrey Turley	ICF
Andy Shapiro	ICF

July 28, 2010

David Burch	ICF
Roy Smith	EPA
Dave Guinnup	EPA
Elaine Manning	EPA
Ted Palma	EPA
Sarah Mazur	EPA
Audrey Turley	ICF
Darcie Smith	EC/R