Insert Date

EPA-SAB-12-001

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Office of Research and Development (ORD) Implementation of its Strategic Research Plans: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)

Dear Administrator Jackson:

After re-aligning its research into six new program areas in FY 2012, the Office of Research and Development (ORD) requested that the EPA Science Advisory Board (SAB) and Executive Committee of ORD's Board of Scientific Councilors (BOSC) provide advice on implementation of these six program areas (Air, Climate and Energy; Safe and Sustainable Water Resources; Sustainable and Healthy Communities; and Chemical Safety for Sustainability; Human Health Risk Assessment and Homeland Security Research). The SAB and BOSC agree that ORD has made remarkable progress towards integrated transdisciplinary research, systems approaches and sustainability despite changes in leadership over the past year. The Strategic Research Action Plans developed by ORD are an important achievement in crystallizing and communicating ORD's new approach to its mission.

There was general consensus that ORD has been highly responsive to previous advice from the SAB and to advice on its restructuring provided by the SAB and BOSC report in 2011. The Air, Climate and Energy; Safe and Sustainable Water Resources; Chemical Safety for Sustainability and Homeland Security program are making good to very good progress. The Human Health Risk Assessment and Sustainable and Healthy Communities programs are also making progress but have more challenges to meet in refining their vision and implementation strategy. All of the programs would benefit from defining sustainability more clearly specifically for their programs. Although the definition of sustainability from the National Environmental Policy Act will work as a common definition, the SAB and BOSC advise that ORD explain more specifically what sustainability means to each research program and how those research goals will be achieved.

From our review, it is clear that ORD's research in social, behavioral and decision sciences is weak. Sustainability cannot be the focus of ORD research if ORD research only involves "one leg of the sustainability stool," which requires the support of research on social, economic and environmental

factors. There needs to be continued focus in this area within ORD, across EPA and with explicit planning to collaborate with and leverage the expertise of external partners. The SAB and BOSC provided advice in 2011 to help ORD strengthen capabilities in this area and we provide additional advice in this report.

In addition to these general points, there is a need to improve ORD's Strategic Research Action Plans in several ways: There is a need to increase research emphasis on ecological risk. There is a need to include research on nonchemical stressors. There is a need for better communication of products and outputs and of findings and knowledge gained from research across ORD programs, across EPA and with other stakeholders. There is a need for "roadmaps," similar to the roadmap being developed for the Nitrogen integration topic, for key projects. And there is a need to identify co-benefits for research activities to help establish priorities.

The SAB and BOSC congratulate ORD leadership at all levels for its continued commitment to integrated transdisciplinary research, systems approaches and sustainability. We encourage them to continue these efforts with the concept of "One Environment" as their touchstone. We look forward to any comments you have at this time on these reflections regarding ORD's new research directions

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB) and the Office of Research and Development (ORD) Board of Scientific Counselors (BOSC). The SAB is a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the agency. The BOSC is also a balanced, expert public advisory group. It provides extramural scientific information and advice to the ORD Assistant Administrator. This report has not been reviewed for approval by the agency, and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency or other agencies in the Executive Branch of the Federal government. Mention of trade names of commercial products does not constitute a recommendation for use. Reports of the SAB are posted on the EPA website at http://www.epa.gov/sab, and reports of the BOSC are posted on the EPA website at http://www.epa.gov/osp/bosc.

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EPA should also use competitions or targeted outreach efforts to identify examples of successful innovation projects implemented in communities and utilities across the country. SAB/BOSC notes that other countries (e.g. India, Brazil and Nigeria) have found success in identifying solutions to their environmental problems by soliciting innovative approaches directly from community groups experiencing the negative impacts for which innovative solutions are sought. 1

Acronyms and Abbreviations

ACE	Air, Climate and Energy
ATSDR	*Agency for Toxic Substances and Disease Registry*
BOSC	Board of Scientific Counselors
CRTS	Community Risk and Technical Support
CSS	Chemical Safety for Sustainability
EDSP	Endocrine Disruptors Screening Program
FTTA	*Federal Technology Transfer Act*
HHRA	Human Health Risk Assessment
HSRP	Homeland Security Research Program
IRIS	Integrated Risk Information System
ISA	Integrated Science Assessments
ORD	Office of Research and Development
QSAR	Quantitative structure–activity relationship models
SAB	Science Advisory Board
SHC	Sustainable and Healthy Communities
SSWR	Safe and Sustainable Water Resources

1. BACKGROUND AND CHARGE

In 2012, the Office of Research and Development (ORD) developed strategic research action plans for its six research areas and an overview plan after receiving advice from the Science Advisory Board (SAB) and Board of Scientific Counselors (BOSC) in 2011 (U.S. EPA SAB 2012). The restructured research programs comprise six program areas: Air, Climate, and Energy; Safe and Sustainable Water Resources; Sustainable and Healthy Communities; Chemical Safety for Sustainability; Human Health Risk Assessment; and Homeland Security. ORD requested additional advice in 2012 on ORD's research implementation plans, efforts to strengthen program integration; and efforts to strengthen and measure innovation.

The SAB and the BOSC held a public meeting on July 10-11, 2012, to discuss the strategic research action plans, information about five integration topics presented by ORD (Nitrogen; Global Climate Change; Children's Health/Environmental Justice; Applying new chemical assessment approaches in human health risk assessment; Endocrine-mediated Dose-Response) and ORD efforts to encourage innovation. [ADD AFTER REVIEW TELECON: SAB and BOSC also held a public teleconference on September 19, 2012 to discuss a draft of this report.]

ORD requested the SAB and BOSC to address a series of charge questions provided in Appendix A. The charge questions included: 1) three charge questions related to first year progress, sustainability and balancing immediate needs and emerging issues for each of the major research areas; 2) specific charge questions for each program area; and 3) general questions pertaining to integration and innovation in ORD programs.

Section 2 provides an overview of general findings and recommendations, applicable to all the research programs, related to the charge questions below.

1. First year progress. How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

2. Sustainability. How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

3. Balancing immediate program needs and emerging issues. As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

4. Integration. Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD

programs? How can different approaches to integration help us achieve our research goals?

5. Innovation. How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Section 3 of this report provides program-specific findings and recommendations to the five questions listed above as well as program specific charge questions.

2. GENERAL FINDINGS AND RECOMMENDATIONS

2.1. Introduction

The SAB and BOSC have strongly supported the consolidation of research programs to align with the EPA Administrator's priorities and to reflect an integrated, transdisciplinary approach to research that takes a systems approach to sustainability (U.S. EPA SAB 2011a; U.S. EPA SAB 2011b). Because this approach is so new and will require significant changes in ORD's approach to research, the SAB and BOSC welcomed the opportunity to review ORD's plans to implement its new programs.

2.2. First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

2.2.1. Response

ORD developed Strategic Research Action Plans for each of the six major research programs (US EPA 2012a, 2012b, 2012c, 2012d, 2012e, 2012f). Creation of these well-structured plans marks major progress for the first year of implementation of ORD's new research program. The plans communicate a central problem statement for each research program and (except for the Homeland Security Program, which has a unique mission and mandate) the program vision. Each plan also briefly describes how the ORD research supports the EPA's priorities and mandates. Each plan describes the program's efforts to collaborate across ORD research programs and build and develop research partnerships within the EPA and with other organizations. The plans identify research themes and priority science questions and provide a summary table of high-level research outputs and expected outcomes by theme.

The Strategic Research Action Plans vary in detail and effectiveness in how they communicate the overall vision of particular programs and how that vision would be achieved. The differences across the plans make it difficult to answer the question about first year progress globally. The plans are most useful when they identify deliverables clearly with specific milestones for achieving desired outcomes and outputs. Section 3 of this report proves more detail on each research program. Generally, the Air, Climate and Energy; Safe and Sustainable Water Resources; Chemical Safety for Sustainability and Homeland Security program are making good to very good progress. The Human Health Risk Assessment and Sustainable and Healthy Communities programs are also making progress but have more challenges to meet in refining their vision and implementation strategy.

The SAB and BOSC recommend that the EPA develop an implementation plan that includes specific tasks and milestones. In some cases the EPA has all deliverables for the completion of a task scheduled for as late as 2017. This makes it difficult to assess the rate of progress that the EPA is making towards completion of the task. While SAB/BOSC understands that an implementation plan is in development, the EPA should consider including a more detailed timeline with deliverables for planned activities with

specific milestones and/or intermediate deliverables. This would assist reviewers in better understanding the anticipated rate of the EPA's progress towards achieving its longer-term goals and plans.

2.2.2. Major recommendations

- ORD should consider including a more detailed timeline with deliverables for planned activities for each research program with specific milestones and/or intermediate deliverables.
- In future Action Plans, ORD should provide a comprehensive mapping of projects to goals, and not just provide examples.

2.3. <u>Sustainability</u>

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

2.3.1. Response

The SAB and BOSC commend ORD for establishing a single definition for sustainability across research programs and recommends that each program define more specifically what sustainability means within the program context. The SAB and BOSC suggest that strategic research action plans incorporate ecological health as well as human health into the definition of sustainability, and that each research program define what sustainability means within the context of that program.

2.3.2. Major recommendations

- Each ORD program should define more specifically what sustainability means within the program context.

2.4. <u>Balancing immediate program needs and emerging issues.</u>

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

2.4.1. Response

Although it will sometimes be difficult to separate basic, immediate research needs from emerging research needs and to make emerging research needs a priority, ORD must identify and address significant emerging research needs. ORD has demonstrated it has the flexibility and capability to make necessary changes in research plans from year to year. The SAB and BOSC encourage ORD to develop a structured way (e.g. through a risk portfolio analysis) to assess the relative priorities of emerging issues *vis à vis* existing and legacy research activities.

A risk portfolio analysis approach to research and development management involves the evaluation of a portfolio of projects to determine their competitive position versus the competitive impact (CITATION NEEDED). Technologies and products would be categorized as base, key or pacing, and the competitive position would be rated from weak to dominant. Another way to determine the type of projects would be to utilize the framework used by the Department of Defense (CITATION NEEDED). and align the research projects from basic, applied, advanced technology development, demonstration/validation, manufacturing development, or management support. (NEED A SENTENCE EXPLAINING HOW THIS WOULD TRANSLATE FOR ORD). Such analyses would facilitate ORD evaluation of resource allocations for the various types of research and development projects. In addition to portfolio analysis, the SAB and BOSC recommend that ORD plan explicitly for the resources needed to advance sustainability research, evaluating its current framework of client interaction to develop a 10 year roadmap for sustainability research.

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Citations?

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Anticipatory research is a strategy to prepare for emerging issues. Equally important is for ORD to try to understand what has contributed to slow responses in the past to identifying and conducting research related to emerging / important issues. What permits the early detection of a signal before it reaches a critical state? What cultural, institutional, technical barriers were there to detecting such signals? ORD should undertake evaluative case studies to identify barriers in the past to identifying and conducting research related to emerging / important issues

Emerging issues will be better identified and anticipated if staff are at the frontier of the science. ORD's transition to a more integrated structure is requiring a considerable increase in staff re-training and an enhanced culture of continual learning, which in turn is expected to result in a more diversified suite of skill sets across ORD. Integration also creates more efficient networks of expertise that can be more rapidly and effectively tapped when new issues arise. Integration also is promoting cross-fertilization of ideas and skill sets. Webinars, seminars, and short-courses also can help keep staff abreast of emerging issues. Many experts travel to locations with ORD staff and it may be possible to interact with these experts at low cost. ORD should make training and development for ORD a priority and seek new ways to interact with scientists outside the EPA through partnerships with other agencies and with academics. All of these will enhance ORD's capacity to adapt to critical emerging issues even in a fiscally lean environment.

2.5. <u>Major recommendations</u>

- ORD should develop a structured approach (e.g. through a risk portfolio analysis) to assess the relative priorities of emerging issues *vis à vis* existing and legacy research activities.
- ORD should make training and development for ORD a priority and seek new ways to interact with scientists outside the EPA through partnerships with other agencies and with academics to keep staff on the frontier of science and alert to emerging issues.

2.6. Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

2.6.1. Response

The SAB and BOSC commend ORD for significantly improving how it integrates research across its programs. ORD's consolidation of research into six major programs is a significant achievement and has stimulated significant rapid progress. The five integration topics discussed provided insightful examples of different ways to stimulate and encourage integration. The Nitrogen and Climate Change integration topics were excellent examples of the potential for integration among program areas. ORD should define how other ideas for integration topics will be identified, how roadmaps are created, and how senior leadership teams with responsibilities for integration can be assembled.

ORD could facilitate progress in the integrated research topics if it developed individual "roadmaps" with goals and an outline of paths to those goals for each of the integrated research topics, similar to the roadmap being developed for the Nitrogen integration topic. In addition, The SAB and BOSC recommend that ORD develop a graphical framework for each integrated research topic that identifies the various participating EPA programs and external agencies and groups, the distribution of responsibilities, and how the various participants are linked to each other and to the research effort. This framework should clearly identify the EPA program that would take the lead in the integrated research effort and resources should be managed accordingly.

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The SAB and BOSC offer the following suggestions to strengthen ORD's work on the five integration topics:

- Whenever possible, try to directly link ORD science to end users, such as regulators at regional office level.
- Highlight key examples of successful integration particularly if the key elements of integration are emphasized. For example, in the Children's Health/Environmental Justice topic integration the integration of both chemical and non-chemical stressors was emphasized.
- The Nitrogen topic could be further integrated by incorporating community ground water exposure data.

Some areas of research integration have obvious rationale, such as integration of chemical safety with air and water research, but the need for integration across other areas requires careful consideration. The five integration topics selected by the EPA are good ones, and probably sufficient for now. Integration of research should be initiated when there is a compelling topic and it makes sense to do so, recognizing that not all topics will require assistance from all program areas.

Another research area where integration is needed involves research in the social sciences necessary to support sustainability at the agency. ORD should collaborate with other partners in the EPA, including the National Center for Environmental Economics, to develop a social science research plan to support sustainability activities. A useful first step would be for ORD to plan a workshop on this topic and seek SAB and BOSC advice in workshop planning. This workshop should address the social science needs identified through ORD's strategic research action plans and take into account past ORD and BOSC advice (U.S. EPA SAB 2012, U.S. EPA BOSC 2009). Another approach might be to examine ORD's five integration topics and identify needs for social, behavioral and decision sciences. An SAB member cautioned that any recommendation for a workshop would require additional resources. and any future SAB-BOSC report should take note of this need. Another member cautioned against forming "horizontal stovepipes" where a community of social, behavioral and decision scientists would become isolated from other ORD science.

Now that integration has been successfully launched at ORD strengthening integration outside of ORD should become a priority. .

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2.6.2. Major recommendations

- ORD should develop individual "roadmaps" with goals and an outline of paths to those goals for each of the integrated research topics, similar to the roadmap being developed for ORD's Nitrogen topics.
- ORD should develop a graphical framework for each integrated research topic that identifies and discusses the responsibilities and relationships of the various participating EPA programs and external agencies and groups.
- ORD should enhance its internal and external communication between research programs and provide more opportunities for formal exchange of research information.
- ORD should collaborate with other partners in the EPA, including the National Center for Environmental Economics, to develop a social science research plan to support sustainability activities. A useful first step would be for ORD to plan a workshop on this topic and seek SAB and BOSC advice in workshop planning.

2.7. <u>Innovation</u>

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

2.7.1. Response

Improving ORD's initial innovation activities

ORD should be commended on its efforts to foster innovation. The success of such an approach is strongly dependent on the leader and the continued fostering of the innovative culture and the first year

results. The program also appears to yield the double benefit of enhancing integration, as many of the innovation projects are characterized by cross-fertilization across disciplines.

The initiation of the Pathfinder Innovation Projects along with the large response for the call for proposals and some preliminary results indicates a very good start. However, it is important to the EPA to make sure that all proposed innovation activities are tied to the agency mission. Innovative activities and support of those activities should be prioritized to reflect the EPA's most pressing needs. ORD should provide more information on the guiding principles that govern how Pathfinder Innovation Projects grants are awarded and how questions for challenges are chosen. What are those Grand Challenges that, if addressed in an innovative way, will lead to a quantum leap in the way the EPA performs its duties? For example, imagine the value of having output of Integrated Risk Information System (IRIS) toxicological profiles increase by an order of magnitude. An overarching Grand Challenge for ORD is to innovate in a contracting fiscal environment and in the public sector which is not designed to foster creativity.

The SAB and BOSC note that much of the innovation program is currently focused on technological innovations ("widgets"). Often the most inventive solutions to environmental problems involve new ways of doing things, through new organizational forms or ways of working together, rather than new technologies (National Academy of Engineering 1999). In addition, existing technologies can become part of solutions that involve changing the way people use technologies, which some call "sociotechnical systems." ORD should provide as much encouragement for social and sociotechnical innovations as for purely technological ones. As the program matures, it may be beneficial to shift the focus from innovation in devices to identifying systemic ways to incorporate innovative thinking into the EPA culture and policies. Specifically, innovation in environmental modeling and in policy strategies (e.g. market based systems) could be targeted. The EPA can use its leverage in regulation and in public information to catalyze additional innovation outside of the agency. Efforts could be broadened to identify ways to promote environmental innovation by businesses, households and consumers in their use of environmental resources; social science research could play a critical role in this process.

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The SAB and BOSC support ORD's efforts to develop innovative ideas from across ORD and also recognize that some individuals are more consistently innovative than others (e.g. repeat Pathfinder Innovation Projects award winners). ORD should undertake additional efforts to identify and leverage the top innovators via mentoring of others and/or assembling the top innovators in small teams to promote further breakthroughs. .

There was concern expressed about the large number of proposals submitted and the low number of proposals funded. Low success rates represent a huge investment of staff time that do not lead to on-going efforts and the possibility that staff morale could decline. Time management needs to be considered, as too much time spent on writing proposals may produce a deficiency in the researcher pursuing regular work activities.

Approaches to innovation beyond the Pathfinder Innovation Projects program could include:

- X-prize engaging the public.

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- Open innovation/crowd sourcing - utilizing communities and students.
- Looking to young investigators for fresh ideas.
- Skunkworks approach—taking a small number of innovative thinkers and encouraging wild ideas and experimentation while accepting that there will be failures but some successes. These investigators would be allowed to operate with minimal reporting requirements and enhanced programmatic flexibility. Innovative thinkers from very different fields would work together to increase the potential for innovation as each brings a completely different set of ideas to the table.
- Using competitions or targeted outreach efforts to identify examples of successful innovation projects implemented in communities and utilities across the country. Other countries (e.g. India, Brazil and Nigeria) have found success in identifying solutions to their environmental problems by soliciting innovative approaches directly from community groups experiencing the negative impacts for which innovative solutions are sought.

Experiences and lessons on innovation from other research organizations

Appendix B provides a list of references on innovation that may be useful to ORD. References include lessons-learned reports, metrics generation, and peer-reviewed articles discussing fostering innovation.

Metrics for assessing the success of ORD innovation efforts

The development of metrics seems to be the Grand Challenge in itself. Other than development of an award system that would align with the desired behavioral changes in moving the ORD culture to one of innovation, the SAB and BOSC at this time have not reached substantive agreement on a single approach to metrics for assessing the success of ORD innovation. Members generally agree that ORD should consider multiple benefits when assessing innovation, but some members suggest that metrics are not important rather the 'just do it' should be the operative direction. Other members suggested that business innovation metrics should be avoided and, instead, that ORD identify and focus its metrics on the goals of EPA's organizations and their specific projects, when assessing potential innovation projects and impacts of innovation projects. Some members suggested metrics that are common for academic decisions on innovation (number of publications, citations, patents etc.) would be acceptable and provided technical research on the subject. Some members note that even learning from failed projects can be seen as a success. Telling success stories, encouraging proposals for innovation, and soliciting innovation challenges could be effective measurement strategies. Tracking the application of innovations and consequent time and cost savings could provide other metrics.

Additionally, there may be different metrics for different aspects of a proposed innovative project, as indicated by the questions below:

- Does the proposal fit a mission area?
- Is the proposal innovative or just evolutionary?
- Are there phases in the proposal (e.g. idea development, proof of concept, or innovation development)? If so there may be metrics needed for each phase in order to justify funding from one phase to the next.

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Where does the term come from.

Commented [E14]: Does the SAB and BOSC want to cite the SAB report/

U.S. EPA SAB. 2000. Commentary Resulting from a Workshop on the Diffusion and Adoption of Innovations in Environmental Protection (EPA-SAB-EEC-COM-01-001). http://yosemite.epa.gov/sab/sabproduct.nsf/0E3FE5546A2DE4DC8525718E0048B067/$File/eecm0101.pdf (accessed 08/17/12)

- What is the transition plan (what happens after the project is successful? Who is the customer? The EPA? If there is no buyer for the technology, does it have value to the agency and still worth pursuing?

Given the importance and complexity of this question, the SAB and BOSC recommend that ORD sponsor a focused workshop on metric development for innovation that would result in a set of metrics that represents a reasonable fit with the ORD mission and desire for innovation.

2.7.2. Major recommendations

- When assessing potential innovation projects and impacts of innovation projects, ORD should consider multiple benefits of such projects, and identify and focus its metrics on the goals of the EPA's organizations and their specific projects rather than on conventional business performance metrics.
- Innovative activities and support of those activities should be prioritized to reflect the EPA's most pressing needs.
- ORD should provide more information on the guiding principles that govern how Pathfinder Innovation Projects grants are awarded and how questions for challenges are chosen
- ORD should undertake additional efforts to identify and leverage the top innovators via mentoring of others and/or assembling the top innovators in small teams to promote further breakthroughs.
- ORD should provide as much encouragement for social and sociotechnical innovations as for purely technological ones.
- ORD should use competitions or targeted outreach efforts to identify examples of successful innovation projects implemented in communities and utilities across the country.
- ORD should develop an award system that would align with the desired behavioral changes in moving the ORD culture to one of innovation
- ORD should sponsor a focused workshop on metric development for innovation that would result in a set of metrics that represents a reasonable fit with the ORD mission and desire for innovation.

3. PROGRAM-SPECIFIC RESPONSES

3.1. Air, Climate and Energy

The Air, Climate and Energy (ACE) program is intended to provide cutting-edge scientific information and tools to support the EPA's strategic goals of protecting and improving air quality and taking action on climate change in a sustainable manner. The SAB and BOSC strongly support the efforts of the ACE program, which aligns with the sustainability paradigm. The responses below suggest ways to strengthen the program through further enhancements to the Strategic Research Action Plan, more investments in systems approaches and analyses (which will require investments in social, behavioral and decision science research) and increased focus and resources for the energy component of the program.

3.1.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The development of the Strategic Research Action Plan for the ACE program is clearly a major accomplishment, providing a well-articulated plan for the newly created program. An area of potential improvement for the plan would be a more explicit mapping of the long list of individual projects and project outputs to strategic research themes and the overarching vision. While the high level goals for this program area are exciting, it was not always evident from the examples presented how these goals are translating into specific research activities. A compelling, well described example of how projects fit together to address strategic research goals was provided by the Nitrogen integration topic. The framework for the Nitrogen topic was based on a previous SAB report (U.S. EPA SAB 2011), which suggests that the SAB could play a catalyzing role in defining these mappings.

Additional areas of potential improvement of the plan would be:1) a more explicit integration of energy research with the plans for climate and air quality research plans, 2) a description of how ORD's ACE activities are positioned within the portfolio of other research activities at the EPA and the research of other federal agencies, 3) broadening the portfolio of projects addressing the interaction of air quality and climate, and 4) the inclusion of more social science and behavioral research. More social and behavioral science research could be integrated in the ACE plan by examining, for example, the impact of air pollution and monitoring activities on different socio-demographic groups, by analyzing different types of innovative policy incentives that would encourage pollution prevention and energy conservation, and by examining the effects of providing information about air quality on decision making and human health.

Plans for activities in FY 13 and beyond appear appropriate and well-positioned to advance the agenda described in the ACE Strategic Research Action Plan. Each of the three primary research themes – assessing impacts of air pollution and climate change, preventing and reducing emissions, and responding to changes in climate and air quality – is supported by activities that will provide information

critical to these themes. Since the Summary Tables of Outputs and Outcomes only provides the year the specified output is expected to be produced, and since so few (30 out of 145) project deliverables are targeted for completion in FY12, it is difficult to have a sense of the overall timeline of and investment in each of the activities; for instance, some may entail major, multi-year efforts and others may be minimal. More discussion of the rationale for selecting and prioritizing the specific research activities planned for 2013 would be informative in assessing their appropriateness.

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The combination of air, climate and energy lends itself to the sustainability paradigm. By considering these three arenas jointly, it is possible to create a more holistic view of how these inter-related areas impact one another and to consider co-benefits and unintended consequences of actions in one area on another. The Strategic Research Action Plan for the ACE program describes these interactions and the EPA's interest in studying co-benefits and unintended consequences, but more development is needed for creating the systems approaches needed. To accelerate the development of systems approaches, it may be helpful to bring systems expertise into the program, and to encourage extramural research in this area.

Incorporating sustainability into research plans and activities will also require more effort in social, behavioral and decision science research. Understanding two of the three elements of sustainability, economic and societal issues, is directly dependent on the social and behavioral sciences. The SAB has repeatedly made the recommendation for increased inclusion of social and behavioral sciences into ORD activities, and ORD has made some progress, but the new focus on sustainability calls for an even greater level of effort. More projects are needed, including some flagship projects that deliberately study all three dimensions of sustainability. This will require more staff, including both junior (post-doc) and senior researchers. In addition, more focus on systems science is needed. Finally, ORD should lead federal agencies in studying and implementing the effectiveness of sustainable business practices at the scale of a large distributed federal agency. This would include evaluating energy and material use and the economic consequences of implementing sustainable practices.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

The ACE program is charting an effective balance between short and long term projects and ending projects that have reached their objectives. As budget challenges grow, ORD will need to increasingly rely on partners for achieving its objectives. A balance between in-house projects and importing externally developed tools will be needed.

To achieve greater efficiency in the use of ORD resources, ORD should conduct a careful assessment of the balance between intramural and extramural research and the positioning of ORD research relative to research in other institutions. ORD should focus its efforts on identifying gaps critical to agency missions and finding ways to apply and adapt research from other organizations.

Commented [E15]: Should this be a major recommendation?

3.1.2. Program –specific question

Integrating ACE research elements as a coherent whole.

> *How do we bring together research on biofuels, oil and gas measurement methods, combustion related pollutant effects and modeling/decision support tools into a coherent whole to address the environmental effects of energy production and use?*

Effectively incorporating more energy projects into the ACE research portfolio will be a key challenge for the ACE group. The scope of potential research at the intersection of energy and the environment is enormous and ORD resources are limited. A mapping of energy research needs for ORD would be useful first step.

In addition, developing a comprehensive and integrated energy program is a prime example of a research area in which systems approaches will be key (see response to Charge Question regarding ACE first-year progress in section 3.1.1). Developing a full understanding of the entire spectrum of human health and ecosystem impacts of energy options (using life-cycle analysis and taking account of externalities) will be critical to providing effective decision support tools and laying the scientific foundation for policy decisions regarding sustainably meeting energy needs on multiple scales (community, regional, national, global). Most current ORD work is on facets of the impacts of energy on air quality and climate, with minimal effort devoted to making the connections between these facets and understanding energy system behavior. This additional systems level focus on energy will require senior leadership (e.g. a Deputy National Program Director for Energy) that would provide necessary systems science expertise and ensure that the connections between energy research projects are drawn and made explicit. In addition, an energy workgroup of staff from across ORD who are working on energy-related issues could convene periodically to review work and identify connections and possibilities for integration and collaboration.

Several synthesis reports on fuels are planned for the 2013-2016 period, and the development of these reports offer opportunities to develop integrated, systems approaches. These syntheses should integrate sustainability issues related to biomass production, land use change, soil carbon and food and fuel markets. The existing research places considerable focus on lifecycle analysis rather than on a developing an integrated framework that allows evaluation of the competitiveness of alternative energy sources, their intended and unintended effects and implications for policy.

Commented [E16]: So, should there be a recommendation for development of such a framework?

Finally, legislative activity and funding has driven a focus on biofuels and hydraulic fracturing is likely to become a research center-piece of focused research in the coming year. While these responses to emerging issues are important, ORD should still seek to develop, in partnership with other groups, a broad set of energy capabilities. Life cycle approaches and frameworks, including consequential issues (such as land use), as well as ecological impacts and responses to catastrophic events such as heat waves

and droughts, will be both critical elements of these capabilities and will stretch ORD's expertise. Again, partnership with other organizations will be critical.

3.1.3. Major recommendations for the ACEprogram

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- While the plans for air and climate are relatively well-developed, a concerted effort needs to be devoted to developing an explicit plan in the area of energy.

Commented [E17]: More key recs?

3.2. Chemical Safety for Sustainability

The Chemical Safety for Sustainability (CSS) program is intended to provide critical research providing the scientific foundations supporting agency programs to ensure safety in the design, manufacture and use of existing and future chemicals. This program is ambitious and bold, and appropriately so as the entire field of chemical safety assessment is in the midst of a radical transformation needed to meet the changing needs of today's world. The demands being placed upon the agency's safety assessment programs are far more challenging than they have ever been in the past, and are prompting questions such as: how to design and produce safer chemicals, how chemicals and their byproducts move through the environment, what are the sources of chemical exposure, how might chemicals and other exposures alter cellular and molecular control pathways leading to adverse outcomes, and what contribution does chemical exposure make to the overall disease burden in humans (including susceptible subpopulations) and the environment.

Clearly, transforming safety assessment to meet these challenges is a major undertaking that will take many years to fully accomplish. However, the journey is now underway and it is imperative that it succeed. At stake are not only major opportunities to improve public and environmental health, but to do so in ways that are swift, cost effective and supportive of our nation's innovation engine (e.g. new, more sustainable products). Overall, the SAB and BOSC voice strong support and endorsement of the Strategic Research Action Plan for the CSS program. This report also offers a number of specific suggestions for improving upon this already strong plan.

3.2.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The SAB and BOSC are impressed with the progress made in the first year of the CSS program's implementation and note that it "exceeded expectations" in some instances. This progress was primarily related to creating a new, highly integrated management infrastructure that is radically different from the previous structure. This was no small task to create, and will also take much work to maintain, but it is fundamental and necessary to achieving the desired level integration along multiple axes and to accomplish the ambitious goals articulated in the Strategic Research Action Plan. It is noted that the

scope of the plan goes beyond the traditional confines of risk assessment by also integrating certain aspects of risk management in its design. Examples of this include the application of high throughput predictive toxicology data and computational approaches to inform "Green Chemical" design, as well as the consideration of product life cycle in the development of new approaches to safety assessment. While not a research product in and of itself, the Strategic Plan should be considered a major accomplishment in its own right.

Given that this is just the first year of a multi-year research program, it is too early to judge success in terms of specific research deliverables, but certainly early progress is very encouraging. Approximately 75 percent of the CSS research program portfolio deals with the development of new tools for safety assessment. Assuming that these new tools are found useful by users and their outputs accepted by stakeholders (more on this later), the impact from the CSS is expected to be quite high and readily quantifiable.

In regard to the appropriateness of the research activities planned for FY 13 and future years for answering the science questions in the Strategic Research Action Plan, the SAB and BOSC consider the CSS research plan to be comprehensive. Reviewers found that it contained all of the key elements needed to answer the science questions in the Strategic Research Action Plan. However, several particular elements warrant further discussion, specifically exposure, cumulative risk and ecosystems.

The SAB and BOSC are pleased that exposure research has a greater presence in the plan than in any previous plan. While it was agreed that exposure is embedded throughout most, if not all, aspects of the plan, additional focus needs to be placed on the refinement and validation of proximal and consumer (also referred to by some as "near field") exposure models. Some members of the SAB and the BOSC suggest that exposure be specifically highlighted as a theme of its own. If such were the case, exposure might get even more attention and resources. This is strongly encouraged. It should be noted that "exposure" as referred to here includes both external exposure and internal exposure (i.e. toxicokinetics), and applies to humans, wildlife and ecosystems. While the SAB and BOSC are aware of legal/policy constraints precluding the conduct of human exposure studies by ORD, it is possible to conduct such studies in a safe and ethical manner as demonstrated by other research organizations. Such studies would bring tremendous value in the assessment of chemical safety and will be important to put the results from the *in vitro* high-throughput screening studies into the appropriate context.

Regarding cumulative risk, one example of the benefits of integration relates to the potential value of systems models and toxicity pathways data for informing chemical grouping schemes based upon common mode of action. The SAB and BOSC also support the inclusion of both chemical and non-chemical stressors (e.g. socioeconomic factors).

It is recommended that the CSS Research Action Plan more clearly state the emphasis on ecosystems research.

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The CSS Strategic Research Action Plan identifies many contributions to sustainability. These contributions include, but are not limited to, the following:

- The use of high throughput, predictive toxicology approaches to inform Green Chemical Design, thus supporting the production of newer chemicals with more sustainable characteristics (e.g. reduced intrinsic hazards, less energy-consumptive, more biodegradable);
- New assessment approaches that consider product life cycles (cradle to grave) to enable protection against not only the chemical itself, but its environmental degradation products and unique types of exposures that might occur during different phases of the product's life cycle;
- Research to understand life stage variability to help enhance protection of sensitive age-specific subpopulations;
- Development of more holistic ecosystems-based approaches to ensure more integrated, "one environment" safety assessments;
- The use of systems approaches to transform chemical safety assessment from a series of isolated tests to a much more integrated and quite likely, more efficient and cost-effective enterprise; and
- "Extrapolation" approaches to link different levels of biological organization.

As previously emphasized by the SAB and BOSC (U.S. EPA SAB 2011a), it is highly recommended that specific metrics be created to measure the contributions to sustainability derived from the CSS program. The SAB and BOSC also recommend that ORD take care, when describing CSS research and its deliverables, to demonstrate how the research impacts upon end users (e.g. risk managers, policy makers) and how it brings value for informing decisions.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Within the CSS program, the SAB and BOSC recommend that ORD increasingly utilize the Adverse Outcome Pathway concept, which covers the span from chemical exposure all the way through the observation of adverse outcomes, including interactions at all levels of biological organization in humans and wildlife, as it is an inherently integrative process in itself. One example is the Duluth lab's project on vitellogenin, which linked the pathway all the way to population level changes.
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3.2.2. Program –specific questions

Endocrine disrupting chemicals, nanotechnology, and computational toxicology

Is the CSS program well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research?

ORD is not only well positioned, but often *uniquely* positioned to support needs in all three areas. In particular, the key partnerships and linkages being established will be extremely helpful. That said, a number of specific suggestions for each of the three key areas are noted below.

Endocrine disrupting chemicals. The SAB and BOSC strongly encourage the CSS program's transition Endocrine Disruptors Screening Program (EDSP), which is extremely cost-, time- and animal-intensive, to an "EDSP21" that relies more heavily on higher throughput methods. There are many challenges associated with a shift from animal-based to high throughput endocrine screening methods, but it is important that ORD address these issues in a direct, objective manner. In the context of the larger movement toward toxicity pathways-based testing, the current suite of pathways falling under the umbrella of the current EDSP program is actually fairly limited (i.e. estrogen, androgen and thyroid). There are numerous other toxicity pathways constituting the complete suite of pathways that warrant evaluation in a comprehensive, high throughput screening program. Therefore, the knowledge gained toward transitioning endocrine screening from its current form to an EDSP21 version will undoubtedly inform similar efforts with other toxicity pathways and thus support future efforts to create an entirely new paradigm of safety assessment.

Nanotechnology. Related to the theme of inherency, which involves research to understand the relationship between inherent physicochemical properties (e.g. mass, conductivity, reactivity, heat of combustion) of a chemical; fate and effects; and human and wildlife health outcomes after chemical exposure, the SAB and BOSC suggest that the plan clarify whether nanomaterials will be compared to the bulk form of the chemical, as well as to environmental transformation products. Clarification as to whether the CSS program will have the appropriate models (e.g. in vivo models, fate and transport models) should be included.

Because nanotechnology is such a large field, ORD's unique roles and anticipated contributions should be clearly articulated to demonstrate differences from those of other research organizations. In other words, CSS should specify the program's niche in the larger world of nanotechnology research.

Computational toxicology. Many new tools are already being generated by the CSS program. However, the plan says little about both the intended transparency of the process and the approach that will be used to "qualify" (i.e. validate is a term used in other circles, but was thought to be less appropriate in this case) these new tools for their intended purposes. The transparency and qualification processes are critical to win the confidence of a multitude of stakeholders within and outside the agency, many of whom are not at all comfortable with these radically new and different methods. Therefore, the SAB and BOSC recommend that the plan describe its proposed approach for transparency and qualification of new tools and that this proposed approach be presented for review by the BOSC. The SAB and BOSC

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The process of developing the tools??

also note that the SAB is developing a report aimed at providing further advice to assist the EPA in advancing the application of ORD's computational toxicology research for hazard screening and risk assessment.

The CSS program is leading a transition from descriptive, effects-based safety assessment schemes to new testing paradigms that predict toxicity based on evaluation of cellular/molecular control pathways. Essentially these pathways are homeostatic control circuits that allow organisms to cope with a constantly changing environment. Adverse outcomes generally result only when the capacity of these homeostatic control systems is breached. Further, many pathways can produce different phenotypic outcomes depending on the context in which they are activated. Therefore, in order to interpret data from toxicity pathway-based assessments, there is a fundamental need to define the normal range of intra- and inter-individual variation in these pathways, understand the context in which these pathways are activated and distinguish changes that are adaptive vs. those that overwhelm homeostasis leading to adverse outcomes. This should involve both experimental and computational efforts.

The new computational toxicology tools being developed by the CSS program will most likely be inserted as components of larger, tiered testing frameworks, with high throughput methods comprising initial tiers, followed by more targeted testing, typically in animal models. The SAB and BOSC recommend that the Strategic Research Action Plan address how the computational toxicology program will dovetail with higher tier targeted testing, describing how targeted testing in animals can fill critical gaps and current limitations of computational methods (e.g. complex cell and organ level interactions, toxicokinetics and determination of dose to the target site). ORD is uniquely positioned to accomplish this integration of computational methods with targeted testing by virtue of two of its world renowned laboratories located in close proximity to one another: the National Center for Computational Toxicology and the National Heath and Environmental Effects Research Laboratory, both located on the Research Triangle Park campus. It is also suggested the CSS program work with the National Toxicology Program (also on the same campus) to suggest types of data that could be generated by National Toxicology Program in order to strengthen bridges between animal-based and computational safety assessment methods.

SAB and BOSC strongly encourage the computational toxicology program to place greater emphasis on toxicokinetics (absorption, distribution, metabolism and elimination) and physiologically-based pharmacokinetic models as these factors are major determinants of toxicity. Some effort has been made in the CSS program towards developing and applying higher-throughput methods for measuring parent chemical metabolic clearance and plasma protein binding, but additional effort (both experimental and computational) need to be made towards estimating volume of distribution/partition coefficients, renal excretion, bioavailability, and what metabolites are generated. Incorporation of these determinants is central to the determination of risk. In the absence of toxicokinetic understanding, risks will be both over- and underestimated for large numbers of chemicals.

Exposure research

How well has the exposure component of the CSS research program progressed since its inception?

Response to this charge question was addressed earlier under the question related to "research activities planned for FY 13 in section 3.2.1.

3.2.3. Major recommendations for the CSS program

General

- Clearly demonstrate how CSS research impacts upon end users (e.g. risk managers, policy makers) and how it brings value for informing decisions.
- Increase focus on the refinement and validation of proximal and consumer exposure models, which include both external and internal dosimetry.

Endocrine Disrupting Chemicals

- In the effort to transition toward EDSP21, place greater attention on the challenges involved in using reductionist approaches (e.g. ToxCast) in evaluating highly integrated physiological networks, such as the endocrine system.
- Frame the research on EDSP21 as a precedent for addressing analogous challenges for evaluating other complex integrated biological systems (e.g. nervous system).

Nanomaterials

- Define ORD's unique niche within the broader landscape of nanotechnology research.

Computational Toxicology

- Clearly and transparently describe the proposed approach for qualification of new computational toxicology tools for their intended purpose, and present to BOSC for review.
- Define the normal range of intra- and inter-individual variation in biological control pathways in order to distinguish between adaptive vs. adverse changes.
- Address how the program will dovetail with higher tier targeted testing.
- Place greater emphasis on integration of toxicokinetics (ADME) and physiologically-based pharmacokinetic models.

3.3. Human Health Risk Assessment

The Strategic Research Action Plan for the Human Health Risk Assessment (HHRA) program articulates the following vision for the program: "The Agency will generate timely, credible human health risk assessments to support all priority Agency risk management decisions, thereby enabling the Agency to better predict and prevent risk." Given this vision, ORD should consider the critical place of risk assessment in the overall activities of the EPA and how to best integrate HHRA's thematic tasks to maximize application, problem scoping and management to support all of the research programs in ORD. Risk assessment represents a methodological foundation for activities of multiple research programs and it should not be placed in a siloed fashion into a single plan. Various reports, from the SAB, the National Research Council, and other bodies, have urged improvements to approaches to risk assessment. ORD has already made significant steps towards implementing some of those recommended improvements, but a more cohesive approach to risk assessment could be taken across the six research areas. Figure 4 in the HHRA Strategic Research Action Plan, which describes the interrelationships

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among the six programs, does not adequately capture the underpinning and broad translational role of risk assessment within the EPA.

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The present plan provides a straightforward description of activities within its four themes [Integrated Risk Information System (IRIS) health hazard and dose-response assessments; Integrated Science Assessments (ISAs) of criteria air pollutants; Community Risk and Technical Support (CRTS) for exposure and health assessments; and Modernizing Risk Assessment Methods], but it neither provides a strong overall vision nor identifies points for synergism across the four components. At this point, the four themes have certain commonalities and their merger into a single program is reflective of these cross-cutting elements, particularly the reliance on the quantitative methods of risk assessment. These limitations of the current plan are well recognized by the HHRA leadership and scientists and there is intent to address them.

The EPA and the HHRA staff have substantial expertise in the methods of risk assessment and their application. With an extensive portfolio of risk assessment activities, the HHRA program provides a platform for carrying out applied research to develop risk assessment methods, and the SAB and BOSC recommend that the leadership of the HHRA pro-actively utilize this opportunity to advance the risk sciences. An agenda of research should be maintained that builds strategically on this opportunity and attention given to assuring that such methodological research is not set aside.

The EPA should carefully examine the placement and support for the risk sciences within the agency to assure that there is sufficient integration and intellectual exchange among risk scientists. The EPA's Risk Assessment Forum provides a platform for discussing specific issues, but perhaps a venue is needed for broader discussion, exchange and collaboration among risk scientists

3.3.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The ORD research programs appear to be progressing very well in the first year of implementation. However, the SAB and BOSC noted that it is early to evaluate the trajectory of progress, and that much remains to be done in the coming years. There is an inherent tension and competition within the program between the need to produce various assessments in a timely fashion and the need to incorporate strategies based in "new and emerging" science into its activities. ORD should explicitly acknowledge this inherent tension and consider it in setting benchmarks for the program.

The Strategic Research Action Plan provides a straightforward description of activities within its four themes. The research activities planned for FY 13 and future years seem appropriate for answering the science questions in the plan. There are potential challenges that may interfere with the planned agenda over the longer-term. One is the already mentioned trade-off between the demands of producing timely assessment while assuring that methodological research continues. In addition, resource limitations and

recent unfunded mandates placed on ORD may constrain efforts to carry out this ambitious set of research activities. Decisions about what to prioritize and what to omit will be challenging and should be made only after the overall vision has been further developed.

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Considering the linkage between the HHRA program and decision making, it is important to remember the importance of the exposure sciences, which are not sufficiently reflected in the Strategic Research Action Plan. The upcoming report from the National Research Council on the exposure sciences is likely to increase attention to this area and provide prioritized research needs. The discussion of exposure sciences should be expanded beyond the brief discussion in Theme 3 (Community Risk and Technical Support) in the plan. All HHRA assessments will benefit substantially from state-of-the-art exposure data and methods. The HHRA program will also benefit from enhanced ties to the ecological risk assessment community.

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The HHRA plan did not contain any specific mention of sustainability, yet this apparent omission does not reflect omission of sustainability from the program's actual mission. The contributions made by the HHRA program in advancing the science underlying the National Ambient Air Quality Standards have driven major air quality improvements nationwide that further sustainability goals. Similarly, the role of the HHRA program in producing high-quality risk assessments (in the IRIS program) and rapid risk assessments (i.e. Provisional Peer Reviewed Toxicity Values) contributes to the goal of identifying and controlling health risks from toxic chemicals and developing new tools to predict chemical risk and to further green chemistry. Finally, efforts to develop and improve the ability to identify and measure cumulative risks can help advance environmental justice and community sustainability.

The SAB and BOSC recommend that the HHRA program more clearly and explicitly communicate its significant contributions to sustainability. Furthermore, the HHRA program's efforts to train risk assessors in state-of-the-art methods and approaches through the Risk Assessment Training and Experience program, which provides comprehensive risk assessment guidance and training, will ensure future contributions to sustainability.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

ORD will need to think and act creatively to deal with the likelihood of reduced budgets, while at the same time addressing requests for assistance from various programs and from an increasingly informed public. In addition, the release of the three groundbreaking National Research Council (NRC) report (NRC 2007, 2008 2009) provides an agenda and an impetus for the EPA to transform its overall

approach to risk assessment. This transformation needs to occur in parallel with the ongoing production of individual risk assessments, since there is a continuing need to provide the most credible possible risk numbers for decision makers. ORD needs to build capacity to incorporate the new toxicology data into a new risk assessment approach.

In addition to more careful coordination and priority setting with the CSS program, ORD has several other options for leveraging available resources. For example, ORD might consider the development of cooperative agreements with outside parties via the Federal Technology Transfer Act (FTTA). This act specifically allows for external funding to be put into the agency in the pursuit of technology developed by the EPA, such as technology developed on emerging issues and/or issues related to sustainability. ORD might also link more directly with other federal agencies, such as the Agency for Toxic Substances and Disease Registry (ATSDR), which has a similar mission for hazard identification and dose-response assessment. For example, ORD might consider jointly developing Provisional Peer Reviewed Toxicity Values and Minimal Risk Levels with ATSDR. Moreover, if ORD has found its current collaboration around toxicity assessment with California to be helpful, ORD could partner with other outside parties, such as the State of Minnesota, National Science Foundation International, or even other governments that also conduct similar hazard identification and dose-response assessment work. Of course, ORD would be well served to work even more closely with existing groups within the agency, such as the EPA's Office of Water or its Office of Pesticides Program for developing dose-response assessment values. As examples, adding recent Office of Pesticides Program risk assessment values or updating older pesticide values would be a valuable addition/update to IRIS.

ORD could also respond to this likelihood of reduced budgets by addressing emerging problems through the use of newer tools, such as high throughput assays, that have the promise of high-quality and abundant data at reasonable cost. These approaches should be assessed and pursued for use by HHRA in order to improve, streamline and make the present assessment programs more cost effective. Demonstration of these emerging tools and early feedback on them would serve to improve their utility, efficacy, and acceptance. Another advantage in the use of these emerging tools is that they have the potential to expedite the overall assessment.

In addition, ORD might consider active partnerships with other entities in order to build opportunities to use high throughput testing and new observational epidemiology studies based in established cohorts. There are several advantages of these approaches including the reduced use of experimental animals, the direct use of human studies and the ready application of high throughput testing.

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Furthermore, ORD should consider producing screening risk levels for chemicals, similar to the established Thresholds of Toxicology Concern or the developing concept of Conditional Toxicity Value. The Thresholds of Toxicology Concern approach is well established for food contaminants and is being actively studied for applicability to other environmental media. The Conditional Toxicity Value approach is more innovative in that it incorporates consideration of new toxicity testing methods. Both approaches would support the establishment of interim risk values for many chemicals of concern. These values could then be used to guide risk management until additional chemical-specific data become available. If ORD decides to take this approach, then linkages with other agencies or organizations with interest in these methods will be particularly helpful.

ORD should consider incorporating shorter-term testing to improve the basis of its risk assessments, as long as time lines for the risk assessment are not unduly lengthy, and the delay is not associated with remediable, ongoing human exposures and potentially significant human health or ecological risk. ORD should also consider how to prioritize within themes 3 and 4 of its research plan, given the possibility of limited resources.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Much of the work of HHRA focuses upon mandated activity and is highly task-oriented. Because of the large amount of mandated work and because HHRA outputs (e.g. IRIS) provide the hazard identification and dose-response assessment basis, in part, for the regulatory and advisory work of the EPA, integration efforts should be prioritized carefully so as not to impose unnecessary burdens (undue time and effort) that could detract from core activities.

Nevertheless there were a number of research topics identified for which there is high need or potential for integration/collaboration between HHRA and the other programs. The SAB and BOSC recommend that cross-program collaboration between CSS and HHRA be emphasized more strongly in the Strategic Research Action Plans for the two programs. While cross- program integration is proposed, the relevant agendas within these two programs are largely separated and the basis for selecting outputs and priority setting is not clear. Even across themes within HHRA there is not adequate connection and synergy. For example, transparent evidence synthesis is integral to both the IRIS Program and the development of the ISAs, but this connection is not made. The SAB and BOSC recommend that ORD revise the CSS and HHRA documents so that they more clearly communicate the inter-related science and research priorities for these two programs.

The areas of children's health and of the health and exposures of other sensitive and vulnerable subgroups require a high level of integration across all ORD research programs. The HHRA Strategic Research Action Plan should identify key gaps between research outputs and assessment needs so that ORD can focus research to address the needed integrative models in the areas of exposure assessment, computational toxicity, developmental toxicity, *in vivo* effects, animal data, mechanistic models and pathway analysis. The HHRA activities can provide multiple reference doses, including short-term duration doses, specifically suitable for evaluating windows of vulnerability to high exposure. HHRA assessments should also identify populations that may face greater risks due to genetic or other factors and should quantify these risks, using the new possibilities afforded by advances in genetics and exposure assessment. There is need for integration of HHRA into various rapid risk assessment processes (e.g. in conjunction with Homeland Security research program), when there are needs for assessment of chemo-toxicity of short-term exposures and for the development of Provisional Advisory Levels. HHRA would also benefit from interaction with the EPA's Office of Toxic Substances, and specifically in its development of Acute Exposure Guideline Levels.

ORD should monitor for topics that are candidates for integrated efforts and ORD should have approaches in place for initiating integrative activities and giving them appropriate priority. Very importantly, when new issues requiring integration arise within HHRA all ORD programs should be notified, since there may be interests in the same topics from researchers in other ORD research programs. Additionally, HHRA, as for other programs, would benefit from the integration of social, behavioral and decision scientists into the activities related to risk assessment methodology in support of decision-making. The SAB and BOSC recommendation in 2011 (U.S. EPA 2011) regarding the importance of integrating social, behavioral, and decision science remains relevant.

Innovation

> *How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?*

Beyond the findings and recommendations provided in section 2.5 above, there are opportunities for innovation to help "reinvent" the IRIS program by: 1) substantially shortening and streamlining the documents to make them easier to use and to review; 2) incorporating Tox21 data, initially in qualitative discussions, then in parallel with traditional toxicology data, and ultimately, as appropriate, as part of critical pathway-based extrapolations; and 3) incorporating the key recent NRC recommendations (NRC 2009) with a particular focus on grappling with cumulative risk, making implicit default assumptions more explicit, improving characterization of uncertainty, and not assuming that the dose-response for all non-carcinogens includes a threshold. These points are all reflected in the HHRA Strategic Research Action Plan but are not described as clearly as they could be.

3.3.2. Program –specific questions

Modernizing methods

> *What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods (e.g. in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)? Additionally, what approaches can be envisioned to enhance risk managers' understanding, use and acceptance of these new methods?*

The SAB and BOSC recommend that ORD begin, as soon as possible, to implement and integrate new types of data and methods into risk assessments. New methods may be used in qualitative if not quantitative ways in such ORD products as Provisional Peer Reviewed Toxicity Values derived for the EPA's Superfund programs and IRIS reviews. The HHRA program has begun to consider "omics" data (e.g. genomics, proteomics, and metabolomics) and NRC-recommended innovations (NRC 2009) in IRIS and other risk assessments. ORD should continue to integrate this information as quickly and effectively as possible as one way to ensure that risk assessors and risk managers become familiar with new types of data and methods and recognize the utility of the new information. Each upcoming IRIS

assessment for which the chemical has undergone testing under the Tox21 regime should at least present the data and incorporate it into a qualitative discussion.

In regard to the variability and uncertainty that may be associated with these new methods, the SAB and BOSC recommend that HHRA incorporate new data and new approaches as they become available and characterize the uncertainty and variability associated with each research result in a transparent manner. As more data become available and methods are tested further, a component of this work should include comparing traditional and non- traditional approaches to evaluate the outcome of using new methods. The data and methods might be helpful in analyzing uncertainty as well.

New methods or approaches are considered widely acceptable when well respected and influential risk assessment programs, including those outside of ORD and those in other agencies, incorporate new approaches in a consistent manner. New approaches and new data will gain greater acceptance by risk assessors and managers if ORD works with multiple EPA programs and other agencies to gain consensus on the use of data and methods. Consensus on each risk assessment is not needed (e.g. the Minimum Risk Levels produced by ATSDR need not match the IRIS reference doses produced by the EPA), but consensus should be achieved on recommended methods, approaches, and to the extent possible, application [e.g., Benchmark Dose (Lower Confidence Limit). methodology is now widely accepted, although different groups may calculate a different value]. Agreement within the risk assessment community on the utility of the new approaches will enhance their credibility with risk managers.

ORD should provide training and education tailored to the information needs and backgrounds of the agency risk managers as well as those outside the agency (risk assessors, risk managers, academia, and science advisors to the communities affected by risk management decisions). The HHRA program has already given this problem careful consideration by meeting with agency risk managers in a focus group venue to learn how risk managers receive and understand information about risk assessments. ORD has also described the Risk Assessment Training and Experience program and an outcome for training (FY15). ORD staff already influence peer scientists through offering, planning, and participating in symposia, workshops, and continuing education offerings at professional meetings. ORD is also hosting webinars and other remote learning opportunities. Many of these current activities are aimed not only at ORD scientists, but also peer scientists.

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Inside or outside the Agency?

While these ORD efforts are laudable, education efforts targeted to risk assessors and managers should be offered frequently and should focus on the new tools and methods in order to ensure that the understanding and acceptance by potential users evolves along with the work that is produced. An added advantage is that early training will provide ORD with timely feedback from stakeholders who may be struggling to implement new approaches. Suggestions for strengthening training activities include:

- Sustaining the development of risk assessment methods and their implementation into practice.
- Targeting innovators and influencers in various sectors (e.g. regional offices, state risk assessment programs, academia, science advisors from the non-profit sector, community leaders) for specific training;

- Optimizing training to match the background, experiences, and needs of change leaders;
- Developing coursework and ensuring it is taught in influential toxicology and exposure science academic training programs;
- Developing public health policy training through public health institutes;
- In-laboratory rotations targeting toxicologists and risk assessors unfamiliar with new technologies; and
- Sharing information about the Risk Assessment Training and Experience program (course content and focus, audience, and delivery) and implement it as early as possible.

Education and training are resource-intensive activities that require dedicated staffing and the support of management, and HHRA should be adding annual output goals in this area.

In regard to the second part of this charge question, which pertains to risk managers' understanding, acceptance and use of these new methods, the SAB and BOSC recommend that the HHRA program systematically study, perhaps through the use of decision science, the utility of the new data sources for decision making, and determine how evidence from new areas of investigation should be combined or presented along-side of more traditional methods of risk assessment. The SAB and BOSC recommend four key steps to enhance risk manager's understanding, use, and acceptance of the new data and methods that are being developed for implementation by HHRA (data such as high-throughput studies and methods such as recommendations by NRC 2009). The key steps include: 1) consistent adoption of new approaches across programs; 2) training and education; 3) immediate implementation of new methods, and 4) evaluating the incorporation of new methods into decision-making. It is clear that risk managers need to have information presented in ways that demarcate what is known from what is not known. Risk managers need information that characterizes uncertainty in a useful way. ORD should conduct research on how to combine results from the new lines of investigation with health risk data from "traditional" toxicity testing and epidemiology. The research should demonstrate the utility of these new data sources for decision-making, not only what risk managers understand about these approaches and how they may use them. ORD should consider involving decision-scientists to study the perceived utility and acceptance of findings by risk managers.

Peer review

> *How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?*

The SAB and BOSC reflected on the difficult balance between the essential role of peer review and the need for timeliness in producing risk assessments of public health importance. In some cases, repeated rounds of demand for peer review may be driven more by external factors rather than by actual limitations of the documents. In other cases, increasingly cumbersome, lengthy, and confusing EPA assessments have made the task of peer review more difficult than it needed to be, and have resulted in negative feedback to the agency. The SAB and BOSC applaud the commitments in the HHRA action

plan to produce more readable, shorter and well-organized IRIS assessments, and this shift should make the peer review process somewhat easier and more efficient in the future. Overall, the SAB and BOSC strongly support HHRA's commitment to the scientific integrity and quality of its HHRA risk assessments and acknowledge that the EPA has improved its responsiveness to peer review comments.

In recent risk assessments, EPA staff has stated its implementation of every suggestion made by peer reviewers. The SAB and BOSC recognize that difficult decisions sometimes arise, such as when a peer review recommends use of a different model or a new uncertainty analysis requiring extensive time and resources to produce and that would be unlikely to significantly change or improve the final assessment, or when there is a lack of consensus among peer reviewers. In such cases, the lack of a 'referee' for the peer review process places the agency in a difficult situation. The SAB and BOSC recommend that ORD consider creating a new role for an independent scientist to review the peer review comments and determine which should be given priority and when they have been adequately addressed. This type of role currently exists for peer review of reports of the National Academy of Sciences as well as for all scientific journals. In other words, there should be a transparent approach to triaging comments received in peer review and giving them priority so as to assure that the most critical revisions are made as efficiently as possible.

The level of peer review should be generally commensurate with the complexity and importance of the document, and with the time-urgency of the assessment, which is the current practice of the HHRA. For example, Provisional Peer Reviewed Toxicity Values -type assessments appropriately undergo a lesser level of peer review than IRIS assessments, and the degree of review accorded an IRIS assessment varies according to its importance. However, in a few cases, additional mandated reviews have created a highly significant strain on the budget and unusual delays. There is concern about how recent mandates may impair the ability of the HHRA program to achieve its goals and objectives in the coming fiscal year. Budget cuts should not impair efforts to incorporate the new scientific data and methods, as these new methods have the potential to ultimately help improve efficiency and better protect public health by allowing screening-level assessments on many more chemicals than can be addressed today.

The agency should have the overall goal of providing its assessments in a timely way. This goal has not always been met, particularly for the IRIS assessments and the past Criteria Documents. More recently, the agency has been completing the peer review of the ISAs in a timely fashion, in part because of court-ordered deadlines. Additionally, the switch from the Criteria Document to the ISA format has led to more synthetic and transparent documents that can be more readily reviewed.

Toxicology reviews, reference doses, and cancer slope factors are extremely important to programs across the EPA and in environmental and public health actions carried out across the country. It is possible that the reforms already being implemented in the IRIS program that lead to greater transparency and stakeholder involvement early in the review process will result in less onerous peer reviews. EPA will be able to address more concerns more directly during the review and stakeholders can target their comments more effectively in a peer review.

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Does it mean "EPA has stated the difficulty of implementing every suggestion"???

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How independent? Inside or outside the agency?

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What is the reference here?

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3.3.3. Major recommendations for the HHRA program

- The EPA should broadly examine the placement of risk assessment activities within the agency and seek to establish connections and integration that will foster ongoing enhancement of methodology.
- The HHRA leadership needs to elaborate a strategic vision that enhances linkages among the thematic areas of the HHRA and with the other research programs and that emphasizes the way that the HHRA program contributes to sustainability.
- A widely reaching plan is needed for incorporating data from emerging technologies, e.g. "omics" and high throughput testing, into EPA risk assessment approaches and for evaluating the utility of these new types of data for decision-making.
- While progress by HHRA has been on pace during its first year, the agenda needs to be set for the longer-term with priorities given to the most critical topics for decision-making, particularly as resources may decline.
- Exposure sciences need greater emphasis within the activities of the HHRA.
- Integration of HHRA approaches with those of other EPA groups would lead to greater efficiency and harmonization of approaches.
- The addition of further social, behavioral, and decision scientists to HHRA would benefit many of its activities and enhance integration.
- Sustained efforts are needed to assure that scientists with HHRA and elsewhere in EPA and decision-makers are fully versed in the latest risk assessment approaches and the interpretation and application of their findings.
- EPA risk managers should also be educated in the new data and approaches in risk assessment, so they feel more confident in the future basing decisions on these approaches.
- Peer reviews of HHRA products could be made more efficient. The plans for changes in the IRIS assessments should benefit peer review. Additionally, the intensity of peer review should reflect the complexity and importance of the product. For extensive peer reviews, it is important to evaluate and improve the process to triage comments so that effort is directed at the points of criticism that are most important and that have significant implications for overall risk estimates and decision-making. A transparent process would be helpful for this purpose, potentially involving an independent referee.

3.4. <u>Safe and Sustainable Water Resources</u>

The Safe and Sustainable Water Resources (SSWR) Strategic Research Action Plan identifies the following vision for the program: uses an integrated, systems approach to research for the identification and development of the scientific, technological and behavioral innovations needed to ensure clean, adequate, and equitable supplies of water that support human well-being and resilient aquatic ecosystems.

3.4.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The SAB and BOSC finds that research activities planned for FY 13 and future years are appropriate for answering the science questions in the SSWR Strategic Research Action Plan and that ORD's planned research activities for FY13 align appropriately with the overall research goals of the program. ORD's progress in implementing the SSWR research program is commendable and the priorities in identifying planned activities within the plan are well balanced.

The SSWR implementation plan includes specific tasks and milestones. In some cases ORD has all deliverables scheduled in 2017 for the completion of a task. This makes it difficult to assess the rate of progress that EPA is making towards completion of the task. While the SAB and BOSC understand that the implementation plan is in development, the EPA should consider including a more detailed timeline with deliverables for planned activities with specific milestones and/or intermediate deliverables. This would assist reviewers in better understanding the anticipated rate of the EPA's progress towards achieving its longer-term goals and plans.

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The SSWR Strategic Research Action Plan appropriately incorporates sustainability and greatly improved how ORD integrates sustainability into its long-term research planning. Sustainability, however, is a far reaching goal, and much of the progress towards achieving a sustainable society lies outside of EPA's purview. The SAB and BOSC recommend that EPA further clarify the agency's focus vs. the focus of other agencies regarding SSWR sustainability-related research. Such clarification will facilitate that partnering and leveraging efforts and activities of others, a critically important activity.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

There are a number of immediate, basic SSWR research needs, such as in the areas of storm water management, microbial contamination of coastal waters and aging water and wastewater infrastructure. As research budgets are reduced, research toward these immediate research needs will necessarily take a larger portion of EPA's SSWR research budget. Many states have a tight budget for protection of water quality. They rely heavily on EPA for research outputs on SSWR high-priority topics. Shrinking budgets

will make it more difficult to prioritize research on emerging water quality issues. Prioritization of emerging issues will be needed.

The SAB and BOSC note that some stakeholder communities and groups will favor prioritization of SSWR research that differs from EPA priorities. EPA should consider the magnitude and distribution of risks associated with not pursuing emerging SSWR research issues that could benefit certain communities such as environmental justice communities. The SAB and BOSC recommend that EPA transparently communicate its efforts to prioritize research and engage with communities when developing SSWR research priorities. Partnering with other federal agencies would help leverage shrinking research dollars.

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Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

ORD should enhance its internal and external communication efforts relating to SSWR and provide more opportunities for formal exchange of research information. EPA currently provides opportunities for communication among research programs through its monthly SWAQ (Subcommittee on Water Availability and Quality) teleconference calls that discuss current agency research, and its periodic half-day meetings of ORD National Program Directors to discuss research and budget priorities. The SAB and BOSC recommend that ORD identify and assess the adequacy of existing formal mechanisms for sharing research information internally and among other agencies (e.g. Department of Energy, National Oceanic and Atmospheric Administration, U.S. Geological Survey, U.S. Department of Agriculture and others), identify barriers associated with such mechanisms (e.g. culture differences between agencies, lack of an inventory of federal environmental research), and take leadership in improving and developing new mechanisms where appropriate.

3.4.2. Program –specific questions

Nitrogen research gaps

ORD has integrated programmatic research, with EPA Program Office input, to begin developing a strategic nutrient management plan for the nation with the intent of accomplishing the SAB's recommended goal to reduce reactive nitrogen by 25 percent. Are there research gaps that would impede accomplishing this goal? (For example, should we be looking at green infrastructure for removing nutrients as well as for controlling storm water?)

There are several potential gaps in the EPA's nutrient research plan. The EPA should invest more in assessing use of market mechanisms for nutrient control, i.e. "nutrient trading," including evaluation of programs that have been initiated in the U.S. and elsewhere. The EPA should also identify metrics for nutrient management, which will govern the direction of actions by the EPA and other federal agencies, state agencies, companies, nongovernmental organizations, and individuals (e.g. metrics that consider financial impacts vs. amount of nitrogen released). The EPA should be engaged with and knowledgeable

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about research on mechanisms and forms of nutrient delivery in agriculture. Application of fertilizers consisting of highly soluble nitrogen-bearing salts is at the core of much of the nitrogen management problem. The EPA should not necessarily be conducting much research itself in nutrient delivery, but should be engaged with those doing such research and motivating advances in this research.

The SAB and BOSC also conclude that ORD should identify and seek opportunities for leveraging limited research dollars and manpower with other federal agencies, and utilize ORD's strengths in areas such as monitoring, data analysis, and modeling within such leveraged efforts. A few potentially significant leveraging opportunities include the U.S. Department of Agriculture's Natural Resource Conservation Service Mississippi River Basin Initiative; the Chesapeake Bay Program's modeling, monitoring, and trading activities; the National Science Foundation's multi-nation request for proposals due on February 1, 2013 entitled "Nitrogen: Improving on Nature[1]" and with private industry. In addition, the SAB and BOSC identified several opportunities for innovation, including mechanisms and forms of nutrient delivery and improvements in nitrogen monitoring instrumentation. Innovative improvements in monitoring toward more robust, less expensive, and portable instruments would be of great value to the EPA Office of Water, U.S. Geological Survey, state agencies, and others, and could be achieved in partnership with the private sector and universities, e.g. through open innovation competitions, and the Small Business Innovation Research program. To encourage innovation, the SAB and BOSC recommend that EPA leverage efforts of others, conduct outreach and broadly engage the public and other federal agencies, and conduct competitions that solicit innovative approaches in target areas.

Natural Infrastructure

> *To better accomplish our goal of using a variety of approaches to address stormwater issues, should EPA also consider incorporating natural infrastructure into research on constructed green and gray infrastructure?*

ORD should incorporate natural infrastructure into its infrastructure research, and take a leadership role in conducting green infrastructure research. The SAB and BOSC recommends that ORD inventory best practices and innovation activities across the United States to identify who's doing what now in green infrastructure. ORD engagement with and support of the storm water research initiatives of the Water Environment Research Foundation is appropriate and commendable, but ORD should do more to be recognized as a leader in storm water research. Additional partners may include the U.S. Department of Agriculture; the Environmental and Water Resources Institute of American Society of Civil Engineers; architectural, engineering, and landscape architectural companies and associations; universities; organizers of the North American Storm Water Conference and Exposition[2];, and other organizations to assess lessons learned on this topic. Innovative solutions in storm water management are being developed in cities such as Chicago, Philadelphia, and Atlanta. Some communities have struck out on their own to investigate innovative options for storm water retention in urban watersheds, since technical leadership from ORD on this topic is limited. Much can be learned from these activities. The SAB and BOSC encourage ORD to develop tools to encourage (and improve) how states help communities

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[1] See http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=504773 (accessed 08/16/12)
[2] See http://www.stormcon.com/ (accessed 08/16/12)

address Combined Sewer Overflow consent order requirements in innovative ways. ORD should also examine the NRC's recommendations (NRC 2008) for regulation and research needs on storm water monitoring and modeling. ORD should also support competitions that solicit innovation in these areas.

3.4.3. Major recommendations for the SSWR program

- ORD should include specific tasks and milestones in the SSWR Strategic Research Action Plan.
- ORD should further clarify what is the agency's focus vs. the focus of other agencies regarding SSWR sustainability-related research.
- As research budgets are reduced, research toward immediate, basic SSWR research needs will necessarily take a larger portion of EPA's SSWR research budget.
- ORD should develop a structured way to assess emerging issues in establishing priorities for SSWR research.
- ORD should consider the magnitude and distribution of risks associated with not pursuing emerging SSWR research issues that could benefit certain communities such as environmental justice communities.
- ORD should transparently communicate its efforts to prioritize research, and engage with communities and conduct outreach when developing SSWR research priorities.
- EPA should invest more in assessing use of market mechanisms for nutrient control, and identify metrics for nutrient management.
- ORD should be engaged with and knowledgeable about research on mechanisms and forms of nutrient delivery in agriculture.
- ORD should identify and seek opportunities for leveraging research with other federal agencies, and utilize EPA's strengths in areas such as monitoring, data analysis, and modeling within such leveraged efforts.
- ORD should assess and encourage opportunities for innovation in nutrient research.
- ORD should take a leadership role in conducting green infrastructure research, and incorporate natural infrastructure into its SSWR research.
- ORD should inventory best practices and innovation activities, and seek partnership opportunities to assess lessons learned related to green infrastructure.
- ORD should develop tools to encourage/improve how states help communities address Combined Sewer Overflow consent order requirements.
- ORD should support competitions that solicit innovation in storm water monitoring and modeling.

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3.5. <u>Homeland Security</u>

The Strategic Research Action Plan for ORD's Homeland Security Research Program (HSRP) states that the program was established "to conduct applied research and provide technical support that increases the capability of EPA to achieve its homeland security responsibilities. The HSRP helps build systems-based solutions by working with agency partners to plan, implement and deliver useful science and technology products." Its role is to help address key science gaps that relate to EPA's homeland security role, which has three parts: helping to protect water systems from attack, assisting water utilities

to build contamination warning and mitigation systems, and leading remediation of contaminated indoor and outdoor settings and water infrastructure.

3.5.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

HSRP has been transdisciplinary with an extensive portfolio of external partners since 2002. In retrospect, the current ORD reorganization mimics much of what HSRP has been doing for a decade. The immediate opportunity is for HSRP and ORD to better integrate internally. National program directors meet regularly to discuss integration issues, and should be encouraged to implement best practices found in any other industry or agency. HSRP is highly accountable and has provided a large number of successfully delivered products for its clients each year (80 in FY 2012).

A sophisticated system exists for partner agreements, timeline adherence, delivering useful products, and client follow-up – a cradle-to-grave approach to project management. Partner needs assessment is a key initial step and continues through to product delivery. The SAB and BOSC find little reason for concern regarding progress to date, based upon the information available. However, the ORD restructuring process is relatively new and a better template is needed for measuring progress. For future reviews, ORD should consider developing metrics for measuring progress and success at project conception. The HRSP should develop a set of metrics to evaluate progress to be reviewed by the SAB and BOSC.

Over the past decade, the HSRP has developed a substantial pipeline of research activities and products. The pipelines of products are developed in partnership with their customers. As a result, HSRP has an excellent focus on specific client needs. It may be helpful for HSRP to capture their client's assessment of their work quality through a customer satisfaction survey.

A tri-agency agreement among the EPA, Department of Defense and the Department of Homeland Security is in place, HSRP has high-quality collaborations with the Centers for Disease Control and other agencies. The planned activities are indeed appropriate for answering the science questions in the Science Research Action Plan.

Although it is encouraging to see long-range planning in the Strategic Research Action Plan, the SAB and BOSC are concerned about the HSRP's maintaining its product stream with diminishing resources. One of the major questions is how will resources be allocated in the future to assure that the major outcomes will be achieved in the desired timeframe. A major opportunity exists for better communication about the broad applicability of HSRP products and expertise; the value proposition to stake-holders; and marketing HSRP expertise to additional partners to increase resource leveraging.

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Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

HSRP has done a very good job of striving to advance sustainability. HSRP is at the core of community sustainability, as defined by the concepts of resilient societies, economies, and the environment. Prevention, mitigation, recovery and emergency responses are core thrusts for HSRP. Its research products and capabilities are highly relevant to sustainability. HSRP products will improve the capacity of communities to recover from not only acts of terrorism, but also the consequences of natural disasters (see response section 3.5.2).

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Maybe say "made serious efforts to advance sustainability, but more should be done"

Commented [E40]: What about the area of resilience? Has the HSRP invested in this and should it? Came up during the July discussions

The HSRP portfolio includes projects such as self-cleaning water treatment facilities and the safe building program, which focus on improving sustainability. Other notable approaches include green chemistry, (e.g. remediation with fewer adverse effects – Enzymatic Decontamination of Chemical Warfare Agents.) A major opportunity exists for HSRP to expand its impact by identifying multiple benefits for its products.

The HSRP could enhance its efforts by investing in the development of future human resources through increasing HSRP's participation in fellowship opportunities such as the American Academy of Arts and Sciences and Science to Achieve Results fellowship programs. As senior ORD scientists retire over the next five years, it would be advantageous for HSRP to increase the number of new post docs and fellows who can assist in developing the new research programs that advance sustainability in HSRP.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

The HSRP process of client needs assessment provides an excellent mechanism for delivering responsive products. The HRSP provides a great example of an applied research culture, where an established network of relationships helps achieve balance between commitments to clients and advancement of science on emerging issues. HRSP should seek out projects with one-to-three-year windows. In addition, HRSP is acclimating well to the culture of innovation. Numerous HSRP projects were included in the Pathfinder Innovation Program.

Commented [E41]: What is this - jargon

Commented [E42]: How?

3.5.2. Program –specific questions

The HSRP has conducted research primary to support EPA homeland security mission, i.e. response to acts of terrorism. In 2011, the SAB and BOSC stated that "the program should consider expanding research and capabilities in relation to natural disasters…" What advice (e.g. strategic, tactical, structural) can the SAB give to guide the program toward this broader role?

The HSRP is a valuable national resource. An all-hazards approach, as recommended by the SAB and BOSC (U.S. EPA SAB 2011a), will further enhance HSRP's value. Current products should be assessed and mapped to the needs of potential new partners. HSRP is strongly encouraged to conduct research portfolio analysis ~~and road mapping to elucidate their current and future research needs.~~

Commented [E43]: What does the stricken language mean?>

Engagement with new partners could allow the partners to benefit from HSRP research capabilities; provide HSRP with ideas for novel research; and stimulate HRSP thinking in new directions. The phrase "natural disasters," as previously used, is not the full universe of events where HSRP expertise is essential. HSRP is already envisioning an all hazards approach. The national Wide Area Recovery and Resiliency Program, in which HSRP is a partner, is an example of an all hazards approach. The cause of a hazard is often not the critical determinant for the ensuing response. While the required technological response measures may be similar, the social responses often necessarily differ. Thus, the absence of social scientists at HSRP is a challenge, given the requirement to engage with diverse audiences, and ORD integration needs. HSRP could take advantage of American Academy of Arts and Sciences and Science to Achieve Results fellowship programs to develop and acquire social science expertise.

Commented [E44]: What about senior researcher/ Isn't there a stronger recommendation that can be made here?

The SAB and BOSC advised in 2011 that the HSRP should proceed with caution into delving into an all Hazards Approach due to their resource constraints. As stated earlier, analysis should be conducted to determine what products currently existing in HSRP could be applicable to other hazards, and these products should be prioritized. Based on the prioritization and their existing relationships with other agencies, HRSP should strive to build relationships with other federal agencies where there is synergy. The SAB and BOSC consider that the HSRP is in the best position to determine where this synergy exists and should be encourage to pursue pilot projects and efforts.

3.5.3. Major recommendations for the HSRP program

Commented [E45]: No major recommendations provided

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3.6. Sustainable and Healthy Communities

The Strategic Research Action Plan for the Sustainable and Healthy Communities (SHC) program identifies the following vision: The Sustainable and Healthy Communities Research Program will inform and empower decision-makers in communities, as well as in federal, state and tribal community-driven programs, to effectively and equitably weigh and integrate human health, socio-economic, environmental, and ecological factors into their decisions in a way that fosters community sustainability." The program has four major themes: 1) data and tools to support community decisions; 2) forecasting and assessing ecological and community health; 3) implementing near-term approaches to sustainable solutions; and 4) integrated solutions for sustainable outcomes.

3.6.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The SAB and BOSC recognize that developing and implementing the Strategic Research Action Plan for such a visionary program is not an easy task and requires major shifts in research direction and culture. The SAB and BOSC applaud what the SHC program has accomplished so far. Overall, the first three themes have made the most progress. The fourth theme will require more time, effort, and—importantly—focus to fully develop. Overall, the SAB and BOSC conclude that the SHC program is on the right track. The SAB and BOSC provide suggestions for strengthening the planned research activities in several important areas: integrating ecological and human health; inclusion of social, behavioral and decision sciences; distinguishing research from implementation; focusing the science questions and research; engaging communities and building partnerships; engaging communities and building partnerships; and building a typology of communities. The SAB and BOSC also identify blow a list of other issues that require ORD attention to further strengthen the program.

Integrating ecological and human health. In particular, the SAB and BOSC commend the program for bringing human health and ecological services together and recognizing this integration as a priority. Although this integration requires considerable effort, its importance makes it worthy of investment Digiulio and Benson 2002). Moreover, EPA is the one agency that is positioned to do this. There was some concern that the communication flow among the different layers of experts (e.g. ecosystem scientists and, human health scientist) was not at the level needed. The SAB recognized that communication and interaction are being attempted. The SAB encourages sustained efforts to promote interaction. The agency should outline the barriers to this integration and think creatively about strategies that might help to overcome them.

Challenges to integrating ecological & human health include:

- Measuring human health at the community scale. Privacy laws make it difficult to obtain fine-scale human health/safety data, which is often needed to link to ecosystem services. ORD is currently doing meta-analyses to try to get better fine-scale information. A current project based in New Bedford MA is an example where they are getting fine-scale ecological and human data.
- Funding, resources and time limitations
- A lack of expertise and critical mass for addressing these challenges (though webinars and meetings are helping the agency to build capacity)
- Entrenched disciplinary mindsets that will take time and effort to overcome.

Inclusion of social, behavioral and decision sciences. Social, behavioral and decision sciences are an essential component of the SHC program. Social, behavioral and decision sciences contribute to understanding human actions that drive environmental, social and economic change, the value of ecosystem services, development of decision-support tools, the design of policies, and the behavioral

Commented [E46]: Citation/

responses to policy changes. SHC has taken a step in the right direction but much work remains to be done. The SAB and BOSC were pleased with the recognition of the importance of integration and efforts to engage social, behavioral and decision scientists. The SAB and BOSC would like to see future efforts expanded.

Distinguishing research from implementation. Throughout the action plan, it was difficult to separate (a) research from implementation and (b) client from partner from community. These lines were gray. There was concern about mission creep with SHC moving into implementation. SHC is not in a position to implement environmental protection programs, both because of limited resources and because the fundamental mission of ORD is research. Implementation should be done by the regional offices, state environmental agencies or partner communities. Implementation is of fundamental importance but the question is who should be doing it. The SAB and BOSC suggest that SHC articulate a plan for interacting with local communities, state environmental agencies, and regional offices and distinguish research from implementation in the text of the Strategic Research Action Plan. For example, the research and tool development conducted by ORD does support local communities, but that support is implemented through the regional offices. This might have been the intention of SHC program, but it was not clear in the wording of the Strategic Research Action Plan.

Focusing the science questions and research. There was some concern that there were too many science questions, with most being sweeping in scope. The Strategic Research Action Plan needs to better explain how the questions will be answered. Moreover, the plan would benefit from being more sharply focused in terms of the stated research objectives, especially in light of resource constraints. Of course, the tension is, do you write a plan towards the resources one has or write a plan towards the resources you want? At the very least, the program should prioritize the science questions. The SAB and BOSC recommend that initially SHC emphasize focused questions and small victories, rather than the most ambitious projects at the beginning. In other words, SHC should emphasize those projects that are tractable and can be understood well.

Engaging communities and building partnerships. The SAB and BOSC commend SHC for engaging stakeholders in community listening sessions. However, more structured and guided methods will allow for a better understanding of community values, needs/wants and constraints. There also remains some confusion about what SHC program means by community engagement. The SAB and BOSC suggest that SHC clarify its view of what community engagement, participatory research and community self-assessment mean for the program. SHC can draw upon the previous work that has been done in this area (Israel et al 2005; NRC 2005; NRC 2008, Pasick et al. 2010; U.S. EPA SAB 2001).

Developing a typology of communities. The SAB and BOSC are concerned about the SHC plan to develop a typology of communities and the classification schemes being used to identify and classify communities. There are several different concerns. Does this effort " reinventing the wheel?" Can the program use definitions already developed, for example, work done in urban planning and demography Frey 2007; Frey 2012)? Studying the typology of communities may not provide the information needed by the SHC program. The program's focus on decision support makes it clear that a typology of *decisions* would be a much more useful study. Having a typology of decisions and the kind of

information that one needs to inform choices, across different decision making contexts or categories would be valuable (Gregory et al. 2012).

Other issues needing attention:

- Clearly identifying the responsible party for various activities and outputs. Sometimes it wasn't clear if it was SHC or a partner that would be doing the work.
- Clarify how SHC would link with program offices and the agency's regulatory decisions.
- Provide an idea of how many communities can/will be studied and how they are being selected. How are they prioritized? The current case study community, Durham, NC, while convenient, is not necessarily representative.
- Clarify what is (and is not) meant by decision-support "tool".
- Improve alignment of science questions, activities, and outputs.
- Explicitly identify the clients and the decisions that the clients need to make.
- Aim for middle-ground models that have the right level of simplicity and synthesis.
- Given that ORD wants to have communities at the table and engaged, the report, the language and text is written in a way that it might not be accessible to many communities.
- Does the program have a definition of sustainability that applies to communities and is more functional relative to the goals of this program than the overall EPA definition? Also, where is the "future generations" piece in the definition – an emphasis on the long-term is missing.
- Better interface with decision-makers - how do models like TRIO support or aid decision-makers? What are the specific decisions that they need to make? What is the level of detail of the data that they need? Will the model provide this?
- More detail about the models is needed (e.g. what is TRIO?). There is considerable confusion about what they are and their level of complexity.

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?

The SHC program has integrated sustainability into its plans exceptionally well. The original foundation and rationale for the existence of EPA, to promote human health and the environment, provide a strong basis to pursue the SHC program. The SHC program brings that statement to life.

The way the problem is framed it suggested that the chief barrier to sustainability is a lack of integration among these complex systems. However, many communities can identify a wide range of specific problems other than lack of integration that present barriers. Integration is one problem but not the only problem.

Commented [E47]: What problem

Commented [E48]: What does this paragraph mean?

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

Because SHC has a strong focus on both (a) developing useful tools and platforms and (b) identifying the best processes for developing those tools, knowledge generated in this program will be translatable across a wide range of issues and will build capacity within the program to meet unanticipated and emerging issues.

3.6.2. Program –specific questions

Providing tools to effectively support communities

The Sustainable and Healthy Communities Research Program incorporated a number of diverse research elements (e.g. ecosystem goods and services, human health outcomes, waste and contaminant remediation, environmental indicators) in building a research program focused on supporting community decision-making. The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective. What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

There is a need to build effective partnerships with communities so that both communities and the agency have input and contribute to the process. This process should not be driven solely by the community or by the agency, but rather be a partnership of the two that builds capacity in both. The EPA should recognize that communities may not always know what they need but that they also often have important knowledge that is difficult for those outside the community to know. To facilitate these interactions, SHC can develop a structure by which communities can engage.

The goal of tool development is not to have SHC "fix" communities but to develop processes that allow communities to make better decisions. To be of greater value, tools should be applicable for a wide range of communities. The SAB also thinks that social, behavioral and decision scientists should be part of this dialogue and play an important role in tool development.

Much useful work has been done outside the agency on community engagement. The SHC program should learn more about the history of community engagement and how past practices have impacted communities. The SHC program doesn't need to start over with new meetings in communities where people have been meeting already for a long time.

SHC should acknowledge that information alone will not ensure that communities will make more sustainable decisions. Information can sometimes help but often other social, behavioral, political or economic obstacles t impede progress. It would be beneficial for SHC to direct more attention to research that identifies how to select and use specific kinds of data to inform decisions and evaluate outcomes.

It is not always obvious to communities or decision makers how to use tools and information. SHC needs to develop a plan to provide training and documentation to support use of the tools and information that will be developed by the program. Even the best tools and information will not be used without such support. Support tools also can provide information on how to make good choices. If the decision support tools allow people to see not only the outcome, but how good decisions are made, then communities will learn about the process of decision making and the lessons will be transferable across a variety of scales and communities.

Providing uniform, national-level data, as with the National Atlas, can be a valuable resource. Having such a resource is likely to spur new applications that may not be known at the outset. The library of ecosystem services is also an important value-added activity of the SHC program. There is opportunity to collaborate with other programs. For example, outputs under "Enhancing Community Public Health" can be pursued collaboratively with HHRA.

SHC Theme 4: Integrated Solutions for Sustainable Outcomes

> *The SHC's fourth theme investigates sustainability practices within four high priority decision sectors identified during SHC community listening sessions. These sectors are: transportation, land use, buildings and infrastructure, and waste and materials management. There are three primary goals: to assess opportunities for communities to achieve greater synergies from practices within a given sector and across multiple sectors; to provide methods to more comprehensively account for these practices in terms of their social, economic, and environmental outcomes; and to collaboratively apply and refine these findings in partnership with specific communities (e.g. Durham, NC). Does the Committee agree that this fourth theme provides a useful way to integrate research within SHC? If so, what are the most important implementation questions that ORD must address?*

The SAB and BOSC applaud the integration that is evident in Theme 4. It is vital that tools and analysis be truly integrative across the range of social, economic and environmental realms. This theme is critical to bringing the SHC program together and, in many ways, represents the fruition of the first 3 themes.

While the set of four decision sectors chosen as a result of feedback from communities are important, they are not all inclusive. It was not clear in the plan that all media (i.e. air, water, and land) will be analyzed for each of the decision sectors.

In the plan, it also was not clear how one extrapolates from one place-based analysis to other places. Extrapolation could occur at the level of the decision support processes and tools that are developed; however, and the SHC program needs to explain this more clearly in the Strategic Research Action Plan. There was also some concern expressed that focusing on a single site is not sufficient. There is value in choosing multiple sites with different environmental, social and economic contexts to provide comparisons. The question of how to scale up and provide nationally relevant information from particular place-based research also deserves further thought. Emphasizing the point of case studies is to learn about process, and the lessons about process can be extrapolated and applied to other places.

There was concern about the ability of place-based research to identify outsourcing of negative impacts. For example, a community that exports wastes may shift problems to other communities. Tools should integrate across space similar to systems approaches that integrate across sectors.

To aid in development of useful tools, the SHC program should review previous efforts at tool development. What other tool development efforts were successful and unsuccessful and why did prior programs succeed or fail. Learning from past failures is as important as learning from past successes. While it is vitally important to take an integrative systems approach, there is a real danger that such approaches can become complex and unwieldy so that they do not deliver useful results in a reasonable time frame. The more one integrates, the more complicated and less tractable the problem can become. Great care needs to be taken to focus on the really crucial interacting pieces and not get overly complicated.

Commented [E49]: Should this word ibe "integrative"

The SHC program should be cautious not to create sector-based silos (e.g. waste, infrastructure) as it removes disciplinary silos. There is opportunity to integrate across the decision sectors, as there are important interactions among them.

Proper balance between breadth and depth

> *Does the Committee feel that SHC has the appropriate balance of breadth and depth in its design? If out year budgets continue to shrink, what areas should SHC maintain as the primary areas of focus? Can the committee recommend areas that SHC should invest in if budgets increase?*

As a whole, there is good balance, with about the right tradeoff between breadth and depth. That said, the plan could better highlight efforts being undertaken to understand system dynamics that include important interrelationships and the possibility of thresholds. Currently, much of the emphasis is on collecting data and developing metrics and less progress has been made on understanding system dynamics.

Data collection should be more tightly linked to the decision-support process. The SAB recommends that SHC explicitly identify the likely suite of community objectives and desired outcomes, determine what metrics one needs to measure performance or progress towards the objectives, and direct data collection efforts for those metrics.

All of the themes were seen as important, with theme 2 perhaps being the most foundational to the other themes and science questions. Were budgets to be cut, the recommendation would be to prioritize the science questions and address the most important of these rather than eliminate any theme. In this regard, it was noted that it is important to consider the architecture of the program and to be attentive to linkages among the themes. For example, there is work being undertaken in other themes that supports efforts focused on theme 2.

There is much valuable research that could be accomplished if budgets were to grow. As it stands, the SHC program has set out a very ambitious plan without sufficient resources in the current budget to accomplish all of it. Expanding the budget would allow the SHC program to accomplish more of its research plan and to do so in greater depth that adds greater value.

There is a strong need to invest more in social, behavioral and decision sciences. Decision-scientists, economists and sociologists should be integrated in a question-specific way. Individuals who study unintended consequences, which often arise because of behavioral responses, would be very useful. Ultimately, investing in these skill sets will increase the efficiency/effectiveness of SHC efforts. It also sends a strong signal to the academic community about the value of interdisciplinary work.

Investment in more communities that represent broader diversity across types would be useful.

3.6.3. Major recommendations for the SHC program

- Integrating ecological and human health. The SAB and BOSC commend EPA for recognizing the importance of bringing together human health and ecosystem services. Although this integration requires considerable effort, it is an important area that is worthy of investment. Moreover, EPA is the one agency that is positioned to do this. There was some concern that the communication flow among the different layers of expertise (e.g. ecosystems, human health) was not at the level needed. The SAB and BOSC encourage sustained efforts to promote interaction. The agency should outline the barriers to this integration and think creatively about strategies that might help to overcome them.

Commented [E50]: Communication among different types of experts (not expertise)

- Inclusion of social, behavioral and decision sciences. Social, behavioral and decision sciences are an essential component of the SHC program because they contribute to understanding human actions that drive environmental, social and economic change, the value of ecosystem services, development of decision-support tools, the design of policies, and the behavioral responses to policy changes. SHC has taken a step in the right direction but much work remains to be done. The SAB and BOSC would like to see future efforts expanded.

- Distinguishing research from implementation. Throughout the action plan, it was difficult to separate (a) research from implementation and (b) client from partner from community. The SAB and BOSC suggests that SHC articulate more clearly its plan for research and how this plan fits in terms of interacting with local communities, state environmental agencies, and regional offices and distinguish research from implementation in the text.

- Focusing the science questions and research. There was some concern that there were too many science questions, with most being sweeping in scope. The SAB and BOSC

recommend that the Strategic Research Action be edited to explain each of these science questions will be answered given the research that will be undertaken. This task would help to bring SHC to bring into sharper focus its stated research objectives, especially in light of resource constraints. The SAB and BOSC also recommend that, at the very least, the program should prioritize the science questions.

- Engaging communities and building partnerships. The SAB and BOSC commend the SHC program or engaging stakeholders in community listening sessions. However, more structured and guided methods will allow for a better understanding of community values, needs/wants, and constraints. There also remained some confusion about what SHC means by community engagement. The SHC program should clarify its view of what community engagement, participatory research, and community self-assessment mean for the program. The SHC program should draw upon the previous work that has been done in this area.

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APPENDIX A: ORD Charge to the SAB and BOSC

APPENDIX B: Bibliography on Innovation in Research

EPA should also use competitions or targeted outreach efforts to identify examples of successful innovation projects implemented in communities and utilities across the country. SAB/BOSC notes that other countries (e.g. India, Brazil and Nigeria) have found success in identifying solutions to their environmental problems by soliciting innovative approaches directly from community groups experiencing the negative impacts for which innovative solutions are sought.