

# REGNET

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## REGNET ENVIRONMENTAL SERVICES

March 27, 2013

Dr. Suhair Shallal  
Designated Federal Officer  
Chemical Assessment Advisory Committee  
EPA Science Advisory Board  
[shallal.suhair@epa.gov](mailto:shallal.suhair@epa.gov)

RE: Written Statement in Response to Notification of a Public Meeting of the Science Advisory Board Chemical Assessment Advisory Committee (78 Fed. Reg. 14299)

Dear Dr. Shallal:

I am writing to share with you and the new members of the SAB Chemical Assessment Advisory Committee (CAAC) various recommendations that were developed as a follow-up to a meeting held on May 21, 2012 between the IRIS Forum and Dr. Vanessa Vu, the previous Executive Director of the SAB. The meeting took place prior to the official formation of the CAAC and focused on issues relating to CAAC's composition and its role in the process for review of IRIS Assessments. This meeting served as a useful forum to emphasize the important role of the CAAC in the ongoing efforts to upgrade both the process and science policy consideration of the IRIS program.

As I intend to relay in oral comments at the meeting, we view the CAAC's role as pivotal to establishing an effective IRIS program and enhancing the credibility and acceptability of the various IRIS assessments by the scientific community and other stakeholders. The following is an excerpt from the July 3, 2012 letter, which addresses generic issues relevant to the CAAC.

### **Development of Charge Questions for IRIS Assessments**

*As discussed at the meeting, there is general recognition over the importance of the Charge Questions to the peer review process. EPA's Peer Review Handbook (2006) notes, "the charge is crucial for an effective peer review" (p. 58). Last October, the SAB Staff Office announced its latest plans for "Public Involvement in Advisory Committees."<sup>1</sup> We were very heartened by SAB's statements that:*

- *"Public comments are welcome on all technical materials prepared for or by an advisory committee, including the charge to the committee";*
- *"The Staff Office and advisory committees will not accept a charge from the agency that unduly narrows the scope of an advisory activity";*
- *"Time will be reserved on meeting agendas for committee members to discuss the charge"; and,*

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<sup>1</sup> <http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/PublicInvolvement?OpenDocument>

- *"Advisory committee reports will continue to focus on scientific and technical – rather than policy – issues . . . ."*

*The procedure currently being followed by the IRIS program is to issue "Charge Questions" typically at the same time the draft assessment is released for public comment. The Charge is apparently made available with no expectation of revision based on the comments submitted on the draft assessment or even comments that might be submitted on the Charge itself.*

*Given the importance of the Charge Questions to the overall peer review process, we encourage the SAB to ensure that the Charge Questions are structured to cover all of the relevant scientific issues identified by EPA and the stakeholders. We believe that the SAB staff should have ultimate responsibility for the adequacy of the Charge Questions. The Charge is usually written by the very same office (typically NCEA) that drafted the assessment to be reviewed. As a consequence, the questions do not necessarily cover all the controversial issues that are sometimes revealed for the first time in the course of the public review of the draft. Additionally, the SAB should solicit from stakeholders as part of the public's review of the draft assessment, comments on the draft Charge Questions and also on the areas of expertise to serve on the peer review panel.*

*In order to ensure that the peer review panels have the necessary expertise, we further encourage the SAB to consider the comments submitted on the draft assessment and the Charge Questions prior to selecting the peer reviewers for a given chemical. This would be consistent with EPA's Peer Review Handbook, which recommends: "To ensure that the selected reviewers have the appropriate expertise, knowledge, skills and experience, the charge to the reviewers should be determined in advance of the selection of the reviewers" (p. 60). For public input on the charge to have any effect on the makeup of the panel, that input has to be solicited at the same time that the public is given the opportunity to review and comment on the draft assessment, and before potential panelists are identified. We urge the SAB to adopt this practice.*

*We believe that the credibility and public acceptability of the IRIS assessments can be greatly influenced if the SAB's peer review activities are conducted in a manner that reinforces its real and perceived independence from the EPA program office that prepared the assessment. All too often, the peer reviews have taken on more of the nature of a PhD thesis review, where the focus of attention is on the author's expertise, clarity in presenting information and ability to advocate a particular position, rather than a session designed to develop a complete and balanced scientific assessment of a substance. We believe that the SAB peer review panel can help ensure that the assessment addresses the available scientific information on a substance, balances competing and sometimes conflicting information, and clearly distinguishes between viewpoints/decisions that are grounded in the science and those that are driven more by policy judgments.*

*We believe that implementing the foregoing changes would greatly enhance the credibility and utility of IRIS assessments and provide greater clarity and transparency to the overall assessment process.*

### **Making the Process More Interactive for IRIS Reviews**

*While we appreciate the opportunities that the SAB allows for public comment, we strongly urge the establishment of a mechanism designed to promote technical exchange among the Peer Review panelists, Agency staff and stakeholder presenters.*

*The current practice for public participation gives non-government scientists/stakeholders, very little time to address the panel and rarely allows for interaction with the panel - despite giving broad discretion to the authors of the assessment (EPA staff) to address and interact with the panel. Even if the world's leading expert on a topic were to be in the audience, input is sought typically only from the EPA staff.*

*Promoting technical exchange is not a novel concept for advisory bodies and we trust that the SAB appreciates the value that results from open scientific dialogue. NAS panels typically conduct an information-gathering session as part of their first meeting; EPA also begins the process of each five-year NAAQS revision by holding a public workshop to determine the state of the policy-relevant science. We believe your office should follow these examples for the new CAAC by specifying that each SAB chemical specific panel, at the outset of its work, organize at least one public, face-to-face session dedicated to gathering information and views regarding the state of the science relevant to the assessment.*

*Such a session could begin with a presentation by EPA staff regarding the draft assessment (or issue) to be reviewed and the relevance of the Charge Questions. Panel members would be encouraged to ask questions of the staff, following the EPA presentation. While Agency staff are still present, interested stakeholders who had previously submitted written comments, should be given time to make presentations regarding the relevant science. Importantly, we believe that stakeholders should not be arbitrarily limited to three - five minutes, a time limit which suggests that the SAB and EPA alike have little interest in hearing alternative views. The time allocated to this information gathering session might need to be controlled, but we would hope that any limits should be scaled to the importance of the topic and the interest of the Peer Review Panel members. The important thing to ensure is that the opportunity to comment is not merely pro forma, but presents a genuine opportunity to engage the Panel's consideration of issues of concern to stakeholders.*

*We would further recommend that consideration be given to structuring the information-gathering session such that the panelists, the various presenters, and EPA staff (and perhaps even non-presenting stakeholders at the meeting) are afforded the opportunity to ask each other questions and engage in a scientific discussion<sup>2</sup>. If needed, a facilitator could ensure that stakeholders and Agency staff answered questions raised by the others.*

#### **Composition of CAAC Review SubCommittees**

*Another suggestion offered at our meeting was for the SAB to consider adding one or more non-voting subject area experts to the peer review panel. Non-voting panel members would be appointed in cases where an individual was recognized as having expertise in the chemical substance being assessed but would otherwise be excluded from participation because of the conflict of the conflict of interest rules. Inclusion of a non-voting expert should not be used as a substitute for the requirement that the SAB include qualified individuals in panels regardless of affiliation, subject to equal and reasonable application of rules regarding conflict of interest or appearance of lack of impartiality. In any case, incorporating experts with the most extensive knowledge on the toxicology of a substance should help to ensure that the best available science is not overlooked by the Panel.*

#### **SAB Involvement in All Phases of the IRIS Development Process**

*We believe that the role of the CAAC, including its specific Peer Review Panels, should not end following completion of its review of the draft assessment. In scientific journal article peer reviews, authors are required to respond to the issues raised by the reviewers, and the editor (i.e., someone other than the author), decides whether the response is appropriate and adequate to address the issue raised in the review. By contrast, in the current IRIS assessment development process, following the peer review step, the same office that prepared the initial draft assessment then prepares a response to comments and decides which of the comments from the peer review panel are to be addressed and what revisions are incorporated.*

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<sup>2</sup> In appropriate cases, it might be worthwhile for the facilitator to present a relevant analytical framework (e.g., the IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans) and invite presenters to explain how they would apply it to the existing body of science.

*It is unclear to us whether the SAB or anyone else provides oversight on the adequacy of the response to the comments – i.e., whether (i) the Agency staff truly understood the substance and thrust of the panel's comment; and, (ii) the revisions incorporated were responsive to the peer review comments. We are not suggesting that the SAB assume the role of policing the Agency's responses but we do believe that the SAB should retain an interest in the impact of its comments on the final assessment. At a minimum, we believe that the CAAC Peer Review committee should review the response document and invite the individual members of the Peer Review Panel to submit any comments to the public docket on the assessment. This would help prevent misinterpretation by the Agency of the panel's recommendations and sharpen any remaining disputes for the benefit of EPA management's consideration before the IRIS assessment is finalized.*

### **SAB Oversight on the Overall Quality of IRIS Assessments**

*We anticipate that CAAC-conducted reviews will be of high quality and as such, we recommend that CAAC also take on the important role of overseeing the overall quality of all IRIS assessments, including peer reviews that it does not conduct.*

*As we explained at our meeting, the process of organizing and running the Peer Review Panels is significantly different from the SAB review process. As a simple example, the areas of expertise and identification of the individual reviewers are kept secret from the public until the day of the review. This prevents any constructive intervention on the part of the public to assure that adequate expertise has been assembled to review the key scientific issues in the subject assessment.*

*As we anticipate that these non-FACA ad hoc, independent panels will continue to review some of the IRIS assessments, we believe that general oversight of that process by the new SAB committee could ensure more uniformity in quality and nature of all of the peer reviews of IRIS assessments.*

*We further contend that it does not serve the SAB - or for that matter the overall IRIS Program - to have only a small portion of the IRIS assessments be assured of high quality reviews. The recent NAS review of the draft formaldehyde IRIS assessment, including its Chapter 7 Roadmap, addressed generic scientific quality issues across the IRIS program. EPA management has embraced the NAS recommendations. If the CAAC sees itself as only a reviewer of certain high profile assessments, we do not see how the SAB will have met the needs of the Agency, and the public, or fulfill the recommendations of the NAS.*

*We are therefore advocating that, in addition to performing its own peer reviews, the new Committee should seek to provide oversight/guidance for the overall IRIS program, both in terms of how peer reviews are conducted as well as to enhance the quality of the scientific assessments themselves. EPA's handling of various cross-cutting issues, such as Weight of the Evidence criteria and other such issues already identified by the NAS in its Chapter 7, could benefit from the Committee's oversight. We hope that the new Committee takes a broad view of its jurisdiction rather than a narrow one limited primarily to peer review of a few specific assessments.*

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Dr. Suhair Shallal  
March 27, 2013  
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Please let me know if you have any questions concerning this exchange.

Sincerely,

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President, RegNet Environmental Services

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