

**Preliminary Comments from Members of the Chartered SAB and BOSC  
Executive Committee on the draft report *Strategic Research Planning for  
2016-2019: A Joint Report of the Science Advisory Board and ORD Board of  
Scientific Counselors***

List of comments received

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### Substantive Comments for Discussion

	Section	Substantive Comment	Commenter
1.	General comments	It strikes me that our review comments fall into two categories that need better distinction and separation. First, we comment on substantive new research or research approaches that need to be integrated. Second, we respond to the Strap by asking for numerous clarifications, elaborations and reviews, description connections to other programs, and other changes that essentially reflect work put into the text of the StRAP but not any kind of substantive change to the research that EPA plans. It is a bit like reviewing a proposal, and having suggestions about the kinds of research that should be done, and suggestions about how the proposal writing could have been improved. The former changes are much more important. Is there a way to flag those few, important recommendations separately, or underscore them?	Indy Burke
2.		For each overarching, program-specific, and integration recommendation, it would be helpful for SAB/BOSC to provide a specific, sharply focused example to illustrate what is meant and how the recommendation might be implemented. This has been accomplished to varying degrees in the text discussion associated with some but not all recommendations. To illustrate, the recommendation on p. 16 to “plan for the human resource needs...” offers the specific examples of strategic use of postdoctoral fellows, development of methods to foster mobility for current EPA scientists, and hiring social scientists.	Sandra Smith
3.		Integration across ORD programs and collaboration with other entities conducting relevant research is a frequent emphasis of recommendations within each StRAP. Improving integration is a specific goal of the crosscutting roadmaps, and the focus of Charge Questions 2c and 9 to the SAB/BOSC. However, outside the StRAPs and roadmaps, there may be opportunities at other levels (both higher and lower) for ORD to further support the overall goal of integration and collaboration. At the project level, for instance, integration might be nurtured by making integration a specific responsibility of each research project director or champion and giving them the framework to accomplish effective integration. For example, research project metrics could be established for each phase of a research project (planning, implementation, project wrap-up) that guide the project director to think through integration questions such as how the research could impact each of the six program areas and cross-cutting research topics, what other entities will have interest in this research, how to maximize collaboration, how to avoid duplication of effort, and how to disseminate project results. It appears there is high level commitment to integration and collaboration at ORD and a process appears to be in place to drive integration at the conceptual level. Are there procedures, frameworks, and tools in place or under development to ensure a sustained focus on integration from project planning through implementation? One of the stated components of “embracing EPA as a high-performing organization” in the EPA Strategic Plan is the statement that “EPA will modernize the workplace and develop and promote collaboration tools to improve communication, cross-program integration, access to information, and transparency”. It would be helpful if the individual StRAPs could refer to these planned collaboration tools. The recommendations on page 24 in Section 4.4.3 and on pages 38-41 in Section 5.5 speak to this issue.	Sandra Smith
4.		Identifying research priorities and clarifying how research priorities are set is another frequent emphasis of recommendations across the StRAPs and roadmaps. Is there guidance on establishing research	Sandra Smith

	Section	Substantive Comment	Commenter
		priorities and/or established agency practices that each StRAP can cite and refer to when responding to these recommendations? There should be some consistency in approach to identifying research priorities in the StRAPs.	
5.		<p>I've read through the draft report and think it looks quite good.</p> <p>I did note one inconsistency in the report that might bear discussing on the conference call. The report in most places appears to encourage ORD to engage in more international work, and in other places appears to discourage such work. It might be good to address this inconsistency and have a clearer and more common message to ORD about how international partnerships and products should be prioritized relative to ones that are focused on domestic issues. Here are three specific locations, with the first one discouraging research on a topic that is of major international (but limited U.S.) importance, and the latter two encouraging international partnerships but without any specifics:</p> <ul style="list-style-type: none"> <li>- p. 35, lines 23-24 - "...the impacts of cookstoves, at least in the United States, are likely to be very small and less important..."</li> <li>- p. 37, lines 6-7 - "International partnerships are also lacking."</li> <li>- p. 38, lines 24-25 - "...and internationally."</li> </ul> <p>I think it might be helpful to sort this out during the call, and then decide whether/how to reword these three sections. I don't have a strong opinion on this front, but I do want to make sure we're not giving confusing messages. There's another reference to international cooperation on p. 9 lines 40-44, that appears to support more international cooperation, so maybe it's just the cookstove comment that's an outlier.</p>	Gina Solomon
6.		<p>The following are substantive points and themes that came out in the report that might merit further discussion at the teleconference:</p> <ol style="list-style-type: none"> <li>(1) Definition of sustainability</li> <li>(2) Implementation is as important as planning.</li> <li>(3) Longer term vs near term needs</li> <li>(4) Climate change</li> <li>(5) Consistency of roadmaps</li> <li>(6) Take advantage of knowledge created outside the United States</li> <li>(7) Avoid reinventing the wheel</li> <li>(8) Prioritization</li> <li>(9) Uncertainty analysis</li> <li>(10) Expertise on social, economic and behavioral dimensions of goals</li> <li>(11) Assessment of adequacy</li> <li>(12) CBPR</li> <li>(13) Plan for actual integration at the onset of research projects</li> <li>(14) Integration of behavioral science</li> </ol>	Francine Laden
7.	Letter, Page	Many of these comments are judgmental and are subjective. For example: line 26,"This	Costel

	Section	Substantive Comment	Commenter
	1, Lines 26-34	is a time of opportunity..." And further, "help communicate ORD's ambitious mission...".	Denson
8.	3. General Findings	<p>Regarding the overall recommendation that the report "describe how decision makers will access information about the uncertainties associated with ORD-generated tools and data." Pages 2 and 10. The Agency staff does an excellent job in the area of addressing uncertainties in their programs. In fact I am concerned that the efforts to address uncertainties, sometimes outweighs the need to finalize conclusions and steps forward. For this reason I would suggest that the recommendation be tempered with a statement that this effort be balanced with the regulatory need for making decisions. That is, there should be some consideration if the overall conclusion is likely to change with an uncertainty analysis. The last sentence of the recommendation on page 10 seems to be consistent with my concern. That is, could "complex, linked models and systems-based models in which feedback loops may lead to unexpected outcomes. "</p> <p>Regarding the overall recommendation to "clarify how sustainability relates to the specific research planned in each program and how sustainability is operationally defined in each program "on page 10. I agree with the recommendation. However I am confused about the last sentence: "What specific changes in ORD's proposed research strategies have resulted and will result from the incorporation of sustainability as a guiding theme?" Are we expecting response to this question? I think we addressed the point earlier in the paragraph, page 10 lines 41-42.</p>	George Alexeeff
9.		<p>I may be in error, but it appears that many of my comments, both pre and post meeting, were not directly incorporated into our SAB report. I apologize for not reviewing this report well ahead of our meeting to determine this. I am not sure how to proceed, but will likely ask about the process by which these comments (mine and others) were winnowed. After understanding this</p> <p>Annotated set of comments attached that show a statement in capital letters either "[NOT MENTIONED]" or "[MENTIONED]". See Attachment A</p>	Michael Dourson
10.	3. General Findings	<p>The main substantive point I'd like addressed at the teleconference is my recommendation to:</p> <p>1 - rename the Sustainable Healthy Communities research area to Safe, Sustainable and Healthy Communities.</p> <p>2 - Position SSHC as the umbrella research area and superstructural framework through which all the others are integrated, including the crosscutting research areas.</p> <p>The recommendations do not include what was suggested and emphasized at the July meeting, especially in the break out group, i.e. articulating the over-arching importance of Safe and Healthy Communities to the other research areas. In fact, I specifically recommended a reconfiguration of the research areas to first expand SHC to SSHC (Safe, Sustainable and Healthy Communities) and then to reconceptualize the interplay amongst the research thrusts to have SSHC as an umbrella research area to which all the other research areas fed in. The diagram is again introduced below:</p>	John Tharakan

Section	Substantive Comment	Commenter
	<p>If the breakout group is not in agreement, I would submit this recommendation as a “Minority Report” from the SHC breakout group. I believe this diagram, as opposed to the one presented at the July meeting, more closely aligns with the Agency’s vision and mission.</p>	
11.	<p>In section 3.1, page 11 on document (page 23 on pdf), lines 4-</p> <p>The recommendation with regard to social, economic and behavioral science could be more specific. Our recommendation should include a call for a) hiring in these sciences and b) training existing EPA staff in these areas in collaboration with appropriate academic institutions or professional associations. Such emphasis is important across all of the StRAPs, roadmaps and associated programs given the cross-cutting emphasis on sustainability and connections with communities.</p>	Courtney Flint

	Section	Substantive Comment	Commenter
	18		
12.	Page 12, lines 3-8	I'm not clear on what we're recommending on p. 12 lines 3-8. This appears to be asking for a complete restructuring of the StRAPs and roadmaps around these 8 'focal points'. Do we really want to make ORD do a full restructuring? That seems like a lot of work, and I'm not at all clear about why these 8 'focal points' are better than the goals and themes that EPA chose.	Gina Solomon
13.	4.1. Air, Climate and Energy	Regarding the recommendation: "clarify relative priorities, with respects to budget distribution and interactions with other agencies," on Pages 13-14. The recommendation acknowledges that other federal agencies may deploy much greater resources on climate and energy issues. I think a diagram that depicts EPA's niche in this area could be helpful, especially if it gave some indication of relative resource allocation.	George Alexeeff
14.	In section 4.2.2 line 41 of page 16 (28 of pdf)	Along these lines (re comment on section 3.1, page 11, lines 4-18), there is brief mention of hiring social scientists.	Courtney Flint
15.	Page 17, lines 19-20	I'm not clear on this idea of using wastewater as a 'source of trace metals'. Is it really economic to filter trace metals out of wastewater and use them for commercial purposes? That seems unlikely to me. Overall, I'm also not clear on why the committee is recommending no longer using the term wastewater. The proposed alternative, "resource", is a very general term and nobody would know what EPA is talking about if they use the term 'resource' instead of 'wastewater'. I suggest reworking this section or deleting it.	Gina Solomon
16.	4.3 Chemical Safety for Sustainability and Human Health Risk Assessment	Regarding the recommendation: "Advance exposure-based approaches on page 20." - I think the last sentence in the paragraph, lines 37-39, is a non sequitur and should be deleted. It states "Exposure data also are necessary for the field to move away from the conventional high-dose animal testing paradigm to a modern testing paradigm which is more relevant to human and ecological exposures." This statement appears to ignore a large volume of literature that discusses the difficulty of human testing and identifying health effects that occur within large populations. - I think the recommendation could be improved if it linked with the Sustainable Healthy Community issues. There is a strong effort to conduct community-based exposure assessment, particularly in potential hotspots. It's not clear why there is no mention of that here.	George Alexeeff
17.	Page 21, lines 13-16	I agree with the broad recommendation of using molecular epidemiology approaches to expand on the in vitro pathway-based assays, but the specific recommendation here doesn't really make sense. I'm not at all clear what information the NIH, FDA, and NHANES would have that would allow ORD to 'leverage' these, and what exactly is being recommended here. I guess I need to understand what the committee is trying to say here and then maybe I can offer up some specific edits. My suggestion for a more specific recommendation on this front would be for ORD to partner with academic researchers that are engaged in cohort studies (especially on occupationally-exposed populations), and add components to these studies looking for perturbations of some of the same pathways that are being screened in Toxcast.	Gina Solomon
18.	4.4	Regarding the recommendation : "Communicate that environmental health is a critical driver of overall	George

	Section	Substantive Comment	Commenter
	Sustainable and Healthy Communities	<p>human well-being and sustainability," on page 23. I suggest that the lines 31-32 be rewritten in a more positive tone. If one refers to the NRC publication Sustainability and the USEPA (2011) page 46 includes a diagram indicating the integration of the factors constitutes well-being. Instead of saying "particularly as communities may not be aware of how to reconcile economic and societal goals with environmental limits," we should stress the importance of integrating the three factors for well-being.</p> <p>Similarly, I suggest that the lines 11-12 on page 25 be rewritten in a more positive tone. Instead of saying that "sustainability is largely a function of tradeoffs made between environmental, social, and economic priorities" we could say "sustainability is largely a function of integrating environmental, social, and economic priorities."</p> <p>In a similar vein, lines 19-25 on page 25 appear to contradict this "tradeoff" concept. It states that "well-being can be connected to economic security." In fact each of the three pillars has a health component.</p>	Alexeeff
19.	Section 4.4.1. line 28 on page 23 (35 of pdf)	With regard to framing "sustainability", the EPA generally orients around the "three-legged stool". It would perhaps be useful to point out that most contemporary sustainability science frameworks visualize these connections as interlocking or nested circles rather than isolated "pillars". We should probably recommend reconciling and updating these contradictory frameworks for a forward-looking EPA vision.	Courtney Flint
20.	Page 24, lines 6-11	"These kinds of fringe issues...". This seems like an odd recommendation for ORD. Seems like the panel is essentially telling ORD to focus its scarce resources on unimportant things. Is that really what we want to say? In other places this report urges ORD to stay focused and to use its scarce resources in a strategic way. Instead, this recommendation encourages more attention to issues "at the fringes of agency, community, and stakeholder concern." Why?	Gina Solomon
21.	Section 4.4.4 line 12 of page 25 (37 of pdf)	Relatedly, in section 4.4.4 line 12 of page 25 (37 of pdf) suggests "sustainability is largely a function of the tradeoffs made between environmental, social, and economic priorities." I would suggest that actually, sustainability is largely a function of finding "synergies" between environmental, social and economic priorities rather than "tradeoffs". In other words, when we focus on tradeoffs (win-lose), we do not move toward sustainability. When we find space where the three dimensions of well-being are not diminished, but instead mutually enhanced or at least maintained, we are more likely to see sustainable progress. This is where economic vs other orientations clash, but I think it's an important distinction.	Courtney Flint
22.	Section 4.4.6, lines 16-21 on page 26 (38 in pdf)	There is discussion of hiring, but we should add a recommendation to develop "training opportunities" of existing EPA personnel in addition to adding personnel.	Courtney Flint
23.	Page 33, lines 33-34	Strongly suggest deleting the word "voluntary" from this sentence. It's not clear why only voluntary approaches for control of runoff should be studied. Why not just study "approaches for control of agricultural runoff", whether those approaches are voluntary or not shouldn't be a deciding factor on whether they deserve study.	Gina Solomon
24.	Section 5	Reviewed Crosscutting topics, all of which underscore the importance of positioning the (Safe), Sustainable and Healthy Communities research area as the "superstructure" through which all the other research areas <i>and</i> all the cross cutting topics need to be integrated. Recommendations made in the	John Tharakan

	Section	Substantive Comment	Commenter
		<p>draft report of SAC/BOSC address this.</p> <p>All the recommendations point to the need to:</p> <ul style="list-style-type: none"> <li>-link basic/observational science to intervention/implementation science to community action/policy toward improving children's health;</li> <li>-Involve communities, articulate, clarify, support and assess/evaluate community engagement.</li> <li>-more clearly describe integration, across StRAPs in all areas and cross cutting topics</li> <li>-expand discussion of linkages between Nitrogen and Co-pollutants crosscutting topic with SHC and ACE</li> <li>-incorporating input from communities to identify problems</li> <li>-integrating community participation throughout and having communities inform research process</li> <li>-articulate specific connections between areas</li> </ul> <p>All of the above recommendations speak to the need to reconfigure Sustainable Healthy Communities as Safe, Sustainable Healthy Communities and place it above the other research areas as an umbrella research area drawing support from the others and linking with the others through the cross cutting research and integration.</p>	

**Text Edits Suggested**

	Page/Line	Suggested Text Edit	Commenter
25.	Cover Letter, , 1st page, Line 24	"two committees" the SAB and the BOSC are not committees. They are boards.	Costel Denson
26.	Cover Letter, , 1st page, Line 24	"...,because EPA research resources are likely to be stable or, in real terms, declining, while the research needs...and scope"	Costel Denson
27.	Cover Letter, , 1st page, Line 33 -34:	Consider rephrasing as follows: "...how ORD sees it's role in generating that research as well as developing the necessary partnerships with others."	John Tharakan
28.	Cover letter, 1 <sup>st</sup> page	Line 45: change to "...how ORD's proposed research will address..." Line 46: change to "...,and how well ORD's overall programs will..."	John Tharakan
29.	Cover Letter, 2nd page, line 22:	"...across ORD programs as well as the disciplinary integration involving the social , behavioral and decision sciences."	John Tharakan
30.	Page viii:	BOSC Membership identification: John Tharakan, Professor (Remove Chair, I am no longer Chair of the department).	John Tharakan
31.	Page 1, line 39	Suggest adding a recommendation in the discussion on <b>Relationship to EPA Strategic Plan</b> concerning clarifying how ORD intends to ensure a sustainable focus on integration and collaboration from project planning through implementation. Integration and collaboration are consistent themes in the EPA Strategic Plan and are a frequent focus of recommendations within each StRAP and roadmap. As noted above, one of the stated components of "embracing EPA as a high-performing organization" in the Strategic Plan is the statement that "EPA will modernize the workplace and develop and promote collaboration tools to improve communication, cross-program integration, access to information, and transparency". Some elaboration on the specifics of the planned collaboration tools would be helpful.	Sandra Smith
32.	Page 2: line 1,	Consider changing to: "Describe how decision makers will access and integrate information about uncertainties associated with ORD –generated tools and data in informing Agency decisions."	John Tharakan
33.	Page 2, line 3	Consider changing for clarity: "Clarify how sustainability is operationally defined at ORD and the Agency, and articulate how sustainability relates to the specific research planned in each program."	John Tharakan
34.	Page 2, line 5	Consider changing "...will develop or access..." to "...and/or access..."	John Tharakan
35.	Page 2, line 12	Consider adding "...the ORD draft planning documents did not explicitly and separately address..."	John Tharakan
36.	Page 2, line 26 -29	Consider rephrasing to clarify. "criteria air pollutants" is confusing and unclear.	John Tharakan
37.	Page 2,line 40	Add commas: "Consider explicit focus on, and analysis of, agricultural sources and other land use contributions to air pollution."	John Tharakan
38.	Page 3, line 33	Page15 of pdf; 3 of doc, line 33: recommendation 3: "Build confidence in new approaches for assessing safety", is a bit vague. Actually all recommendations are not as clearly formed as the two previous ones	Francine Laden

	Page/Line	Suggested Text Edit	Commenter
		(ACE and Water)	
39.	Page 3, line 34	Can this recommendation (Continue integrating in a targeted and purposeful manner) be focused a bit better to clarify its meaning?	Sandra Smith
40.	Page 4, line 9-25	Summary of Sustainability. This whole section is asking for things (also in main body of report) that EPA asked for NRC to work on, regarding getting input on tools, etc. , For instance on Page 4, line 23, the summary recommendations say: "Look outside the agency for tools". EPA has had NRC do two studies now on sustainability in EPA – seems to me this work is already done and we should reference those two recent reports. The final comment about "clarifying the 3 pillar approach" seems like a very minor recommendation to be in the summary. There are many documents describing this, so all the EPA StRAP needs to do is reference that or say "incorporating the "3 pillars" (reference): social, environmental, and economic.	Indy Burke
41.	Page 4, line 15	Can this recommendation (Plan for robust and flexible decision tools) be worded to better distinguish it from the first bulleted recommendation?	Sandra Smith
42.	Page 4, line 32	Consider rewriting: "...the mission has recently been broadened in the draft StRAP to include both terrorist and natural disaster threats to water supplies and post-disaster cleanup.	John Tharakan
43.	Page 5, line 12	Add period	Sandra Smith
44.	Page 5, line 26	Add hyphens: "...The Nitrogen and co-pollutant roadmap is well-written and well-organized."	John Tharakan
45.	Page 9, line 10	Consider rephrasing: Sustainability, communities etc are not strategies! Recommend "...and to five cross-cutting thematic emphases (sustainability, communities etc..."	John Tharakan
46.	Page 9, line 21	Is the word "client" necessary?	Sandra Smith
47.	Page 10: line 26	Consider rewriting as follows: "Environmental complexity and biological variability make it critical to conduct broad uncertainty analyses and present a comprehensive set of results for statistical reliability of models including contexts where models are tested and found to be reliable, contexts where reliability is poor or has not been well-established	John Tharakan
48.	Page 10, line 26-29	Can the sentence beginning on line 26 be broken into two sentences to clarify its meaning?	Sandra Smith
49.	Page 10, line 33-35	This recommendation requests clarification on how sustainability is operationally defined in each program. Can the SAB/BOSC propose a working definition for sustainability? There should be some consistency across the programs in how sustainability is defined.	Sandra Smith
50.	Page 13, line 21	achievable to "achieve"	George Alexeeff Sandra Smith
51.	Page 14, line 25 and 29	Can the word "public" be used instead of "civil society"?	Sandra Smith

	Page/Line	Suggested Text Edit	Commenter
52.	Section 4.11, page 31	slight typo, should say "SLIDE" instead of "SIDE"	Indy Burke
53.	Page 14, line 5	I suggest inserting the underlined words: "Explicit recognition of the priorities, how they are reflected in the budget <u>and in statutory mandates</u> , and in turn how ACE anticipates resource allocation shifting as a result of the strategic plan should occur early and clearly in the document." This may help clarify constraints in this area.	George Alexeeff
54.	Page 15, line 3	There is a comma missing before the "and"	Jeanne VanBriesen
55.	Page 21 line 33	"which" should be "that" in this sentence.	Jeanne vanBriesen
56.	Page 19, line 9	The word "examples" should not be plural.	Sandra Smith
57.	Page 20, line 2	Add period	Sandra Smith
58.	Page 22, line 15	Correct "difficult" to "difficulty"	John Tharakan Francine Laden
59.	Page 22, line 36-38	Recommend changing sentences to: "ORD's crosscutting research devoted to environmental justice needs to be more tightly integrated into the SHC StRAP. The SHC StRAP also needs to clearly distinguish between stakeholders and partners and clearly articulate the relationships between the two."	John Tharakan
60.	Page 22, line 43	Recommend inserting: "...the SAB and BOSC question the ability of ORD research, as currently articulated and configured in the StRAP, to provide effective decision support across all contexts."	John Tharakan
61.	Page 23, line 1-2	The last sentence, "Simple solutions....facing communities" is obvious and seems superfluous; recommend removing.	John Tharakan
62.	Page 23, line 9-16	Completely concur with this statement but draw attention to it in regard to my earlier recommendation that SHS be changed to SSHC, Safe, Sustainable and Healthy Communities.	John Tharakan
63.	Page 24, line 2	Recommend changing "...respond efficiently..." to "...respond effectively and efficiently..."	John Tharakan
64.	Page 24, line 4-16	Comment: Once again we see how important the other research areas (ACE in this example used) contribute to and inform SHC, underscoring the "umbrella" nature of the (S)SHC research area and why a reconfiguration of SSHC as the overarching research area is more closely aligned with Agency mission.	John Tharakan
65.	Page 24, line 13	Page 36 of pdf; 24 of doc, line 13 - not sure you need the word "also"	Francine

	Page/Line	Suggested Text Edit	Commenter
			Laden
66.	Page 24, line 29-30	Recommend changing "...achieve needed implementation." to "...achieve needed integration."	John Tharakan
67.	Page 24, line 33	Recommend adding "...such detailed information was not discussed <i>or presented</i> in the StRAPs".	John Tharakan
68.	Page 25, lines 4-13	Comment: Again we see the importance of the Human Health Risk Assessment (HHRA) research program to contributing to and informing SHC, again underscoring the "umbrella" nature of (S)SHC, and repeating my comment above.	John Tharakan
69.	Page 25, line 20	Change "that" to "the": "...be more explicit about <i>the</i> fact that there...."	John Tharakan
70.	Page 25, line 36	Recommend adding to end: "...and measures that characterize these objectives, and work towards developing a matrix of metrics that can be used to assess well-being in a context and community-specific manner.	John Tharakan
71.	Page 26, line 3	Correct: "There are an extensive number of publications...."	John Tharakan
72.	Page 26, Line 28 - 29	Rephrase: "This latter view of sustainability seemed to be the focus of the information in the SHC overview slides presented at the SAB-BOSC meeting, but not in the StRAP itself." (i.e. remove redundant 'presented').	John Tharakan
73.	Page 26, line 35	Page 38 of pdf; 26 of doc: line 35: should be "EPA goals of protecting water supplies and on post-distaster clean-up.." remove the "on"	Francine Laden
74.	Page 28, line 21	Add period.	Sandra Smith
75.	Page 30, line 35	Remove bullet symbol after "Recommendation:".	Sandra Smith
76.	Page 31, line 35:	Extra open parenthesis before obesity.	John Tharakan
77.	Page 35, line 21-23	Can the sentence beginning "Many agricultural activities..." be worded to better clarify its relevance to climate change?	Sandra Smith
78.	Section 5.2.3. (lines 31-33, page 33 – or 45 in pdf)	A minor edit: The quote in section 5.2.3. (lines 31-33, page 33 – or 45 in pdf) is attributed to a member of the SAB. It is actually a quote from a member of the BOSC (me).	Courtney Flint
79.	Page 37, lines 1-26	Can the wording and discussion of the first two recommendations on this page be focused to better distinguish the differences between the two recommendations?	Sandra Smith

	Page/Line	Suggested Text Edit	Commenter
80.	Page 38, lines 5-7	Can the last sentence in the paragraph be stated as a recommendation and formatted as the other recommendations are formatted?	Sandra Smith
81.	Page 39 line 1	"for" at the end of this line should be removed.	Jeanne VanBriesen
82.	Page 39	Page 51 of pdf; 39 of doc: line 1: "communicating a clear vision for that lays out the key science needs..." something missing between "for" and "that"	Francine Laden
83.	Page 39 line 5	Remove period after 'plans'	Jeanne VanBriesen
84.	Page 40, line 30.	Missing period between "needs" and "In" at the end of the line.	Jeanne VanBriesen
85.	Page 40, line 11	delete the word "an"	George Alexeeff
86.	Page 40, line 12	The word "provides" should be "provide".	Sandra Smith
87.	Page 40, line 30	Period needed after the word "needs".	Sandra Smith
88.	Page 40, line 30.	Missing period between "needs" and "In" at the end of the line.	Jeanne VanBriesen
89.	Page 40, line 32	Missing comma before 'and'	Jeanne VanBriesen
90.	Page 40, line 345	Missing word "be" before "brought"	Jeanne VanBriesen
91.	Page 40, line 32	It looks like this edit might be appropriate: "community" <del>is emphasized</del> , is rarely defined with any precision...	Sandra Smith
92.	Page A-5, line 5	Number should be "9", not "8".	Sandra Smith

## Attachment A: Pre and post meeting comments provided by Michael Dourson on 1/12/15

SAB/BOSC Charge Questions

### 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. [NOT MENTIONED]

**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. [MENTIONED]

### 1. 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?

### 2. 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?

### 3. 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.

#### 4. 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. [NOT MENTIONED]

#### 5. 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. [NOT MENTIONED]

##### [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. [NOT MENTIONED]

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.

[MENTIONED IN PART]

[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. [NOT MENTIONED]

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. [NOT MENTIONED]

[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. [NOT MENTIONED]

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. [NOT MENTIONED]

## **6. 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?

## **7. 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). [NOT MENTIONED]

## **8. 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. [NOT MENTIONED]