UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

September 28, 2012

EPA-SAB-12-012

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

Subject: Implementation of ORD Strategic Research Plans: A Joint Report of the Science Advisory Board and ORD Board of Scientific Counselors

Dear Administrator Jackson:

The Science Advisory Board (SAB) and the Executive Committee of Office of Research and Development (ORD's) Board of Scientific Counselors (BOSC) have strongly supported the consolidation of EPA's research programs as part of an integrated transdisciplinary approach to research that aligns with your priorities and takes a systems approach to sustainability. Over the past year, the ORD has realigned its research into six new 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 Research. ORD requested that the SAB and the BOSC provide advice on implementation of these new program areas. The SAB and the 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 for its six research programs are important achievements. These plans crystallize and communicate ORD's new approach to its mission.

There was general consensus that ORD has been highly responsive to previous advice from the SAB and the BOSC, including advice on program restructuring provided by the SAB and the BOSC in 2011. The Air, Climate and Energy; Safe and Sustainable Water Resources; and Chemical Safety for Sustainability programs are making good progress on identifying and implementing a new vision for ORD research that emphasizes sustainability, integration across programs and alignment with the EPA's goals. The Human Health Risk Assessment, Homeland Security, and Sustainable and Healthy Communities programs have also made progress but could benefit from further refinement of their vision and implementation strategy.

The SAB and the BOSC recommend that the EPA develop an implementation plan for each research program that includes specific tasks and milestones. In some cases the EPA has listed all deliverables for completion of a task as due in 2017. This makes it difficult to assess the interim progress that the EPA is making towards completion of the task. While the SAB and the BOSC understand that implementation plans are 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.

ORD has wisely adopted a common definition of sustainability for all ORD programs. In addition, however, research plans should identify more clearly how each ORD research program links to the concept of sustainability and describe how the plans incorporate ecological health and human health into the definition of sustainability.

We have identified several other major recommendations to strengthen ORD research across all six programs. Sustainability research integrates social, economic, and environmental components, requiring a greater commitment on the part of EPA to augment research in the natural sciences with social, behavioral, and decision science research. The SAB and the BOSC provided advice in 2011 to help ORD strengthen capabilities in this area, and we provide additional advice in this report. We recommend that ORD coordinate research planning with EPA's National Center for Environmental Economics and develop strategies to address the social, behavioral and decision science research needed to accomplish the goals of ORD's major programs.

We recommend that ORD develop "roadmaps" depicting key linkages across ORD programs, linkages to other EPA research programs, linkages to the research of partners outside EPA, and linkages to the decisions EPA must make to address environmental problems. ORD has made a good start on such a roadmap for its nitrogen work, which is built on a robust conceptual model.

ORD should build on its initial effort to develop strategic research action plans to link research activities more clearly to the goals of research programs and their major themes. Consistent with this recommendation, ORD should focus the next efforts of its innovation program on the major goals and themes identified for its six research programs and use the innovation program to address some of their most challenging research questions. There is a need for ORD to communicate more effectively the findings and knowledge gained from ORD research and the value of that knowledge for the EPA and other stakeholders. Understanding the relationships between the many benefits of ORD research and environmental decisions can help focus research priorities.

The report attached provides recommendations to strengthen each research program. Some highlights are listed below:

- The Air, Climate and Energy program should include a plan for energy research and indicate how this research will integrate with the plans for climate and air quality research.
- The Chemical Safety for Sustainability program should demonstrate how its research products impact upon end users (e.g., risk managers, policy makers) and how it brings value for informing decisions.
- The Safe and Sustainable Waters program should identify and seek opportunities for leveraging research of other federal agencies and engage with communities in setting the program's

research priorities and research development. Program linkages with sustainability, nutrient management and green infrastructure are critical to the success of this program.

- ORD should develop and implement a strategic vision for the Human Health Risk Assessment program to enhance linkages among the program's four thematic areas and other research programs, particularly the Chemical Safety for Sustainability program.
- The Homeland Security Research Program, a valuable national resource, should evaluate its potential contributions to sustainability and consider adopting a broader mission that considers the multiple benefits of its products and application of its research to help respond to a wide variety of environmental disasters.
- The Sustainable and Health Communities program should focus its science questions and research more clearly; articulate how it will interact with local communities, state environmental agencies and regional offices; and clearly distinguish research from implementation of environmental programs.

Finally, the EPA will be best equipped to address emerging environmental issues if the EPA's scientists are at the frontier of environmental science. The best way to ensure that the agency is aware of the latest trends and problems is to ensure that its scientists serve as leaders in research areas critical to informing environmental decisions. ORD should strive wherever possible to craft its research so that it fulfills the dual goals of meeting specific programmatic goals while also maintaining and expanding the Agency's core capabilities in critical research areas.

The SAB and the BOSC congratulate ORD leadership at all levels for its continued commitment to integrated transdisciplinary research, systems approaches and sustainability. We encourage the agency to continue these efforts to promote research and science integration to inform decision making. We look forward to any comments you have on these reflections regarding implementation of ORD's new research directions.

Sincerely,

/Signed/

Dr. Deborah L. Swackhamer
Chair
Science Advisory Board

/Signed/

Dr. Katherine von Stackelberg
Chair
ORD Board of Scientific Counselors

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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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 Assessment
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

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1. BACKGROUND AND CHARGE

In 2012, the EPA 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) (U.S. EPA SAB 2011a) on the research framework documents. 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 (strategic research action 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; and endocrine-mediated dose-response) and ORD efforts to encourage research innovation. The SAB and the BOSC also held a public teleconference on September 19, 2012 to discuss a draft of this report.

ORD requested the SAB and the BOSC to address a series of charge questions provided in Appendix A. The charge included questions related to first year progress, sustainability and balancing immediate needs and emerging issues for each of the major research areas; specific questions for each program area; and 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. Section 3 provides program-specific findings and recommendations and responses to the program specific charge questions. ORD research programs appear in section 3 in the order they were discussed during the face-to-face meeting on July 10-11, 2012.

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2. GENERAL FINDINGS AND OVERARCHING RECOMMENDATIONS

2.1. Introduction

The SAB and the 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 and 2011b). Because this approach is new and will require significant changes in ORD's approach to research, the SAB and the 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 integrate across ORD research programs and collaborate with research partners within the EPA and with external organizations. The plans identify research themes and priority science questions. They provide a summary table of major 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 collectively. The plans are most useful when they clearly identify deliverables and outputs with specific milestones for achieving desired outcomes. Section 3 of this report provides more detail on each research program. The Air, Climate and Energy; Safe and Sustainable Water Resources; and Chemical Safety for Sustainability programs are making good to very good progress on identifying and implementing a new vision for ORD research that emphasizes sustainability, integration across programs and alignment with the EPA's goals. The Human Health Risk Assessment, Homeland Security, and Sustainable and Healthy Communities programs have also made good progress but could benefit from further refinement of their vision and implementation strategy. ORD has wisely adopted a common definition of sustainability across all ORD programs. Research plans, however, should identify more clearly how each ORD research program links to the concept of sustainability and describe how the plans incorporate ecological health and human health into the definition of sustainability.

The SAB and the BOSC recommend that the EPA develop an implementation plan for each research program 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 interim progress that the EPA is making towards completion of the task. While the SAB and the BOSC understand that

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implementation plans are 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. 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. Sustainability

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

2.3.1. Response

All of the programs would benefit from defining sustainability more clearly and specifically for their programs. Although the definition of sustainability from the National Environmental Policy Act provides a common definition across programs, the SAB and the BOSC advise that ORD explain more specifically what sustainability means to each research program and how those research goals will be achieved.

The SAB and the BOSC suggest that strategic research action plans explicitly incorporate ecological health as well as human health into the definition of sustainability.

Incorporating sustainability into research plans and activities will also require greater integration of social, behavioral and decision science research in addition to the natural sciences. Investment in social and behavioral sciences is needed to complement ORD's investments in ecological and human health research. The SAB has repeatedly made the recommendation for increased inclusion of social and behavioral sciences into ORD activities (U.S. EPA SAB 2011a and 2011b), 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 the economic, social, and environmental 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.

The SAB and the BOSC recommend that 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 research. 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 integration of the social and natural sciences necessary to achieve the goals of ORD's strategic research action plans and build on past SAB and BOSC advice (U.S. EPA BOSC 2009; U.S. EPA SAB 2011a). Focusing on ORD's five integration topics would also provide an opportunity to identify specific applications for social, behavioral and decision sciences.

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If social scientists cannot be brought into ORD's research programs easily, ORD should take advantage of avenues such as EPA's Science to Achieve Results fellowship program, the American Academy of Arts and Sciences program, or EPA's Title 42 Authority to develop and acquire social science expertise.

2.3.2. Recommendations

- Each ORD program should define more specifically what sustainability means within the program context, and identify how each plan incorporates ecological and human health into the definition of sustainability.
- ORD should collaborate with other partners in the EPA, including the National Center for Environmental Economics, to develop a plan to develop the social, behavioral and decision science needed to support sustainability research and other goals identified in ORD's six major research programs. A useful first step would be for ORD to plan a workshop on this topic and seek SAB and BOSC advice in workshop planning.

2.4. 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?

2.4.1. Response

Although it will sometimes be difficult to separate basic, immediate research needs from emerging research needs, ORD must identify and address significant emerging research needs. ORD has demonstrated the flexibility and capability to make necessary changes in research plans from year to year. The SAB and the BOSC encourage ORD to 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.

A risk portfolio analysis approach to research and development management would involve the evaluation of a portfolio of current and potential ORD projects to determine ORD's competitive advantage, namely, areas where ORD is uniquely able to make progress on scientific issues important to the EPA's mission. The BOSC has advised ORD to use decision science tools in a structured way to plan its portfolio of research activities (U.S. EPA BOSC 2009). A specialized literature exists to describe the institutional changes that would be necessary to make such an approach successful (NRC 1999; Youngblood et al. 2003; Serewitz and Thernstrom 2012). In addition to portfolio analysis, the SAB and the BOSC recommend that ORD plan explicitly for the resources needed to advance sustainability research, evaluating its current framework of client interactions to develop a roadmap for future research.

Anticipatory research requires a strategy to identify and evaluate emerging issues. Equally important is for ORD to assess 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 an environmental problem reaches a critical state? What cultural, institutional, technical barriers to detecting such signals have existed? ORD should undertake evaluative case studies to identify past barriers to identifying and conducting research related to important emerging issues.

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Emerging issues will be better identified and anticipated if the EPA's scientists are at the frontier of the science. The best way to ensure that the agency is aware of the latest trends and problems is to have scientists who are leaders in research areas critical to informing environmental decisions. ORD should strive wherever possible to craft its research such that it fulfills the dual goals of meeting specific programmatic goals while also maintaining and expanding the Agency's core capabilities in critical research areas.

The SAB and the BOSC realize that the EPA's mandates have become so broad, and science changes so rapidly, that it is not possible for its staff to be the scientific leaders in every endeavor relevant to the mission. Accordingly, it is also imperative that the agency continue to utilize the external scientific community through a variety of avenues, from collaborative or sponsored research in specific areas to the regular solicitation of input from its advisory groups on emerging issues.

ORD's transition toward greater integration across disciplines requires a considerable increase in staff re-training and an enhanced culture of continual learning, which is expected to result in a more diversified suite of skill sets across ORD. Integration creates more efficient networks of expertise that can be more rapidly and effectively tapped when new issues arise. Integration also promotes cross-fertilization of ideas and skill sets. Webinars, seminars, and short-courses can help keep staff abreast of emerging issues. ORD should make training and development of its scientists a priority and seek new ways to interact with colleagues outside the EPA through partnerships with other agencies and academic institutions. These steps will enhance ORD's capacity to adapt to critical emerging issues even in a fiscally lean environment.

2.4.2. Recommendations

- ORD should develop a structured approach (e.g., through a risk portfolio or decision science-based 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 staff a priority and seek new ways to interact with scientists outside the EPA through partnerships with other agencies and academic institutions to keep staff on the frontier of science and alert to emerging issues.
- ORD should strive wherever possible to craft its research such that it fulfills the dual goals of meeting specific programmatic goals while also maintaining and expanding the agency's core capabilities in critical research areas.

2.5. Integration

Based on the presentation of five integrated topics, what advice can the SAB and the 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?

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2.5.1. Response

The SAB and the 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 rapid progress. The five specific integration topics presented by ORD at the July 2012 SAB-BOSC meeting (climate change; nitrogen; children's health and environmental justice; applying new chemical assessment approaches in human health risk assessment; and nonmonotonic dose response curve analysis) provide insightful examples of different ways to stimulate and encourage integration. The nitrogen and climate change integration topics are excellent examples of the potential for integration across program areas. ORD should define how other topics for integration 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 the 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.

The SAB and the BOSC offer the following additional 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 the regional, or program office level.
- Highlight examples of successful integration. For example, in the children's health/environmental justice integration topic, the integration of both chemical and non-chemical stressors was emphasized.
- The nitrogen topic could be further integrated by incorporating consideration of community-based ground water exposure data.

Some areas of research integration have an 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 discrete integration topics selected by the EPA are good ones. 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.

2.5.2. 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 topic.
- 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.

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- ORD should enhance its internal and external communication between research programs and provide more opportunities for formal exchange of research information.

2.6. 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 the BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

2.6.1. Response

Improving ORD's initial innovation activities

ORD should be commended on its efforts to foster innovation. The innovation program has four major components: (1) Pathfinder Innovation Projects (an internal competition for Agency scientists that provides one-year seed funding and time for projects deemed to be innovative, high-risk, and high-reward); (2) Open Innovation (processes for "challenges" and prizes to fill priority gaps in environmental protection programs; (3) Apps and Sensors for Air Pollution (development of real-time, low-cost environmental sensors and apps that hold promise for regulators, researchers and communities); and (4) Culture and Collaboration (programs and activities to move EPA and ORD toward a culture of innovation, where interdisciplinary collaboration and risk-taking are supported and rewarded). The success of ORD's innovation efforts is strongly dependent on ORD leadership and the continued fostering of innovation within ORD. The program also appears to yield the additional 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 many responses to the call for proposals and some preliminary results, indicates a very good start. However, it is important that the EPA ensure 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 questions for challenges are chosen and how Pathfinder Innovation Projects grants are awarded. What are those Grand Challenges that, if addressed in an innovative way, will lead to a major transformation 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.

The SAB and the 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 "socio-technical systems" that involve changing the way people use technologies (Trist and Bamford 1951; Cherns 1975; Fox 1995; Trist 1981; Waden 2011). ORD should provide as much encouragement for social and socio-technical innovations as for purely technological ones. As ORD's innovation program matures, it may be beneficial to shift the focus from innovation in devices to identifying systemic ways to incorporate innovative thinking into the agency's 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

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resources. Research in the social, behavioral and decision sciences could play a critical role in this process.

The SAB and the BOSC support ORD's efforts to develop innovative ideas from across ORD but also recognize that some individuals are innately more innovative than others (i.e., there are 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.

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

- Public competitions to provide incentives for competition for environmental innovation modeled after the efforts of the X Prize Foundation to provide incentives for technological development;[1]
- 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 as well as 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); and.
- 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[2] and Brazil (Löbler 2012)] 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 from other research organizations that may be useful to ORD. References include lessons-learned reports, publications on innovation related to research and innovation metrics.

Metrics for assessing the success of ORD innovation efforts

The development of metrics presents an enormous challenge. Other than development of an award system that encourage innovative research and further development of a culture of innovation within ORD, the SAB and the 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 as important as initiating and conducting innovative research. Some members suggest that metrics that are common for academic decisions on innovation (number of publications, citations, patents etc.) would be acceptable. Other members suggest 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 the impacts of innovation projects. Some members note that

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[1] See http://www.xprize.org/ (accessed 09/05/12).

[2] Gupta, Anil. 2010. *India's hidden hotbeds of invention*. TED; Ideas Worth Spreading. http://www.ted.com/speakers/anil_gupta.html (accessed 09/04/12).; Villgro incubates, funds and supports early-stage, innovative social-enterprises that impact the lives of India's rural poor. http://www.villgro.org/ (accessed 09/04/12); Society for Research Initiatives for Sustainable Technologies and Institutions, http://www.sristi.org/cms/en (accessed 09/04/12); next billion; development through enterprise http://www.nextbillion.net/ (09/04/12).

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learning from failed projects can represent 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.

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 different 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.
- 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 the 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.

2.6.2. 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 need 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 solicit and support innovation research projects 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.

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3. RECOMMENDATIONS FOR SPECIFIC RESEARCH PROGRAMS

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 the 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 ACE Strategic Research Action Plan, more investments in systems approaches and analyses, more investments in social, behavioral and decision science research and increased focus and resources for the energy component of the program.

3.1.1. 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?

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 the ACE goals translate 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.

Additional areas of potential improvement of the plan include: (1) development of an explicit energy research plan and more explicit integration of energy research with the plans for climate and air quality research; (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 that address the interaction of air quality, energy 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 ACE 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, 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.

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3.1.2. Sustainability

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

The sustainability paradigm provides a framework for integrated research on air, climate and energy. By considering these three areas 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 within the ACE program will require more effort in social, behavioral and decision science research as well as a greater focus on systems science. 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.

3.1.3. 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?

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 EPA's mission and finding ways to apply and adapt research from other organizations.

3.1.4. 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 a 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). For example, encouraging human behavior that promotes safer,

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sustainable use of chemicals throughout the energy life cycle may offer an effective lever for solving many energy-based environmental problems. Developing a full understanding of the entire spectrum of human health and ecosystem impacts of energy options (using life-cycle analysis and incorporating externalities) will be critical to providing effective decision support tools and providing the scientific foundation for policy decisions regarding sustainably meeting energy needs on multiple scales (community, regional, national, global). Most current ORD work focuses 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 systems behavior. This additional systems-level focus on energy will require senior leadership to provide necessary systems science expertise and ensure that the connections between energy research projects are drawn and made explicit. In addition, a workgroup of staff from across ORD and the agency who are working on energy-related science 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. An integrated framework should be developed that allows evaluation of the competitiveness of alternative energy sources, their intended and unintended effects and implications for policy.

Finally, legislative activity and funding has driven a focus on biofuels and hydraulic fracturing that 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 will help ORD address issues such as the impacts of land use changes and the ecological impacts and responses to catastrophic events such as heat waves and droughts. Demographic, regional migration patterns and other social changes (including responses to threats and to protection/management programs and outcomes) may also be very important components of the energy/climate/environment dynamic. Again, partnership with other organizations will be critical.

3.1.5. Recommendations for the ACE program

- ORD should more explicitly map the long list of individual projects and project outputs in the Strategic Research Action Plans to strategic research themes and the overarching vision.
- The Strategic Research Action Plan should include a plan for energy research and indicate how this research will integrate with the plans for climate and air quality research.
- To support this additional systems-level focus on energy, ORD should identify senior leadership to provide necessary systems science expertise and ensure that the connections between energy research projects are drawn and made explicit.
- The Strategic Research Action plan should include 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.
- The Strategic Research Action Plan needs more comprehensive and greater depth in planned social science and behavioral research.

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3.2. Chemical Safety for Sustainability

The Chemical Safety for Sustainability (CSS) program is intended to provide critical research supporting the scientific foundations of agency programs to ensure safety in the design, manufacture and use of existing and future chemicals. This program is appropriately ambitious and bold, consistent with the radical transformation across the entire field of chemical safety assessment required to meet the changing needs of today's world. The CSS program must be prepared to address questions such as: how to design and produce safer chemicals; how chemicals and their byproducts interact in 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; how to promote safer, sustainable use of chemicals throughout their lifecycle; 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 development of new, more sustainable products. Overall, the SAB and the 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. 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 the 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. The scope of the plan goes beyond the traditional confines of risk assessment. Examples 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 the BOSC consider the CSS research plan to be comprehensive. It contains all of the key elements needed to answer the

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science questions in the Strategic Research Action Plan. This report highlights three areas of special interest: exposure, cumulative risk, and ecosystems.

The SAB and the 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 this were the case, exposure might get even more attention and resources, which 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. The SAB and the BOSC encourage the EPA to obtain information on ranges of human health exposure levels to ensure that highly exposed populations are not ignored and that the levels of toxicological assessment from *in vitro* high-throughput assays can be applied in a risk assessment 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 on common modes of action. The SAB and the 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 and describe how the research relates to chemical impacts on ecosystems and ecological endpoints (e.g., high-throughput for ecological endpoints).

3.2.2. Sustainability

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

The CSS Strategic Research Action Plan identifies many contributions to sustainability research. 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 the 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 the BOSC also recommend that ORD take care, when describing CSS research and its deliverables, to demonstrate how the research impacts end users (e.g., risk managers, policy makers) and how the research helps inform decisions.

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3.2.3. Integration

Based on the presentation of five integrated topics, what advice can the SAB and the 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 the BOSC recommend that ORD increasingly utilize the Adverse Outcome Pathway concept, defined as "a conceptual construct that portrays existing knowledge concerning the linkage between a direct molecular initiating event and an adverse outcome at a biological level of organization relevant to risk assessment" (Ankley et al. 2009). Such an approach is an inherently integrative process in itself. One example is the project on vitellogenin from ORD's laboratory in Duluth, Michigan, which linked the pathway from disruption of key cellular events to population level changes (Miller et al. 2006).

3.2.4. 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 the BOSC strongly encourage the CSS program's transitional 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 the BOSC suggest that the CSS Strategic Research Action 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 and leverage the many ongoing efforts in this area.

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Computational toxicology

Many new tools are already being generated by the CSS program. However, the plan says little about how these new assays and tools will be "qualified" or verified (validate is a term used in other circles, but was thought to be less appropriate in this case) for their intended purposes. This verification process needs to be done in a transparent and robust manner in order to gain the confidence across diverse stakeholders within and outside the agency, many of whom are not at comfortable or familiar with these methods. Therefore, the SAB and the 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 the BOSC 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 a dependence on *in vivo* testing for safety assessment to a new strategy using a large battery of high throughput *in vitro* assays predictive of toxicity. This strategy will require an understanding of adverse outcome pathways and how these will be revealed in the large amount of data being generated from high-throughput assays. Many pathways can produce different phenotypic outcomes depending on the context in which the pathways are activated, and both adaptive and adverse outcomes are possible. There is a need to define the typical range of intra- and inter-individual variation in pathway activation. At the beginning, 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 the 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 because two of its laboratories are located in close proximity to one another (i.e., the National Center for Computational Toxicology and the National Heath and Environmental Effects Research Laboratory are both located on the Research Triangle Park campus). The SAB and the BOSC suggest that the CSS program also 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.

The SAB and the 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 efforts (both experimental and computational) need to be made towards estimating volume of distribution/partition coefficients, renal excretion, bioavailability, the metabolites generated, and the potential toxicity of metabolites. 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.

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3.2.5. 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.

3.2.6. 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 verification of proximal and consumer exposure models, including 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 verification of new computational toxicology tools for their intended purpose and with respect to risk assessment, and present to BOSC for review.
- Define the typical 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. Linkages to all relevant ORD research programs should be emphasized in the HHRA plan to reflect the importance and broad translational role of risk assessment within the EPA. Reports from the NRC (NRC 2009, 2011) and other bodies (e.g., U.S. Government Accountability Office 2008, 2011), have recommended 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.

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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 (Theme 1); Integrated Science Assessments (ISAs) of criteria air pollutants (Theme 2); Community Risk and Technical Support for exposure and health assessments (Theme 3); and Modernizing Risk Assessment Methods (Theme 4)]. However, it neither provides a strong overall vision nor identifies synergies across the four components or across related programs such as CSS. At this point, the four themes have certain commonalities and their merger into a single program reflects 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 ORD leadership, ORD scientists and other EPA scientists and there is intent to address them.

The EPA and ORD staffs 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. The SAB and the 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, but perhaps a venue is needed for discussion, exchange and collaboration among risk scientists more broadly.

3.3.1. 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?

As for most ORD programs, it is early to evaluate the trajectory of progress within the HHRA program, and 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 (HHRA Themes 1-3) and the need to incorporate strategies based on "new and emerging" science into its activities (HHRA Theme 4). 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 seem appropriate for answering the science questions in the plan but they are only generally specified for later years covered by the plan. There are potential challenges that may interfere with the planned agenda over the longer-term. One is the trade-off between the demands of producing timely assessment while assuring that methodological research continues. In addition, ORD resource limitations 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.

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. Exposure assessment cuts across the four themes but the underlying exposure sciences do not receive sufficient emphasis. The National Research Council report on the exposure sciences (NRC

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2012) is likely to increase attention to this area and provide prioritized research needs that should be considered in the planning for the HHRA program. The discussion of exposure sciences should be expanded beyond the brief discussion in Theme 3 (Community Risk and Technical Support) in the plan. The use of 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 to better integrate human and ecological health considerations.

3.3.2. Sustainability

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

The HHRA plan did not specifically mention sustainability, yet the program mission by definition contributes to sustainable decision-making. The HHRA program generates data and tools that help decision makers achieve goals designed to be sustainable. The HHRA program advances the science underlying National Ambient Air Quality Standards that have driven major air quality improvements nationwide that further sustainability goals that pertain to human health and ecological health. Similarly, the HHRA program produces risk assessments for high priority chemicals (in the IRIS program) and rapid risk assessments (i.e., Provisional Peer Reviewed Toxicity Values). These assessments contribute to the goal of identifying and controlling health risks from toxic chemicals and, through HHRA's Theme 4 (Modernizing Risk Assessment Methods), contribute to developing new tools to predict chemical risk using less *in vivo* data. The HHRA efforts in Theme 4 to develop and improve the ability to identify and measure cumulative risks can help advance environmental justice and identify opportunities for communities to reduce exposures. Finally, 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. The SAB and the BOSC recommend that the HHRA program more clearly and explicitly communicate its significant contributions to sustainability science.

3.3.3. 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?

ORD will need to think and act creatively to work 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, three recent NRC reports (NRC 2007; NRC 2008a; NRC 2009) provide an agenda and a strong 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 new toxicology data from the CSS program and other sources 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.

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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 toxicity 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 sources of data, such as high throughput assays, that have the promise of 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 assessments overall.

In addition, ORD might consider active partnerships with other entities in order to build opportunities to use high throughput testing and to develop complementary opportunities based on new epidemiology studies or on established cohorts to apply such methodologies. There are several advantages of these approaches including the reduced use of experimental animals, the direct use of toxicity data based on human cell cultures and the ready application of high throughput testing.

The EPA's effort to develop the concept of Conditional Toxicity Values (CTV) (Guyton 2012) is particularly noteworthy because it incorporates consideration of new toxicity testing methods, and offers the potential to create screening or interim risk values for large numbers of chemicals of concern. The CTV and other similar approaches[3] are designed to produce health-protective risk values that can help to guide risk management until additional chemical-specific data become available. If the HHRA specifically or ORD generally decides to take this approach, then linkages with other agencies or organizations with interest in these and related methods will be important.

ORD should consider incorporating shorter-term testing to improve the basis of its risk assessments, as long as timelines for the risk assessment are not unduly lengthy. Such shorter-term testing should not be considered when a delay would be associated with remediable, ongoing human exposures and potentially significant human health or ecological risk. ORD should also consider how to prioritize within Theme 3 (Community Risk and Technical Support for exposure and health assessments) and Theme 4 (Modernizing Risk Assessment Methods) of its research plan, given the possibility of limited resources.

3.3.4. Integration

Based on the presentation of five integrated topics, what advice can the SAB and the 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?

[3] See ISLI. n.d. Threshold of Toxicological Concern Task Force, http://www.ilsi.org/Europe/Pages/TF_ThresholdToxicological.aspx (accessed 09/21/2012)

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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 basis for hazard identification and dose-response assessments, in part, for the regulatory and advisory work of the EPA, integration efforts should be prioritized carefully so as not to impose unnecessary burdens (i.e., 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 other ORD programs. The SAB and the 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 mentioned, the relevant agendas within these two programs are largely separated and the basis for selecting outputs and priority setting is not clear. For example, transparent evidence synthesis is integral to both the IRIS Program and the development of the ISAs, but the methodologies used by the groups are distinct. The SAB and the BOSC encourage heightened interactions between the groups working in Themes 1 and 2 that could lead to synergy in development of methods. Additionally, the SAB and the 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 EPA 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. With children's health and environmental justice as an integrating focus, the HHRA program should plan to 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 activities and approaches 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.

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 with other programs, would benefit from the integration of social, behavioral and decision scientists into the activities related to risk assessment methodology to support environmental decision-making. The SAB and the BOSC recommendation in 2011 (U.S. EPA 2011a) regarding the importance of integrating social, behavioral, and decision science remains relevant. That report stated that ORD should conduct or support social, behavioral and decision science research and analyses to understand the public's perception of uncertainty and risk assessment. Shedding light on public attitudes and knowledge will enable the agency to communicate HHRA findings more effectively.

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3.3.5. 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 the 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, 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 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.

3.3.6. 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 the 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 the 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 concordance of outcomes.

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

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possible, application [e.g., Benchmark Dose (Lower Confidence Limit) methodology is now widely accepted, although different groups may calculate different values]. 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 at peer scientists within and outside of 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 implementing 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 the 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 with more traditional risk assessment approaches. The SAB and the 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

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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.

3.3.7. 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 the 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, cumbersome, lengthy, and poorly written EPA assessments have complicated the peer review process resulting in negative feedback to the agency. The SAB and the 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 the 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.

EPA often faces difficult decisions regarding as to implement conflicting or cumbersome recommendations by peer reviewers. This issue extends beyond HHRA and is inherent in the peer review process itself. Given the workload of HHRA and the demand of addressing peer review comments, the SAB and the BOSC suggest that strategies be developed to more efficiently address peer review comments while preserving the integrity and benefits of the peer review process. There are approaches used by other entities that may offer strategies. For example, the National Academy of Sciences typically solicits multiple peer reviews for their reports, generally 10 to 15 depending on the report. An independent review monitor evaluates the substance of the comments and provides guidance to the committee on the most critical issues to be addressed in the revised report. An editor plays a similar role in the peer review process for manuscripts submitted to journals; the editor informs the authors as to which peer review comments require changes to a manuscript. In cases where a consensus body, such as the SAB or the National Academy of Sciences peer reviews an agency document, it would be most helpful for the EPA to request that the group clearly distinguish priority recommendations from other suggested advice in the peer review.

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, the mandated requirement for outside review of documents by the National Research Council has created a strain on the budget and led to delays. Recent mandates may impair the ability of the HHRA program to achieve its goals and

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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 for many more chemicals than can be addressed today.

The agency should have the overall goal of providing its assessments in a timely fashion. This goal has not always been met, particularly for the IRIS assessments and past National Ambient Air Quality Criteria Documents. More recently, the agency has completed 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 integrated and transparent documents that can be more readily reviewed.

Toxicology values (including reference doses, reference concentrations and cancer slope factors) are extremely important to programs across the EPA and in risk assessments conducted on behalf of state and other federal agencies. 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. Stakeholders and peer reviewers may be able to target their comments more effectively and to allow the EPA to address potential concerns.

3.3.8. Recommendations for the HHRA program

- The EPA should broadly examine the diverse venues where risk assessment activities reside within the agency and seek to establish connections and integration that will foster ongoing enhancement of methodologies that are common to risk practitioners throughout the Agency.
- ORD leadership should elaborate a strategic vision that enhances linkages among the thematic areas of the HHRA and with the other research programs, particularly the CSS program, and that emphasizes the way that the HHRA program contributes to sustainability research. This vision will be needed for revising the HHRA strategic plan.
- A wide- 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 data for decision-making. This activity needs emphasis in Theme 4.
- 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 and further expertise is needed in this cross-cutting area.
- The addition of further social, behavioral, and decision scientists to HHRA would benefit many of its activities and enhance integration with other programs. This recommendation echoes prior reports and speaks to the broad, multidisciplinary nature of decision-making and communication with regard to risk in the face of uncertainty. Long-standing gaps in expertise within the Agency should be addressed.
- Concerted and 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 about new data and approaches to risk assessment, leading to greater confidence in decisions based on these approaches. They need to be kept aware of advances made under Theme 4.
- Peer reviews of HHRA documents and assessments could be made more efficient. The plans for changes in the IRIS assessments should benefit the peer review process. Additionally, the

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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. This may be facilitated by an independent "monitor" or "editor."

3.4. Safe and Sustainable Water Resources

The Safe and Sustainable Water Resources (SSWR) Strategic Research Action Plan identifies the following vision for the program: to use 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. 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 the BOSC find 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 ORD is making towards completion of the task. While the SAB and the BOSC understand that the implementation plan is in development, ORD 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 ORD's progress towards achieving its longer-term goals and plans.

3.4.2. Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and the 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 the sustainable use and management of water lies outside EPA's purview. The SAB and the BOSC recommend that ORD further clarify the agency's focus vs. the focus of other agencies regarding SSWR sustainability-related research. Such clarification will facilitate partnering and leveraging efforts and the activities of others, a critically important activity.

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3.4.3. 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?

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 the SSWR research budget. Many states have a tight budget for protection of water quality. They rely on ORD 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 the BOSC note that some stakeholder communities and groups will favor prioritization of SSWR research that differs from EPA priorities. Where research on emerging issues could benefit certain communities, and those communities' priorities initially differ from EPA's priorities, ORD should consider the magnitude and distribution of risks associated with the alternative research options. The SAB and the 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.

3.4.4. Integration

Based on the presentation of five integrated topics, what advice can the SAB and the 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. ORD 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 the 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.

3.4.5. 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?)

In the SSWR Strategic Research Action Plan, there are several gaps in the description of EPA's strategic nutrient management 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

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United States and elsewhere. The EPA should also identify metrics for nutrient management (e.g., metrics that consider financial impacts vs. amount of nitrogen released) to help direct actions by the EPA and other federal agencies, state agencies, companies, nongovernmental organizations, and individuals. The EPA should be engaged with and knowledgeable 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 the 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[4]" and with private industry. In addition, there are 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 the BOSC recommend that EPA leverage efforts of others, conduct outreach to engage the public and other federal agencies, and conduct competitions that solicit innovative approaches in target areas.

3.4.6. 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, which overlaps and integrates with ecosystem services. The SAB and the BOSC recommends that ORD inventory best practices and innovation activities across the United States to identify the current leaders in green infrastructure and their activities. 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; and organizers of the North American Storm Water Conference and Exposition[5]. Innovative solutions in storm water management are being developed in cities such as Chicago[6], Philadelphia[7], and Atlanta[8]; their experience can supplement and stimulate EPA's efforts.

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[4] See http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=504773 (accessed 08/16/12)
[5] See http://www.stormcon.com/ (accessed 08/16/12)
[6] See http://www.cmap.illinois.gov/strategy-papers/stormwater-best-management-practices/stormwater-management; see also http://www.epa.gov/owow/NPS/natlstormwater03/21Malec.pdf (accessed 08/29/12)
[7] See http://www.phillywatersheds.org/watershed_issues/stormwater_management (accessed 08/29/12)

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Much can be learned from these activities. The SAB and the BOSC encourage ORD to develop tools to encourage and improve how states help communities address Combined Sewer Overflow consent order requirements in innovative ways. ORD should also examine the NRC's recommendations (NRC 2008c) for regulation and research needs on storm water monitoring and modeling. ORD should also support competitions that solicit innovation in these areas.

3.4.7. Recommendations for the SSWR program

- ORD should include specific tasks and milestones in the SSWR Strategic Research Action Plan.
- The SSWR program should further clarify what is the agency's focus vs. the focus of other agencies regarding SSWR sustainability-related research.
- The SSWR program should develop a structured way to assess emerging issues in establishing priorities.
- The SSWR program 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 conduct outreach and actively engage with communities when developing SSWR research priorities.
- EPA should invest more in assessing use of market mechanisms for nutrient control, and identify metrics for nutrient management.
- The SSWR program 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 related to nutrients with other federal agencies and utilize ORD'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.
- The SSWR program should take a leadership role in conducting green infrastructure research and incorporate natural infrastructure into its research.
- The SSWR program should inventory best practices and innovation activities, and seek partnership opportunities to assess lessons learned related to green infrastructure.
- The SSWR program 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.

3.5. Homeland Security

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.

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[8] See http://www.atlantawatershed.org/bureaus/storm/WP-Stormwater-Mitigation-mainpage-a2.htm; see also http://www.cleanwateratlanta.org/stormwater/default.htm (accessed 08/29/12)

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3.5.1. 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?

HSRP has engaged in transdisciplinary research with an extensive portfolio of external partners since 2002. Indeed, ORD's current emphasis on transdisciplinary, problem-solving research reflects much of what HSRP has been doing for a decade. The immediate opportunities are for HSRP and ORD to better integrate internally, for HSRP to communicate more clearly how its activities relate to sustainability, and to explore extension of some of its research into an all-hazards approach (see section 3.5.4).

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 the 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 the 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 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 the BOSC are concerned about the HSRP's maintaining its product stream with diminishing resources. One of the major questions is how resources will 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 and marketing HSRP expertise to additional partners to increase resource leveraging.

3.5.2. Sustainability

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

HSRP has advanced 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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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 fellows who can assist in developing the new research programs that advance sustainability in HSRP.

3.5.3. 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?

The HSRP process of client needs assessment provides an excellent mechanism for delivering responsive products. The HRSP provides an example of an applied research culture with 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.

3.5.4. 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 the 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 the 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 develop road maps to illustrate the linkages across current and future research.

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.

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The SAB and the 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 existing relationships with other agencies, HRSP should strive to enhance relationships with other federal agencies where there is synergy. The SAB and the BOSC consider that the HSRP is in the best position to determine where this synergy exists and should be encouraged to pursue pilot projects.

3.5.5. Recommendations for the HSRP program

- ORD should develop metrics for measuring progress and success at project conception.
- The HSRP should document its impact by identifying the multiple benefits of its products. It should concurrently expand its communication about the broad applicability and many benefits of HSRP products and expertise; outline the value proposition to stake-holders; and market HSRP expertise to additional partners to increase resource leveraging.
- The HSRP, as a valuable national resource, should adopt an "all-hazards" approach to enhance its 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.
- HRSP should continue to enhance its relationships with other federal agencies where there is synergy.

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. 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 the 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 the 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 the BOSC conclude that the SHC program is on the right track. The SAB and the 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; and building a typology of communities. The SAB and the BOSC also identify in this section a list of other issues that require ORD attention to further strengthen the program.

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Integrating ecological and human health
In particular, the SAB and the BOSC commend the program for using ecosystem services as the vehicle for integrating human and ecological health and for recognizing this integration as a priority. Although this integration requires considerable effort, its importance makes it worthy of investment (Di Giulio and Benson 2002). Moreover, EPA is the one agency that is positioned to do this. Although the communication flow among the different experts (e.g., ecosystem scientists and human health scientists) does not always occur at the level needed, ORD is attempting to make these interactions happen. Sustained efforts to promote interaction and integration are needed. ORD 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 conducting meta-analyses in an effort to derive fine-scale information);
- 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); and,
- Entrenched disciplinary mindsets that will take time and effort to overcome.

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

Distinguishing research from implementation
Throughout the action plan, it was difficult to separate: (1) research from implementation, and (2) client from partner from community. These lines were gray. The SAB and the BOSC expressed concerns that the SHC Strategic Research Action Plan seems to indicate a move from research into program 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 others, including regional offices, state environmental agencies or partner communities. Although implementation is of fundamental importance, the question is who should be doing it. The SAB and the BOSC suggest that SHC articulate a plan for interacting with local communities, state environmental agencies, and regional offices to better 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.

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Focusing the science questions and research
The Strategic Research Action Plan has too many science questions, most of which are broadly defined. The plan needs to better explain how the questions will be answered. Moreover, the plan would benefit from a sharper focus in terms of the stated research objectives, especially in light of resource constraints. The SAB and the BOSC recognize the tension inherent in writing a plan for the resources one has or writing a plan towards the desired resources. At the very least, the program should prioritize the science questions. The SAB and the 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 the 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 the SHC program means by community engagement. The SAB and the 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 2008b; Pasick et al. 2010; U.S. EPA SAB 2001).

Developing a typology of communities
The SAB and the BOSC are concerned about the time investment required to support 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. SHC's efforts to include both social and ecological data in their typology can improve its usefulness to the EPA and distinguish the effort from traditional approaches to typology, but the SAB and the BOSC recommend that the SHC program identify and build upon typologies of communities already developed, for example, work done in urban planning and demography (Frey 2007; Frey 2012). Furthermore, 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 ongoing efforts to develop a typology of decisions related to the environment will likely offer the most useful investment. Having a typology of community decisions and the kind of information needed to inform choices, across different environmental decision making contexts or categories would be valuable (Gregory et al. 2012). Ideally this typology would be widely accessible to those outside the agency as well.

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);
- Clarifying how SHC would link with program offices and the agency's regulatory decisions;
- Providing information about 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 of many other communities);
- Clarifying what is (and is not) meant by decision-support "tool;"
- Improving alignment of science questions, activities, and outputs;
- Explicitly identifying the clients and the decisions that the clients need to make;
- Aiming 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, communicating the message of the Strategic Research Action Plan in ways accessible to communities;

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- Refining the definition of sustainability that applies to communities and offers greater functionality relative to the goals of the program than the overall EPA definition;; in addition, determining where the "future generations" piece fits in the definition;
- Developing a better interface with decision-makers and explaining how models like TRIO support or aid decision-makers (e.g., What are the specific decisions that they need to make? What is the level of detail of the data that they need? Which model will best provide this?); and,
- Providing additional details about the models is needed (e.g., what is TRIO?). There is considerable confusion about the application of specific models and their level of complexity.

3.6.2. Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice do the SAB and the 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, provides a strong basis to pursue the SHC program. The SHC program brings that statement to life.

However, the emphasis on lack of integration as the chief barrier to sustainability does not sufficiently recognize that communities themselves are better able to identify a wide range of specific problems other than lack of integration that present barriers. Examples of barriers within the agency include disparate goals among staff, and media-specific regulations that do not recognize the interconnectedness of the environment. Barriers within the community may include lack of technical expertise, lack of data, and lack of professional staff. Integration is one problem, but not the only problem.

3.6.3. 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?

Because SHC has a strong focus on both: (1) developing useful tools and platforms, and (2) identifying the best processes for developing those tools, knowledge generated in this program will be applicable across a wide range of issues. This approach is well designed to build capacity within the program to meet unanticipated and emerging issues.

3.6.4. 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

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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 collaboratively develop best practices and model structures 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. The tools that offer the greatest value will be applicable for a wide range of communities with different social and ecological attributes and resources. The SAB and the BOSC recommend that social, behavioral and decision scientists be a part of this dialogue and play an important role in tool development so that tools, once developed, fit communities' needs and budgets.

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 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 can also provide information on the process for making good choices. If the decision support tools allow stakeholders 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.

3.6.5. 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 the BOSC applaud the integration that is evident in Theme 4. It is vital that tools and analysis be truly integrative across 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 three themes.

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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.

The Strategic Research Action Plan does not clearly communicate how the extrapolation from one place-based analysis to others occurs. Extrapolation could occur at the level of the decision support processes and tools that are developed. 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. 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. Decision-making tools should integrate across space just as systems approaches integrate across sectors.

The SHC program should review previous efforts to develop decision-making tools to ensure the utility of the current effort. What contributed to the success or failure of other tool development efforts? 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 so complex and unwieldy that they do not deliver useful results in a reasonable time frame. The more processes and feedback loops that are integrated, the less tractable the approach becomes. Great care needs to be taken to focus on the crucial aspects of the analysis for integration and resist the impulse to overcomplicate the approach.

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

3.6.6. 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 the right balance between breadth and depth. However, the plan could better highlight to understand system dynamics, including 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 and the BOSC recommend that SHC explicitly identify the likely suite of community objectives and desired outcomes, determine the metrics needed to measure performance or progress towards the objectives, and direct data collection efforts for those metrics.

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All of the themes were seen as important, with Theme 2 (forecasting and assessing ecological and community health) 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, work is being undertaken in other themes to support 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 in greater depth, offering commensurate added value.

There is a strong need for more investment in social, behavioral and decision sciences. Decision-scientists, economists, and sociologists should be integrated in ways appropriate to the specific question. Individuals who study unintended consequences, which often arise as a result 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 regarding the value of transdisciplinary integration.

3.6.7. Recommendations for the SHC program

- Integrating ecological and human health. The SAB and the 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. Although the communication flow among the different experts (e.g., ecosystem scientists and, human health scientists) does not always occur at the level needed, ORD is attempting to foster these interactions. Sustained efforts to promote interaction and integration are needed. ORD should outline the barriers to this integration and think creatively about strategies to help overcome them.

- 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 driving environmental, social and economic change, the value of ecosystem services, development of decision-support tools, the design of policies, and behavioral responses to policy changes. SHC has taken a step in the right direction but much work remains to be done. The SAB and the 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 the 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 too broad in scope. The SAB and the BOSC

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

- Engaging communities and building partnerships. The SAB and the BOSC commend the SHC program 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 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 in this area.

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APPENDIX A: CHARGE TO THE SAB AND THE BOSC

I. DRAFT SAB/BOSC CHARGE QUESTIONS FOR EACH BREAKOUT GROUP

1. FIRST YEAR PROGRESS

The Strategic Research Action Plans were developed during 2011, with the benefit of SAB and BOSC advice [*Office of Research and Development (ORD) New Strategic Research Directions: A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)*. (EPA-SAB-12-001)].

Charge Question: 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

The SAB and BOSC concluded in the October 21, 2011 report that "…ORD's research frameworks can advance EPA's adoption of sustainability as a core principle by more consistently and clearly describing where and how ORD research relates to sustainability."

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

3. BALANCING IMMEDIATE PROGRAM NEEDS AND EMERGING ISSUES

Meeting program and regional needs is a primary objective of ORD research. The highest priority needs of the programs tend to be those that are most immediate. Another important role for ORD is to anticipate the future scientific needs of the programs and regions, areas of research that tend to get less support from the EPA partners. Anticipating emerging issues and investing in innovative approaches that could lead to more sustainable, less expensive or timely solutions often requires longer term and potentially higher risk research. The Strategic Research Action Plans strike a balance in addressing current priorities and future science needs; however, new emerging issues will likely arise that are not currently anticipated.

Charge Question: 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?

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PROGRAM SPECIFIC QUESTIONS

Air, Climate and Energy Charge Question:
To create an integrated program, research in ACE is organized in three Themes: 1) Assess Impacts, 2) Prevent and Reduce Emissions, and 3) Respond to Changes in Climate and Air Quality. Research related to energy and environment is not a specific focus, but is most prevalent in Theme 2. Relevant topics include research on near-road air pollution, multi-pollutant research, and greenhouse gas impacts.

- 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?

Safe and Sustainabile Water Resources Charge Questions:

- 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?)*
- 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?

Sustainable and Healthy Communities Charge Questions:

- 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?
- 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?
- 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?

Chemical Safety for Sustainability Charge Questions:

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

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

Human Health Risk Assessment Charge Questions:

- The HHRA research program is committed to modernizing methods to evaluate the health effects of pollutants, consistent with advice of the SAB/BOSC and National Academy of Sciences. 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?
- In the 2010 mid-cycle progress review of the HHRA program the Board of Scientific Counselors noted that "IRIS assessments and ISAs are among the most heavily peer reviewed documents provided by scientists anywhere." 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?

Homeland Security Charge Question:

- The HSRP has conducted research primary to support EPA's 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?

II. DRAFT CHARGE QUESTIONS FOR GENERAL ORD/PLENARY SESSION

1. INTEGRATION ACROSS PROGRAMS

By their very nature, environmental issues are cross-disciplinary. Pollutants move and change across air, land, water and species. Energy, health, environmental justice and ecology are cross cutting topics. To organize research that is so intertwined requires a structure. By realigning its program from 16 distinct research topics to six related programs, ORD has made it a priority to eliminate stove-piped research and foster integrated, transdisciplinary research.

In the first year of implementation, the National Program Directors are in the early stages of managing each research program, while also taking steps to integrate across the six programs. This requires a balance of formally organizing and integrating research that relates to multiple programs, without creating additional, separate research programs.

While there are numerous topics that involve integration, ORD has selected five examples to present as case studies for the SAB and BOSC to consider. These five integrated topics reflect a range of dimensions including:

- topics that ORD has just begun to integrate and others that are further developed
- topics germane to every research program and others more narrowly focused among two or three
- topics that are more immediately client-driven and others that are longer-term

Integrated Topics:

- Nitrogen
- Global Climate Change
- Children's Health/Environmental Justice
- Applying new chemical assessment approaches in human health risk assessment

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- Endocrine-mediated Dose-Response

Charge Question: 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. INNOVATION

The Path Forward principles that guide ORD's realigned research program emphasize pursuing innovative, ground-breaking research. To address increasingly complex and expensive environmental problems, innovative solutions are needed.

Charge Question: 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?

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APPENDIX B: REFERENCES ON INNOVATION IN RESEARCH

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