

**Summary Minutes of the Science Advisory Board Meeting  
September 13-14, 2004, Region 9 Headquarters Office, San Francisco, CA**

**Board Members:** See Roster – Attachment A.

**Date and Time:** Monday, September 13, 2004, 9:00 A.M. – 5:30 P.M. and Tuesday, September 14, 2004, 8:30 A.M. – 3:00 P.M.

**Location:** Arizona Room, EPA Region 9 Headquarters Building, 75 Hawthorne St., San Francisco, CA

**Purpose:** The purpose of this meeting was for the Board to:

- a) learn of and discuss science issues and needs with EPA Region 9 personnel;
- b) consider two draft reports for approval;
- c) discuss the SAB report review process;
- d) discuss the advisory process for the EPA science and research budgets; and
- e) discuss the SAB 2004 Annual Meeting

See Attachment B for the meeting agenda and Attachment C for the Federal Register notice for the meeting.

**Attendees:**

**Chair:** Dr. William Glaze (9/13 and 9/14/04)

**Board Members:**

Dr. Gregory Biddinger (morning only 9/13/04)

Dr. James Bus (9/13 and 9/14/04)

Dr. Trudy Cameron (9/13 and 9/14/04)

Dr. Deborah Cory-Slechta (9/13 and 9/14/04)

Dr. Myrick Freeman (morning only 9/13/04)

Dr. Meryl Karol (9/13 and 9/14/04)

Dr. Catherine Kling (9/13 and 9/14/04)

Dr. George Lambert (9/13 and 9/14/04)

Dr. Jill Lipoti (9/13 and 9/14/04)

Dr. Henry Anderson (CHPAC) (9/13 and 9/14/04)

Dr. Gene Matanoski (9/13 and 9/14/04)

Dr. Michael McFarland (9/13 and 9/14/04)

Dr. Granger Morgan (9/13 and 9/14/04)

Dr. Rebecca Parkin (9/13 and 9/14/04)

Dr. David Rejeski (phone only—1:00 – 3:00 pm 9/14/04 only)

Dr. Kristin Shrader-Frechette (9/13 and 9/14/04)

Dr. Thomas Theis (9/13 and 9/14/04)

Dr. Robert Twiss (9/13 and 9/14/04)

Dr. Lauren Zeise (9/13 and 9/14/04)

**Others attending:** See Sign in Sheets (Attachment D)

## **Meeting Summary**

The discussion generally followed the issues and general timing as presented in the meeting Agenda (Attachment C).

### **Monday, September 13, 2004**

#### **1. Introductory Remarks and Welcome**

Mr. Thomas Miller, Designated Federal Officer (DFO) for the Board opened the meeting and noted that this meeting was being conducted pursuant to the Federal Advisory Committee Act, and other relevant statutory and policy requirements. Dr. Vanessa Vu welcomed the members and noted the importance of the topics to be discussed. Dr. Glaze welcomed and thanked the members for coming. He briefly reviewed the agenda.

#### **2. Presentations by Region 9: Use of Science in Regional Decision Making**

**a) Overview and Introduction to Region 9 Programs and Issues:** Dr. Laura Yoshii, Deputy Regional Administrator, Region 9, welcomed members and noted her appreciation of the SAB's assistance to EPA in its use and development of science. Region 9 is diverse and includes states, territories, and tribes. Regional responsibilities include implementation of various environmental regulations, permitting, enforcement, and providing assistance to the public and regulated entities. Many emerging issues are first recognized at the Regional Office level (e.g., perchlorate, MTBE, and vapor intrusion). Geography, land use, and culture are major considerations in the Regional Office staff's day-to-day operations. Water, both for drinking and irrigation, are major issues in Region 9.

Dr. Yoshii noted the need for strong connections between her staff and the EPA Office of Research and Development (ORD). ORD provides significant assistance to the Region. The Regions have developed strategic plans to better reflect the needs that they face. In the past such planning was usually top-down. This permits the unique Regional characteristics, issues, and needs to be reflected in what they plan to do to support EPA's mission, and in how they mobilize resources to achieve that mission. Deputy Regional Administrators meet regularly to discuss programs, problems and solutions. This helps to share outcomes from one part of the nation to others that might have similar problems.

**b) Overview of Region 9 Science Structure and Function:** Dr. Tom Hutteman stated that Region 9 has the fastest growing population in the U.S. and it is the largest Region geographically. It produces 50% of the nation's produce, has 25% of its dairies, 25% of agriculture workers, and 95% of the nation's coral reefs (see Attachment E and F).

Significant challenges for Region 9 include: the nation's worst air quality; 5,000 beach closure/advisories a year in California; 20% of drinking water wells with arsenic above 10 ppb; numerous mega-dairies (those with 10,000 to 25,000 cows); perchlorate contamination in the drinking water supplies for over 15 million people; environmental degradation on the Mexico border; and it has the most law suits filed against it than any other EPA regional office. Regional priorities are contained in the Regional Strategic Plan (see Attachment F).

Region 9 is organized into Media Divisions (Air, Water, Waste, Superfund, Communities and Ecosystems) and Support Divisions (Regional Counsel, Public Affairs, Policy Support and Management).

Most of the science support for the regional office is decentralized. Approximately one-third of the regional staff positions require some scientific background. Science activities in Region 9 include: pollutant testing/monitoring; modeling; engineering; risk assessment; and technical review. Most activities require networking for technical support/expertise and most are heavily deadline driven. Science is important to the Region's credibility with the public.

The Scientific resources of Region 9 include: a full service Laboratory (10,000 analyses per year); a Quality Assurance Office; Science and Technical Support staffs in various divisions; Contractors; GIS program contractors; ORD's two staff positions in the Region; and the Regional Science Council.

Region 9 participates in the ORD Regional Applied Research Effort (RARE) and receives limited funds for regional research through that program. RARE has funded projects on chronic toxicity in California's ambient waters; toxicity identification evaluation with sea urchin and sand dollars; dioxin emission factors for fireplace and woodstove combustion in the SF Bay Region; derivation and application of macroinvertebrate tolerance values; body burdens of PBDEs and HHBCD; and transport pathways of invasive species across Pacific estuaries.

Scientist to scientist collaborations are pursued and have had successes in studies on MTBE, and in the development of a tiered approach for calculating risk-based screening levels for clean up goals for TPH. The ORD regional research partnership program has been used to design an integrated assessment of the San Joaquin Valley, and landscape and aquatic resource characterizations using hyperspectral imaging.

Regional activities provide opportunities to enhance EPA's science. Regions are "laboratories" for developing advances in environmental protection and for promoting innovation when it comes to finding neighborhood solutions for national standards. There is a need to enhance the feedback loop between the national and regional levels. Regions provide an opportunity for collaboration outside EPA at a local level and to look into local/regional indicators.

**Regional challenges include** maintaining high caliber science staff; obtaining quick access to science expertise/resources; acquiring data to accurately understand the complex environmental situations faced at local levels; tools to better interpret and use environmental data; and the need to keep up with scientific advances. **Specific science needs for Region 9** include: control technologies for fine and ultra-fine particulates; feasible arsenic treatment technologies for small drinking water systems; measures that link health outcomes and environmental protection; strategies to respond to emerging pollutants; optimization techniques for groundwater cleanups; improved remote monitoring techniques; genomics capabilities.

Dr. Huttemann referred Board members to the 45-day study of regional science – “Strengthening the Support Structure for Regional Science”.

Members commented on or asked the following questions of Dr. Huttemann:

- a. How linked the regional staff is to the STAR program (it is a place for Regional improvement).
  - b. The decision process for RARE funding from ORD (it involves a Regional solicitation under the coordination of the regional science council and project selection by the Deputy Regional Administrator).
  - c. What is the extent of regional staff interaction with the extensive academic expertise in Region 9 (it is not as good as it needs to be and this is an area that the regional staff needs to pursue). Members suggested that it might be possible to set up a network and obtain some pro bono academic support.
- c) **EPA’s Regional Science Needs Study: *Using Science in Regional Decision Making: A Collaborative Analysis of the 45 Day Task Force Report.***

Dr. Jan Baxter began her presentation with a discussion of the role of the National Regional Science Council (NRSC). The NRSC is composed of Chairs of each Regional Science Council. Their role is to enhance science in regional offices, improve knowledge and expertise, identify cross-regional issues, and support strategic Regional science planning. The NRSC and the RSC’s are good resources for carrying out recommendations in the 45-day study.

Dr. Baxter gave an update on the “45-Day Study” of regional science needs. The study was completed in July, 2003 (See Attachment G). A Workgroup was established to analyze the report’s findings (identify recommendations needing additional clarification, identify offices/organizations with primary responsibility, consider other options for overcoming obstacles), to prioritize recommendations on needs (with resource requirements), and to develop a general plan for implementation.

Dr. Baxter noted a number of Regional science issues – some existing and some emerging:

- i) Enhanced research on mixtures (synergistic effects, toxicity, environmental fate of metabolites, effects of multi-media exposures);

ii) Standardized measurement methods (need recognized methods for permits and enforcement, especially for congeners and emerging pollutants), and

iii) Regionally-relevant environmental indicators –staff who are more generalist in their focus need assistance in developing information on the components of Regional problems that must be used in developing an integrated picture of the situation.

A major challenges in meeting Regional scientific needs is that there are many such needs and simple, “one size fits all,” solutions do not exist for Regional situations where there are many real-world ecosystems, histories, cultures, pollutants, etc. present. The next steps for the agency, as a result of the “45-day study,” include:

i) providing support to the proposed “data accessibility” initiative and continue to support databases useful to Regional Offices;

ii) exploring the feasibility of Technical Support Centers for programs other than Superfund;

iii) exploring the feasibility of developing a Regional Applied Science Effort (RASE) similar to ORD’s RARE program;

iv) increase ORD, Program Office, and OEI efforts to assist Regions in using new science.

Dr. Baxter closed by noting that prioritizing the “top” needs of Regions could mean that many region-specific needs will not be addressed. Pursuing many of the needs identified by the report will require improvements in internal coordination. Overall, there is a need to improve how we address the diversity of ecosystems and regional cultural differences. There is also a need to improve the utilization of outside expertise.

Members commented on the following issues:

i) Graduate students might be mobilized to work on some Regional research issues. It is not unusual for such students to be in need of specific concrete projects for their research focus.

ii) Regions should challenge the reality of the agency’s “yardstick” that requires the showing of national implications to obtain resources to put into problems identified in one region.

iii) Failure analysis of “practices” involving the environment could reveal lessons learned to help prevent future problems (e.g., perchlorate issue).

iv) There is a need for the Board to learn about the important projects that exist that are not funded because of resource limitations – this information could be

used by the SAB as it decides on its advice during the FY 2006 science program budget advisory.

v) Members were interested in the parallel track for scientists.

d) **Challenges in Making Remedial Decisions Involving Contaminant Vapor Intrusion into Indoor Air from Subsurface Sources.**

Drs. John Beach and Katherine Baylor discussed the challenges to remedial decision making that are caused by vapor intrusion into indoor air from subsurface sources (see Attachment H). The situation has only recently been recognized and it is still not well understood. Currently, Region 9 uses draft guidance from OSWER to evaluate the problem. Regional activities include indoor air measurements and soil gas measurements. Region 9 also conducts community outreach on the issue. At a national level, the agency is developing better sampling methods, improved guidance, and compiling and analyzing data on the problem. Outreach is an important part of the activity.

A key issue in vapor intrusion assessment is the complexity of the Johnson & Ettinger model used in assessments (many equations for many factors each with their own variability and uncertainty); there is uncertainty about the preferential pathways involved in intrusion as well. There is also variability introduced by the state of the art for sampling devices available to study the issue. Overall, the vapor intrusion issue is a problem for Agency remedial decision making and Agency confidence about our characterization and the exposure potential is not as great as we desire. We need the basic science to describe variables and identify key variables and to do uncertainty and sensitivity analyses. We also need to understand the temporal aspects of the problem.

**The SAB can help Region 9 in this regard by helping in communicating the magnitude of the problem to policy-makers; helping focus resources on the science needs; identifying alternative approaches; promoting the use of good science in decision making; and helping us with the issue of “how certain is certain enough” for our remedial decisions.**

Questions and comments from members:

i) The problem seems to be tailor-made for the EPA 3MRA model that now targets issues at the national level.

ii) There are practical needs in terms of what we can tell people they should do as a result of vapor intrusion.

iii) Vapor intrusion is key for radon. Is EPA building on its experience in radon in addressing vapor intrusion from Superfund sites? Can you build in protective systems during housing construction for this as we do for radon?

- iv) Does the agency interact with the Lawrence-Berkeley Lab on this issue? It is an excellent source for the issue.
  - v) How does Region 9 interact with ORD to prioritize these issues for study? The region is beginning to look at key uncertainties/variability as input to research planning. **This is an area that the SAB can help the Region in advancing.**
  - vi) EPA should consider statistical approaches to understanding this issue along with what it now does on models. Models will be limited.
  - vii) EPA might gain lessons from its work on methane migration from landfills (under RCRA) as it seeks to better understand the Superfund vapor intrusion issues.
- e) **Impact of Scientific Uncertainty on Regulatory Programs: Superfund Approach to New Information On Environmental Contaminants. Case in Point-Perchlorate.**

Mr. Harold Ball discussed general uncertainty and decision-making in the Superfund program (see Attachment I). Mr. Kevin Mayer provided an example of the issue with a discussion of perchlorate.

In Superfund, the goal is to protect human health and the environment. Risk management is key to site cleanup decisions that are informed by risk assessments. Toxicity data, from scientific studies, is key to risk assessment. Information used in determining Superfund decisions comes from scientific studies, IRIS values, existing standards (e.g., MCLs), Superfund acceptable, relevant, and appropriate values. All of this is captured in a record of decision for the cleanup.

Acceptable risk, is the goal in our decisions. However sound the Agency's analytical work is, there are always questions in the eyes of the public about the scientific integrity and acceptability of our risk management decisions. For communities, there is a strong desire for cleaning sites, often to a zero risk level and they look for certainty. Site decisions though reflect "acceptable risk." The question is, "what is acceptable risk in the eyes of the public?" Examples of contentious contaminants include: TCE, dioxin, asbestos, and perchlorate.

Kevin Mayer then discussed the perchlorate example (see Attachment J). He discussed the background and history, occurrence, toxicity, and regulatory status of the contaminant which was first manufactured around 1908 and which has had extensive use in solid rocket fuels and explosives for many years. Perchlorate is highly soluble, mobile, and stable in water. It is difficult to treat with routine clean up measures and until late in the 1990s difficult to detect. EPA set a provisional reference dose of from 4 – 18 ppb in the mid-1990s. Region 9 began requesting information on perchlorate from manufacturers in 1998 and alerted Headquarters, Regions, and States about perchlorate issues beginning in 1997.

Perchlorate manufacturers and users are well dispersed throughout the United States and releases have been widespread. Regulatory issues include toxicity (referred to NAS with a final report due in 2005); treatment technologies (full scale units are costly); and occurrence. For toxicity the issue is what endpoint to use and what uncertainty factors to apply. For now, there is a 0.6 ppb Public Health Value published by California, but there is no Federal Standard. EPA is considering whether to do a standard now or to employ a Health Advisory level for interim guidance. Other states and some tribes have established Advisory levels in addition to California (ranging from 1 ppb to 18 ppb).

Typical uncertainties factored into EPA's reference dose (no or lowest observed effect level divided by various uncertainty factors) include: differences in sensitivity of various humans; animal to human differences; short-term study to long-term effect; and deficiencies in the database.

There are treatment systems operating at full scale. The systems are costly and the overall cost of clean ups will be directly related to the levels that are ultimately set by the Federal government.

Questions and comments from members:

- i) There is a perception that the impact of economics is growing in the minds of the public. The agency agrees that economics is a big driver in clean up decisions.
  - ii) Members asked about the worst case scenario associated with perchlorate. Based on what is known, the worst case is not clear and it is not certain that effects could be readily measured in the population and all relevant endpoints are not well researched.
  - iii) Members wondered how the Regional Office interacts with Headquarters to obtain needed data in cases such as this. Mr. Mayer noted that in all such cases, there is pressure to move forward to resolve the issue at the local level. Regions interact with Headquarters on actions to take and for perchlorate, the action has moved from the Region to Headquarters and now likely to the White House. The role of the Region in such cases is to continue to press for resolution.
- f) **Central California Air Quality Studies.**

Dr. Carole Bohnenkamp discussed the Air Quality studies in Central California as an example of a major issue addressed by the Region 9 air program (see Attachment K). She noted that there had been steady progress in reducing the maximum (1-hour) ozone concentration in the San Joaquin Valley. Not as much progress has been made with the 8-hour concentration. Particulate matter (PM) is also an issue because precursors (VOCs, NOx, ammonia) affect ozone presence as well as particulate matter. PM exceedances occur in the fall and winter (fall is dominated by coarse fractions while winter exceedances are dominated by the fine fraction). Issues include: transport of ozone, visibility, transport and deposition to Lake Tahoe, and forest/ecosystem health.

Air quality studies are being conducted to address the broad ozone and PM attainment issues in the San Joaquin Valley. Air Quality Monitoring occurred from December 1999 to January 2001. An emissions inventory was developed from December 1999 to June 2004. Data analysis is ongoing and modeling will continue through December 2005.

Important questions include: 1) What design values are important (peaks, different types of PM, have all episode types been captured); 2) what sources contribute to exceedances; 3) what is the local versus regional nature of source contributions; and 4) what emissions reductions are needed to attain the standards for PM and ozone?

Science, policy and planning issues for the future include: model performance, episode selection for models (varying model performance, varying database quality, anomalous events such as fires, day specific inventory adjustments), integration of modeling and data analysis techniques; the role of ammonium nitrate, resource availability for the development of guidance updates, and how new information is to be incorporated into the analyses?

Questions and comments from members:

i) The study is geared toward determining issues related to attainment. There is no biology or economics involved.

ii) The whole approach from regulation development through attainment can take decades.

**g) The Secret Life of Selenium: A Study of the Interaction of Science, Environmental Policy and Industry in California.**

Dr. Eugenia McNaughton discussed issues associated with selenium in Region 9 (Kesterson Wildlife Refuge – since 1982 it has been filled in and capped, San Pablo Bay refineries, Tulare Lake evaporation ponds). Selenium is a micronutrient as well as a toxicant and it bio-accumulates in the food chain. Toxicity has been shown in chickens, fish, and wildlife. Selenium is not just a California issue (reference also North Carolina fly ash issues, West Virginia mountain top mining, and Lower Great Lakes uptake).

EPA will review its water quality criteria for selenium. Criteria for selenium are developed differently than for other metals and metalloids. Water concentrations may not be relevant. Regional science is helping to develop California site-specific criteria and evaluating conditions in the SF Bay-Delta (e.g., wildlife thresholds, applying the Great Lakes Water Quality Initiative model to wildlife; modeling protective criteria.

There is a need for data on site-specific water concentrations. Concerns include the best medium to use (sediment, biota) for the criteria and translating that to water; averaging periods that are selenium-specific; and site-specific bioavailability, bioaccumulation, and field studies. To reduce selenium contamination, there is a need to: study selenium

cycling under different environmental conditions, make ecosystem connections, encourage multi-jurisdictional efforts, and support source reduction efforts (including land use planning).

**h) Dairies in the San Joaquin Valley: Science Needed to Reduce Pollution and Support Implementation of the Clean Air and Clean Waters Acts.**

Dr. James Liebman discussed California's San Joaquin Valle Dairies which contribute to the Valley's environmental pollution. There is a need for basic and applied research to quantify pollution from dairies and to support the development of manure treatment technologies that are environmentally and economically sound.

Dairy manure contributes to pollution via release of VOCs (ozone and PM precursors); ammonia (PM precursor); methane (global warming); Nitrogen (groundwater pollutant); and salts.

Typical dairies in California are feeding operations and the cows are never on grasslands. Manure is collected in holding ponds and water is pumped out periodically for use in irrigating and fertilizing crops. The structure of the dairy industry in California has contributed to the magnitude of this problem. Dairy is the number 1 agricultural product in California. The Valley also has the largest herd sizes in the U.S. The result is more animals and more manure in a smaller area. Also, the problem is compounded by the fact that the Valley is the fastest growing area in California and by weather patterns in the valley.

There is a SJV Dairy Manure Collaborative (USDA, NRCS, RD, DOE, EPA, California state agencies, dairy industry, public interest groups, and university researchers/extension agents) working to determine solutions to the problem. The goal of their activity is to think of and utilize manure as a resource (nutrients, soil amendments, bedding, clean renewable energy) and to reduce emissions of pollutants.

Science needs include:

- i) reducing uncertainties in VOC emissions from all parts of dairy operations; speciation; and transport and reactivity to form ozone
- ii) technology evaluation to determine the advantages and unknowns for each – energy production, dehydrations and redistribution, composting, converting nutrients to biomass, trapping of aqueous nitrogen, nitrification/denitrification; and use of centralized treatment plants.

Dr. Liebman concluded by noting that we need basic research, applied research on engineering and economics of manure treatment technologies and demonstration and research on facilities.

Questions and Comments from Members:

- i) The dairy problem is very similar to the agricultural waste issues in the corn belt's animal feeding operations.
- ii) Focusing on the end of the problem avoids looking at the systemic issues at the front end of the issue that cause it (e.g., subsidized water in California and price supports). Also, true trading programs, that might be a part of the solution, require a true cap. Finally, we know very little about these issues.
- iii) Use of manures in rangeland are not likely a fix in California because of the long distance transport required.
- iv) Economic factors may solve the problem in the long run because of the cost associated with the structure of the industry (Nitrogen removal costs, e.g.).
- v) Biohazard has been identified in England for manures – mad cow disease. Also we wonder about human health effects from growth hormones in milk.
- vi) Public education needs exist for this problem.

Dr. Glaze thanked the Regional representatives for their strong presentations. They will provide the Board with much to consider as it goes forward in its science and research budget advisory as well as in other activities. Issues we might want to note in our future activities could include:

- i) the utility of data quality objectives in resolving the need for standard methods for Regional monitoring issues;
- ii) the need to look at Regional science needs when EPA makes science and research program budget decisions at the margin;
- iii) the need for time to permit staff to develop as scientists under the parallel career tracking that is being considered;
- iv) the value of increased levels of Regional staff interactions with the excellent academic institutions that are located in the region -- all regions not just Region 9;
- v) the consideration of how the Regional needs for rapid information development might require novel approaches beyond the more methodical approach of planning and budget development (e.g., intern programs with universities, cooperative agreements with universities, potential creation of “accounts” within central research entities that could be drawn on to provide rapid science support to Regions, etc.);

The meeting was adjourned for the day.

Tuesday, September 14, 2004

**3. Updates of SAB Staff Office Activities**

- a) Dr. Vanessa Vu discussed the FY 2004 accomplishments (Attachments N and O).
- b) Dr. Vu introduced Dr. Rebecca Parkin who briefed the Board on a draft letter (see Attachment P) to the Administrator that was developed as a result of the combined SAB Environmental Health Committee (EHC) / Integrated Human Exposure Committee (IHEC) July 26, 2004 meeting during which the EPA Office of the Science Advisor Staff Paper *An Examination of EPA Risk Assessment Principles & Practices* (<http://www.epa.gov/osa/ratf-final.pdf>) was discussed. The letter affirms document's message that favors using available and relevant data instead of default assumptions when such data are present and encourages EPA to formally affirm this position and undertake a vigorous campaign to encourage risk assessors to adopt this approach. The letter also affirms the document's suggestion on the usefulness of probabilistic methods in performing hazard and dose-response assessments. The letter encourages EPA to continue to promote and use probabilistic methods for not only exposure assessments but also health effects and dose-response assessments. For both issues, the letter urges EPA to provide necessary resources to ensure that these improvements to the risk assessment process can be successfully implemented.

**ACTION: The letter will be sent to the Board members for their reaction prior to delivery to the Administrator.**

- c) Dr. Vu. Introduced Dr. Deborah Cory-Slechta who noted that this is to be the 25<sup>th</sup> anniversary for the SAB's review of EPA's studies submitted for recognition in the Scientific and Technical Achievement Awards program. It is a large job for members involved who often read as many as 40 reports. She suggested that the Board take advantage of this milestone anniversary to bring additional recognition to the program which rewards good science.
- d) Suggestions by members of things that could provide additional visibility, included: i) advise staff at *Environmental Science and Technology* and *Science* magazines so that they can develop news articles on the event; or ii) identify a number of STAA awarded reports from the past that have provided major contributions to EPA science and show case them in an appropriate manner.

**ACTION: Dr. Cory-Slechta and Dr. Vu will develop ways to showcase this event and its 25<sup>th</sup> anniversary and consult with the Board on how to implement the idea.**

**4. Review and Approval of SAB Draft Reports:** Dr. Glaze introduced the topic and how the enhanced review process was established during the SAB's 2003 reorganization.

**a) Review of the SAB Draft Report on EPA's 3MRA Modeling system:**

Dr. Thomas Theis discussed the Panel's review of EPA's *Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) Modeling System* (see Attachments Q and R). The review was extensive, involving two public face-to-face meetings and ten public conference call meetings. Because the Vice-Chair, Dr. Grasso, was chairing a concurrent meeting of an SAB Panel, QRC member Dr. Michael McFarland summarized the recommendations of the QRC which met on August 23, 2004. After considering the Panel's report and praising its quality, the QRC recommended that the Board approve it with the following changes: the cover letter was to be shortened by removing the discussion of site-specific applications, topic sentences in the Executive Summary were to be bolded, and language was to be added to acknowledge more of the difficulties of performing the probabilistic risk assessments for health endpoints recommended by the Panel. After these changes were made, the report was forwarded to the Board on August 31, 2004.

[Note: EPA representatives joined in on this session via telephone. Those identifying themselves included: Rose Russo and Justin Babendreier of EPA Athens; Steven Kroner of OSW; and Barnes Johnson of OAR].

While Board members were pleased with the Panel's report, making only a few small editorial recommendations, there were two areas which received more extended discussion. The first involved model validation, uncertainty analysis and back-calculations of uncertainty. 3MRA is an early member of a new class of higher order models to which traditional model validation approaches cannot easily be applied, in part because there is not, and probably never will be, a single data set that will stress the system's 17 modules equally. (The 17 modules are legacy models which have been well validated individually.) For models of this type, M. Bruce Beck and others have proposed a different set of validation criteria. The Beck approach represents a departure from traditional notions of data matching as the only criterion, to an inclusive view of validation as a process of model evaluation, rather than a state of model condition. The Panel supported the use of the Beck approach to validating the 3MRA modeling system.

One member, who expressed concern over whether the best available science is good enough or some other approach should be used, suggested this concern could be addressed by requiring the Agency to provide a back-calculation of uncertainty. The member had found this valuable in an IAEA review of a DOE model of Yucca Mountain. Other members and the Agency thought that, because the model system – which incorporates uncertainty analysis – was a framework a single summary back calculation could not be provided for the entire framework, although it could be generated for individual narrowly defined single-chemical scenarios. The Agency staff referenced some of the specialized analyses they had provided the original Panel as potentially helpful in allaying these concerns. After some discussion, the suggestion of requiring a

back-calculation was moved and seconded; however, it was not supported by a vote of all members.

The second area was the desirability and difficulty of performing probabilistic risk assessments for health and environmental endpoints as recommended by the Panel. Current Agency practice is to stop the probabilistic analysis with the exposure assessment. While one member was concerned that being overly simplistic in characterizing uncertainty is more deceptive than not characterizing at all, other members felt that the zero bound estimates are wrong and that the 3MRA model would move in the right direction by including uncertainty for health and environmental endpoints. The 3MRA Panel's recommendation was in harmony with a draft letter independently generated by the EHC/IHEC as a result of their consultation with EPA on its risk assessment staff paper (see above in these minutes). Dr. Morgan proposed that a cautionary sentence be added to the effect that, historically, early quantitative risk assessments have tended to underestimate uncertainties related to health effects. Dr. Zeise wanted a couple of additional caveats be added and offered to draft them after the meeting. One member noted that the issue under discussion is not one of suggesting that the original panel erred in its evaluation and draft report. The Board is not re-reviewing the model: it is reviewing a draft report from the panel that has been judged to have done a good job in its expert review. The Board is merely asking for caveats to be added. This is not a major problem.

A motion was made and seconded to accept the report subject to concurrence between the Panel Chair and the QRC on the changes discussed. If they are unable to agree, the report should be returned to the Board for final action. The motion passed without dissent.

**b) Review of the SAB Draft Report on EPA's *Report on the Environment 2003*:**

Dr. George Lambert introduced the report and the review Panel's approach to responding to the Agency's charge (in lieu of the Chair's introduction which was not available due to inadequate telephone connections from her location in Germany). The panel reviewed the ROE 2003 with the idea of making comments that will improve future reports on the environment.

Dr. Genevieve Matanoski presented the QRC's conclusions and recommendations (see Attachments S and T). She noted that since ROE 2003 is not to be revised itself, the nature of the action is actually "advisory" and not a peer review. She noted that the QRC believed that the draft report clearly addressed the charge questions and that it did not note major technical errors. The report is generally clear and logical but that a few clarifications were requested by the QRC. She suggested that the report might have too much specificity and also introduced this as a general issue to be resolved in the Board's directions for report preparation, i.e., the level of specificity that reports should generally target. She noted that the QRC thought the conclusions and recommendations were excellent and that they will, if addressed by EPA in its future work, make the next documents better. She recommended that the letter be shorter --

again this is a generic issue for SAB reports. She noted that the QRC endorsed the draft report's call for EPA to begin addressing global climate change in these reports. The report was approved by the QRC and forwarded to the Board recommending approval.

Board Members and Dr. Lambert discussed a number of issues, including:

- 1) how specific the report should be in its advice – the concern was that too much specificity can serve to make decisions on content and approach ours and not EPA's (this applies to things such as the form of the ultimate report EPA might produce for these assessments and some substantive information in the report) – we might best point out the issue and indicated that EPA needs to resolve these;
- 2) Lack of citations to some statements in the panel report;
- 3) Some sections of the draft are not as clear as they might be; .e.g, page 27, question 3 on the precautionary principle; point 4 below that;
- 4) The EPA report is not really the first such assessment; CEQ in the past did annual assessments for quite some time
- 5) Including information on global climate change is important;
- 6) The need to ensure that EPA actually does continue to do these reports and that the SAB recognizes that the 2003 Report will remain a draft and that SAB comments will be considered in developing those reports.;
- 7) The importance of making it clear that the Board is ready to continue to provide advice on future reports;
- 8) The Board might want to suggest to EPA what a report on the environment should include;
- 9) The need for the report to make it clear that EPA should identify staff to do this report and allocate resources for its conduct - and that these funds should be new funds and not those shifted from other EPA science efforts;
- 10) The Agency needs to ensure that there is a solid link between status and trends changes and the drivers that they are linked to before indicting such things in these reports;
- 11) The need to ensure it is known that "Trends in the Environment" includes human health trends as well as ecosystem trends (which is pointed out in the draft SAB report);
- 12) The ROE 2003 is more a public document and there is a need for environmental census data based on appropriate measures year to year as a technical backup—there is a need to be clear on who the audience for the document is so the content is driven by that decision.

A motion was made to approve the document contingent upon the Panel Chair and the QRC working together on the issues raised, generalizing the issue of what a public document needs, the issue of specificity and needed citations, and the Board's willingness to assist in reviewing future iterations of the report. The Board voted unanimously for approval of the report and sending it on to the EPA Administrator.

**ACTION: The Chair and Staff will do the final formatting of the report and transmit it to the QRC for final approval prior to sending it to the Administrator and the relevant EPA offices.**

**c) SAB Review Process for Draft Reports:**

Dr. Glaze discussed the origins of the report review process that the SAB now conducts on certain draft reports (see Attachment U). The need derives from the SAB Charter that, in accordance with FACA, requires that reports to the Administrator be approved by the Chartered SAB, i.e., the Board. Item 7 of the *Implementation Plan for the New Structural Organization of the EPA Science Advisory Board* (EPA-SAB-04-002, 2003), to which Dr. Glaze directed Members' attention provides additional information on the quality review. The conduct of this secondary review was the result of the Board's desire to ensure the thorough review of draft reports prior to approval and to allow it to spend additional time deliberating on issues that would allow it to provide advice that will help EPA move into the future with better science. The Board must pick wisely the way it will use its time so that it can accomplish this end. It must also ensure the quality of reports delivered to the Administrator.

The SAB's secondary review is similar to that done by the National Research Council prior to its release of reports. Not all reports will go through the full process using the Quality Review Committee (QRC) procedure – the more controversial the report topic, the more likely it will be that it will go through the QRC. In response to a question about *De Novo* Review Panels, Dr. Vu explained the types of activities that the Board and the SAB Committees conduct for EPA (e.g., consultation, advisory, review, etc.) and the types institutional “committees” that the SAB can use to carry out these efforts. She noted that *De Novo* Review Panels are established for a one time purpose and that they generally are involved with more contentious peer review items.

Dr. Glaze stated that the intention to use the SAB Vice Chair to chair all Quality Review Committee activities was proving to be burdensome and that the Board would open the chairing task up to other Board members. He suggested that in the future, one of the 3 to 4 Board members serving on specific QRCs would be appointed to chair that QRC.

Issues raised by Board members during the discussion of the evolving report review process included:

- 1) The QRC is not to redo the work of the original review panel.
- 2) It is likely that the more contentious issues would be discussed by *de novo* peer review panels.
- 3) A larger number of Board members on a QRC can help assure us that the review has not missed something.
- 4) A one-hour QRC conference call is too short and it does not provide for the dynamic interactions that are possible face-to-face.
- 5) Narrowly focused QRC's can limit the broader dimensions that some topics raise.

- 6) Having QRCs be responsible for ensuring there are “no” errors or omissions implies a substantive review requirement for the QRC and small groups may not have the expertise to do this.
- 7) QRC’s should not be responsible for identifying all of the errors and omissions in a report. Instead, they should serve as “trial consumers” of the report, and identify ambiguities or inconsistencies that may complicate the use or interpretation of the report further down the line. Substantive issues are the purview of the experts who authored the report, whereas the exposition of these experts’ conclusions should be a primary concern of the QRC.
- 8) The number of experts should be as small as possible to ensure that their work on reviewing the draft report does not end up as a new review of the Agency document.
- 9) The QRC should trust the Panel Report on “substance” and focus on whether the body of the report is fairly translated into the executive summary and the letter to the Administrator.
- 10) Report format issues remain and some guidance on the level of detail in report components may be needed – some reports are too detailed.
- 11) QRC members might improve the final report review if they could observe the review process of the panel.
- 12) The QRC task is to review the review report, not re-review the topic—the process may not be so broken.
- 13) It might be useful to open the process to self-nomination of persons to serve on the QRC for specific reports.

As a result of the discussion, Dr. Vu proposed the following:

- 1) Staff provides preliminary background information to the Board on the review
- 2) Draft reports will be sent to the full Board for review and comment at the same time that the QRC receives the draft.
- 3) Members provide any comments they have on draft reports to the QRC members in writing.
- 4) The QRC evaluates comments received, as well as their own, and decides how these comments and issues are to be pursued with the original review panel Chair.
- 5) QRC discusses the comments and issues with the Chair of the original review panel to resolve as many issues as possible prior to the final approval of the Board.
- 6) Panel Chair revises the report, or interacts with original review panel if needed, to consider and make revisions identified by the QRC (and the Board comments).
- 7) The QRC sends this “final draft” version of the report forward to the Board for approval (in public meetings) – the revised report is to be sent with a transmittal noting issues raised and how they were resolved and identifies any issues still needing Board resolution, as well as a recommendation for final disposition.

Dr. Morgan summarized the information for the Board and provided a draft flow diagram for a new process.

**ACTION:**

Staff Office personnel were tasked with putting the essence of this process into a “straw” document for the Board’s review, comment, revision, and approval.

## **6. Discussion of the SAB’s Development of Strategic Advice on EPA Science and Research Programs**

Dr. Glaze discussed the importance of providing strategic advice to the Administrator and the influence of that need in the 2003 SAB reorganization. The review of EPA’s science programs, and Agency investments in science program components, is an important type of strategic advice that occurs each year and one in which both the Administrator and the Congress obtain useful information on Agency science program investments and focus. It is important that the SAB’s advice on the agency science programs is meaningful for the Administrator and the Congress. Dr. Glaze has noted the changes made by the SAB during FY 2003 and 2004 to enhance the Board’s ability to provide strategic advice.

A needed enhancement in the Board’s advice to the Administrator and the Congress on science program content and investments is to be able to identify for these clients the types of things that are missing in a given year’s science program investment proposal. To do this, the Board needs to engage in a continuous learning process on EPA’s science programs and for that, the Agency will need to take a proactive role in providing information to the Board to support that learning activity. It is also important to look carefully at EPA Regional Office Science needs that are often qualitatively different from the science needs of Program Offices that largely make decisions on a national basis (e.g., standards, regulations, etc.). Also, to more accurately understand what components of the Agency’s proposed science program that EPA is actually able to implement, the Board needs to receive updated information from the Agency on actual appropriation levels for these programs each year (as contrasted with the investments contained in proposed budgets).

An important need for the SAB is to learn more of the OMB Program Assessment Rating Tool (PART) because it has gained prominence in OMB’s decisions regarding program funding for EPA science (as well as other EPA activities).

The Board process for preparing for and conducting this advisory activity will include (see Attachment A for details):

- |                           |   |
|---------------------------|---|
| a) September, 2004:       | Team formation  |
| b) October-November 2004: | DFOs/Teams assemble available information   |
| c) October-November 2004: | DFOs/Teams characterize information on science programs for each Goal   |
| d) October 2004:          | Staff Director, Board Chair, Agency representatives agree on Charge   |
| e) October-December 2004: | DFOs/Teams interact with EPA representatives to obtain supplemental information on science programs of interest |

- f) November 30, 2004: SAB Goal Teams meet with EPA representatives to discuss science programs within Goals and agree on additional information to pursue
- g) December 2004-January 2005: Teams, DFOs, Agency representatives continue to interact on science programs with the intent to have Board members learn more about the programs
- h) February, 2005 (1<sup>st</sup> week): Receive and evaluate FY 2006 Budget documents (Budget in Brief, Congressional Justification, Budget Tables, ORD/PO/RO background information)
- i) Feb 17-18, 2005: Board face-to-face meeting with EPA
- j) February – March 10, 2005): Prepare and send report to Administrator and Congress
- k) March or April, 2005: Testify as requested
- l) May 2005 – January 2006: Continue learning cycle/information sharing activities among the Board and EPA.

## **ACTION**

The Board agreed that it will work in Goal-specific Teams to prepare for the FY 2006 advisory on this issue and that each Team, supported by SAB Staff Office DFOs, will begin to assemble and evaluate information on science program components that fall within each Goal area. Further, the Teams will meet with Agency representatives for each Goal (ORD, Program Office and Regional Office, OCFO, etc.) to discuss programs and information needs in preparation for the February 2005 face to face meeting that will provide the interactions leading to Board consensus advice to the Administrator, and to Congress.

Additionally, specific activities to be pursued to make this happen will include at least:

- a) Shift members of some teams as appropriate,
- b) Add members to teams from AHC, SCs, CASAC, Council,
- c) Draft advisory/learning process for Board (and EPA) consideration,
- d) DFO's work with EPA representatives and Board Goal Team Leaders to assemble available information for each Goal and to provide summary information to each Team that will be useful in their learning about component science programs and for use as a baseline in evaluating the FY 2006 program budget proposal,
- e) Organize Team meetings for 11/30 to discuss programs with EPA clients and determine additional efforts and information needed by the Teams to be able to conduct the February meeting.

**7. Planning for the SAB Annual Meeting**

This session was held to allow Board members to discuss and further plan for the December 1-2 Annual meeting and the Board’s afternoon meeting on November 30, 2004. Two of the Board’s proposed projects for FY 2005 have been combined into a workshop to learn about the implications of the convergence of a number of high technology fields (chemical synthesis, nanotechnology, information technology, systems biology, etc.) to EPA’s ability to conduct relevant science to support its mission in the future. The relevance of the convergence of these technologies to solving legacy environmental problems will also be a consideration. The intent of the workshop is to learn of the issues, discuss them with experts from the field and EPA, and to consider what the SAB might do to assist EPA in responding to this rapidly changing world.

The Workshop will include a plenary session during which experts will present on several component topics of these converging technologies and then members will disperse to break out sessions to consider what the Board might do to support EPA in this area.

**ACTION: Staff, led by Dr. Maciorowski, will continue to plan the meeting for December 1-2, 2004.**

Dr. Glaze adjourned the meeting at 12:05 pm.

Respectfully Submitted:

Certified as True:

*/ Signed /*

*/ Signed /*

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Thomas O. Miller  
Designated Federal Officer

\_\_\_\_\_  
Dr. William Glaze  
Chair, EPA Science Advisory Board

## ATTACHMENTS

Attachment A:	Roster of the Executive Committee
Attachment B:	Meeting Agenda
Attachment C:	Federal Register Notice
Attachment D:	Sign In Sheets 9/13-14, 2004
Attachment E:	Science Structure and Function in R 9- Presentation
Attachment F:	Region 9 Strategic Plan – Appendix C
Attachment G:	1-Improving Regional Science- 45 Day Presentation 2-45 Day Study (Exec Summary)
Attachment H:	Vapor Intrusion - Presentation
Attachment I:	Uncertainty and Decisions Superfund Challenge Presentation
Attachment J:	Perchlorate - Presentation
Attachment K:	Central California Air Quality Studies - Presentation
Attachment L:	The Secret Life of Selenium - Presentation
Attachment M:	Dairies in California’s San Joaquin Valley-Presentation
Attachment N:	FY 2005 Advisory Projects Table
Attachment O:	FY 2004 Advisory Projects Table
Attachment P:	Draft Letter to the Administrator from SAB IHEC/EHC
Attachment Q:	Minutes from the US EPA SAB QRC Teleconference on its Draft 3MRA report, August 23, 2004
Attachment R:	<i>Report of the US EPA SAB’s 3MRA Panel</i>
Attachment S:	Minutes from the US EPA SAB QRC Teleconference on its Draft ROE report, August 18, 2004
Attachment T:	<i>Review of EPA’s Draft Report on the Environment 2003.</i>
Attachment U:	Review and Approval of SAB Reports – extract from SAB Implementation Plan and Charge to Board for reviewing draft SAB reports