

**United States Environmental Protection Agency (U.S. EPA) Science Advisory Board (SAB)  
Teleconference Meeting  
March 7-8, 2013  
Meeting Minutes**

**Date and Time:** March 7, 2013, 10:30 a.m. to 5:00 p.m.; March 8, 2013, 10:30 a.m. – 1:00 p.m.  
Eastern Time

**Location:** By teleconference only (due to inclement weather)

**Purpose:** To conduct quality reviews of three draft reports, to receive an update briefing on Office of Research and Development (ORD) research; and to discuss information provided by the EPA on planned actions and their supporting science.

**Meeting Participants:**

**SAB Members**

Dr. David T Allen, Chair	Dr. Madhu Khanna
Dr. Pedro Alvarez (March 7 <sup>th</sup> only)	Dr. Nancy K. Kim
Dr. Joseph Arvai	Dr. Francine Laden
Dr. Thomas Burbacher (March 7 <sup>th</sup> only)	Dr. Cecil Lue-Hing
Dr. Ingrid Burke	Dr. Elizabeth Matsui
Dr. Thomas Burke (March 7 <sup>th</sup> only)	Dr. Surabi Menon
Dr. Edward Carney	Dr. James R. Mihelcic
Dr. Terry Daniel	Dr. Christine Moe
Dr. Otto C. Doering, III	Dr. Horace Moo-Young (March 7 <sup>th</sup> only)
Dr. Michael Dourson	Dr. Eileen Murphy
Dr. Joel Ducoste	Dr. James Opaluch
Dr. David Dzombak (March 7 <sup>th</sup> only)	Dr. Duncan Patten
Dr. T. Taylor Eighmy	Dr. Martin Philbert (March 7 <sup>th</sup> only)
Dr. William Field	Dr. Gina Solomon (March 7 <sup>th</sup> only)
Dr. Cynthia M. Harris	Dr. Daniel Stram
Dr. Robert Johnston	Dr. Peter Thorne
Dr. Kimberly L. Jones	Dr. Jeanne VanBriesen
Dr. Bernd Kahn	Dr. John Vena
Dr. Catherine Karr	Dr. R. Thomas Zoeller

**Liaisons to the SAB:**

Dr. Pamela Shubat, Chair, Children's Health Advisory Committee  
Dr. Daniel Schlenk, Chair, FIFRA Scientific Advisory Panel (March 7<sup>th</sup> only)  
Dr. Katherine von Stackleberg, Chair, Board of Scientific Counselors

**EPA presenters:**

Dr. Robert Kavlock, Deputy Assistant Administrator for Science, ORD

Ms. Jan Matuszko, Branch Chief, Engineering and Analytical Support Branch, Office of Science and Technology, Office of Water  
Ms. Kathryn Sergeant from the Office of Transportation and Air Quality in the Office of Air and Radiation

**SAB Staff:**

Dr. Angela Nugent, SAB Staff Office, Designated Federal Officer (DFO)  
Mr. Christopher Zarba, Acting Director, SAB Staff Office  
Dr. Thomas Carpenter, SAB Staff Office

**Meeting Summary March 7, 2013:**

The DFO announced that the meeting, previously announced as a face-to-face meeting, was being held as a teleconference because of inclement weather in Washington, DC. The teleconference generally followed the issues and timing as presented in the agenda.<sup>1</sup>

**Convene the meeting**

Dr. Nugent formally opened the meeting and noted that this federal advisory committee meeting of the SAB<sup>2</sup> had been announced in the Federal Register [published February 10, 2013 (78 FR 9689-9690), see Attachment B]. She briefly noted that the SAB is an independent, expert federal advisory committee chartered under the authority of the Federal Advisory Committee Act (FACA). The SAB is empowered by law, the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), to provide advice to the EPA Administrator on scientific and technical issues that support EPA's decisions. The DFO noted that the Federal Register notice announcing the meeting had provided the public with an opportunity to provide written and oral comment. There was one request for oral comment. Two sets of written public comments had been received on a draft SAB report on computational toxicology that was to be quality reviewed during the teleconference and one slide presentation was received from a public commenter on the draft SAB report on emissions estimating methodologies from animal feeding operations was received. These materials had been submitted, provided to SAB members and posted on the SAB web page for the meeting. Attachment A lists members of the public who requested the call-in information for this advisory teleconference.

She noted that the SAB consists entirely of special government employees (SGEs) appointed by EPA to their positions. As government employees, all the members are subject to all applicable ethics laws and implementing regulations. The SAB Staff Office has asked one SGE advisor, Dr. Robert Johnston, to recuse himself from any part of the May 8, 2013 discussion of EPA planned actions that may touch on the planned EPA action AF-14, Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category. With that caveat, EPA has determined that advisors participating in this meeting have no financial conflicts of interest or appearance of lack of impartiality relating to the topics to be discussed at the meeting.

Mr. Christopher Zarba, Acting Director of the SAB Staff, welcomed members of the Board and expressed appreciation for their attendance by teleconference.

## Goals and agenda for the meeting

Dr. David Allen, the SAB Chair, welcomed the group. He summarized the purpose of the meeting and emphasized the importance of the quality review function performed by the chartered SAB. Through the quality review process, the chartered SAB determines whether draft reports are ready to be finalized and transmitted to the EPA Administrator.

### **Quality review of the draft report, *SAB Review (Draft 10/22/2012) of EPA's Retrospective Cost Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies (March 2012)***

#### Presentation from the Panel Chair

Dr. David Allen introduced Dr. Madhu Khanna, Chair, SAB Environmental Economics Advisory Committee (EEAC) and asked her to provide some background on the draft report.<sup>3</sup> Dr. Khanna expressed appreciation for the insightful quality review comments received from members.<sup>4</sup> The SAB EEAC had reviewed a draft EPA white paper designed to explore why EPA *ex post* cost estimates often differed from *ex post* costs, sometimes by a wide margin. EPA's paper was intended to guide and improve future *ex ante* cost estimates supporting EPA rulemakings. The white paper focused on five case studies.

The SAB EEAC's draft review report made several observations and recommendations. The EEAC determined that EPA needed to develop and apply a systematic framework for *ex ante* cost estimates. They also noted that the EPA's five studies relied on limited data, insufficient to draw firm conclusions about the divergence between *ex ante* cost estimates and *ex post*. The EEAC recommended that EPA conduct a large number of randomly selected studies and conduct more qualitative analysis of divergence with the goal of understanding the reasons for divergence. With existing methods it may be reasonable only to identify the direction of divergence and the drivers, not the absolute amount of divergence. She concluded by expressing thanks to EEAC members and the EEAC DFO Dr. Holly Stallworth.

#### Chartered SAB Discussion and Disposition of the Report

After Dr. Khanna completed her remarks, Dr. Allen asked the lead reviewers to briefly summarize their major comments. The first lead reviewer, Dr. Terry Daniel, expressed appreciation for the beautifully written and informative text of the report. He stated that the key points of the report need to be better emphasized in the letter, including the most important recommendation to place greater emphasis on the "drivers" that cause *ex ante* cost estimates to exceed *ex ante* costs, rather than on the any of the case studies *per se*. The SAB report should emphasize that EPA's white paper be revised to focus on these drivers. He also supported the EEAC's recommendation that EPA develop a conceptual model that could be used in the case study analysis.

Dr. Daniel provided recommendations for revisions to the body of the report. He suggested that the introduction be expanded to provide a context for the technical recommendations and to clarify recommendations related to phase 2 of EPA's study. In his view, that phase should focus

on drivers and the sample selected should be selected as a stratified random sample, based on a conceptual model. The report should clarify what is meant by a “less quantitatively focused analysis” and what would be gained by a qualitative approach.

Dr. Otto Doering, the second lead reviewer, commented that the draft report should include a reference to the National Research Council’s (NRC’s) recent report, *Review of the EPA’s Economic Analysis of Final Water Quality Standards for Nutrients for Lakes and Flowing Waters in Florida*. This report includes a chapter devoted to cost analysis and provides a useful template. He also expressed the view that building a database of *ex ante* versus *ex post* cost comparisons (the topic of EPA’s charge question 10) may not be worth the effort.

Dr. Robert Johnston, the third lead reviewer, commended the report for its clarity. He agreed with the general conclusions and comments from prior reviewers. He stated that revisions to the report should highlight a major finding: the difficulty of drawing conclusions from a small sample. He noted that the Agency charge questions were “difficult to encapsulate,” because they were sometimes “wandering,” and sometimes too broad, but he recommended that the report be revised to provide some additional response to a few questions that were addressed too tersely. He recommended that the report be revised to “reconcile two things that seem discordant on the surface.” Although the study points out flaws and shortcomings with *ex post* analyses, it proceeds to suggest that EPA collect more of these data. The draft report should explain how these flaws should be addressed. Should they be ignored? Are there recommendations to fix the problems? Are the flaws related to data limitations to be considered as background to be aware of and dealt with? He suggested that the report clarify what is meant by “qualitative studies.” Such a term may refer to incomplete studies that do not yield a bottom-line cost estimate. The EEAC should consider challenges in using these partial studies, particularly any potential for meta-analysis.

Dr. Allen summarized the comment from the fourth lead reviewer, Dr. Stephen Polasky, who was unable to join the teleconference. Dr. Polasky commented that the draft SAB report should discuss more fully how the analysis of differences between *ex ante* and *ex post* costs should be used. He also expressed skepticism about the need for a conceptual framework and asked for greater attention to the mean and variance of the estimates.

Dr. Allen asked Dr. Khanna to respond to the lead reviewers’ main points. Dr. Khanna agreed to highlight important recommendations and conclusions in the letter to the Administrator so they are not missed and to more clearly link key recommendations to the charge questions. She agreed that the report should emphasize that the goal of the white paper should be to improve the future *ex ante* estimates, rather than calculate the magnitude of past differences. The report will be revised to acknowledge the NRC report and other European sources it references. It will clarify recommendations relating to the timeline of expenditures and voluntary expenditures industry makes with the knowledge of impending regulations. To the extent these costs could be inferred as related to the regulations, they should be included. The report will clarify what is meant by “qualitative studies” the locomotive industry offers a good example. The report will clarify that EPA should synthesize insights across case studies, rather than synthesize data. It is difficult to conduct any kind of meta-analysis, given the limitations of the data. Although many studies are incomplete, there may be insights into the ways in which the potential for innovation and

industry behavior can be understood. In regard to Dr. Polasky's comments, the draft report can clarify EPA's requirements for cost-benefit analysis, which the SAB EEAC took as a given. The report also can explain what it means by the term "conceptual framework." The EEAC did not intend a case-specific approach, but instead a more systematic approach that would cut across cases.

After the panel chair had concluded her response to comments from the lead reviewers, other SAB members then provided additional comments and questions. One member echoed the importance of revising the letter to the Administrator to explicitly discuss the principal conclusions and recommendations. Another member emphasized the importance of recommending that EPA address how it will deal with timeline factors, given different industries, if the draft report advises the agency to develop a systematic approach to estimating *ex ante* costs. Dr. Khanna agreed to make this change in conjunction with a discussion of the rate of technological change. Timeline considerations might involve induced innovation in the pre-regulation phase as well as post-regulation considerations. There may be a need for sensitivity analyses to ensure that induced innovation do not lead to substantial errors in estimating *ex ante* costs.

After discussion had concluded, Dr. Allen asked for a motion to dispose of the report. He reminded members that the purpose of the quality review is to determine if the report is ready to transmit to the Administrator as an SAB report and under what conditions. Dr. James Opaluch moved that Dr. Khanna revise the draft report as discussed during the teleconference to reflect the written and oral comments received, followed by review by the Lead Reviewers, and final review by the SAB Chair to determine that the revisions adequately responded to all the points made. Dr. Terry Daniel seconded the motion. The SAB Chair asked for discussion. There was no discussion of the motion. The motion passed unanimously with no abstentions.

Dr. Allen concluded the discussion by thanking Dr. Khanna and the EEAC for their work on this activity. He expressed thanks to the lead reviewers and Board members for their quality review comments and engagement in the discussion.

The DFO recessed the teleconference at 11:50 a.m.

### ***Quality review of the draft report, SAB Advice (Draft 1/29/2013) on Advancing the Application of Computational Toxicology Research for Human Health Risk Assessment<sup>5</sup>***

The DFO reconvened the teleconference at 1:15 p.m.

#### Public Commenters

Dr. Allen introduced the public commenter, Dr. Catherine Willett, from The Humane Society of the United States. He asked the commenter to limit her oral comments to three minutes.

Dr. Willett stated that she had provided written comments<sup>6</sup> and a slide presentation<sup>7</sup> to guide members through her oral comments. She noted that she generally supported the report. She

noted that her comments provide specific suggestions for strengthening the report similar to those provided by chartered SAB member Dr. George Daston.

Among other comments, she noted that in response to Question 1, the report should acknowledge the EPA's many peer-reviewed publications regarding Adverse Outcome Pathways (AOPs). She pointed out that the EPA's most impressive attempt to incorporate computational toxicology in risk assessment involved the endocrine disruptor pathway. She suggested that the report acknowledge the FIFRA Scientific Advisory Panel meeting, Prioritizing the Universe of Endocrine Disruptor Screening Program (EDSP) Chemicals Using Computational Toxicology Tools. January 29 – Feb 1, 2013, on this point. In regard to Question 2, she noted several reasons why the report should discuss caution in instituting animal results as the gold standard to which *in vitro* results should be compared. In regard to question three, she suggested that the report acknowledge efforts of the Organization for Economic Cooperation and Development (OECD) to harmonize the integration of computational toxicology into risk assessment. Scientists from the EPA have participated in these efforts; the report should acknowledge the EPA's participation.

There were no follow-up or clarifying questions from chartered SAB members.

#### Presentation from the Panel Chair

Dr. David Allen introduced Dr. R. Thomas Zoeller, Chair, SAB Exposure and Human Health Committee and asked him to provide some background on the draft report. Dr. Zoeller began by noting that the report was an SAB-initiated activity and he thanked the EPA for its cooperation in providing committee members with briefings and information. He noted that the committee focused on the ToxCast program, a large program of industry *in vitro* assays used to determine the extent to which high throughput assays could be used to be predictive. This program is only one component of the EPA's Computational Toxicology program, and he acknowledged that the draft report is "ToxCast-centric."

The draft report addresses a few central questions: 1) whether the outputs of the Comptox Program are being used by EPA; 2) how they are aligned with EPA's needs; 3) how they are used for risk assessment and risk characterization; 4) barriers to their use; 4) how might barriers be overcome; and 5) how results could be more effectively communicated. Overall, the committee was impressed with the progress made by the Computational Toxicology program, especially in terms of peer-reviewed publications. The draft report recommended cooperation with epidemiologists and other outside scientists as the program matures. The draft report recommended that EPA develop data use guidelines to guide future use of data from this program. It encouraged stakeholder engagement and use of the EPA website to make data available to the public.

#### Chartered SAB Discussion and Disposition of the Report

After Dr. Zoeller completed his remarks, Dr. Allen asked the lead reviewers to briefly summarize their major comments in response to the SAB's four quality review questions:

- 1) Were the charge questions to the committee adequately addressed?

- 2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?
- 3) Is the draft report clear and logical?
- 4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Dr. Michael Dourson was the first lead reviewer. He stated that he liked the overall report, the diversity of thinking and concerns communicated. He made two principal comments. First, the report needs to comment more clearly that research naturally has blind alleys and that identifying blind alleys is appropriate progress for a research Program. Second, *in vivo* data generally do not allow estimation of the toxicology of mixtures existing in the environment and computational toxicology can more effectively test mixtures than EPA's current toxicology approach. He acknowledged a written comment provided by Dr. George Daston that the Computational Toxicology program is broader than the ToxCast program. He also noted a written comment provided by Dr. Elaine Faustman that the EPA document that the draft report does not address many types of *in vivo* endpoints that are not clinically oriented. The report should be revised to communicate more clearly about other critical effects, such as decreased body weight.

Dr. Nancy Kim, the second lead reviewer, communicated her enthusiasm about the EPA's Computational Toxicology program. She expressed the view that the charge questions were adequately addressed but that the responses were not communicated clearly. She recommended that the report address how outputs from the Computational Toxicology program would be used for risk management. Such a discussion might lead to different recommendations. Although the Deep Water Horizon case represented a "good application" of computational toxicology data, it would be useful to take a retrospective look. How adequate were those data for decision making? She also stated that the report should prioritize among its recommendations and justify them more fully.

Dr. Eileen Murphy, the third lead reviewer, observed that the key question addressed by the draft report was whether the results of computational toxicology are now or can they soon be used by the EPA in a regulatory setting. She noted that the program is still research oriented; there are many questions to address before the results of this research can be used for regulatory purposes. She highlighted language on page 6 of the draft report that observed that assays would replace testing for regulatory decisions. She suggested that this language be revised; such substitutions were a "far-off goal." Computational toxicology research, however, does generate information that can be used for priority setting or other purposes outlined by draft report. She noted that it was difficult to understand the priorities among recommendations in the draft report. The draft presents a great deal of information about the barriers to use of computational toxicology and additional good suggestions have been made by chartered SAB members and the public commenter. These factors need to be addressed before EPA uses computational toxicology research for regulatory purposes. Because much research and development still needs to be done, it is premature to ask the results of the computational toxicology program are being used by other parts of the EPA.

Because the fourth lead reviewer, Dr. George Daston, was unable to participate in the teleconference, the SAB Chair summarized Dr. Daston's major comments that had not been

mentioned by other lead reviewers. Dr. Daston noted that the draft report requires more explicit mention of other aspects of the Computational Toxicology program than ToxCast. He called for the report to more clearly and accurately describe the history of the program and to provide more clarity and rationale for its recommendation that the EPA develop Data Use Guidelines for information generated by the Computational Toxicology program.

Dr. Allen asked Dr. Zoeller to respond to the reviewers' main points and points made by the public commenter. Dr. Zoeller noted that all chartered SAB review comments<sup>8</sup> and the public comment were helpful. He agreed that the report should clarify the role of the ToxCast program within the Computational Toxicology program and focus explicitly on the CompTox program, the component of most interest to the Committee. The report should prioritize its recommendations. In response to a question from the SAB Chair, Dr. Zoeller noted that the report could expand on its recommendation for an external advisory process to help guide ORD to a more integrated approach to this program that would explore the many different potential uses for outputs from the Computational Toxicology Program.

After the panel chair had concluded his response to comments from the lead reviewers, other SAB members then provided additional comments and questions. One member reiterated the need to revise the letter to the Administrator so it emphasizes the key recommendations in the body of the report. Another member expressed surprise that the report did not mention computational toxicology work associated with the OECD and the United Nations Environmental Program. The European Union has banned *in vivo* testing of consumer products, based on *in vitro* high throughput assays. Dr. Zoeller responded that the committee had a broad interest in those efforts, as well as those of the Food and Drug Administration and Tox 21, but decided to focus on EPA instead, given the limited time available to the committee. He noted that EPA is well aware of other computational toxicology efforts.

Another member recommended that the report be retitled to focus on advancing the application of the ToxCast system; she agreed with many recommendations made by Dr. Daston. She also supported written comments provided by Dr. Dourson and noted that the report should address the value of this research for purposes other than risk assessments and for applications not related to adverse outcome pathways. The report should distinguish between recommendations for possible current applications of the *current research program* vs. recommendations relating to *future applications* of research. There is a continuum of research that needs to be communicated more clearly. She also noted the unevenness of the report. The draft report should discuss more clearly how computational toxicology could contribute to risk assessments for mixtures. Dr. Zoeller agreed that the report's title should change and focus on the ToxCast program and explore the use of adverse outcome pathways for endpoints such as endocrine disruption vs. general toxicity.

Another member stated that data use guidelines should not be generated solely from assays, but instead should be also framed around potential applications and considerations of how data are to be used. He recommended that the report cite research by Dr. Rusty Thomas concerning the external predictive ability of ToxCast data. He also noted that the SAB draft report does not accurately describe the state of toxicology. Although there are many data gaps, the EPA has generated a considerable body of toxicity information on agricultural chemicals and high

production volume chemicals. The report should be revised to provide a more balanced view of the current state of toxicological knowledge, as well as the “big opportunity” for use of computational toxicology data.

Other members made additional points. One member noted that the report should broaden its definition of green chemistry and recognize the potential of computational toxicology in this area. Another member stated that the report include more discussion of modeling as part of the ToxCast program; more work needs to be done to improve data mining and network inference approaches. Yet another member suggested that the report distinguish between two different situations. Although the EPA is not ready to consider situations where replacing animal testing with computational toxicology assays for regulatory purposes, there is a possibility such assays could fill in where there are no available data. The draft report should consider those different thresholds separately. In the context of the Deep Water Horizon spill, just a short endocrine battery was done. Decisions were based only on endocrine effects, but those do not give the whole picture. The reports should better discuss what might be gained with broader batteries of assays. She also commended the report for its “nudge” to improve research relating to exposures. The SAB Chair made a final comment that it may be useful to add an Executive Summary to the report.

After discussion had concluded, Dr. Allen asked for a motion to dispose of the report. Dr. Eileen Murphy moved that Dr. Zoeller revise the draft report to address written and oral comments made by chartered SAB members, in consultation with members of his committee, followed by review by lead reviewers and self-identified members of the chartered SAB. This review would be followed by review by the SAB Chair. SAB members wishing to participate in this additional review could self identify by contacting DFO. This motion was seconded by Dr. Kim. The SAB Chair asked for discussion. The motion passed unanimously with no abstentions.

Dr. Allen concluded the discussion by thanking Dr. Zoeller for his leadership on this activity and committee members for their work.

***Quality review of the draft report, SAB Review (Draft 12/3/12) of Emission Estimating Methodology for Broiler Animal Feeding Operations and for Lagoons and Basins at Swine and Dairy Animal Feeding Operations (EEMs Report)***<sup>9</sup>

Dr. David Allen introduced Dr. Taylor Eighmy to serve as acting chair to conduct this quality review, because Dr. Allen had served as the Chair of the SAB Animal Feeding Operations (AFO) Emission Review Panel (AFO Panel) that had developed the draft report. Dr. Eighmy began by thanking Dr. Allen, the panel, the panel DFO Mr. Edward Hanlon, and chartered SAB members for their quality review comments.<sup>10</sup> Dr. Eighmy noted that the SAB had also received comments from Mr. Stephen Page of EPA’s Office of Air and Radiation concerning the draft report.<sup>11</sup> He asked whether any representative of the agency wished to provide remarks. No agency representative responded.

### Presentation from the Panel Chair

Dr. Eighmy asked Dr. Allen to lead off the discussion with background on the draft report. Dr. Allen noted that the requirement for EEMs resulted from a voluntary compliance agreement. EPA was charged with developing EEMs for AFOs. The purpose of the EEMs is to determine whether AFOs would face regulatory responsibilities under several agency statutes including the Clean Air Act, Comprehensive Environmental Response, Compensation, and Liability Act and Emergency Planning and Community Right to Know Act.

AFOs can emit such pollutants as ammonia, hydrogen sulfide, particulate matter, and volatile organic compounds. The EPA drafted two EEMs reviewed by the SAB panel: EEMs for broiler confinement houses (chicken raised for meat) and a lagoon EEM, which addressed emissions from a lagoon that collects manure effluent from swine and dairy confinement houses. The EPA plans to develop other EEMs. The agency provided a background document on the draft EEMs, as well as briefings and supplementary information. The agency EEMs were informed by the National Air Emissions Monitoring Study (NAEMS), a two-year study of AFO emissions funded by the AFO industry as part of the 2005 voluntary air compliance agreement with the EPA.

The panel was charged with answering seven charge questions concerning the suitability of EEMs for the intended application. Overall, the panels draft report found that the EEMs, as currently constructed, are not suitable for use in extrapolating to the broad AFO community. There are a limited number of sampled facilities (3 broiler houses; two in California, one in Kentucky) and a small number of lagoons. The small number of facilities sampled would be less problematic if the EPA employed a model that incorporated fundamental processes (e.g., process-based model) resulting in emissions or that was parameterized for them. The panel strongly argued that EPA's statistical approach could not be extrapolated to a large number of locations. The draft report recommends reformulating the emission models to incorporate fundamental AFO processes and also made recommendations for improving presentation of statistics. The panel found that it was inappropriate for EPA to combine swine and dairy data sets to derive a data set for lagoons. Such combination was inappropriate, given the different biochemistry of the animal wastes and the purpose of the model. The draft report finds that EPA's choice of static predictor variables was not appropriate. It recommends alternative approaches for ammonia estimation and how EPA might handle zero or negative values. The panel also made suggestions for modeling volatile organic compound data in the NAEMS dataset.

### Public Commenter

Dr. Eighmy introduced a public commenter, Dr. Al Heber, from Purdue University and Director of the NAEMS Study. Dr. Heber spoke from a slide presentation<sup>12</sup> that provided an update on the NAEMS dataset and its relationship to SAB's draft report. Among other points, he noted that EPA should eliminate data from its data set when the ventilation rate is zero. He offered several technical corrections to the draft report. After his comments were completed, Dr. Eighmy asked if chartered SAB members had clarifying or follow-up questions. One SAB member asked for Dr. Heber's understanding of the problem formulation motivating development of the EEMs. Dr. Heber responded that his understanding was that the EPA was protecting the environment under

the Clean Air Act by determining how much is emitted from AFOs so that the agency could estimate whether a facility is exceeding its estimated threshold level.

### Chartered SAB Discussion and Disposition of the Report

After the discussion with Dr. Heber was finished, Dr. Eighmy asked the lead reviewers to briefly summarize their major comments. The first lead reviewer, Dr. Pedro Alvarez, found that the report was overall clearly written and logical. It provided valuable suggestions that would increase credibility of estimates of emissions. He agreed with the draft report's recommendations and suggested that the report might provide more guidance about how to implement recommendations for development of a process-based model. The report might identify criteria to validate model, the minimum number of sites to enhance the statistical power in the short term, and guidelines about minimum source and geographical variability

The second lead reviewer, Dr. Joel Ducoste, agreed with that it would be helpful to characterize the specificity of model that would be appropriate. Although he agreed with the recommendation to use a process-based model, such models can be data intensive. It would be helpful for the SAB report to provide a starting point for developing the kind of model needed. He agreed with the report conclusions that a statistical analysis depends on a minimum data set that would include certain types and numbers of farms.

Dr. David Dzombak, the third lead reviewer, considered the report well written and well organized. He suggested that the letter to Administrator be revised to more explicitly summarize the charge.

Dr. Daniel Stram, the fourth lead reviewer, commented that he found that EEMs in EPA's broiler report demonstrated a good fit to individual farms in the data set, while using very simple variables. He stated that the draft SAB report should separate the generalization of results from the analysis itself. The generalization issues pertained to the design of the study and involved such questions as whether the farms sampled broadly represent the industry. In his view, much of the broiler industry generates a standardized product. He suggested that the report be revised to provide more comment on EPA's regression methodology and to provide more detail about the recommended process method. He cautioned that process-based approaches involve many variables that would need to be compared to the dataset.

Dr. Eighmy, the fifth reviewer, observed briefly that points made in the report, Executive Summary, and Letter to the Administrator mapped well and were consistent.

Dr. Eighmy asked Dr. Allen to respond to the reviewers' main points and points made by the public commenter. Dr. Allen thanked Dr. Heber for his update on the status of NAEMS data and quality assurance. The SAB draft report will be updated to note that some of the data used by EPA that were zeroes were now invalidated. He will make the minor corrections noted.

He noted that Dr. Alvarez suggested adding a discussion of goodness of fit criteria and minimum number of sample sites. Because the Panel did not receive guidance from the EPA about how they would be interpreting data, the Panel was not comfortable about providing quantitative

discussions of this nature. The report could be revised, however, to add a general discussion of this issue. For regulatory purposes the EPA will need to define data quality objectives related to regulatory requirements.

In regard to Dr. Ducoste's comments, he acknowledged that the report should note that process models will be data intensive and that models will need to be parameterized to the type of facilities in question and be subject to statistical validations. In response to Dr. Dzombak, he agreed to summarize the charge in the letter to the Administrator.

In response to Dr. Stram's comments, he observed that although the EPA's current statistical models do fit the individual farms in the dataset well, the SAB panel was concerned about the few numbers of facilities sampled and how the models would be applied to other animal feeding operations. Making reasonable extrapolations for parameters as simple as varying bird weight result in unrealistic results; AFOs with different temperature ranges would result in different emissions. He agreed to add more detail about the design of a process-based model, drawing on the 2003 National Research Council (NRC) report, which examined this topic. Chapter 5 of that report describes how models that embed key variables related to the physical and chemical process can have a greater predictive capability.

After the panel chair had concluded his response to comments from the lead reviewers, other SAB members then provided additional comments and questions. Dr. Eighmy asked the SAB who provided written comments if they wished to make oral comments. One member suggested that the report discuss the challenges in developing process-based models and how one would validate them and decide they were adequate. Another member asked for more mention of the public health issues associated with emissions. Yet another member commended the report for its clarity and supported its recommendations. He asked whether industry funding of the NAEMS report had any impact on the data chosen to be included and their generalizability. Another asked how "representativeness" was defined in the context of EEMs for AFOs. Two members asked Dr. Allen about the strongly worded memorandum from Dr. Stephen Page providing comment on the panel's draft report.

Dr. Allen responded to all of these comments. He noted that EEMs are tools for estimating air pollutant emissions for industries subject to regulation where site-specific data do not exist because of costs or other factors. He agreed to expand on this point in the body of the report. Although the lack of data is a challenge, there are many additional sources of data than those used by EPA and these additional sources should be used for validation. He agreed that the report could be revised to discuss what one would look for in validation. He also noted that the report could draw on the NRC report to discuss parameters to guide EPA in selecting sites to have greater generalizability. He also noted that process-based modeling can have various levels of complexity, but that the sense of the panel was that it was important to begin by adopting simpler forms of the model and refining them as more data is made available.

Finally, Dr. Allen commented on the EPA's written remarks. The EPA chose to focus on the goodness of fit for farms for which they had data, rather than focus on broader conditions. There is no reason why the existing data couldn't be used to begin developing a process-based approach. A process-based approach would not need to identify all possible variables. The Panel

concluded that it was important to encourage EPA to move toward more fundamentally based functional forms for the EEMs. Such EEMs would be based on physics, chemistry, and biology of AFOs. He agreed that the draft report could communicate this point more clearly. He also noted that the panel envisioned a tiered approach to modeling, which would not require a high level of complexity for all facilities.

After the SAB members' discussion had concluded, Dr. Eighmy asked for a motion to dispose of the report. Dr. Dzombak moved that Dr. Allen, in consultation with panel members, revise the report in light of the comments discussed during the teleconference and submit it to the Acting Chair to determine that it was ready to be sent to the Administrator. This motion was seconded by Dr. Joseph Arvai. The SAB Chair asked for discussion. The motion passed unanimously with no abstentions.

### **Update on ORD Research**

Dr. David Allen introduced Dr. Robert Kavlock, Deputy Assistant Administrator for Science, ORD, to provide an update on ORD research since EPA received the 2012 advisory letter from the SAB and ORD's Board of Scientific Counselors entitled [\*Implementation of ORD Strategic Research Plans: A Joint Report of the Science Advisory Board and ORD Board of Scientific Counselors\*](#) (BOSC) (EPA-SAB-12-012). Dr. Kavlock expressed thanks for that report and noted that the EPA Administrator had provided a [response](#) dated February 13, 2013 that provided detailed information about ORD's response to specific recommendations in the SAB-BOSC report. He observed that ORD's strategic planning efforts and interactions with the SAB and BOSC had "placed his program in the best possible position" to respond to the current fiscal challenges that EPA faces, because ORD has invested in planning that will help with prioritization. He provided a slide presentation with an ORD update.<sup>13</sup> The slide presentation gave an overview of: 1) events since the SAB and BOSC met in July 2012; 2) sustainability research; 3) emerging issues; 4) innovation (Dr. Kavlock informed the SAB that ORD intends to request SAB review of ORD's innovation activities); 5) responses to SAB-BOSC recommendations for ORD's six research programs; and 6) upcoming activities (including establishment of six BOSC subcommittees to provide advice on implementation of research programs and ORD's intention to seek SAB advice next year on strategic planning for 2016-2020).

Dr. Allen expressed appreciation for the specificity of the information Dr. Kavlock presented. SAB members then asked follow-up questions. An SAB member asked how ORD is seeking research integration and avoiding stovepipes. Dr. Kavlock responded that ORD is still going through a culture change. The new team of National Program Directors (NPDs) meets weekly and also meets with Laboratory and Center Directors once a week. ORD has identified "grand challenges" for strategic research action plans that cut across programs. He encouraged the SAB to look critically at ORD integration efforts as part of the next round of strategic research direction discussions in 2014. He asked the NPD for the Safe and Sustainable Water Resources program to explain how ORD is developing case studies to transfer guidance, models, and tools to other sites. Dr. Van Drunick described a green infrastructure study conducted in Omaha that generated information easily transferred to other locations. Other ORD Staff confirmed that they are seeking opportunities to generalize findings from individual sites.

An SAB member observed that ORD should do more than to reach out to EPA's National Center for Environmental Economics (NCEE) to build a capacity for social, behavioral and decision science because NCEE has disinvested in decision sciences. Dr. Kavlock responded that ORD would welcome specific suggestions from the SAB regarding social, behavioral, and decision expertise to add to its capabilities.

The SAB Chair asked about ORD's plan and timetable for developing roadmaps in addition to the nitrogen roadmap already developed. ORD personnel responded that a climate roadmap was expected in June and work is underway to develop a roadmap for children's health to focus on early life stages that would incorporate computational toxicology. ORD plans to debut an initial draft of this children's health roadmap at the April 2013 meeting of the Children's Health Protection Advisory Committee. ORD staff noted that they are also considering factoring environmental justice considerations into a children's roadmap and climate roadmap. Dr. Pamela Shubat, SAB Liaison and Chair of the EPA Children's Health Protection Advisory Committee, thanked ORD for developing the children's health roadmap in coordination with EPA's Office of Children's Health Protection.

The DFO recessed the teleconference at 4:55 p.m.

### **Meeting Summary March 8, 2013:**

The DFO reconvened the meeting at 8:30 a.m. She noted that agency personnel had requested to make three sets of oral remarks related to the chartered SAB's discussion of planned agency actions and their supporting science. She also reiterated that the SAB Staff Office has asked one SGE advisor, Dr. Robert Johnston, to recuse himself from any part of the May 8, 2013 discussion of EPA planned actions that may touch on the planned EPA action AF-14, Effluent Limitations Guidelines and Standards for the Steam Electric Power Generating Point Source Category. She expressed thanks to Dr. Johnston for identifying this potential conflict of interest for the SAB Staff Office's attention. Dr. Allen commended Dr. Johnston for his diligence providing this information and highlighted the importance of SAB members' identifying potential conflicts of interest related to EPA's planned regulatory actions as the SAB engages in discussion of the agency's semi-annual regulatory agenda. Dr. Allen stated that prior to the teleconference he had informed the SAB Staff Office that one of his research projects was funded jointly by an environmental group and nine natural gas producers to measure methane air emissions from national gas producers. The SAB Staff Office determined that there was no conflict of interest. He emphasized the importance of transparency as the SAB engages in discussion of planned agency actions and their supporting science.

### **Discussion of Planned Agency Actions and their Supporting Science**

Dr. David Allen introduced Dr. James Mihelcic, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science. Dr. Allen noted that this discussion was a new agenda item for the chartered SAB. He commended Dr. Mihelcic, the SAB Work group, and the SAB Staff Office for preparing a memorandum with supporting materials<sup>14</sup> for the Board's consideration. He noted that the discussion was based in the authority provided by

ERDDAA for the Board to identify actions where it wants to provide “its advice and comments on the adequacy of the science and technological basis” of planned agency actions.

Dr. Mihelcic described the background for the Board’s discussion of planned agency actions. He noted that in January 2012, Michael Goo, Associate Administrator for the Office of Policy, issued a memorandum to strengthen EPA’s coordination with the SAB by providing the Board with information about proposed agency actions. In March 2012, the chartered SAB discussed the results of a pilot considering the science underlying four proposed rules identified by OAR. Based on the pilot, the SAB concluded that a meaningful assessment of the Board’s interest in proposed actions would require information beyond what is presented in the semi-annual regulatory agenda. Since that time, the SAB Staff Office participated in an agency work group to develop a process for identifying EPA planned actions for SAB consideration of the underlying science. This semi-annual process, supported by senior agency managers, requires the EPA to provide short descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda.

The SAB Work Group was formed in January after publication of the most recent semi-annual regulatory agenda on December 21, 2012. The Work Group was charged to: (1) review information provided by EPA; (2) determine if additional information is needed; and (3) provide recommendations on which actions may be priorities for SAB advice and comment as authorized by ERDDAA and identify one or two actions as the highest priority. The memorandum provided to the chartered SAB resulted from the SAB Work Group’s deliberations. Members of the Work Group included Drs. Joseph Arvai, Michael Dourson, David A. Dzombak, H. Christopher Frey, Kimberly L. Jones, H. Keith Moo-Young, Duncan Patten, and Peter S. Thorne.

Dr. Mihelcic emphasized that the process was a dynamic one, in which all participants (i.e., the SAB Work Group, the SAB Staff Office, and the EPA program offices) are still learning how to make the process work well.

Dr. Mihelcic described that the work group developed factors to consider when assessing information provided for each planned major action. These factors were derived from historical SAB criteria and included whether the action:

- already had a planned review by the SAB or some other high level external peer review [e.g., National Academy of Sciences, Clean Air Scientific Advisory Committee, Federal Insecticide, Fungicide and Rodenticide (FIFRA) Scientific Advisory Panel];
- was primarily administrative (i.e., involved reporting or record keeping);
- was an extension of an existing initiative;
- was characterized by EPA as an influential scientific or technical work product having a major impact, or involved precedential, novel, and/or controversial issues;
- considered scientific approaches new to the agency;
- addressed an area of substantial uncertainty;
- involved major environmental risks;
- related to an emerging environmental issue; or
- exhibited a long-term outlook.

He noted that the Work Group reviewed 41 major actions and reached consensus regarding recommendations of actions to highlight for SAB attention. These actions are identified in Tables 1 and 2 of the Work Group Memorandum. Table 1 identifies actions where the associated science is appropriate for high-level review and the agency has already requested that the SAB or CASAC conduct the review. Table 2 summarizes actions that the SAB Work Group recommends as priorities for SAB comment on the supporting science.

Dr. Mihelcic briefly identified the four actions in Table 2 and summarized the rationales for the Work Group's recommendations.

The SAB Work Group identified two actions as having the highest priority. The first, Control of Air Pollution from Motor Vehicles: Tier 3 Motor Vehicles Emission and Fuel Standards (2060 AQ86), merited inclusion because of the large scope and implications of the rule, which has implications for multi-pollutant air quality management. Based on the information provided to the Work Group, the Work Group was not convinced that the letter peer review conducted for some individual science components supporting the rule was sufficient for a regulatory activity of this importance. The second action, Effluent Guidelines and Standards for Unconventional Oil and Gas Extraction Including Coalbed Methane and Shale Gas Extraction (2040 AF35), merited inclusion because it is associated with an emerging and controversial topic, hydraulic fracturing, where a high level of science advice may be appropriate.

The SAB Work Group identified two other actions as having high priority. The first, Revised Regulations for Environmental Radiation Protection Standards for Nuclear Power Plant Operations (2060 AR12), is an advance notice for revisions of Environmental Radiation Protection Standards issued in 1977. Early SAB advice on science questions associated with the rule would be appropriate. The SAB Work Group identified the second action, Petroleum Refinery Sector Risk and Technology Review (RTR) and New Source Performance Standards (2060 AQ75), because: (1) new technologies have been developed; (2) EPA withdrew a 2009 rule because of inadequate characterization of the risks of petroleum production emissions; (3) EPA is using new data for its RTR assessment; (4) there is a large exposed population; and (5) exposures may pose an important environmental justice issue with considerable disparity in the exposed vs. unexposed population.

He concluded his presentation with a summary of Work Group recommendations regarding improvements to the process for identifying EPA planned actions for SAB consideration. There is a need for EPA to provide additional brief information about the existing science and the new science supporting the planned regulatory actions. The Work Group also saw a need for more information about the nature of peer review conducted by the Agency, including the kinds of charge questions asked and the qualifications of peer reviewers, if a letter review will be or had been conducted.

Before turning to EPA personnel who had requested to provide oral remarks, Dr. Allen asked if chartered SAB members had clarifying questions for Dr. Mihelcic. One member asked how the Work Group decided on the ranks of "high" and "highest." Dr. Mihelcic responded that the group first identified actions that were worthy of review, then Lead Discussants participated in a

full Work Group discussion of the most important actions for SAB attention. There was general agreement on the four actions selected and how those were characterized.

Another member asked if there were any actions that were very near completion. The DFO responded that the Work Group did not consider regulatory actions already proposed. Dr. Mihelcic noted that the Work Group based its decision on scientific and problem driven criteria, not timing.

The SAB Chair asked if the Work Group discussed the 2006 NRC report *State and Federal Standards for Mobile Source Emissions*, which discusses harmonization between Tier 2 and California Low Emission Vehicle (LEV) standards. Dr. Mihelcic responded that the Work Group did not discuss the report.

A member commended the Work Group for highlighting environmental justice science issues associated with regulating petroleum refineries as a point for discussion. Dr. Mihelcic responded that the work group did not have a separate environmental justice criterion for all actions. The Work Group was informed that the EPA is supposed to consider environmental justice for all activities. Environmental justice did emerge as a significant Work Group consideration for this action.

After the chartered SAB's initial discussion of clarifying questions was complete, three EPA representatives provided brief remarks.

The first EPA representative was Ms. Jan Matuszko, Branch Chief of the Effluent Guidelines Program in the Office of Water. She provided a slide presentation, *ELGs for Unconventional Oil and Gas*.<sup>15</sup> She provided background on the Effluent Limitations Guidelines and Standards (ELGs) program and detailed the plans for revisions to an existing ELG for oil and gas extraction. The planned rule would introduce pretreatment standards for shale gas extraction discharges to Publicly Owned Treatment Works (POTWs) under the existing oil and gas ELG. The planned rule would also develop requirements for coalbed methane extraction discharges. She described the major steps in developing effluent guidelines and the science required at each step. She briefly noted that the Office of Water was coordinating with ORD, which is conducting a study of hydraulic fracturing to determine whether it may impact drinking water resources.

After Ms. Matuszko's presentation, Dr. Allen asked for clarifying questions from chartered SAB members. In response to questions, Ms. Matuszko clarified that current regulations prevent facilities from discharging wastewater to waters of the United States. The planned rule would affect facilities releasing to POTWs and require them to appropriately treat those waters.

An SAB member asked how well the agency understood the additive products used for oil and gas extraction, whether it would get full disclosure of the composition of those chemicals, so EPA can understand what needs to be removed. Ms. Matuszko responded that the Office of Water was coordinating with ORD to understand indicator parameters for those additives. Controlling for indicator parameters for such additives as Principal Organic Contaminants gives the agency confidence that it would be controlling for additives generally since the EPA cannot

look at every single pollutant. She also acknowledged that consideration of biosolids derived from treatment of effluent waste would be a consideration in the rule-making.

In response to other questions, Ms. Matuszko confirmed that the EPA's plan to limit data collection to nine or fewer companies was constrained by the requirements of the Information Collection Act and by a desire to limit the information collection burden to the agency and the industry. She also stated that ELGs do not typically involve peer review. Since effluent guidelines do not typically involve new methodologies, peer review is not necessary. Such rules typically involve standard processes for data collection. In response to a question, she stated that the narrow scope of the planned rule, which uses standard practices and involves no new science, was not an action that she thought was appropriate for SAB consideration. She clarified that the rule focuses on wastewater and treatment technologies to prevent discharge to waters of the United States; it does not concern ground water. She also explained that the Office of Water coordination with ORD involves conversations to identify where activities overlap (e.g., in the area of additives) and where literature searches conducted by the Office of Water could be useful to ORD.

The second EPA representative, Ms. Penny Lassiter from the Office of Air Quality Planning and Standards in the Office of Air and Radiation provided written supplemental material, entitled *Supplemental Information on Petroleum Refinery Risk and Technology Review and New Source Performance Standards (NSPS)*.<sup>16</sup> She stated that the planned actions were technical amendments to existing Refinery New Source Performance Standards. The timing of the current action is being determined by negotiations with litigants who have filed a mandatory duty lawsuit over EPA's failure to conduct the eight-year RTR for this sector. These negotiations may impose a very tight, inflexible timeframe for developing a proposed rule. The general methodology for conducting the RTR, including the approach for both inhalation and multipathway exposure, was well established and had been reviewed by the SAB in 2007. The new developments identified for the RTR focus on controls and operational practices already being employed by the refining industry and a potential requirement for refineries to use passive monitoring at the facility fence line to ensure facilities are achieving emissions reduction requirements for fugitive emissions. She noted that passive monitoring is a well-established technology and has been accepted by the American Society for Testing and Materials and adopted by the European Union for regulatory purposes. Although the technology is not new, EPA plans to propose a new application in a regulatory context for notice and comment. Ms. Lassiter also noted that the EPA plans to include in the proposal an amendment for operational requirements for flares.

After Ms. Lassiter's presentation, Dr. Allen asked for clarifying questions from chartered SAB members. One member noted that the Office and Radiation had originally provided information to the SAB Work Group that stated that the RTR approach focuses on cost-effective methods introduced since the last rule. It seemed like your presentation implied no new technology had been introduced in last the decade; was that true? Ms. Lassiter responded that the agency is considering technologies currently being used in the refinery industry, such as "delayed cokers." There is no consideration of novel technologies that are not currently being used in industry.

The third EPA representative, Ms. Kathryn Sergeant from the Office of Transportation and Air Quality in the Office of Air and Radiation, provided written supplemental material entitled Supplemental Information on Tier 3 Motor Vehicle Emissions and Fuel Standards.<sup>17</sup> She spoke about the purpose and context of the planned action, timing considerations, the new science supporting the action, and the letter peer review conducted. The planned Tier 3 rulemaking builds on Tier 2 regulations that integrated consideration of fuels and vehicles. The Tier 3 standard is being developed in response to a White House memorandum of May 2010 calling for a national vehicle program to integrate greenhouse gas and non greenhouse gas regulations. The intent is to harmonize with California standards for both types of pollutants and to have regulations in place to inform the 2017 automotive model year. The proposal for the planned action is currently undergoing interagency review projected for publication this month. EPA plans to publish a final rule by the end of this calendar year.

She noted that her office had designated the science supporting the planned rule as influential scientific information because it supported a significant rule, not because of novel or precedential science issues. She characterized the peer review as a robust review by academics and consultants. A summary of peer review comments will be made available when the rule is proposed.

After Ms. Sergeant's presentation, Dr. Allen asked for clarifying questions from chartered SAB members. The Chair of the SAB Work Group asked why the EPA had not shared the peer review report with the Work Group. Ms. Sergeant responded that she wasn't aware that the Work Group desired to see the peer review report. The EPA does not generally make that available until a proposed rule is released.

After all agency presentations were complete and members' questions answered. The SAB Chair reiterated the ERDDAA charge to the SAB, to identify actions where it wishes to provide "advice and comments on the adequacy of the science and technological basis" of the proposed actions. The SAB Staff Office would subsequently negotiate the timing and the process for the review with the Agency.

The Chair asked if the chartered SAB wished to consider any actions other than those recommended by the SAB Work Group. No SAB member identified any other issues for consideration.

Before initiating the Board's deliberations on the Work Group recommendations, the SAB Chair asked Dr. Mihelcic for any additional comments on the Work Group recommendations. Dr. Mihelcic stated that the SAB Work Group could only make decisions on the information provided. It is frustrating when program offices do not provide substantive information about peer review and peer review products.

Dr. Mihelcic noted that for the planned Tier 3 Motor Vehicle rule, EPA decisions will have a substantial impact for years to come and there has not been recent SAB review or high level peer review of the science supporting this action. Dr. Allen noted that a 2006 NRC report focused on criteria air pollutants, Corporate Average Fuel Economy (CAFE) standards, integration of fuel and vehicle type, and harmonization with California standards. Although the Tier 3 Vehicle rule

has some different elements, the basic scientific and technical procedures were reviewed in the NRC report. Dr. Mihelcic acknowledged that the timeline discussed by Ms. Sergeant made it difficult to provide SAB advice.

Dr. Mihelcic provided some additional comment related to the planned revisions to the Effluent Guidelines for Unconventional Oil and Gas Extraction. He commended Ms. Matuzko for her presentation and discussion with chartered SAB members where she clarified that the planned regulatory action is focused on discharges to POTWs. The SAB Work Group recommended this action because of the importance of hydraulic fracturing to the economy. The Work Group also concluded that SAB peer review could help EPA determine whether the planned rule provided adequate public health protection against potential adverse effects of novel components of reclaimed effluents or of biosolids derived from resource recovery efforts. He also noted that reclamation of potable water from POTWs receiving discharges from Unconventional Oil and Gas Extraction might be a concern. Although this regulatory action is narrow, it has national significance and some new data have not received scrutiny from the scientific community.

When SAB members expressed interest in the general area of hydraulic fracturing (i.e., a broader topic than the rule under consideration), the SAB Chair invited the SAB Staff Office to describe upcoming Board activity related to ORD's study of the potential impacts of hydraulic fracturing on drinking water resources. Mr. Thomas Carpenter from the SAB Staff noted that the SAB Staff Office is forming a Hydraulic Fracturing Research Panel to provide ORD with advice. Chartered SAB members then asked whether the ORD or Office of Water efforts would consider the following: 1) proprietary data used in hydraulic fracturing; 2) how a POTW functions as a water resource from a systems perspective; and 3) potential widespread consequences from use of hydraulic fracturing.

The SAB Chair concluded the discussion by noting that the chartered SAB members had great interest in this area and wished to take a holistic look. The interest in this action was motivated by a broader concern than the specific action under discussion. He suggested that a fact-finding group be formed to gather more information about this potential action and report back to the chartered SAB at a future time.

Dr. Mihelcic then provided some additional comment related to the advance notice of proposed rulemaking being planned for Revised Regulations for Environmental Radiation Protection Standards for Nuclear Power Plant Operations Nuclear Power. The Work Group recommended this action because it was a good opportunity for the EPA to receive input at an early stage on the science and technology associated with updating a rule promulgated in 1977. The SAB DFO noted that EPA's Office of Air and Radiation had confirmed a desire for SAB input in this area. An SAB member noted that EPA's Radiation Advisory Committee had provided advice on a related radiation topic, *in situ* leach mining, in recent years. SAB members asked for more detail about the timing of potential SAB review and advice. Several SAB members noted that it would be valuable for the SAB to be involved at an early stage of a regulatory action. The SAB Chair suggested that a fact-finding group be formed to gather more information about this potential action and report back to the chartered SAB at a future time.

Dr. Mihelcic then introduced the fourth action, the Petroleum Refinery Sector Risk and Technology Review (RTR) and New Source Performance Standards for discussion. Discussion touched on the following points:

- Although the EPA presenter suggests there is no new technology, the EPA did receive new industry data on technology in 2010. How is this discrepancy explained?
- A large population is potentially impacted by emissions; are there environmental justice concerns associated with emissions from the facilities?
- Are there novel science and technology issues associated with passive monitoring, and fence line monitoring and related exposure assessment?

Dr. Allen noted that a request had been received during the teleconference from a member of the public to provide oral comments. The DFO introduced the speaker, who was allowed three minutes to comment. Ms. Jane Williams, Executive Director of California Communities Against Toxics, voiced concern about plans for the refinery rule. She stated that the EPA is not adopting SAB recommendations on risk assessment. She voiced concern about how SAB review related to this action would fit with the timing of a proposed rule. She noted new information on flares that indicates that flares were “much less efficient than previously surmised.” She stated that she will ask the EPA to look at new data from air districts and states on this point and to also examine lead detection issues. Although the rule would not be associated with new science, she will be “pushing EPA to push industry to reduce fugitive emissions.” The planned rule would affect communities at the fence line. There is an opportunity to encourage EPA Staff and rule writers to “take a better look at kids’ health and community health.”

Dr. Allen asked whether Chartered SAB members had clarifying questions for the presenter. One member asked the speaker to clarify what SAB risk assessment recommendations is EPA not using. Ms. William answered: cumulative impact analysis, numbers being used to assess risks to children.

To dispose of the Work Group recommendations, the SAB Chair, Dr. David Allen, asked for a motion to take one or more actions off the table. Dr. Nancy Kim moved that the Tier 3 Motor Vehicle Rule be removed for consideration. Dr. Eileen Murphy seconded the motion. Dr. Kimberly Jones offered a friendly amendment to clarify that the Tier 3 Motor Vehicle Rule was being removed for consideration because of timing considerations. Dr. Murphy accepted the amendment. Members then discussed the motion. Several members emphasized the importance of actions coming to the SAB early in the development process so time constraints would not prevent review. One member suggested that timing should be a consideration in the Work Group’s deliberations. Another member expressed concern that SAB advice and comment not be limited because of regulatory time schedules. Yet another member noted that this meeting was the first discussion of EPA planned actions and their supporting science; if reviews happen semi-annually, timing should not be such a barrier.

The motion came to a vote and passed with one Nay vote.

SAB members did not identify any other actions to be removed from consideration.

Dr. Allen thanked the SAB Work Group for successfully completing their initial screening effort of EPA's 41 major actions and noted that it had successfully met its charge. He suggested that three new fact-finding groups be formed composed of SAB members with particular interest in the remaining three actions:

- Effluent Guidelines and Standards for Unconventional Oil and Gas Extraction Including Coalbed Methane and Shale Gas Extraction (2040 AF35),
- Revised Regulations for Environmental Radiation Protection Standards for Nuclear Power Plant Operations (2060 AR12), and
- Petroleum Refinery Sector Risk and Technology Review (RTR) and New Source Performance Standards (2060 AQ75).

The fact-finding groups would work with the SAB Staff Office to obtain information for each action that would respond to the questions raised by chartered SAB members during the teleconference. The Chartered SAB would hold another public teleconference call to deliberate on this information and conclude the discussion of the Work Group recommendations regarding planned EPA actions. He set a goal of concluding the fact finding within three weeks and holding an SAB teleconference soon thereafter.

It was the sense of the group that the proposed approach was appropriate. The SAB Chair asked chartered Board members to contact the DFO by March 15, 2013 regarding their interest in participating in one of the fact-finding groups. He also asked the DFO to inform Dr. Mihelcic about the formation and activities of the fact-finding groups.

The SAB Chair expressed thank to Dr. Mihelcic, the SAB Work Group, and the SAB Staff Office for preparation of materials and development of procedures for discussing a novel, complex topic. SAB members in turn expressed thanks to the new SAB Chair for facilitating the two-day teleconference.

The DFO adjourned the meeting at 12:50 p.m.

Respectfully Submitted

Certified as Accurate

\_\_\_\_\_/Signed/\_\_\_\_\_  
Dr. Angela Nugent  
SAB DFO

\_\_\_\_\_/Signed/\_\_\_\_\_  
Dr. David T. Allen  
SAB Chair

\_\_\_\_\_/Signed/\_\_\_\_\_  
Dr. T. Taylor Eighmy  
Acting SAB Chair for Review  
of the EEMs Report

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

**Attachment A: Members of the public attending the public meeting:**

Tina Bahadori, EPA  
Nancy Beck, OMB  
Patricia Bishop, People for the Ethical Treatment of Animals  
Peter Bloomfield, North Carolina State University  
Erik A. Carlson, General Electric Company  
Emma Cheuse, Earthjustice  
Melissa Chun, EPA  
Dan Costa, EPA and  
Suzanne van Drunick, EPA  
Larry Elmore, EPA  
Jennifer Bowen, EPA  
Casey Deitrich, CQ Transcriptions  
Sandy Evalenko, EPA  
Robert Fegley, EPA  
Ann Ferris, EPA  
Larry Elmore, EPA  
Rebecca A. French, EPA  
Andrew Geller, EPA  
Dennis Guignet, EPA  
Robert Hagevoort, New Mexico State University Agricultural Science Center  
Al Heber, Agricultural and Biological Engineering, Purdue University  
Maria Hegstad, Managing Editor, Risk Policy Report  
Cheryl Hogue, Chemical & Engineering News  
Bridget Huber, Fair Warning  
Jamie Jonker, National Milk Producers Federation  
Stacey Katz, EPA  
Elizabeth Kopits, EPA  
Elizabeth Lonoff, EPA Office of Research and Development  
Michael Loughran, EPA  
Richard Mattick, EPA  
Carl Mazza, EPA  
Sarah L. Mazur, EPA  
Ashley McDonald, National Cattlemen's Beef Association  
Michael McDonald, EPA  
Al McGartland, EPA  
C.A. (Andy) Miller, EPA  
Cynthia Morgan, EPA  
Caryn Muellerleile, EPA  
Amy Nail, Honestat LLC  
Will Ollison, API  
Grace Olsen, EPA  
Nicole Owens, EPA  
Roberta Parry, EPA Office of Water  
Carl Pasurka, EPA

Aditi Prabhu, EPA  
Anne Rea, EPA  
David Reynolds, Inside EPA  
Grace Robarge, EPA  
Pat Rizzuto, BNA  
Gregory Sayles, EPA  
Ron Shadbegian, EPA  
Sally L. Shaver, Shaver Consulting, Inc., Cary, NC  
Glenn Sheriff, EPA  
Nathalie Simon, EPA  
Eric Smith, Virginia Polytechnic Institute and State University  
Julia Turner, Shaver Consulting, Inc  
John Vandenberg, EPA  
Tim Watkins, EPA  
Katherine P. Weber, American Chemical Society  
Will Wheeler, EPA  
Ann Wolverton, EPA  
Lynn Zipf

# Attachment B: Federal Register Notice announcing the Meeting



set to end on February 11, 2013, is extended to April 12, 2013.

To submit comments, or access the docket, please follow the detailed instructions as provided under **ADDRESSES** in the December 12, 2012 **Federal Register** document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: February 5, 2013.

**Steven Bradbury**,

*Director, Office of Pesticide Programs.*

[FR Doc. 2013-03032 Filed 2-8-13; 8:45 am]

BILLING CODE 6560-50-P

### ENVIRONMENTAL PROTECTION AGENCY

#### National Advisory Council for Environmental Policy and Technology

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Advisory Committee Meeting.

**SUMMARY:** Under the Federal Advisory Committee Act, Public Law 92463, EPA gives notice of a public meeting of the National Advisory Council for Environmental Policy and Technology (NACEPT). NACEPT provides advice to the EPA Administrator on a broad range of environmental policy, technology, and management issues. NACEPT represents diverse interests from academia, industry, non-governmental organizations, and local, State, and tribal governments.

The purpose of this meeting is for NACEPT to discuss and approve draft recommendations in response to the National Academy of Sciences' report on "Sustainability and the U.S. EPA." NACEPT's second letter on sustainability will address two topics: (1) What strengths EPA can leverage to successfully deploy sustainability practices across the Agency, and (2) what 3-5 year breakthrough objectives are related to sustainability implementation and recommended measurement systems for assessing progress toward EPA's sustainability vision. A copy of the agenda for the meeting will be posted at <http://www.epa.gov/ofacmo/nacept/cal-nacept.htm>.

**DATES:** NACEPT will hold a two-day public meeting on Thursday, March 7, 2013, from 9:00 a.m. to 5:30 p.m. (EST)

and Friday, March 8, 2013, from 8:30 a.m. to 2:00 p.m. (EST).

**ADDRESSES:** The meeting will be held at the U.S. EPA East Building, 1201 Constitution Avenue NW., Room 1117, Washington, DC 20004.

**FOR FURTHER INFORMATION CONTACT:** Mark Joyce, Acting Designated Federal Officer, at [joyce.mark@epa.gov](mailto:joyce.mark@epa.gov), (202) 564-2130, U.S. EPA, Office of Federal Advisory Committee Management and Outreach (1601M), 1200 Pennsylvania Avenue NW., Washington, DC 20460. **SUPPLEMENTARY INFORMATION:** Requests to make oral comments or to provide written comments to NACEPT should be sent to Eugene Green at [green.eugene@epa.gov](mailto:green.eugene@epa.gov) by Thursday, February 28, 2013. The meeting is open to the public, with limited seating available on a first-come, first-served basis. Members of the public wishing to attend should contact Eugene Green at [green.eugene@epa.gov](mailto:green.eugene@epa.gov) or (202) 564-2432 by February 28, 2013.

**Meeting Access:** Information regarding accessibility and/or accommodations for individuals with disabilities should be directed to Eugene Green at the email address or phone number listed above. To ensure adequate time for processing, please make requests for accommodations at least 10 days prior to the meeting.

Dated: January 29, 2013.

**Mark Joyce**,

*Acting Designated Federal Officer.*

[FR Doc. 2013-02929 Filed 2-8-13; 8:45 am]

BILLING CODE 6560-50-P

### ENVIRONMENTAL PROTECTION AGENCY

[FRL-9778-2]

#### Notification of a Public Meeting of the Chartered Science Advisory Board

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public meeting of the chartered SAB to: (1) Receive an update briefing on the EPA's Office of Research and Development's (ORD) implementation of strategic research plans; (2) conduct quality reviews of three draft SAB reports [on the use of computational toxicology (CompTox) to advance risk assessment; on EPA's retrospective study of the costs of EPA regulations; and on methodologies for estimating air emissions for broiler animal feeding operations and for lagoons and basins at

swine and dairy animal feeding operations]; and (3) to discuss information provided in the agency's regulatory agenda, specifically planned actions and their supporting science.

**DATES:** The public meeting will be held on Thursday, March 7, 2013, from 10:30 a.m. to 6:00 p.m. and Friday, March 8, 2013, from 8:00 a.m. to 1:00 p.m. (Eastern Daylight Time).

**ADDRESSES:** The meeting will be held at the Washington Marriott, 1221 22nd Street NW., Washington, DC, 20037.

**FOR FURTHER INFORMATION CONTACT:** Any member of the public who wants further information concerning the meeting may contact Dr. Angela Nugent, Designated Federal Officer (DFO), EPA Science Advisory Board (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; via telephone/voice mail (202) 564-2218, fax (202) 565-2098; or email at [nugent.angela@epa.gov](mailto:nugent.angela@epa.gov). General information concerning the SAB can be found on the EPA Web site at <http://www.epa.gov/sab>.

#### SUPPLEMENTARY INFORMATION:

##### Background

The SAB was established pursuant to the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies. Pursuant to FACA and EPA policy, notice is hereby given that the SAB will hold a public meeting to discuss and deliberate on the topics below.

##### Briefing on Implementation of ORD Strategic Research Plans

The SAB and ORD's Board of Scientific Councilors (BOSC) provided a joint report to the Administrator in September 2012 entitled *Implementation of ORD Strategic Research Plans: A Joint Report of the Science Advisory Board and ORD Board of Scientific Counselors* (EPA-SAB-12-012). ORD will provide a briefing to update SAB members on recent significant ORD activities to implement the recommendations in the ORD-BOSC report, available on the SAB Web site at <http://yosemite.epa.gov/sab/sabproduct.nsf/3822EB089>

FCCB18D85257A8700800679/\$File/  
EPA-SAB-12-012-unsigned.pdf.

#### Draft SAB Report on the Use of CompTox To Advance Risk Assessment

The chartered SAB will conduct a quality review of a draft report providing advice to assist the EPA in advancing the application of ORD's CompTox research for human health risk assessment to meet the agency's programmatic needs. The SAB undertook this initiative to identify applications for outputs from the CompTox Research Program, barriers to their use, and strategies for overcoming those barriers. The CompTox Research Program conducts research that integrates advances in molecular biology, chemistry and innovative computer science to more effectively and efficiently rank chemicals based on risks. The goal of the CompTox Research Program is to provide high-throughput chemical screening data and decision support tools for assessing chemical exposure, hazard, and risk to human health and the environment. Information about this advisory activity can be found on the Web at: [http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr\\_activites/CompTox%20data%20in%20RA?OpenDocument](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/CompTox%20data%20in%20RA?OpenDocument).

#### Draft SAB Report on EPA's Retrospective Study of the Costs of EPA Regulations

The chartered SAB will conduct a quality review of a draft report providing a review of the EPA's retrospective study of the costs of EPA regulations. The EPA conducts benefit-cost analyses of its rules and regulations and strives to use the best available information to conduct its analyses. Benefit-cost analyses are by definition predictive, relying on *ex ante* or forecasted information. To improve future benefit-cost analyses, it is important to learn how well EPA's estimates compare with actual (*ex post*) costs and, if they differ substantially, to understand why. EPA's National Center for Environmental Economics prepared a series of case studies attempting to assess compliance costs retrospectively that, if successful, could help identify reasons for any systematic differences between *ex ante* and *ex post* cost estimates. The EPA requested the SAB's review of its approach to assessing *ex post* costs as detailed in a draft paper entitled "Retrospective Study of the Costs of EPA Regulations: An Interim Report" (March 2012). Information about this advisory activity can be found on the Web at: <http://yosemite.epa.gov/sab/sabproduct.nsf/>

[fedrgstr\\_activites/Retrospective%20Cost%20Study?OpenDocument](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/Retrospective%20Cost%20Study?OpenDocument).

#### Draft Report on EPA's Emissions Estimation Methodologies (EEMs) From Broiler Animal Feeding Operations and From Lagoons and Basins at Swine and Dairy Animal Feeding Operations

The chartered SAB will conduct a quality review of a draft report providing review of EPA's draft methodologies for estimating air emissions from animal feeding operations (AFOs). The EPA developed the draft methodologies to address commitments in a voluntary air compliance consent agreement signed in 2005 between the agency and nearly 14,000 broiler, dairy, egg layer and swine AFO operations. The goals of the agreement are to reduce air pollution, monitor AFO emissions, promote a national consensus on methodologies for estimating emissions from AFOs, and ensure compliance with the requirements of the Clean Air Act, the Comprehensive Environmental Response, Compensation, and Liability Act and the Emergency Planning and Community Right-to-Know Act. The EPA's Office of Air and Radiation has requested the SAB review. Information about this advisory activity can be found on the Web at: [http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr\\_activites/AFO-AEEM?OpenDocument](http://yosemite.epa.gov/sab/sabproduct.nsf/fedrgstr_activites/AFO-AEEM?OpenDocument).

#### Discussion of Information Provided in the Agency's Semiannual Regulatory Agenda

The EPA has recently underscored the need to routinely inform the SAB about proposed and planned agency actions that have a scientific or technical basis. Accordingly, the agency provided notice to the SAB that the Office of Management and Budget published the "Unified (Regulatory) Agenda" on the Web on December 21, 2012 (<http://www.reginfo.gov/public/>). The SAB will discuss whether it should provide advice and comment on the adequacy of the scientific and technical basis for EPA actions included in the Agenda.

**Availability of Meeting Materials:** A meeting agenda and other materials for the meeting will be placed on the SAB Web site at <http://epa.gov/sab>.

**Procedures for Providing Public Input:** Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to the EPA. Members of the public can submit relevant comments pertaining to the EPA's charge, meeting materials, or the group providing advice. Input from the public to the SAB will have the most impact if it provides specific scientific or technical information or analysis for the SAB to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the DFO directly.

**Oral Statements:** In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes. Persons interested in providing oral statements at the March 7-8, 2013, meeting should contact Dr. Angela Nugent, DFO, in writing (preferably via email) at the contact information noted above by February 27, 2013. **Written Statements:** Written statements for the March 7-8, 2013, meeting should be received in the SAB Staff Office by February 27, 2013, so that the information may be made available to the SAB for its consideration prior to this meeting. Written statements should be supplied to the DFO in the following formats: either an electronic copy (preferred) via email (acceptable file format: Adobe Acrobat PDF, MS Word, WordPerfect, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format) or in hard copy with original signature. Submitters are asked to provide electronic versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

**Accessibility:** For information on access or services for individuals with disabilities, please contact Dr. Nugent at the phone number or email address noted above, preferably at least ten days prior to the meeting, to give the EPA as much time as possible to process your request.

Dated: January 30, 2013.

**Thomas H. Brennan,**  
Deputy Director, EPA Science Advisory Board  
Staff Office.

[FR Doc. 2013-02925 Filed 2-8-13; 8:45 am]

BILLING CODE 6560-50-P

### Materials Cited

The following meeting materials are available on the SAB Web site, <http://www.epa.gov/sab>, at the page for the [March 7-8, 2013](http://www.epa.gov/sab) teleconference meeting: <http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/e8ce4f3ab391b61485257ad80049f231!OpenDocument&Date=2013-03-08>

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<sup>1</sup> Agenda

<sup>2</sup> Roster of SAB members

<sup>3</sup> *SAB Review (Draft 10/22/2012) of EPA's Retrospective Cost Study of the Costs of EPA Regulations: An Interim Report of Five Case Studies (March 2012)*

<sup>4</sup> "Retrospective Cost" Compilation of Member and Liaison comments as of 03.04.13;  
"Retrospective Cost" Compilation of Member and Liaison comments as of 03.06.13.

<sup>5</sup> *SAB Advice (Draft 1/29/2013) on Advancing the Application of Computational Toxicology Research for Human Health Risk Assessment*

<sup>6</sup> Comment from Catherine Willett, The Humane Society of the United States, regarding the draft CompTox report.

<sup>7</sup> Slide Presentation from Catherine Willett of the Humane Society regarding the draft CompTox report.

<sup>8</sup> "Use of Computational Toxicology" Compilation of Members' and Liaisons' Comments

<sup>9</sup> *SAB Review (Draft 12/3/12) of Emission Estimating Methodology for Broiler Animal Feeding Operations and for Lagoons and Basins at Swine and Dairy Animal Feeding Operations (EEMs Report)*

<sup>10</sup> "Emissions Estimating Methodologies" Draft Report - Compilation of Members' and Liaisons Comments as of 03.04.13

<sup>11</sup> Comment from Stephen Page, OAR/OAQPS, on the Emissions Estimating Methodologies draft report.

<sup>12</sup> Slide Presentation from Al Heber, Purdue University, regarding the "Emissions Estimating Methodologies" Draft Report

<sup>13</sup> Slide Presentation - ORD Update; Presentation from Robert Kavlock

<sup>14</sup> Memorandum from the SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science with recommendations for chartered SAB consideration

<sup>15</sup> Slide Presentation - ELGs for Unconventional Oil and Gas, Presentation by Jan Matuszko, Office of Water

<sup>16</sup> Supplemental Information on Petroleum Refinery Risk and Technology Review and NSP

<sup>17</sup> Supplemental Information on Tier 3 Motor Vehicle Emissions and Fuel Standards