

## SAB/BOSC Charge Questions

### 1. ORD's Strategic Directions

1a. Considering the proposed research directions and focus, how well is ORD as a whole poised to support EPA in meeting the goals of the EPA Strategic Plan?\_

[POST MEETING COMMENT]

EPA needs more resources. In addition to leveraging existing funds by working with outside partners, EPA could enhance its use of FTTA Cooperative Research and Development Agreement (CRADA). This program allows outside funding of important work, especially that with a commercial application.

1b. What are the SAB/BOSC perspectives overall on the proposed research directions providing research to address environmental issues of 2020 and beyond?\_

[POST MEETING COMMENT]

EPA has described more research than it appears it is able to do. EPA should enhance cooperation with outside parties, including the private sector, to maximize limited resources.

### 2. Program Specific Charge Questions

2a. How well will the research directions in each Early Draft StRAP (2016-2019) support EPA in achieving the relevant Agency objectives and cross-cutting strategies, as described in the EPA Strategic Plan (2014 -2018)?

2b. What are the SAB/BOSC perspectives on the proposed research directions in each StRAP providing research to address environmental issues of 2020 and beyond?

2c. For each program, do the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

### 3. Air, Climate and Energy Charge Questions

3a. Does the SAB/BOSC have suggestions regarding how ACE should target its efforts to understand, model, and convey the potential environmental impacts of possible energy choices?

### 4. Sustainable and Healthy Communities

4a. Does the research program contain the elements necessary to integrate these two critical elements of EPA's mission?

4b. Is increased well-being the appropriate outcome to aim for, rather than amelioration of specific health conditions? If so, does the SAB/BOSC have recommendations for shaping the Community Public Health research project more toward broader well-being impacts?

4c. SHC is interested in thoughts and suggestions from the SAB/BOSC on ways to conduct research on the science of sustainability.

### 5. Safe and Sustainable Water Resources

5a. Where can EPA make a significant research contribution in moving toward a sustainable water-energy future, with consideration of energy, water, nutrients, and other resources?

[POST MEETING COMMENT]

NCEA's risk assessment scientists would do well to assist the Office of Water in its development of methods to determine risks above the Reference Dose (RfD), or in the parlance of the OW, Unreasonable Risk to Health. Part of this effort could be to use suggestions from Science and Decisions (NAS, 2009) in a collaborative effort with outside parties.

**6. Chemical Safety for Sustainability and Human Health Risk Assessment Charge Questions:**

6a. Please comment on approaches the HHRA research program might target to better tailor its exposure and response assessment approaches to address fit-for-purpose characterizations (e.g., risk prioritization, risk screening, risk assessment).

[PRE-MEETING COMMENT]

EPA could take a note from several other risk assessment research and development organizations to establish a Threshold for Toxicological Concern for all chemicals without sufficient toxicology or epidemiology information on which to base an assessment, or for which an assessment has not already been established. The US FDA and NSF International are examples of two organizations that already do this. But others exist as well. This would help with the risk prioritization and risk screening parts of the examples above. Getting state priorities on individual chemicals or mixtures from California EPA, TCEQ or ECOS (stated partners/stakeholders) might also help tailor the program to national needs, or otherwise improve fit for purpose assessments.

[POST MEETING COMMENT]

EPA NCEA should consider the development or refinement of methods to extrapolate from a 28-day experimental animal study to 90 days, so that an additional set of preliminary Reference Doses (RfDs) can be developed for additional chemicals. Numerous 28-day studies are now being done as part of REACH. NSF International in Ann Arbor, Michigan already has a draft method to do this.

6b. Please comment on approaches proposed by CSS and HHRA research programs to identify and integrate novel data streams to develop innovative fit-for-purpose assessment products.

[PRE-MEETING COMMENT]

The CSS program appear to be heading in a direction that will yield additional information on which to base credible, fit for purpose, risk assessments, but a premium is needed on having erudite risk assessment scientists make the judgments on the use of these data for risk assessment, which is presumably the job of NCEA. It is hard enough for risk assessment experts to do this with existing data on occasion, and having risk assessment novices make the judgments with these new data streams would likely prove problematic. How can you tell if someone is an expert? The quote of Arnold Lehman of FDA lore (the toxicologist after which SOT named an its risk assessment award) may help: "Risk assessment is easy, you can learn it in two steps; each step takes 10 years." So look to the NCEA or other agency folks that have more than 20 years, and this is the group likely to make the best judgments. NCEA has several folks of this stature, but so do some of the Regional offices---Region 8, for example; and other EPA offices such as OPP and OW). A number of former Agency folks exist outside of EPA

now of this stature and whom are still active.

[POST MEETING COMMENT]

One of the public comments was to suggest the use of a confidence framework for prediction of HTS assays. This is a good idea and should be pursued. A recent publication by Cox et al. (2014) offers some thoughts along these lines. This paper was submitted as part of public comments.

6c. Are there other areas of fit-for-purpose characterizations (e.g., risk prioritization, risk screening, risk assessment) that are ripe for such collaboration/ integration?

[PRE-MEETING COMMENT]

My impression of the CSS program is that it is highly collaborative and interactive with numerous outside parties. The supplemental material provided by EPA was particularly helpful in this regards. These CSS interactions will prove to be highly advantageous to EPA as it brings its limited resources to bear on this vexing area.

The same collaborative spirit appears to be developing with the risk assessment program, although I know of many folks outside of EPA (and some even within EPA) that would likely disagree with this statement. Even though the stated partners/stakeholders list is large, I am trying to envision if I spoke to folks in these partners/stakeholders if they would agree. I am not sure that all of them would. EPA's memoranda with ATSDR and NIOSH are good, but expected. NCEA also needs to reestablish interactions with risk assessment experts in EPA's OPP---notably absent from the list of EPA partners. Furthermore, a host of organizations and individuals now exist outside of EPA that do credible risk assessment work in both methods and individual chemical assessments. All of these groups would welcome EPA risk assessment participation. The Alliance for Risk Assessment (ARA)---a stated partner of NCEA---has a project on going "Beyond Science and Decisions: From Problem Formulation to Dose Response" that boast 35 case studies and 56 supporting organizations. As EPA steps forward to apply some of the findings of NAS (2009) Science and Decisions, this ARA project would be a good place to look (EPA's RAF is already an ARA partner). The International Toxicity Estimates for Risk (ITER) database on the National Library of Medicine's Toxnet gets more hits at the NLM than the Integrated Risk Information System (IRIS). EPA would be welcome to have a larger role in this effort.

[POST MEETING COMMENT]

The International Toxicity Estimates for Risk (ITER) houses risk assessment values from health agencies around the world and independent values that have been through a rigorous peer review. This database can be viewed to ascertain risk assessment values when EPA does not have one available.

One of the public comments was on whether NCEA would use an independent monitor for its revised IRIS assessments, based in part on a recommendation by BOSC/SAB in its 2012 review of the ORD program. While the use of an independent monitor is still a good idea, the recently launched CAAC committee within the SAB fulfills this role, at least in part. The CAAC review is consensus and the expectation of SAB is that NCEA will adhere to its consensus recommendations.

## 7. Homeland Security Charge Questions

7a. What advice (e.g., strategic, tactical, structural) can the SAB/BOSC give to further guide the program toward this broader role?

7b How could the research program better incorporate this systems thinking and engage its partners in this systems thinking from a strategic and tactical standpoint?

## 8. Roadmaps for Cross-cutting Issues

Please address question 8a for each roadmap for: climate change research, children's environmental health, nitrogen and co-pollutants, and environmental justice.

8a. How effective is each Draft Roadmap in presenting a problem statement, elucidating key research topics, capturing relevant research in each of the six programs, and identifying any important scientific gaps?

### [POST MEETING COMMENT]

The Environmental Justice roadmap, and specifically slide 6, engages communities to build scientific capacity. Building such capacity in risk assessment understanding will be difficult and EPA should employ its best risk communicators for this task. Several former Region staff, particularly in Region 5, are grandmasters at such communication; they might be contacted for advice.

The Nitrogen & Co-pollutant roadmap appears to have over-parameterized models. Perhaps EPA should consider Bayesian statistics/models in this endeavor, since uncertainties can often be more readily characterized. NCEA has at least one scientist familiar with Bayesian models for toxicology data and might be contacted for advice.

The Children's Environmental Health roadmap offers a complex and voluminous picture of ongoing research. One reasonable approach to investigating children's potential health problems is to use existing whole animal toxicology tests that specially look at young experimental animals. Tests for developmental, reproductive and developmental neurological are well established and can be modified, if chemical specific information suggests this. Such tests can also be used to test hypotheses that otherwise are developed from ecological epidemiology studies. Finally, if an effort to study children for a particular chemical or mixture yields negative results, EPA needs to also consider other sensitive subgroups. This is because young animals (and by analogy children) are often not the most sensitive members of a population, at least for risk assessment purposes. See for example Dourson et al. (1992), Scheuplein et al. (2002) and Dourson et al. (2002) (see <http://www.tera.org/Publications/Publications.html> for citations).

## 9. Integration across the Programs

9a. Do ORD's plans, taken collectively, indicate that integration, where appropriate, will develop the needed scientific knowledge and produce results that advance EPA's ability to address complex problems?

### [POST MEETING COMMENT]

EPA has numerous well-credentialed scientists in its Office of Pesticide Programs. NCEA should redevelop a working relationship with this group, as it had prior to 1995 as part of the IRIS program. This interaction will serve to enhance the overall expertise of both groups and

lead to risk assessment positions within both offices that are better support by science.