

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?

- ORD appears to be very well positioned to support EPA in meeting the goals of EPA's Strategic Plan. The thematic reorganization seems to be working to align ORD well with EPA's needs, and there is clearly an impressive amount of excellent research work underway and planned.
- The reduction of resources to ORD is worrisome. It appears that the strategy to address the financial situation is to focus more narrowly on the Strategic Plan, which makes logical sense. However, this can lead to an overall Agency "tunnel vision", in which anything that was omitted from the Strategic Plan for any reason is pruned from the research effort. This may mean that issues that might have merited a small ongoing research effort in better times are eliminated altogether, perhaps to the detriment of public health and the environment.
- Overall, it would be helpful for ORD to be clearer about what research efforts have been abandoned, or are planned to be dropped over the coming years, so the SAB and BOSC can comment on whether it is appropriate to deprioritize these efforts.

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

- The proposed research directions seem well-aligned with the top-tier important research issues that should be addressed by EPA. I wish there were sufficient resources to also support and explore some second-tier issues, but that doesn't seem to be the reality at this time.

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)?

- It's hard to tell how well the research directions will actually help achieve the Agency objectives, since the documents are generally written at a very high level, and don't contain enough specifics to fully evaluate their likelihood of success. In addition, the degree to which these research directions actually help achieve EPA objectives depends quite a bit on the resources that are allocated to them. However, the broad research directions are aligned with Agency objectives, so there is consistency in the approach.

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?

- This question is difficult to answer, since it depends on which StRAP plan is being

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discussed. See below.

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?

- Yes, it is gratifying to see that the plans all do contain significant attention to integration across topic areas and programs. This is something for which ORD should be commended.

3. 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).

- The HHRA research program has done a very good job explaining how they are tailoring their risk assessment approaches to various purposes, so there is little to add in this regard.
- The three components that seem most helpful for tailoring exposure and response assessment approaches to different purposes all are reflected in the StRAP, including: (1) applying systematic review and evidence integration approaches – particularly relevant to data-rich chemicals; (2) integrate the application of emerging data streams into risk assessment to support prioritization and rapid screening of risks; and (3) expand cumulative risk assessment methods to support place-based risk assessments, including evaluation of chemical and non-chemical stressors. These three components capture some of the most forward-thinking things that HHRA is doing, even though all of the elements described in the plan are important and will help to move this objective forward.

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.

- The last time the SAB reviewed the CSS and HHRA programs, the Toxcast and other related novel data streams were fairly nascent and there was not as much data to “play with” at the time. In addition, there was concern about the utility of the new data, except perhaps for purposes of priority-setting. The SAB did also recommend evaluating the data from Toxcast and other sources when doing IRIS reviews of data-rich chemicals, both for purposes of evaluating consistency, and for potential additional information on the MOA.
- Although there are many ongoing uncertainties and concerns about the data emerging from these programs, it seems time to really put the data to the test in some risk assessments. This intention seems to be reflected in the HHRA and CSS StRAPs, and this is something that should be encouraged at this point.
- Overall, the CSS StRAP is a bit difficult to comment on, since it contains very high-level summary points presented repeatedly in the document in various formats. The same text is repeated verbatim in the Intro and the Program Purpose (and probably will be repeated yet again in the Executive Summary when it’s written). The outline-form section on Research Topics should be a place to go to get a bit more detail (just one more sentence would help in a lot of places!) but it too is too big-picture to get a full sense of the plan. Overall, the CSS StRAP contained a lot of great vision and big ideas, and there is a lot to applaud in this document, but it also left this reader really wanting to

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see more flesh on the bones, and just a bit more detail on the various components.

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?

- In addition to priority-setting for further evaluation, specific applications in chemical assessment that are already done or could be done include: (1) comparative evaluation of classes of chemicals in which some members of the class have fairly well-known risks and others do not (eg. phthalates, perfluorinated chemicals, etc.); (2) comparative evaluation of alternatives to toxic chemicals, regardless of class (eg. various BPA replacements, flame retardants, or solvents – although the latter are often not testable in high-throughput systems); (3) use of reverse-dosimetry models to predict in vivo levels that would correspond to AC₅₀'s and either compare these with risk levels from more conventional data, or ultimately use numbers derived in this manner (with appropriate uncertainty factors) as provisional risk numbers.

4. 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?

- Yes, these plans – if executed properly and if sufficiently resourced - are likely to develop the needed scientific knowledge to allow EPA to better address complex problems. These plans reflect a level of energy, focus, and innovation within ORD that deserves recognition and is worthy of support. There is evidence of an impressive degree of unity of purpose and a real vision behind these plans. The degree to which they will produce results will depend on resources and continued leadership, but there seems to be a good chance of success.