



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

January 27, 2015

EPA-SAB-15-004

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Strategic Research Planning for 2016-2019: A Joint Report of the Science Advisory Board and Board of Scientific Counselors

Dear Administrator McCarthy:

The Science Advisory Board (SAB) and the Executive Committee of the Board of Scientific Counselors (BOSC) provide this letter to you at a time of great promise and important choices for the EPA's Office of Research and Development (ORD). ORD requested our two committees to provide early advice to inform the agency's strategic planning for ORD's six major program areas and four priority cross-cutting topics to cover the period 2016-2019. ORD's integrated research programs inaugurated in 2012 have matured to the point where strategic plans can help communicate ORD's ambitious mission and serve as a guide to how it will generate or leverage the most significant research the EPA needs. ORD faces, however, important decisions regarding these plans. EPA research resources are likely to be stable or, in real terms, declining, while the research needs envisioned increase in complexity and scope. For the strategic plans to be truly useful, they must provide a transparent way for the agency and the public to understand how ORD views its role in generating needed research and partnering with others.

The SAB and the BOSC held a public meeting on July 24-25, 2014, to develop the preliminary input for the enclosed report. The SAB and the BOSC also held a public teleconference on January 13, 2015, to reach agreement on the report. In those deliberations, the SAB and the BOSC reviewed draft Strategic Research Action Plans (StRAPs) for the following six programs: Air, Climate and Energy; Safe and Sustainable Water Resources; Chemical Safety for Sustainability; Sustainable and Healthy Communities; Human Health Risk Assessment; and Homeland Security. The committees also reviewed draft roadmaps for four cross-cutting research topics (Children's Environmental Health, Nitrogen and Co-pollutants, Climate Change, and Environmental Justice) identified by ORD. ORD asked our committees to respond to several over-arching questions regarding the relationship of ORD's programs to the agency's Strategic Plan, how ORD's proposed research will address environmental issues of 2020 and beyond, and how well ORD's overall research program will position the agency to address complex environmental problems. There were also specific questions for ORD's six program areas and four cross-cutting topics. The SAB and BOSC addressed all these questions and provide in this report recommendations to strengthen ORD strategic planning.

The full report responds to the broad scope of ORD's request. Key observations and recommendations include the following:

- ORD's draft StRAPs and roadmaps are closely aligned with the goals in the EPA strategic plan and represent an impressive transformation in ORD's research planning process.
- The plans are appropriately broad and ambitious, but they do not effectively communicate the scope of achievable research relative to ORD's anticipated resources. The StRAPs should communicate ORD's highest priority research related to the EPA's mission and decision-makers' needs and ORD's role in generating that research and partnering with others.
- Sustainability is stated as a goal in all the StRAPs, yet a common operational definition of sustainability across programs is not evident. The EPA's specific role of protecting human health and ecosystems within a sustainability framework needs to be highlighted.
- The draft StRAPs and roadmaps are in different stages of development. The various recommendations in the enclosed report are offered to improve them as communication and planning tools.
- It is critical for ORD to develop both short- and long-term human resource strategies to attract and develop a scientific staff capable of accomplishing the planned research, which depends on integration across ORD programs as well as disciplinary integration involving the social, behavioral and decision sciences. Any short-term strategy, such as hiring post-doctoral fellows, should be complemented by a long-term strategy for hiring and training staff for this type of research.
- ORD's cross-cutting roadmaps represent a significant step forward for the EPA. They provide a framework for research integration on large-scale, complex environmental challenges. The report provides recommendations for strengthening the roadmaps.
- The SAB and BOSC stress that implementation is as important as planning. ORD should explain how each StRAP and roadmap will be used and develop methods for evaluating their effectiveness.

The SAB and BOSC commend ORD for seeking advice at this early stage in strategic planning. Both committees are ready to assist the agency with additional advice to advance EPA's priority research. We look forward to your response regarding the advice in the enclosed report.

Sincerely,

/signed/

Dr. David T. Allen
Chair
Science Advisory Board

/signed/

Dr. Katherine von Stackelberg
Chair
Board of Scientific Counselors

Enclosure

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB) and the EPA 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 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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TABLE OF CONTENTS

Acronyms and Abbreviations	xiii
1. EXECUTIVE SUMMARY	1
2. BACKGROUND AND CHARGE	7
3. GENERAL FINDINGS AND OVERARCHING RECOMMENDATIONS	8
3.1. RELATIONSHIP TO THE EPA STRATEGIC PLAN	8
3.2. OVERALL PERSPECTIVES ON PROPOSED RESEARCH TO ADDRESS ENVIRONMENTAL ISSUES OF 2020 AND BEYOND	10
4. PROGRAM-SPECIFIC RECOMMENDATIONS FOR RESEARCH	12
4.1. AIR, CLIMATE AND ENERGY	12
4.2. SAFE AND SUSTAINABLE WATER RESOURCES	15
4.3. CHEMICAL SAFETY FOR SUSTAINABILITY AND HUMAN HEALTH RISK ASSESSMENT RESEARCH	17
4.4. SUSTAINABLE AND HEALTHY COMMUNITIES	20
4.5. HOMELAND SECURITY	25
5. RECOMMENDATIONS FOR INTEGRATION	29
5.1. CHILDREN'S ENVIRONMENTAL HEALTH	29
5.2. NITROGEN AND CO-POLLUTANTS	31
5.3. CLIMATE CHANGE	34
5.4. ENVIRONMENTAL JUSTICE	35
5.5. INTEGRATION ACROSS ORD PROGRAMS	37
REFERENCES	41
APPENDIX A: CHARGE TO THE SAB AND THE BOSC	A-1
APPENDIX B: TECHNICAL COMMENTS ON CROSS-CUTTING TOPICS	B-1

Acronyms and Abbreviations

ACE	Air, Climate and Energy
ATSDR	Agency for Toxic Substances and Disease Registry
BOSC	Board of Scientific Counselors
CEH	Children's Environmental Health
CBPR	Community-based participatory research
CRTS	Community Risk and Technical Support
CSS	Chemical Safety for Sustainability
DOE	U.S. Department of Energy
EDSP	Endocrine Disruptors Screening Program
HHRA	Human Health Risk Assessment
HSRP	Homeland Security Research Program
IPCC	Intergovernmental Panel on Climate Change
IRIS	Integrated Risk Information System
ISA	Integrated Science Assessment
ORD	EPA Office of Research and Development
NOAA	National Oceanic and Atmospheric Administration
NHANES	National Health and Nutrition Examination Survey
NRC	National Research Council
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAB	Science Advisory Board
STAR	Science to Achieve Results
SHC	Sustainable and Healthy Communities
SSWR	Safe and Sustainable Water Resources
USDA	U.S. Department of Agriculture
VOIA	Value of information assessment

1. EXECUTIVE SUMMARY

In 2011 and 2012, the Science Advisory Board (SAB) and the Board of Scientific Counselors (BOSC) Executive Committee provided advice to the EPA's Office of Research and Development (ORD) on strategic directions as ORD realigned its research into six integrated programs. The initial research plans guided ORD for 2012-2016. ORD is now beginning the development of Strategic Research Action Plans (StRAPs) to address research needs from 2016-2019 for the six programs:

- Air, Climate and Energy
- Safe and Sustainable Water Resources
- Chemical Safety for Sustainability
- Sustainable and Healthy Communities
- Human Health Risk Assessment
- Homeland Security

The update of these plans is in the formative stages, providing an opportunity to solicit early input and insights from the Chartered SAB and the BOSC Executive Committee. A joint meeting was held July 24-25, 2014, to discuss these StRAPs in the context of specific charge questions (provided in Appendix A). The results of that meeting are presented in this report. The first charge question focuses on the relationship of the StRAPs to overall priorities of the agency as described in the new EPA Strategic Plan (2014-2018). The second charge question relates to ORD's ability to anticipate the science that will be needed for environmental protection for 2020 and beyond. The next set of charge questions is specific to each research program. The remaining charge questions address specific examples of crosscutting, coordinated and transdisciplinary research across programs as demonstrated through draft roadmaps for four cross-cutting research topics identified by ORD (Children's Environmental Health, Nitrogen and Co-pollutants, Climate Change, and Environmental Justice) and for ORD research overall. Summarized below are the major topics addressed by the SAB and the BOSC and the major themes and key recommendations related to those topics. The full list of recommendations are detailed in the body of the report.

Relationship to the EPA Strategic Plan

ORD's draft StRAPs and roadmaps demonstrate high-level strategic thinking in linking ORD's efforts to the EPA strategic plan. They also attempt to frame, in a coordinated way, how ORD programs support sustainability. This represents a major change in the EPA's research planning.

The overall agency strategic plan appears to adopt the original National Environmental Policy Act definition of sustainability: "conditions under which humans and nature can exist in productive harmony and fulfill the social, economic, and other requirements of present and future generations." Although sustainability is invoked in each StRAP, the specific manifestation of the sustainability concept and relevance for each program's research remains largely abstract and unstated.

ORD's StRAPs can be powerful tools for communicating how the EPA's complex and inter-related research relates to the agency's mission. Although the ORD plans are impressive in scope, it is challenging to evaluate the StRAPs and roadmaps as internal strategic planning documents without a better understanding of ORD resources, personnel, and personnel backgrounds and capabilities.

Major themes and key recommendations:

- Communicate more consistently in the StRAPs and roadmaps the EPA's specific research niche and how ORD plans to partner with other entities, including international organizations and other federal agencies.
- Use the StRAPs and roadmaps to communicate the most important priorities for ORD to address.
- Communicate more clearly how research is being planned to inform specific agency decisions.
- Describe how decision makers will access and integrate information about the uncertainties associated with ORD-generated tools and data.
- Clarify how sustainability is operationally defined at ORD and elsewhere in the agency, and articulate how sustainability relates to the specific research planned in each program.
- Explain how ORD will develop or access the social, economic and behavioral sciences needed to achieve the goals of the EPA's Strategic Plan.

Overall perspectives on proposed research to address environmental issues of 2020 and beyond

ORD has made significant progress through the StRAPs and roadmaps in placing its research in a framework of the major environmental challenges confronting the United States. However, given that the ORD draft planning documents did not explicitly address longer-term vs. near-term needs, it is difficult for the SAB and BOSC to evaluate whether the proposed research areas will address the key environmental issues facing the agency in 2020 and beyond.

Major themes and key recommendations:

- Provide a more explicit description of the approach used to identify research necessary to anticipate emerging environmental issues.
- Add a section to each StRAP and roadmap whose purpose is to describe anticipated research needs for the next decade.

Air, Climate and Energy

The EPA's Air, Climate, and Energy research program (ACE) has a strong strategic plan, linking well to the EPA Strategic Plan and agency priorities, and addressing some of the most important current and emerging issues facing environmental quality, human health, and society in the coming decades. The program is exceptionally broad, with its scope encompassing criteria air pollutants, greenhouse gases, climate change, and energy. Energy, in particular is an extensive component, as the life cycle of energy influences all elements of the environment, and overlaps with the other five program areas.

Major themes and key recommendations:

- Include a conceptual framework in the StRAP to show linkages among elements of the ACE program.
- Document progress in agency programs addressing greenhouse gases and plan the research needed to inform future decisions.
- Plan to incorporate renewable energy scenarios and pathways developed by other organizations in ORD's analysis of environmental impacts.

Safe and Sustainable Water Resources

The Safe and Sustainable Water Resources (SSWR) StRAP outlines research activities in support of the EPA's Strategic Plan's goal of *Protecting America's Waters*. The major research topics were developed from an overarching theme of maintaining environmental, social and economic sustainability in the face of significant stressors, including climate change, extreme events, land use, aging infrastructure and population growth.

Major themes and key recommendations:

- Prioritize research and leverage partnerships to allocate financial and human resources across research areas (strengthening integration with the ACE and Human Health Risk Assessment programs), while balancing immediate and long-term needs and leveraging areas of strength completed by partnerships.
- Build on the EPA's dual role of research and regulation to identify a unique research role in moving toward a sustainable future related to water and energy needs, with particular emphasis on the nation's changing regional needs and demographic shifts.
- Utilize the EPA's research and regulatory role to pursue the concept that wastewater is a valuable resource.

Chemical Safety for Sustainability and Human Health Risk Assessment Research

Overall, the draft StRAPs for the EPA's Chemical Safety for Sustainability (CSS) and Human Health Risk Assessment (HHRA) research programs are scientifically robust and well aligned to the overarching EPA Strategic Plan. In fact, the programs were considered to be on a path to revolutionize chemical safety assessment and viewed as leading the field.

Major themes and key recommendations:

- Communicate more effectively the priorities within the programs and the approach to priority setting.
- As these two programs are effectively driving construction of a new paradigm for safety assessment, it is critical that the intended uses of new tools be specified as a key element of the architectural plan for the new paradigm.
- Advance exposure- and epidemiologically-based approaches.

Sustainable and Healthy Communities

ORD's Sustainable and Healthy Communities (SHC) StRAP provides a thoughtful applied roadmap for advancing high-priority agency research. SHC focuses on conducting basic research on community-oriented environmental and health issues. It also focuses on providing information to communities and the agency's regional offices concerning the development and application of sustainable practices relating to environment, society and economy.

Major themes and key recommendations:

- Develop a decision-support framework that is responsive to varied contextual and situational needs of decision makers. An effective suite of decision-support tools will be applicable across a wide range of contexts and will be accessible to a wide range of stakeholders and decision-

makers. A “one-size fits all” approach to decision support is unlikely to provide effective support for the range of problems and opportunities facing communities.

- Place additional emphasis on research focused on the fundamental values, concerns, and objectives that comprise environmental health and sustainability. Because these values, concerns, and objectives are important inputs to decision-making processes, addressing this need will require bilateral communication channels across many very different communities, as well as with researchers working in different aspects of environmental and social systems.
- Include an increased focus on environmental health as a critical component of sustainability. The current emphasis on the social and community aspects of sustainability do not adequately account for the environmental risks and ecological concerns identified in the agency Strategic Plan. Planned SHC research on sustainability indicators and sustainability objectives related to decision making focuses too narrowly on social and economic metrics, which may be at odds with ecological constraints. This, in turn, may result in a failure to account for the critical importance of environmental health as a driver of overall human well-being.

Homeland Security

The Homeland Security research program (HSRP) has a primary mandate of performing research related to the EPA goals of protecting water supplies and providing post-disaster clean-up in both indoor and outdoor environments. ORD has recently broadened the mission in the draft StRAP to include both terrorist and natural disaster threats to water supplies and post-disaster clean-up.

Major themes and key recommendations:

- Find approaches to deal with limited resources given the expansion of mission to “all threats,” including developing additional partnerships with other disaster-related agencies and with the EPA’s regional offices.
- Integrate terrorism-related and non-terrorism-related disaster and prevention research into the HSRP and expand tools relevant to multiple hazards.
- Clarify, develop, and expand appropriate systems approaches to research planning to meet the expanded mission of the HSRP.

Integration across ORD programs

Integration is critical given the EPA’s resource-limited environment and the interdisciplinary and cross-program nature and application of the science data, tools, knowledge and products ORD plans to produce. Integration must occur internally within the EPA, externally with the agency’s U.S. partners, and internationally. The ORD’s four cross-cutting roadmaps (Children’s Environmental Health, Nitrogen and Co-pollutants; Climate Change; and Environmental Justice) represent a very important step forward. The SAB and BOSC commend ORD’s progress in undertaking this integrated planning, and offer recommendations for strengthening the roadmaps and making them more consistent, moving from research planning to research execution, and defining a successful process for providing research to decision makers that incorporates institutional learning about that process.

Major themes and key recommendations:

- Identify and communicate ORD research priorities in the roadmaps and commit ORD resources to them.
- Acknowledge and plan for integration, which requires active collaboration and human and information resources.
- Implement a process for identifying ORD cross-cutting research topics and managing their life cycle, including criteria and a process for evaluating research “results that advance EPA's ability to address complex problems.” This process should include consideration of SHC as a possible future cross-cutting topic.

Children's Environmental Health

The Children's Environmental Health (CEH) cross-cutting roadmap preliminary draft is superbly developed and represents a great start to integrating research on CEH across the six programs. The EPA's ORD has a unique niche and important leadership role in selecting CEH as a cross-cutting area.

Major themes and key recommendations:

- Develop a more comprehensive translation research strategy to enhance the links from basic and observational science to intervention/implementation science to community action/policy toward the goal of improving children's health.
- Clarify and support research on communities' roles and involvement and leverage partnerships.
- More clearly describe how research themes in the StRAPs will be integrated to support the issues described in the CEH roadmap including development of more clearly specified research priorities.

Nitrogen and Co-pollutants

Research on the biogeochemical cycling of nitrogen and co-pollutants spans multiple environmental media and requires integration of basic science, models and mechanisms across multiple EPA program areas. Consequently, it is an excellent choice for cross-cutting research and integration across ORD program areas. The Nitrogen and Co-pollutants roadmap is well written and well organized. It is highly responsive to previous SAB input and recommendations (U.S. EPA SAB 2011b).

Major themes and key recommendations:

- Partner with USDA to study the effectiveness of approaches for management of nitrogen in agriculture (both crop and animal), including control of runoff and other emissions bearing nitrogen.
- Include an extended discussion of uncertainties associated with modeling and assessment of impacts of proposed management actions.
- Clarify how research priorities are set based on gap analyses and consider a value of information assessment approach.

Climate Change

Creating the EPA climate change cross-cutting roadmap is a challenge and the current draft roadmap on climate change is somewhat disappointing. The EPA's resources devoted to climate change, a critical environmental issue, are a small percentage of the overall federal climate change budget. ORD can best

approach this budget challenge by focusing resources on “actionable science” that informs ways the EPA can help address how climate influences air and water quality.

Major themes and key recommendations:

- Describe how planned research will inform future EPA decision making and guide research.
- Describe more clearly the ORD climate change research niche - “actionable science”- and how it works with other international and federal partners to meet EPA’s science needs.
- Improve the flow of the climate change roadmap, better identify research priorities and expand discussion of social sciences, uncertainties, decision-relevant scale, and synthesis.

Environmental Justice

The Environmental Justice roadmap provides a good framework for a research path in environmental justice. Although the problem statement is well described, specific goals and objectives are not. Without anticipated achievements, it is difficult to know which steps should be taken in a research roadmap to lead to effective results.

Major themes and key recommendations:

- Incorporate input from communities to identify problems associated with environmental, biological, behavioral, social, economic and spatial stressors, and how they interrelate.
- Integrate community participation throughout each science challenge and have community members inform the research process.
- Consider including examples to illustrate relationships to ORD’s six research areas and employing Community-Based Participatory Research (CBPR) to promote research relevance.

2. BACKGROUND AND CHARGE

The EPA's research programs in the Office of Research and Development (ORD) are structured to understand environmental problems and inform sustainable solutions to meet the agency's strategic goals. The research programs are organized into six national 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.

After receiving advice from the Science Advisory Board and Board of Scientific Counselors in 2011 (U.S. EPA SAB 2011a) on new strategic directions for its research programs and in 2012 on implementation of these programs (U.S. EPA SAB 2012), ORD requested the SAB and BOSC to provide early advice to inform research planning for the period 2016-2019. This planning included development of Strategic Research Action Plans (StRAPs) for the six program areas and "roadmaps" for four cross-cutting areas (Children's Environmental Health, Nitrogen and Co-pollutants, Climate Change, and Environmental Justice)

The SAB and the BOSC held a public meeting on July 24-25, 2014, to discuss the preliminary draft StRAPs and roadmaps. The SAB and the BOSC also held a public teleconference on January 13, 2015, 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 general questions related to ORD strategic directions; program-specific topics; roadmaps for cross-cutting topics; and program integration.

Section 3 provides responses to overarching, ORD-wide questions. Section 4 provides responses to ORD's program-specific charge questions. Section 5 addresses questions concerning the draft roadmaps for ORD's four cross-cutting topics and for ORD programs more generally. Additional technical comments for each cross-cutting topic are included in Appendix B. Discussions of ORD programs and cross-cutting topics appear in this report in the order they were discussed during the face-to-face meeting on July 24-25, 2014. All sections include recommendations, organized by the charge questions.

3. GENERAL FINDINGS AND OVERARCHING RECOMMENDATIONS

3.1. Relationship to the EPA Strategic Plan

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

In its strategic plan (U.S. EPA 2014), the EPA has committed itself to five environmental goals (Addressing Climate Change and Improving Air Quality; Protecting America's Waters; Cleaning Up Communities and Advancing Sustainable Development; Ensuring the Safety of Chemicals and Preventing Pollution; Protecting Human Health and the Environment by Enforcing Laws and Assuring Compliance) and to four cross-cutting strategies (Working Toward a Sustainable Future; Working to Make a Visible Difference in Communities; Launching a New Era of State, Tribal, Local, and International Partnerships; and Embracing EPA as a High-Performing Organization). ORD's draft StRAPs and roadmaps show high-level strategic thinking in linking ORD's research efforts to the EPA strategic plan and in framing, in a coordinated way, how ORD programs support progress toward the goal of sustainability. This represents a sea change in EPA's research planning. The draft documents are effective tools for communicating how the EPA's complex and inter-related research relates to the agency's mission, with one important caveat. The reorganization and redirection of ORD over the past decade and the specific research plans presented in the draft 2016-2019 StRAPs are directed toward providing the scientific foundation for a new integrated systems approach that attends to broad goals of enhanced and sustained health of the environment and the health and well-being of human communities. In contrast to the more traditional focus on informing regulation and compliance, this new broader mission may not be well understood and accepted by other parts of EPA, by the regulated community, and by the public. To the extent that understanding and support is lacking, the ORD should consider making a more concerted effort to "prepare the ground" for the new directions they intend to pursue in the coming decades.

Although the ORD plans are impressive, evaluating the StRAPs and roadmaps as internal strategic planning documents proves challenging without knowing more information about ORD resources, personnel, and personnel backgrounds and capabilities. Given stable or declining funding (in real terms) overall across program areas, there is some concern that the ambitious language in the StRAPs and roadmaps is not likely to match concrete research deliverables. The SAB and BOSC offer the recommendations immediately below to help ORD develop more effective research plans to support the EPA in meeting the goals of the agency Strategic Plan. Recommendations relating to strengthening the relationship of specific national programs to the EPA Strategic Plan may be found in the discussion of each program in section 4.

Recommendation: Communicate more consistently the EPA's specific research niche and how ORD plans to partner with other entities, including international organizations and other federal agencies.

Given the complexity of environmental problems and stable or declining resources, the StRAPs and roadmaps should communicate ORD's specific research focus within larger environmental issues and describe how ORD or the agency more broadly is meeting the science and research needs associated with those issues. The need for international cooperation is appropriately emphasized generally, but the StRAPs and roadmaps do not describe how the EPA plans to take advantage of knowledge created outside the United States and, in some cases, the StRAPs appear to be "reinventing the wheel." For example, the Chemical Safety for Sustainability StRAP does not mention two major international programs of direct relevance to that StRAP, namely the European Union Registration, Evaluation,

Authorisation and Restriction of Chemicals (REACH) Program, and the Canadian Priority Substances List. Similarly, the ORD can only focus on a small component of climate change research important to the EPA. How will other agency climate change research needs be met and how can ORD best leverage the many national and international efforts in this area? The EPA could also enhance its use of Cooperative Research and Development Agreements (CRADA) authorized under the Federal Technology Transfer Act. This program allows the EPA to transfer federal technologies into the marketplace, and collaborate on environmental research and development projects with outside entities, such as industry, consortia, academia, trade associations, and state and local agencies.

Recommendation: Use the StRAPs and roadmaps to communicate the most important priorities for ORD to address. As noted above, the plans and research directions for the six ORD research programs are generally well aligned to support EPA in meeting the goals of the EPA Strategic Plan. The challenge is that many of the planned activities are under-funded, often leading to narrow project scopes with modest projected impact. Considering the broad mission and range of expectations for ORD research programs and the reality of steadily declining ORD budgets, there is no easy way to address this shortcoming. ORD should seek advice from the SAB and BOSC to help it prioritize, rather than just expand the list of general research that EPA should be doing by virtue of its broad mission.

Recommendation: Communicate more clearly how planned research will inform specific agency decisions. ORD can best support the EPA's strategic goals if it develops research that is clearly linked to the information needs of agency decision makers and adheres to the EPA Strategic Plan core value of "transparency." ORD should consider expanding the use of the "dashboard for decision makers," which provides access to ORD-generated tools and research, as articulated by the Chemical Safety for Sustainability program, into other ORD programs.

Recommendation: Describe how decision makers will access and integrate information about the uncertainties associated with ORD-generated tools and data. In general, users of ORD research need more information on the reliability of models and forecasts, how to interpret the results of uncertainty analyses, and how uncertainty analysis will be incorporated into systems-based modeling approaches. Environmental complexity and biological variability make it critical to conduct broad uncertainty analyses and present a comprehensive set of results for statistical reliability of models. These models should include contexts where models are tested and found to be reliable and contexts where reliability is poor or has not been well-established. Essential elements include model verification, calibration and sensitivity analyses, particularly in the context of complex, linked models and systems-based models in which feedback loops may lead to unexpected outcomes.

Recommendation: Clarify how sustainability is operationally defined at ORD and the agency and articulate how sustainability relates to the specific research planned in each program. Although sustainability is presented as a central cross-cutting focus of the StRAPs, the formal role of sustainability is presented only in abstract terms, and sustainability tradeoffs and synergies are not discussed. The StRAPs do not convey a research agenda driven by the type of detailed, transparent consideration of sustainability recommended by the National Research Council (NRC 2011). The overall agency strategic plan appears to adopt the original National Environmental Policy Act definition of sustainability: "conditions under which humans and nature can exist in productive harmony and fulfill the social, economic, and other requirements of present and future generations," yet the specific manifestation of the sustainability concept and relevance for each program's research remains largely abstract and unstated. In at least one of the StRAPs (HHRA), the word sustainability could be entirely stricken from the document without any obvious impact. All of the StRAPs would benefit from a more

explicit treatment of sustainability, including how the concept is defined and how it influences the specific research that is proposed.

Recommendation: Explain how ORD will develop or access the social, economic and behavioral science needed to achieve the goals of the EPA's Strategic Plan. In terms of strategic emphasis, clarity, and motivations, the StRAPs are best developed in ORD's traditional areas of strength such as the natural sciences, risk assessment and human health. The draft StRAPs provide good roadmaps for continuing progress in these areas. Supporting the EPA Strategic Plan's six major goals and focus on sustainability, however, requires the agency to develop or access social, economic, and behavioral sciences. Past reviews of ORD research planning (U.S. EPA SAB 2011a, 2012) have noted the lack of a clear research agenda and expertise required to address important social, economic and behavioral dimensions of the EPA's goals. This shortcoming remains evident in the current ORD planning documents. The draft StRAPs are not well developed in the social, economic and behavioral sciences and in cross-cutting areas that involve these sciences. Although social, economic and behavioral aspects are mentioned in the StRAPs, the discussion is less sophisticated and developed compared to parallel topics in natural science, risk and health. Although the relative importance of social sciences varies across ORD program areas, social and human dimensions are relevant to all areas. ORD should describe its plans for hiring in the social, economic, and behavioral sciences and for training existing EPA staff in these areas in collaboration with appropriate academic institutions or professional associations.

3.2. Overall perspectives on proposed research to address environmental issues of 2020 and beyond

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

ORD has made significant progress through the StRAPs and roadmaps in placing its research in a framework of the anticipated major environmental challenges confronting the United States. However, this charge question is difficult for the SAB and BOSC to address because the ORD draft planning documents did not distinguish between longer-term vs. near-term needs. The SAB and BOSC offer recommendations to position ORD research so it explicitly addresses environmental issues of 2020 and beyond and also offers recommendations for particular areas of focus. Recommendations relating to the capacity of proposed research described in specific StRAPs to address environmental issues of 2020 and beyond may be found in the discussion of each program in section 4 of this report.

Recommendation: Provide a more explicit description of the approach used to identify research necessary to anticipate emerging environmental issues.

Although the draft StRAPs and roadmaps clearly acknowledge the complexity of emerging issues indicated in the EPA Strategic Plan, more detail could be provided on how these longer-term focal points and emergent issues might be better anticipated. ORD should better articulate early risk detection efforts at multiple geographic and temporal scales. A considerable amount of work outlined in the strategic plans involves assessment efforts, yet these may not be tuned to pick up on outliers that might be emerging and trend analysis to monitor trajectories of issues not yet in the cross-hairs of EPA programs and research. Early detection requires ongoing consultation with advisors and a wide spectrum of partners, stakeholders and experts to identify emerging problems and research needs.

Recommendation: Add a section to each StRAP and roadmap whose purpose is to describe research needs for the next decade. ORD's proposed research directions are focused on the near future (e.g., 2016-2019) rather than on 2020 and beyond. Adding to each StRAP and roadmap a section whose

purpose is to describe research needs of the next decade (2020s) and how current research relates to anticipated future issues would force the discussion. The section should discuss how those anticipated future needs will be identified and the process for managing the evolution of the research program. The exercise would also help direct ORD's current research projects and objectives into the future.

Although the SAB and BOSC review does not permit an extended discussion of future environmental issues, this report suggests that many anticipated issues will arise as a direct result of the tension between growth (e.g., population, consumption, economic) and finite resources (e.g., natural resources, biodiversity) and the ways in which a constrained ecological system can best be managed to meet human needs. SAB and BOSC members suggest that ORD consider as focal points issues that are a combination of stressors, drivers, and impacts, including, for example: (1) climate change; (2) habitat loss; (3) introduced/invasive species; (4) eutrophication; (5) chemical contamination; (6) evolving demographics and social systems; (7) technologies affecting the extraction and use of energy; and (8) continued transformations of land use and land cover.

4. PROGRAM-SPECIFIC RECOMMENDATIONS FOR RESEARCH

4.1. Air, Climate and Energy

The EPA's Air, Climate, and Energy (ACE) research program has a strong strategic plan, linking well to the EPA Strategic Plan and agency priorities, and addressing some of the most important current and emerging issues facing environmental quality, human health, and society in the coming decades. The program is exceptionally broad, with its scope encompassing criteria air pollutants regulated under the Clean Air Act, greenhouse gases, climate change, and energy. Energy, in particular, is an extensive component, as the life cycle of energy influences all elements of the environment and overlaps with the other five program areas.

4.1.1. **Support for the EPA Strategic Plan and Overall perspectives on proposed research to address environmental issues of 2020 and beyond**

Charge Questions 2a and 2b. How well will the research directions in each Early Draft StRAP (2016-2019) support EPA in achieving the relevant Agency objectives and cross-cutting strategies, as described in the EPA Strategic Plan (2014 -2018)? What are the SAB/BOSC perspectives on the proposed research directions in the StRAP providing research to address environmental issues of 2020 and beyond?

Recommendation: Document the progress addressing greenhouse gases resulting from agency programs and plan the research needed to inform future decisions. While the SAB and BOSC found the overall structure and substance of the ACE strategic plan to be sound, this report suggests a few changes that will strengthen the presentation and sharpen the focus. The plan is ambitious, and as such, may seem to be difficult to achieve. The StRAP should be revised to include a bold statement of what the EPA can do to forge a better future. A compelling introduction might begin by reporting on the potential success of the new greenhouse gas regulations in reducing emissions. While the Climate Action Plan is mentioned, the transformational nature of the EPA's new role in greenhouse gas emissions should be declared as an example of how the new vision and strategic plan can inform major advances for air, climate, and energy both nationally and internationally.

Recommendation: Include a conceptual framework linking program elements in the ACE StRAP.

A graphical representation of a conceptual framework at the outset will allow the reader to understand the scope, focus, and anticipated impact of the program (such as that provided in the presentation given by Dr. Daniel Costa, slide #4 at the July 24-25, 2014 meeting). Such a figure should show linkages among the elements of the complicated program hierarchy: (1) three elements of the program (air, climate, and energy); (2) the three research objectives (assess impacts, prevent and reduce emissions, and adapt/mitigate); (3) the five research topics; and (4) their short- and long-term aims. Such a diagram and description at the outset might further crystallize motivations and necessary interactions. The objectives are not presented until quite late in the document and represent the driving force for the strategic plan. A crisp vision for each of the research objectives should be succinctly presented at the very outset in a format that links clearly to the conceptual framework.

Recommendation: Clarify relative priorities, with respect to budget distribution and interactions with other agencies. The scope of the program is very large, but investments in the individual components (air, climate, and energy) are skewed, with a very large proportion of the effort focused on the "air" component, relative to the "climate" and "energy" elements. This occurs both as a result of the traditional focus on criteria pollutants within the EPA and because other federal agencies deploy

enormous resources toward climate and energy research issues [e.g. National Oceanic and Atmospheric Administration (NOAA), the Department of Energy (DOE), the U.S. Global Change Research Program]. Explicit recognition of the priorities, how they are reflected in the budget and in statutory mandates, and in turn how ACE anticipates resource allocations shifting as a result of the strategic plan should occur early and clearly in the document. Targets for inter-agency actions that will assist ORD in meeting its climate and energy goals should be elaborated. Research on mitigation represents a special opportunity for collaborative work that could be led by the EPA.

Recommendation: Elaborate and/or expand the research to be conducted on mitigation of climate change impacts. The current document (in the research topic on Climate Change Impacts, Mitigation, and Adaptation) is unclear with respect to what work is planned related to mitigation. For instance, there are no short-term goals at all related to mitigation. The SAB and BOSC recommend proposing tractable work in this arena. Connecting the work to the Intergovernmental Panel on Climate Change (IPCC) report on mitigation would be helpful.

Recommendation: Focus the distributed monitoring of air quality on quality data collection and distribution to citizens. The current document (in the research topic on emissions and monitoring) mixes two endpoints of a spectrum of environmental data from, on one end, accurate and precise regulatory-quality data from a limited number of sites, to the other end, ubiquitous citizen-science generated data of uneven overall accuracy and precision. The SAB and BOSC recommend that ACE work with and motivate entrepreneurs for the development of extensive high quality data that are available to the public in real time and potentially available for use for regulatory purposes. The rapid advances in sensing technology, the concomitant increases in accuracy and precision, and decreases in cost have highlighted the potential to deploy environmental sensors at orders of magnitude greater density than is currently the case. When combined with effective visualization, it is possible to provide the public with a much greater understanding of variations in environmental quality at a scale that matters to individuals. ORD is well positioned to help ensure that the quality of the data that flows from this sensor revolution is both accurate and inter-compatible. Given the large private investment already being made in the development of sensors, a convening and coordinating role is where ORD's investment would have the largest leverage.

Recommendation: Consider explicit focus and analysis of agricultural sources and other land use contributions to air pollution. Agricultural sources of air pollutants are significant. These sources include hazardous air pollutants, ammonia, methane and nitrogen dioxide fluxes stemming from fertilization and livestock, particulate matter from cultivation practices, and both direct and indirect impacts of energy use in agricultural production. The draft StRAP (essentially all research topics: Climate Impacts, Mitigation and Adaptation; Emissions and Measurements; Modeling and Decision Support; National Ambient Air Quality Standards and Multipollutant; Sustainable Energy Evaluation) is silent on agricultural sources, and their inclusion in the strategic plan and subsequent research is important.

Recommendation: Provide more specific targets for the short-term research aims. The current table in the strategic plan provides both short- and long-term research aims for each of the research topics. The short-term goals are likely still too diffuse, and it will be difficult to identify metrics that will allow evaluation of success. The SAB and BOSC recommend more specific targets focused on key knowledge gaps that can be used to define those metrics and actionable work plans.

4.1.2. Design for integration

Charge Question 2c. Did the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

Recommendation: Consider specifying projects that integrate ACE with other programs. The current ACE strategic plan presents opportunities for integration with other programs but does not identify goals for integrated research. Such goals for integrated projects would assure that the work occurs. The Sustainable and Healthy Communities program provides especially good synergy, with respect to the Emissions and Monitoring research aim, and the Sustainable Energy Evaluation research aim. Neither of these relationships is currently identified.

4.1.3. Integrating ACE research elements as a coherent whole

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

Recommendation: Consider incorporating energy efficiency/conservation research. The StRAP (Research Topic 5: Sustainable Energy Evaluation) avoids the topic of energy efficiency and energy conservation, even though energy use represents the single largest source of pollutants and increased efficiency is one of the most achievable means for reducing energy-related impacts. The EPA's Office of Atmospheric Programs manages the Energy Star program, which emphasizes the implementation of incentives for energy efficiency on a small-scale. Will ACE conduct research related to the behavioral and economic forces related to energy efficiency or on the opportunities for innovation in the arena of energy conservation and efficiency?

Recommendation: Plan to incorporate renewable energy scenarios and pathways developed by other organizations in ORD's analysis of environmental impacts. ORD should plan to use the renewable energy scenarios and pathways developed by other organizations as bases to analyze environmental impacts of importance to the EPA. For example, because of EPA's significant expertise in applied life sciences, it would be useful to engage DOE and other relevant agencies in the development of synthetic biology methods, which are already in research and development in the private sector as an alternative means of chemical synthesis and renewable biobased energy. The StRAP should include more discussion of ORD's coordinating efforts with DOE, the U.S Department of Transportation, U.S. Department of Agriculture and NOAA around likely scenarios for alternative fuels, vehicle standards, conservation, renewables and the reasons for their selection.

4.1.4. Major themes and key recommendations for ACE

- Include a conceptual framework in the StRAP to show linkages among elements of the ACE program.
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- Document progress in agency programs addressing greenhouse gases and plan the research needed to inform future decisions.

- Plan to incorporate renewable energy scenarios and pathways developed by other organizations in ORD's analysis of environmental impacts.

4.2. Safe and Sustainable Water Resources

The Safe and Sustainable Water Resources (SSWR) StRAP outlines research activities in support of the EPA's Strategic Plan's goal of *Protecting America's Waters*. The major research topics were developed from an overarching theme of maintaining environmental, social and economic sustainability in the face of significant stressors, including climate change, extreme events, land use, aging infrastructure and population growth. The purpose of the StRAP is to guide resources and activities over the next four years. The current plan is in its early stages and will be further developed and refined over the next year in consultation with numerous EPA partners and stakeholders.

4.2.1. Support for the EPA Strategic Plan

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

Recommendation: Prioritize research in order to allocate resources across research areas, balance immediate and long-term needs, and leverage areas of strength completed by partnerships. The four priority areas in the StRAP - watershed sustainability, nutrients, green infrastructure, and water systems – align well with the Strategic Plan at a high level and represent a balanced plan for the next four years. ORD is commended for the efforts taken to parse all of the potential research activities into four focused target areas, but it is essential to prioritize even among these objectives given declining budgets. SSWR must determine how to allocate resources across research areas and strike a balance between meeting immediate needs of the Office of Water while continuing to work toward longer-term strategic objectives.

There are several agencies actively involved in maintaining the health of the nation's waters. SSWR should identify areas of strength for the EPA and strive to make significant advances in those areas while developing complementary partnerships with other agencies and stakeholders.

4.2.2. Overall perspectives on proposed research to address environmental issues of 2020 and beyond

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

Recommendation: Plan for the human resource needs required by increased collaboration, integration and partnerships. As SSWR works to meet its research goals, partnerships will be essential. While the EPA should focus on identified research areas, the agency cannot move forward without strong collaborations across other agencies, both within the United States and internationally. Within the EPA, collaboration should occur at the ORD level, not just at the level of individual researchers. As the need for collaboration increases, additional staff dedicated specifically to developing and maintaining integration within and outside of the agency will be needed.

As SSWR plans for future research areas and begins to recruit researchers with the necessary expertise, it should develop a strategic plan to adequately meet human capital needs. Some examples

include: strategic use of postdoctoral fellows, development of methods to foster mobility for current EPA scientists, and hiring of social scientists.

Recommendation: Anticipate regional needs and changing demographics. SSWR should continue to anticipate regional issues as well as understand the implications of changing population demographics. Research on regional and watershed scales (e.g., wildfires, drought) should be included in overall research activities. Changing populations will affect the size and characteristics of populations being exposed to certain contaminants, as well as the types of contaminants present in water and other environmental media. De-population of urban areas (e.g., Detroit) should also be considered as this phenomenon may affect resiliency to extreme events, for example.

A stronger focus on invasive species related to regional and national needs should be included, including implications of climate change and modeling/prediction of secondary transport.

Recommendation: Develop models with appropriate capability to communicate uncertainties. In general, model results should clearly communicate uncertainties and limitations to decision makers and the public. Wherever possible, uncertainty should be quantified. This can be done by complementing the use of complex process models that do not allow estimation of uncertainties with simpler probabilistic models that lend themselves to uncertainty analysis.

Recommendation: Communicate the concept that wastewater is a resource. SSWR should actively promote the transition of the term “wastewater” to “resource” to reflect that wastewater is a secondary resource that has potential for multiple beneficial reuses, both as a source of water but also as a source of trace metals, nutrients and other resources.

4.2.3. Design for integration

Charge Question 2c. Did the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

Recommendation: Increase integration with ORD’s Human Health Risk Assessment and ACE programs and with other federal agencies. The SSWR research plan is generally well integrated with other programs. The plans indicate linkages between the four priority research areas in SSWR and other programs. Strong linkages exist with Sustainable and Healthy Communities, but integration with Human Health Risk Assessment should be increased. Additional focus on the water-energy nexus would strengthen the existing integration with the ACE StRAP. Beyond integration among the ORD programs, the SSWR StRAP should reflect improved engagement and collaboration with other agencies, particularly USDA and DOE.

4.2.4. Research for a sustainable water-energy future

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

Recommendation: Build on the EPA’s dual role of research and regulation to identify a unique research role in moving toward a sustainable water-energy future. The StRAP positions the EPA well in the water-food-energy-climate space and builds on the EPA’s dual role of research and regulation. Since there are many agencies with interest, expertise and resources dedicated to the water-energy nexus, it is important that the EPA carve out a unique role by partnering with other players and actors in this area and avoid duplication of efforts.

The EPA's work in providing technical assistance to municipalities is useful, particularly for small systems that lack a research budget. Expertise in areas such as water reuse and systems analysis will help to reduce energy needs in water treatment and distribution, as well as to develop a life-cycle approach for water. Strengths in fate and transport modeling, uptake and human and environmental risk analysis are additional assets for the EPA. Additional focus could be added to climate uncertainties, understanding extreme conditions and events, and developing mechanisms for adapting to and managing these situations.

The EPA could make a significant contribution in deployment of policies and technologies to address the water-energy nexus (e.g., social and technological aspects of green infrastructure adoption, development of monitoring technologies and approaches).

4.2.5. Major themes and key recommendations for SSWR

- Prioritize research and leverage partnerships to allocate financial and human resources across research areas (strengthening HHRA and ACE integration), while balancing immediate and long-term needs and leveraging areas of strength completed by partnerships.
- Build on the EPA's dual role of research and regulation to identify a unique research role in moving toward a sustainable future related to water and energy needs, with particular emphasis on the nation's changing regional needs and demographic shifts.
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- Utilize the EPA's research and regulatory role to pursue the concept that wastewater is a valuable resource.

4.3. Chemical Safety for Sustainability and Human Health Risk Assessment Research

Overall, the draft StRAPs for the EPA's Chemical Safety for Sustainability (CSS) and Human Health Risk Assessment (HHRA) research programs are scientifically robust and well aligned to the overarching EPA Strategic Plan. In fact, the programs were considered to be on a path to revolutionize chemical safety assessment and viewed as leading the field. While the current iterations of the StRAPs were intentionally high-level strategic documents that did not include many details on implementation, the availability of the National Program Directors for CSS and HHR during preliminary webinars and the CSS/HHRA breakout group meeting was extremely helpful in providing additional clarification. The comments and recommendations below reflect common themes based on both written and verbal input from SAB and BOSC members. Unless noted otherwise, the comments apply to both the CSS and HHRA programs.

4.3.1. Support for the EPA Strategic Plan

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

Recommendation: Communicate more effectively the priorities within the programs and the approach to priority setting. At a high level, the research directions appear to align with the highest priority issues for the EPA, are cross-cutting, and should help the agency achieve its objectives. However, the proposed research programs are extremely ambitious in their scope. In fact, it seems that there is enough research in the plans to last well beyond 2020, yet not enough resources to accomplish everything within the

2016-2019 time frame. Therefore, it is recommended that subsequent versions of the StRAPs clearly indicate those projects which are considered highest priority and can be realistically accomplished with available resources. In setting priorities, the SAB and BOSC recommend that the landscape of relevant global research activities be considered in order to avoid duplicative efforts and ensure that the EPA is working in areas which best play to its strengths. Also, it will be important to resist the temptation to deprioritize long-term programs in order to overcome budgetary constraints on more urgent deliverables.

Recommendation: Clarify the intended uses of new tools. Both the CSS and HHRA StRAPs speak in high-level terms about generating new tools which should enable the agency to make “better informed, more timely decisions about chemicals.” While the phrase “fit for purpose” was frequently used throughout both documents, limited information was provided on what those purposes were. Therefore, it is recommended that more information on intended applications of new methods be provided to ensure that the research products delivered by the program actually are fit for purpose in the eyes of end users. Since National Program Directors for both programs were able to provide verbal examples of “fit for purpose” projects that they had prioritized, the SAB and BOSC recommend that these example details be added to the plans. Some suggested applications of the new tools might include:

- Setting priorities among the research programs and plans in the StRAP;
- Using ToxCast + ExpoCast data to increase the throughput of Provisional Peer-Reviewed Toxicity Values (PPRTVs) and to increase the certainty of the ones already generated; and
- Creating new Integrated Approaches to Testing and Assessment (IATA’s) and/or new Organisation for Economic Co-operation and Development (OECD) testing guidelines.

4.3.2. Overall perspectives on proposed research to address environmental issues of 2020 and beyond

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

Recommendation: Build confidence in new approaches for assessing safety. The CSS program in particular conveys an overall tone of exuberant enthusiasm, which gives the impression that the new tools are ready for use today. In reality, some new tools are very close to being ready for agency application, but many others will require much more work to prove their validity and utility. As the program contemplates its strategic direction beyond 2020, it would be extremely useful to internal and external stakeholders to have an approximate time line describing targets for transferring research products into actual practice within the agency. Such a time line would foster a methodical, step-wise transition from conventional to modern “21st century” methods and approaches, and would ultimately build stakeholder confidence. Toward this end, an iterative approach to tool creation, evaluation, and application is strongly recommended in order to maintain confidence during this period of transition. This approach should involve partnerships between researchers, end users and key stakeholders.

A number of other activities for building confidence in new approaches also are recommended, including:

- Quality control to verify the accuracy of high throughput/high content data already collected;
- Demonstration projects in collaboration with program offices to show how new methods can be put into practice. It is recommended that highly experienced risk assessors within the agency be involved in such projects;
- Evaluation projects to qualify new methods for specific assessments;
- Leveraging of human data to evaluate the ability to predict human toxicity;

- Contingency plans to account for the possibility that predictive models may not always be predictive (especially for highly complex end points, susceptible life stages, etc.); and
- Bridging of newer molecular and cellular level toxicity end points with conventional toxicology end points through the use of systems- and Adverse Outcome Pathway-based approaches.

4.3.3. Design for integration

Charge Question 2c. Did the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

Recommendation: Continue integrating in a targeted and purposeful manner. Integration is clearly and deliberately emphasized in both StRAPS. In fact, both programs have already come a long way in terms of integrating and collaborating with other programs inside the EPA and with federal partners, in no doubt due to a robust process in place to drive this integration. CSS/HHRA are expanding integration by working with, or planning to work with, the World Health Organization, the European Commission (European Chemicals Agency, the Joint Research Centre), OECD, and China. Program Directors for CSS and HHRA discussed their revised approaches to work with these groups using a targeted approach that addresses the EPA's needs. Given the time consuming and labor-intensive nature of integration, ORD's targeted and purposeful approach to integration is applauded. As mentioned previously, it is important to know what other organizations are doing in this space so that the efforts to integrate are synergistic rather than duplicative.

One important area of integration which appears to have been overlooked is the need to pay close attention to large-scale chemical assessment programs in other regions of the world (e.g., European Union's REACH, Korea and China) that continue to generate animal toxicity data on hundreds, if not thousands of chemicals. Will these data preempt the need for high throughput data on these same chemicals? Can the EPA partner with these organizations on the development of alternative, non-animal approaches? Can some of the subchronic animal data generated in REACH be used to predict longer-term toxicity end points (notwithstanding issues around access to proprietary data)?

4.3.4. Exposure and response assessment approaches for the HHRA program

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

Recommendation: Advance exposure-based approaches. There was strong support for the use of risk-based approaches which combine hazard identification, dose-response assessment and exposure, as these should enable the agency to allocate resources to the problems that will have the greatest impact on public health. In fact, the effort to obtain exposure data on a large universe of chemicals in different products at a variety of life stages is truly game-changing. Incorporation of exposure into early stage screening (e.g., endocrine screening) will make such screening more effective and meaningful.

4.3.5. Novel data streams

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

Recommendation: Take a methodical, step-wise approach to incorporation of novel data streams. As a general concept, the SAB and BOSC support the increased incorporation of novel data streams into

EPA assessments. With respect to high throughput and/or high content data, there are questions about what these new data are telling us and how they will be used in different types of assessments. As mentioned previously, the StRAPs would benefit from more clarity and detail around the intended uses of these new data for various agency programs as the approach to using new data streams will vary between different tiers of assessments (e.g., screening vs. quantitative risk assessment). As the field develops approaches for using modified experimental techniques including but not limited to pathway based approaches, new *in vitro* models and modified *in vivo* models, the CSS and HHRA programs should use a transparent and stepwise approach to incorporate these novel data streams. CSS and HHRA research should leverage human disease literature and human epidemiology data from sources such as, but not limited to, the National Institutes of Health, Food and Drug Administration and Centers for Disease Control. Use of the National Health and Nutrition Examination Survey (NHANES) would also be useful. Lastly, it is also recommended that ‘omics’ technologies be incorporated into the array of bioprofiling tools in the ToxCast program. Such methods enable extremely broad coverage of biological responses to chemical exposure.

Recommendation: Continue to emphasize communication, education and outreach. The CSS program in particular has realized that the tools it is developing are transformative and may be unfamiliar to staff in program offices and regions that are distant from the research and have long-standing ways of doing their work. As such, the initiatives dealing with education, training, and outreach are strongly encouraged and are considered essential for stakeholder understanding and acceptance of new approaches.

4.3.6. Other approaches

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

Recommendation: Develop novel approaches to address cumulative risk in a holistic manner. Some of the new tools for both toxicity testing and exposure assessment are expected to lead to novel approaches for assessing cumulative risk that were not possible before. In addition, there is strong support for holistic approaches which consider both chemical and non-chemical stressors. In the future, cumulative risk could become the next new cross-cutting roadmap area.

4.3.7. Major themes and key recommendations for CSS and HHRA

- Communicate more effectively the priorities within the programs and the approach to priority setting.
- As these two programs are effectively driving construction of a new paradigm for safety assessment, it is critical that the intended uses of new tools be specified as a key element of the architectural plan for the new paradigm.
- Advance exposure- and epidemiologically-based approaches.

4.4. Sustainable and Healthy Communities

ORD’s Sustainable and Healthy Communities (SHC) StRAP provides a thoughtful, applied roadmap for advancing high priority agency research. SHC focuses on conducting basic research on community-oriented environmental and health issues and providing information, tools, and data to communities and the agency’s regional offices concerning the development and application of sustainable practices that address environment, society and the economy.

Listed below are recommendations for addressing the complex challenges associated with developing sound approaches to SHC research. In identifying these challenges, the SAB and BOSC recognize that the SHC StRAP is intended to serve as a high-level guidance document, not as a detailed accounting of its research agenda. The SAB and BOSC strongly recommend that ORD revise the StRAP to acknowledge these challenges both up-front and throughout the document.

4.4.1. Support for the EPA Strategic Plan

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

Recommendation: Address the challenges of developing good community-based decision support tools and maintaining and sustaining partnerships. The SHC StRAP does a good job of addressing the need for a multi-criteria approach to decision-making, and supporting the establishment of partnerships and community decision-making. However, it may underestimate the difficulty of developing good decision support tools general enough for broad application and flexible enough to address decision making in a regional context.

A key element of the SHC StRAP is to establish a research agenda focused on collecting information, and developing methods and tools for supporting agency and community decision-making. The desire for improved decision-making runs the gamut from agency to community concerns (e.g., air, water, contaminated sites) and involves differing temporal and spatial scales. The SAB and BOSC strongly endorse ORD's proposed work in this area. Advancements in how to improve the quality and defensibility of agency decision-making at the community level is needed to help the EPA achieve its sustainability goals operating as a high-performing organization responding to citizens' needs and expectations. However, the StRAP does not adequately address many of the challenges likely to be encountered in a research agenda focused on decision-making, especially at the EPA Region and community levels.

Many of these challenges are the crux of the SHC research agenda and, therefore, warrant greater attention:

- *Recognition that the development and application of effective decision-making approaches (and specific decision-making tools) will depend upon building and—importantly—maintaining effective partnerships and engagements with communities.* Effective engagement with communities is especially important when considering the unique needs of marginalized stakeholders and communities. ORD's crosscutting research devoted to environmental justice needs to be more tightly integrated into the SHC StRAP. The SHC StRAP also needs to clearly distinguish between stakeholders and partners and clearly articulate the relationships between the two.
- *Acknowledgement of the complex, multifaceted nature of decision-making processes.* Effective decision-making processes are highly sensitive to context, with different decision problems (and decision opportunities) requiring varying levels of technical sophistication. Although ORD currently has ongoing research to identify a typology of communities and the contextual basis for decision-making, the SAB and BOSC question the ability of ORD research, as currently articulated and configured in the StRAP, to provide effective decision support across all contexts.

- *Acknowledgement that setting and implementing a research agenda focused on decision-making will not be easy.* In addition to the challenges outlined above, the development of decision-making approaches and tools will require careful evaluation. Evaluation will require that ORD establish systems for communication across different communities to maximize opportunities for cross-community and cross-approach learning. Community needs and priorities will change over time, so decision tools require flexibility and adaptability.
- *Recognizing that a research agenda focused on sustainability and decision-making may be a “tough-sell” in some communities.* Communities dealing with certain classes of problems (e.g., contaminated sites) may simply want *straight answers* and not *better processes*. They may want to identify how to *fix* problems and not just *think about* or analyze problems. Thus, the SHC program should include research on more fundamental concerns around environmental health and “sustainability” as inputs to decision-making processes. Addressing this challenge will require bilateral communication channels across many very different communities, as well as with researchers working in different aspects of environmental systems.

Recommendation: Communicate that environmental health is a critical driver of overall human well-being and sustainability. The SHC focus on “sustainability” should include an increased focus on environmental health. Some members found that the current emphasis on community sustainability did not adequately account for the environmental risks and ecological concerns identified in the agency Strategic Plan. In other terms, the planned SHC research on sustainability indicators and sustainability objectives related to decision making focus too much on social and economic metrics that may be at odds with ecological constraints and may result in the EPA (and the communities the agency serves) inadvertently failing to account for the critical importance of environmental health as a driver of overall human well-being.

4.4.2. Overall perspectives on proposed research to address environmental issues of 2020 and beyond

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

Recommendation: Plan for robust and flexible decision tools. The state-of-the-art in the different disciplines that comprise the science of decision-making continue to evolve, and the data and information used to inform decision making is always in flux. Therefore, the approaches and tools being developed by ORD should be sufficiently robust and flexible to address both present and emerging environmental issues and take advantage of new information. From the information provided, it was unclear to reviewers whether the planned SHC research considered expected changes such as aging populations, immigration, flooding of coastal communities with sea-level rise, or the changes occurring in legacy cities (e.g., Detroit) or whether planned tools and decision support systems were adaptive enough to respond effectively and efficiently to changing conditions.

Recommendation: Assess emerging environmental issues with special attention to changing demographics, cumulative impacts, and energy-related environmental impacts. The SAB and BOSC recommend that ORD devote some of its resources to tracking and assessing changing environmental conditions and concerns at the community level, which will be sensitive to changing demographics. These kinds of changes, which may initially appear relatively unimportant or insignificant, have the potential to develop into those that pose the greatest challenges to the EPA in 2020 and beyond. In addition, the committees recommend that ORD closely monitor issues for which cumulative effects might likely be problematic. For example, ORD should monitor concerns that arise on the chain of

energy development, from site-specific environmental concerns to energy transport (e.g., interstate and—in many cases—international risks from pipelines, rail, and ship transport) to energy use (e.g., carbon pollution and air quality concerns), which, clearly, will involve integration and cooperation with ACE and other programs.

4.4.3. Design for integration

Charge Question 2c. Did the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

By and large, the answer is yes. Integration is very evident at the conceptual level of the StRAP. And, where specific discussions of integration across the other five national research programs—as well as the different crosscutting roadmaps—were absent, reviewers found it easy to see the connections between those activities and planned SHC research activities.

Recommendation: Make integration of research planning a priority for management and capacity building. Although integration is evident at the conceptual level of the SHC StRAP, it was not clear that the reality of implementing research described in the EPA StRAPs and roadmaps will achieve needed integration. Without management attention, the six national program areas could devolve into six isolated silos. The SAB and BOSC observe that, while *specific* recognition of collaboration among the six national program areas was evident in the presentation made by ORD at the SAB-BOSC meeting of July 24-25, 2014, such detailed information was not discussed in the StRAP.

The SAB and BOSC recommends that ORD senior leadership ensure that effective communication and integration across the six national program areas takes place. Both leadership on, and resources devoted to, building transdisciplinary capacity within the EPA will be required to effect and maintain integration.

4.4.4. Providing tools to effectively support communities

Charge Question 4a. Does the research program contain the elements necessary to integrate two critical elements (ecological and human health) of EPA's mission?

Broadly speaking, the answer to this question is, yes. However, greater clarity is required in the StRAP with respect to the extent to which human health and ecological health are being addressed as parts of *integrated systems* or being developed separately from each other following a traditional stressor-response paradigm.

Recommendation: Address ecological and human health as parts of integrated systems. SHC research should treat ecological and human health as components of coupled natural-human systems. The SAB and BOSC identified weaknesses in the StRAP's discussion of systems-based approaches and topics requiring transdisciplinary research. For example, some of the individual research examples outlined in the StRAP seemed to focus on individual elements of systems and not the coupling of different human and natural dimensions within systems. The SAB and BOSC recommend that specific and direct lines of collaboration be developed between SHC and the Human Health Risk Assessment programs. The SHC StRAP should include a focus on life-cycle analysis and recognize explicitly that sustainability is largely a function of the tradeoffs and synergies among environmental, social, and economic priorities.

4.4.5. Increased well-being

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

The SAB-BOSC answer to the charge question is a definite yes. However, the committee recommends that the StRAP state more explicitly that there is more to “well-being” than environmental and human health. For example, well-being can be connected to economic security, as well as various social and psychological considerations that are likely to be evident at both the community and individual levels. Moreover, well-being—much like the concept of sustainability—will have an evolving definition based on the decision context for which it is being considered. Further, the definition of well-being may differ *within* and *between* communities.

Recommendation: Continue and expand research focused on defining and measuring well-being, building on existing resources on this topic. The SAB and BOSC recommend that ORD continue and expand its research focused on measures of human well-being and its relationship to environmental health. This report strongly recommends that ORD review the wealth of existing research, across a broad range of disciplines, focused on defining and measuring well-being (McGillivray and Clarke, Eds. 2007; McGillivray 2008; Helliwell et al 2013; ecoAmerica 2014). This research can provide a valuable basis for assessing and determining well-being across different communities. Moreover, under its research efforts devoted to decision-making, ORD should attempt to identify the varied objectives of stakeholders that will comprise “well-being” and work toward developing measures and measures that characterize these objectives to assess well-being in community-specific contexts (Diener 2009, United Nations 2012).

4.4.6. Science of sustainability

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

The SHC’s emphasis on research in decision-making processes and the foundational data to support those processes is precisely where ORD should be focusing its efforts. However, to inform decisions regarding ways to conduct research on the science of sustainability, the SAB and BOSC provide the recommendations below.

Recommendation: Conduct a thorough review of ongoing research in the science of sustainability. There are an extensive number of publications focused on research on the science of sustainability that can inform ORD’s thinking about ways to conduct its own research. Sustainability science is increasingly well-defined and research agendas have been published; presumably these are known to ORD and can provide additional perspective (see, for example, NRC 1999a; NRC 1999b; Kates et al. 2001; Clark and Dickson 2003; Swart et al. 2004; Kates, 2011; NRC 2012a; NRC 2012b).

Recommendation: Look outside the agency for ideas about research methods. The generation of ideas from outside ORD would add significant value for the agency. Calls for research proposals from scientists outside the EPA through EPA’s Science to Achieve Results (STAR) program, as well as through partnerships with other government agencies and foundations (e.g., the National Science Foundation), would almost certainly lead to the development of new research approaches and practices that would be applicable to the SHC’s mission.

Recommendation: Build transdisciplinary and applied social science research capacity within ORD.

There is a need to build capacity in the social and behavioral sciences and to effectively integrate these sciences with ORD's traditional strengths in the natural sciences. The SAB and BOSC recommend that ORD, when hiring opportunities occur, explore adding personnel with training in transdisciplinary approaches to addressing issues and opportunities at the environment-human nexus, in addition to additional personnel with expertise and skills in the applied social and behavioral sciences. ORD should also train existing EPA staff in these areas in collaboration with appropriate academic institutions or professional associations.

Recommendation: Clarify the “three-legged stool” approach to sustainability. “Sustainability” in this StRAP relies on the concept of the “three-legged stool” (i.e., environment, society, economy), although this is not the definition offered by any other StRAP or the Strategic Plan. The more recent sustainability literature critiques the pillars (which lend themselves to silos) in favor of more holistic representations in recognition of the hard constraints imposed by environmental limitations (Dawe and Ryan 2003; Raskin et al. 2010; Díaz et al. 2011; Costanza et al. 2012). This latter view of sustainability seemed to be the focus of the information presented in the SHC overview slides at the SAB-BOSC meeting, but not in the StRAP itself.

Systems-based approaches, emphasized as necessary across all the StRAPs, will by definition require integrated approaches to achieve agency objectives. ORD should revise the StRAP to acknowledge the reliance of societal and economic metrics on environmental constraints (Rockström et al. 2009, Baronsky et al. 2012; Costanza et al. 2012), particularly as communities may not be aware of the tradeoffs and synergies among economic, societal, and environmental goals.

4.4.7. Major themes and key recommendations for SHC

- Develop a decision-support framework that is responsive to varied contextual and situational needs of decision makers. An effective suite of decision-support tools will be applicable across a wide range of contexts and will be accessible to a wide range of stakeholders and decision-makers. A “one-size fits all” approach to decision-support is unlikely to provide effective support for the range of problems and opportunities facing communities.
- Place additional emphasis on research focused on the fundamental values, concerns, and objectives that comprise environmental health and sustainability. Because these values, concerns, and objectives are important inputs to decision-making processes, addressing this need will require bilateral communication channels across many very different communities, as well as with researchers working in different aspects of environmental and social systems.
- Include an increased focus on environmental health as a critical component of sustainability. The current emphasis on the social and community aspects of sustainability do not adequately account for the environmental risks and ecological concerns identified in the agency Strategic Plan. Planned SHC research on sustainability indicators and sustainability objectives related to decision making focuses too narrowly on social and economic metrics, which may be at odds with ecological constraints. This, in turn, may result in a failure to account for the critical importance of environmental health as a driver of overall human well-being.

4.5. Homeland Security

Within ORD, the Homeland Security research program (HSRP) has a primary mandate of performing research related to the EPA goals of protecting water supplies and post-disaster clean-up, both outdoors

and indoors. ORD has recently broadened the mission in the draft StRAP to include both terrorist and natural disaster threats to water supplies and post-disaster clean-up.

4.5.1. Support for the EPA Strategic Plan

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

The HSRP's historical focus and new "all threats" mission supports many agency objectives including, protecting America's waters, preventing pollution, clean-up from long term pollution releases as well as immediate disasters, enhancing community resilience, and reducing community vulnerabilities.

Recommendation: Explore a systems approach and develop partnerships to stretch limited resources to help meet the HSRP historical focus and new "all threats" mission. The main question of concern is how the HSRP can widen its focus to include all threats, given that HSRP resources are not being expanded. While the review of the StRAP does not provide an opportunity to provide detailed advice, the SAB and BOSC suggest that the EPA utilize systems approaches to meeting the agency's overall mandates, exploiting commonalities between threats, cleanup-measures etc. Section 4.5.5. addresses the systems approach topic further. In addition, the HSRP should seek creative partnerships with other agencies and entities conducting research on topics relevant to the EPA HSRP mission.

4.5.2. Overall perspectives on proposed research to address environmental issues of 2020 and beyond

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

Overall, the general strategy of providing tools, technology, and data for threat prevention, decontamination or cleanup, is relevant to threats likely to be faced in 2020 and beyond. Some of the threats to water supplies and cleanup requirements to be faced are potentially predictable on the basis of today's knowledge as infrastructure ages and as *ad hoc* containment systems fail, although assembling and maintaining databases and providing new tools to identify the most vulnerable aging infrastructure is a daunting task.

On the other hand, there are inherent uncertainties in other future threats. For example, identifying the locations at primary risk of future flooding due to global warming and the resulting flood-related chemical and biological contaminations and cleanup needs are dependent upon uncertain speeds of ocean rise. Specific terroristic threats are also uncertain. Based on today's knowledge, it is difficult to know whether future failures in cyber security could allow terrorists at a distance to perpetrate major threats to water supplies through contamination releases from highly automated modern factories or storage locations. More generally all terrorist threats depend upon the unknown levels of specific expertise and access, technological sophistication, and the motivations of the future actors in future events.

Recommendation: Plan for tools relevant to multiple related hazards and invest in innovation programs. The HSRP tends to be driven by many short-term immediate demands in highly applied research topics, and indeed flexibility is very important for the response to disaster needs. It is, however, also very important to make efforts to build tools that will be relevant to multiple related hazards when responding to specific disasters or prevention requirements.

Because the HSRP is producing outputs on a continuous basis and getting continuous input, the HSRP research products will be coming out in a phased manner, so these needs will be better identifiable and addressable as 2020 approaches.

The SAB and BOSC recommend that the HSRP participate in ORD's innovation programs to allow interesting potentially high-reward research ideas and projects to be considered.

4.5.3. Design for integration

Charge Question 2c. Did the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

Recommendation: Maintain the current high level of integration with ORD research programs and terrorism-related research of other agencies and build partnerships with non-terrorism, disaster-related agencies as well as EPA regional offices. The HSRP is best designed to deal with a higher level of uncertainty about its future research directions than most other ORD programs. Nevertheless, there are many tasks of the HSRP that are clearly joint projects with other portions of ORD and other agencies. These include but are not limited to: further developing knowledge about the transport and long term fate of specific contaminants; contaminant detection; exposure assessment; and risk assessment. Overall the draft StRAP describes collaboration within ORD very well. It is clear also that the HSRP is very well integrated with the terrorism-related areas of other agencies. The HSRP is probably less well integrated with the non-terrorism, disaster-related agencies. Such integration will need to be deepened as HSRP fully embraces its "all threats" mandate. The SAB and BOSC specifically encourage the HSRP to work through the EPA regional offices in an effort to expand its understanding of potential threats to be faced as well as to reach all relevant stakeholders.

4.5.4. All-hazards research

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

Recommendation: Plan to integrate terrorism-related and non-terrorism disaster response and prevention research. An overriding issue is how the HSRP can broaden its mission without weakening its role in security research, especially given budgetary constraints. Whenever possible the HSRP should aim to exploit the tools, lessons, and science developed for terrorism-related research to all hazards rather than starting from scratch if the problems addressed are similar enough. Employing systems thinking will also help identify specific research projects which address multiple hazards. The program should avoid developing two silos of programs, one related to terrorism response and prevention and the other related to non-terrorism disaster response and prevention.

The HSRP should continue to develop strategic and synergistic partnerships with other agencies and stakeholders. The HSRP already is well integrated with terrorism-related agencies and research programs. Generalizing these sorts of synergies and integrations to the all-threats component of the program will be extremely helpful in meeting the expansion of the HSRP mission.

4.5.5. Systems approach

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

Recommendation: Clarify in the StRAP what is meant by the HSRP systems approach and how it will be used in research planning. The HSRP StRAP should include a clearer explanation of its systems approach, clarifying which models are being applied, the level of complexity of the models, and describing how they will be implemented. It is important to clarify how much investment is being made in formalizing the systems approaches to be used, e.g., by use of specific systems engineering software or specific tools for graphical representation of the life cycle of projects. More generally, the StRAP should clarify how a systems approach is to be differentiated from approaches that do not take a systems approach in actual practical application and how a systems approach is to be used in the prioritization of HSRD research.

Expanding on comments above, the HSRP should inform multiple federal partners about this research (e.g., Department of Health and Human Services, Federal Emergency Management Agency), as well as the EPA regional offices, since having such partners informed and involved will help HSRP achieve goals related to the systems research being planned. Clear explanation of how ORD plans to use system approaches in planning and prioritization will help partners understand ORD research and how to complement it.

The SAB and BOSC note that HSRP is in a position to be a lead federal government research program addressing environmental fate and transport issues that are currently associated with Homeland Security threat agents but involve environmental pollutants and particles. Outside of DOE, there may not be another focused federal agency research effort on this topic. ORD should continue to build a leadership role in this valued area.

4.5.6. Major themes and key recommendations for HSRP

- Find approaches to deal with limited resources given the expansion of mission to “all threats,” including developing additional partnerships with other disaster-related agencies and with the EPA’s regional offices.
- Integrate terrorism-related and non-terrorism-related disaster and prevention research into the HSRP and expand tools relevant to multiple hazards.
- Clarify, develop, and expand appropriate systems approaches to research planning to meet the expanded mission of the HSRP.

5. RECOMMENDATIONS FOR INTEGRATION

ORD requested the SAB and BOSC to address the following charge question for four crosscutting topics: *Charge Question 8. How effective is each Draft Roadmap in presenting a problem statement, elucidating key research topics, capturing relevant research in each of the six programs, and identifying any important scientific gaps?* The four crosscutting topics are Children’s Environmental Health, Nitrogen and Co-pollutants, Climate Change, and Environmental Justice. ORD’s specific charge question is addressed for each of these topics and additional technical comments for each topic are included in Appendix B. This section also responds to ORD’s request for general advice on enhancing integration across all of ORD’s programs.

5.1. Children's Environmental Health

Research in Children’s Environmental Health (CEH) spans and develops links from basic science, models, and mechanisms to the health and well-being indicators of the next generation and their neighborhoods. Consequently, it is an excellent choice for crosscutting research and integration across ORD program areas. The CEH preliminary draft is well developed and provides a sound framework for integrating research on CEH across the six ORD Program areas. This type of integrative research is not being done in any other research program or organization.

5.1.1. Problem statement and key research topics

The research directions outlined in the CEH cross-cutting roadmap preliminary draft contribute to a holistic science base in support of children’s environmental health with specific calls for applied research under the general goals, articulated in EPA’s Strategic Plan, of cleaning up communities and advancing sustainable development, and ensuring safety of chemicals and preventing pollution.

The importance of research that incorporates cumulative impacts of chemical and non-chemical stressors across life stages is noted and of key importance. The key research topics (four research priority areas) are well presented in the context of their “drivers”. The Introduction effectively summarizes the recent actions in children’s environmental health and explains the current drivers that define the need and focus of the CEH. The translational framework for CEH (Figure 2 in the roadmap) is excellent in its clarity and comprehensiveness, and the summary of key governmental and international actions (Table 1 in the roadmap) is excellent and helpful, however, it is unclear as to why some international programs were not included (e.g., *Canada 2010 National Strategic Framework on Children’s Environmental Health* [http://www.hc-sc.gc.ca/ewhsemt/pubs/contaminants/framework_childrencadre_enfants/index-eng.php#a0]; European Union Helix Project (<http://www.projecthelix.eu/>)).

Recommendation: Develop a more comprehensive translation research strategy to enhance the links from basic and observational science to intervention/implementation science to community action/policy toward the goal of improving children’s health. There seems to be much greater emphasis on the ends of the translational research spectrum (metrics, tools and policies) and less emphasis on the “middle” of this spectrum (key perturbations, targets and exposures; individual and community risks). The emphasis appears to be on both foundational research (animal models, toxicology studies and tools, observational cohorts) and then, at the other end, community action. The pieces that appear to be quite limited are: (1) the development of interventions; (2) the science of implementing proven interventions; (3) the science of assessing the impact of implementing the intervention on environment and health outcomes; and (4) the science of dissemination.

Recommendation: Clarify and support research on communities' roles and involvement. In a community context, there is emphasis on the development of tools that can be used by communities to assess risk and plan, but it is not clear that there is a plan to support research aimed at understanding how often the various tools are used, by whom, whether they lead to any change in the community or action by the community, and whether that change has beneficial effects.

5.1.2. Relevant research in each of ORD's six programs

Recommendation: More clearly describe how research themes in the StRAPs will be integrated to support the issues described in the CEH roadmap. Direct links are made to strategic goals on communities and chemical safety, but links to other goals are deep into the report and not fully elaborated. For example, highlighting the role of water and air as pathways for toxicity toward children as a vulnerable population seems highly relevant (CEH Roadmap, p. 18). Further, the extensive risk assessment and decision-support tools from HHRA could be better integrated into the CEH Roadmap. The list of activities in Appendix B is helpful, but attention to these links could be better integrated into the text.

5.1.3. Important scientific gaps

Recommendation: Recognize and optimize the role of leveraging partnerships and prior investments. Environmental health research now encompasses human epidemiologic and clinical trial studies that require very large sample sizes. Specific examples of the kinds of studies that are needed include those that examine gene-environment interactions, Epigenome-Wide Association Studies (EWAS), and exposome and mixture studies, along with chronic exposure studies. These require extremely large sample sizes and longitudinal designs. Maintaining the investments made in successful, established large studies and enhancing partnerships across studies are ways to make progress with limited resources. Leveraging U.S. population-based surveys such as the NHANES and National Health Interview Survey (NHIS) offer additional opportunities for maximizing the impact of ORD funds. In particular, data on environmental contaminant uptake in children using biomarkers in the age group under six years is needed to complement the current national CDC biomonitoring program, which does not routinely include this life stage.

Recommendation: Research gaps are noted but more specificity and synthesis is needed. Important research gaps are identified but in broad, unspecific terms. Examples of specific gaps that are not highlighted that should be considered include expanding the priority health outcomes to include pediatric cancer [in addition to birth outcomes, neurodevelopment/neurobehavior, metabolic (obesity), and asthma/airway function] and elucidating the human microbiome within children's environmental health research.

5.1.4. Implementation

Recommendation: Describe how research priorities will be set. This roadmap comprises ambitious and broad crosscutting activities. The list of research objectives and future projects is reasonable for significant progress to be achieved by 2019. However, given uncertainties of resource allocation, the roadmap would benefit from a description of how prioritization might be achieved.

Recommendation: Identify mechanisms for motivating and evaluating the responsiveness of ORD's research programs to the CEH roadmap. The roadmap lacks a description of the stewardship needed to foster its implementation and success. Experience suggests that achieving and sustaining the needed

level of commitment often depends upon how research budgets are determined and distributed and on how well individual scientists' professional goals are supported and their work is recognized and rewarded in the context of this and the other cross-cutting research enterprises.

5.1.5. Major themes and key recommendations for CEH roadmap

- Develop a more comprehensive translation research strategy to enhance the links from basic and observational science to intervention/implementation science to community action/policy toward the goal of improving children's health.
- Clarify and support research on communities' roles and involvement and leverage partnerships.
- More clearly describe how research themes in the StRAPs will be integrated to support the issues described in the CEH roadmap including development of more clearly specified research priorities.

5.2. Nitrogen and Co-pollutants

Research on the biogeochemical cycling of nitrogen and co-pollutants spans multiple environmental media and requires integration of basic science, models and mechanisms across multiple EPA program areas. Consequently it is an excellent choice for cross-cutting research and integration across ORD program areas. The Nitrogen and Co-pollutants roadmap is well written and well organized. It is highly responsive to previous SAB input and recommendations (U.S. EPA SAB 2011b).

5.2.1. Problem statement and key research topics

The six over-arching science questions and challenges in the Nitrogen and co-pollutants roadmap are well-formulated and provide an effective framework. The overarching goals, outcomes, and output of the roadmap are explicitly articulated, and well-oriented to informing policy and decisions, however, the summary in the roadmap is too short.

Recommendation: Include a discussion of the scale of important components of environmental problems associated with nitrogen and co-pollutant discharges. In presenting the science challenges, the issue of scale is not called out and discussed explicitly. The concept of scale as a key variable and important challenge should be discussed. The large-scale aspect of important components of the problem of nitrogen and co-pollutant discharges will require flexibility in responses, and this should be recognized in the roadmap.

Recommendation: Provide a more balanced discussion of the benefits nitrogen provides and the impacts of treatment and control of nitrogen and co-pollutants. The roadmap should discuss more in its Introduction the benefits that nitrogen provides to society, and the cost-benefit analysis involved in deciding how much control to undertake. Treatment and control of nitrogen and co-pollutants has associated environmental impacts, e.g., the energy and chemicals required to remove nitrogen from municipal wastewater. In the interest of providing balanced R&D to inform decisions, benefits of nitrogen and impacts of control measures should be recognized in the roadmap.

5.2.2. Relevant research in each of ORD's six programs

The roadmap makes connections to the StRAPs for the six ORD research programs, especially SSWR, but this could be strengthened in the document. Conceptual mappings to the six ORD program areas (e.g., Table 1) should be expanded.

Recommendation: Strengthen discussion of nutrient resource recovery and related technologies. The roadmap should make a stronger connection to the priority area in the SSWR StRAP on transforming the concept of “waste” to “resource” in management of “wastewater,” especially the capture of nutrients. The roadmap is weak in the area of development and demonstration of nutrient resource recovery technology. More generally, the roadmap can be more explicit about the relationship between prioritized research needs as presented in the StRAPs and research gaps.

There has been great progress made on the ability to remove nitrogen from municipal wastewater. The roadmap should note this, and discuss how this technological advancement can be leveraged and incorporated in ORD programs to help address the challenge of controlling nitrogen and co-pollutants.

Recommendation: Expand discussion of linkages with the SHC and ACE programs. The roadmap mentions linkages with the SHC research program, but there are more overlaps with SHC that could be discussed. A number of the science challenges presented in the roadmap involve value judgments, and relate to ongoing research in the SHC program.

There are also linkages with the ACE research program that should be discussed. The roadmap has little discussion of releases of nitrogen to the atmosphere and atmospheric inputs of nitrogen to land and water. What research is needed to enable adequate reduction of nitrogen emissions to the atmosphere? Also, considering the uncertainty in the recently updated national climate assessment about whether nitrogen emissions will induce cooling, it would be useful to have more discussion about nitrogen impacts on climate.

5.2.3. Important scientific gaps

Recommendation: Evaluate effectiveness of approaches for management of nitrogen in agriculture. The importance of agriculture and related EPA research needed should be addressed more in the document. One member of the BOSC stated: “It is striking how little the word ‘agriculture’ is used in this narrative document given the preponderance of evidence that [agriculture] is a key driver of nutrient loading.” It is recommended that the roadmap should include study of the effectiveness of approaches for control of agricultural runoff of nitrogen and other emissions of nitrogen from non-point sources, and should make clear the need for substantial engagement with and leveraging of USDA programs and resources. In the context of USDA engagement, the USDA Mississippi River Basin Healthy Watersheds Initiative is a research and demonstration program of national importance in which ORD should be engaged.

The roadmap also makes only brief mention of the Chesapeake Bay program, the national, full-scale experiment in how to control nutrients on land and discharge to water. There should be more discussion about ORD engagement with this program and its importance with respect to the roadmap.

Recommendation: Provide a more explicit discussion of the process for cross-agency, industrial, and international cooperation. There is discussion in the roadmap about the importance of research coordination and about an envisioned cross-agency team to identify research that would inform development of effective policies for implementation of an integrated and sustainable reactive nitrogen and co-pollutant management program. The StRAP, however, makes no specific recommendations about the envisioned team.

The discussion of cross-agency, industrial, and international cooperation is insufficient. The Gulf of Mexico and Great Lakes are obvious candidates for international cooperation. There is also great

opportunity for coordinating with and making use of research on control of nutrients and co-pollutants being conducted in other countries. There should be more discussion of cooperation and collaboration opportunities in the roadmap.

Recommendation: Include an extended discussion of uncertainties associated with modeling and assessment of impacts of proposed management actions. There is little mention of scientific uncertainty; this is a serious omission. Modeling and assessments of impacts of proposed management actions should be accompanied by a defensible quantitative statement of uncertainty. If stakeholders and/or decision makers are considering management actions based in part on modeling/assessment, they must be provided with some measure of the confidence (uncertainty) in the science. For too long and too often, the EPA has failed to insist on this requirement for predictive models. As a consequence, ORD has tended to stress large elaborate models, such as that described in the section on integrated multimedia modeling, that appear to be motivated by the assumption that models must be sufficiently detailed so the modelers can “get the processes right.” The result of stressing the development of elaborate models is that these models can become over-parameterized. Among experienced modelers, it is well-recognized that many sets of parameter values will fit large simulation models about equally well; similar predictions can be obtained by simultaneously manipulating several parameter values in concert. This is expected because all models are approximations of actual ecosystem processes, and because all parameters represent aggregate processes (spatially and temporally averaged at some implicit scale) and are unlikely to be represented by a fixed constant across scales. In addition, many mathematical structures impart extreme correlation among model parameters, even when the model is over-determined. It is recommended that ORD routinely require uncertainty analysis of model forecasts.

Recommendation: Clarify how research priorities are set based on gap analyses and consider a “value of information assessment” approach. It is good to see frequent referral to gap analysis however, it is unclear how research priorities will be established based on the gap analysis. This should be clarified in the document

“Adequate” is a word that is frequently used in the draft roadmap to characterize expectations for new research (e.g., “to determine if an approach is adequate”). However, the document does not address how “adequacy” of a research program is to be rigorously assessed.

5.2.4. Implementation

Recommendation: Address how the roadmap will be implemented. There is no implementation plan in the roadmap. Who will be responsible for overseeing, monitoring, and coordinating implementation of the roadmap? This is a very important concern for the SAB and BOSC.

5.2.5. Major themes and key recommendations for Nitrogen and Co-pollutants

- Partner with USDA and study of the effectiveness of approaches for management of nitrogen in agriculture (both crop and animal), including control of runoff and other emissions bearing nitrogen.
- Include an extended discussion of uncertainties associated with modeling and assessment of impacts of proposed management actions.
- Clarify how research priorities are set based on gap analyses and consider a value of information assessment approach.

5.3. Climate Change

Although climate is explicitly a part of ORD's ACE program, the science and impacts of climate change span all ORD Program areas, and therefore it is an excellent choice for cross-cutting research and integration across ORD. Creating the EPA climate change cross-cutting roadmap is a challenge and the current draft roadmap on climate change is somewhat disappointing. The EPA's resources devoted to climate change, a critical, crosscutting environmental issue, are a small percentage of the overall federal climate change budget. ORD can best approach this budget challenge by focusing resources on "actionable science" that informs ways the EPA can help address how climate influences air and water quality.

5.3.1. Problem statement and key research topics

Recommendation: Describe how planned research will inform future EPA decision making. The roadmap should address what science can be brought to bear on the consequences of some high profile decisions [e.g., Corporate Average Fuel Economy (CAFE) standards, power plant emissions, renewable fuel standards]. Moving forward, the EPA should focus on what the life cycle consequences of renewables—solar, wind, tidal, and biofuels—might be. For biofuels and biochar, in particular, knowledge of the impacts on water availability, crop production and disease needs improvement. Many agricultural activities have substantial impacts on air pollution and human health that need investigation. It is important for the StRAP to focus on actionable science related to the EPA's regulatory, voluntary, and information-based programs, as well as technologies and outreach to other countries.

Recommendation: Describe more clearly the ORD climate change research niche ("actionable science" and its plan to work with other international and federal partners to ensure EPA's science needs are met). The roadmap should describe integration with key domestic and international research efforts on mitigation/adaptation. Although some of this information was communicated verbally in the Climate Change Roadmap presentation at the July 24-25, 2014 SAB-BOSC meeting, the roadmap should include this basic information. The roadmap should address how ORD accounts for research needs not currently addressed by its own research programs. An example is the water-climate question, i.e., why ORD seems only to analyze a one-way relationship, considering only the climate impact on water and not how water affects climate. If other agencies are focusing on the water-climate question, how is that incorporated? A clear guideline for such partnerships should be included in the roadmap. The roadmap should also communicate more clearly the unique role that ORD has in climate change research relative to other federal partners.

Recommendation: Improve the presentation and flow of the climate change roadmap. The roadmap would be improved by the addition of diagrams, model schematics, and other organizing approaches to help convey the systematic approach that ORD is taking in this important cross-cutting area.

5.3.2. Key research topics and relevant research in each of ORD's six programs

Recommendation: Identify research priorities associated with the problem statement. The climate change topic is broad and the EPA research role is not well defined in the roadmap. Outlining a few basic components of research to inform future EPA decision making would be useful. The roadmap should more clearly identify its relationship to the EPA's *Climate Change Adaptation Plan*. The roadmap should also more clearly communicate the rationales for the EPA program-identified "Research Needs" listed in Appendix C.

5.3.3. Important scientific gaps

Recommendation: Expand the roadmap discussion of “Research gaps and priority research needs” (social sciences, uncertainties, decision-relevant scale, and synthesis). The SAB and BOSC recommend that the roadmap describe more clearly the research intended to address these gaps. In regard to the social sciences, there is an opportunity in the climate change roadmap to clearly identify what is meant by social science research supporting the EPA’s mission and how such research would be used. It is important to “unpack” the heterogeneity of social sciences and to learn what is most needed for the agency. The social sciences may be especially important for ORD to consider because EPA’s climate change science must be communicated clearly to and with the public. The SAB and BOSC also are interested in how ORD plans to help inform decision makers of the timing, magnitude and uncertainties of climate change. Communication to decision makers regarding these topics is an additional area of important research.

5.3.4. Implementation and intended use of the roadmap

Recommendation: Provide a discussion of how the roadmap will be used to guide research. Many of the suggestions above indicate a need for further development of the roadmap. A revised roadmap should include discussion of implementation factors (e.g. dependency on personnel, resources), and the intended use of the roadmap. The roadmap should indicate how it will evolve and whether there will be indicators or milestones for evaluating the program. Successful integration depends on how participating programs and laboratories commit to collaborations proposed. The roadmap should discuss how budget and personnel resources are committed to the roadmap activities and how planning across ORD to meet the climate change research needs will occur.

5.3.5. Major themes and key recommendations for the Climate Change

- Describe how planned research will inform future EPA decision making and guide research
- Describe more clearly the ORD climate change research niche - “actionable science”- and how it works with other international and federal partners to meet EPA’s science needs.
- Improve the flow of the climate change roadmap, better identify research priorities and expand discussion of social sciences, uncertainties, decision-relevant scale, and synthesis.

5.4. Environmental Justice

Research in Environmental Justice, as was the case with CEH, spans and develops links from basic science, models, and mechanisms to the health and well-being indicators of communities and their neighborhoods. Consequently, it is an excellent choice for cross-cutting research and integration across ORD program areas. The Environmental Justice roadmap provides a good framework for a research path in environmental justice.

5.4.1. Problem statement and key research topics

Although the problem statement is well described, specific goals and objectives are not. Without anticipated achievements, it is difficult to know which steps should be taken in a research roadmap to lead to effective results.

Recommendation: Incorporate input from communities to identify problems associated with environmental, biological, behavioral, social, economic and spatial stressors, and how they interrelate. The roadmap mentions the involvement of stakeholders but doesn’t specifically describe their expertise or experience, or what demographics they represent. ORD should partner with individuals from a variety of communities that represent various situations and circumstances. International

partnerships are also lacking. The roadmap does include non-chemical stressors, which provides the broad approach to problem identification and evaluation. However, conducting conversations with communities is critical in identifying these problems and possible desired solutions, as well as strategizing effective research approaches. This type of expertise that can only be obtained from community partners is lacking in the draft roadmap. Incorporating this input would allow for the identification of problems related to environmental, biological, behavioral, social, economic and spatial stressors, and how they interrelate. Community involvement also fosters a “practice” approach to problem-solving, as well as a research-based regimen.

The draft roadmap does not include specific research topics or proposed methods to address environmental justice issues. As such, research priorities are not identified, along with the trade-offs of their inclusion. Three science challenges are listed, with community engagement included as a separate item. It is suggested to integrate community participation throughout each science challenge and have community individuals inform the research process. Community involvement will also help identify research priorities. Section B.4. in Appendix B provides suggestions for research topics/approaches to explore. Involving individuals within communities as research partners at the onset of developing environmental justice research strategies and throughout the research process ensures that the research is “highly relevant and responsive” (Environmental Justice Roadmap goal).

5.4.2. Relevant research in each of ORD’s six programs

Recommendation: Add text to Appendix A that explains specific connections to each program area, using the CEH roadmap as a model format. The draft roadmap demonstrates the need for environmental justice across ORD’s six research programs showing some synergies, particularly with the SHC program area. More detail, however, is needed. Table 1 and Appendices A and B begin to show how environmental justice can provide a research foundation for the research program areas, but there are not as many examples of an environmental justice presence within some research programs as might be expected. It is suggested to add text to Appendix A that explains specific connections to each program area. Although sets of projects are listed that show how environmental justice can be integrated, the current format is disjointed rather than an informative, “stand-alone” document. It is suggested to use the CEH roadmap as a model for communicating such information.

Recommendation: Consider including examples to illustrate relationships to ORD’s six research areas and employing Community-Based Participatory Research (CBPR) to promote research relevance. The inclusion of non-chemical stressors in the Environmental Justice draft roadmap helps address the cross-cutting issues related to the six research program areas, but including specific examples would better illustrate these relationships. To promote research relevance, CBPR could be employed in each research program area. This could lead to the incorporation of environmental justice issues and help develop relevant Requests for Proposals (RFPs). This roadmap could provide the needed intersections for each of the six research programs, which would provide an overall framework for ORD’s research strategy.

5.4.3. Important scientific gaps

Recommendation: Identify environmental justice scientific gaps emerging in major ORD research programs. The draft roadmap does not identify scientific gaps. As details regarding key research topics and how they relate to the six research program areas emerge, scientific gaps should become apparent.

5.4.4. Implementation and intended use of the roadmap

Although the Environmental Justice cross-cutting roadmap well documents the need for cross-cutting research in this area, it provides a relatively abstract discussion of the science. The issues are discussed in general, but the specific science proposed to address needed knowledge gaps is either omitted or discussed in general terms. Because of the preliminary nature of the document, sections on research gaps and research needs, examples of ORD integration, and opportunities for additional integration are not included. While the underlying science challenges are well-described in a general sense, the cross-cutting roadmap should include discussions of these topics so that ORD research in this area is coordinated as a well-organized whole.

5.4.5. Major themes and key recommendations for Environmental Justice

- Incorporate input from communities to identify problems associated with environmental, biological, behavioral, social, economic and spatial stressors, and how they interrelate.
- Integrate community participation throughout each science challenge and have community members inform the research process.
- Consider including examples to illustrate relationships to ORD's six research areas and employing Community-Based Participatory Research (CBPR) to promote research relevance.

5.5. Integration across ORD programs

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

Integrated research is critical because of the EPA's resource-limited environment and the interdisciplinary, cross-program application of ORD's data, tools, knowledge and products. Integration must occur internally within the EPA, external to the EPA within the United States with the agency's partners, and internationally. The ORD's cross-cutting roadmaps represent a very important step forward for the EPA in providing a framework for research integration on large-scale, complex environmental challenges. These roadmaps provide frameworks for integrating research across ORD programs and offices, and with other agencies, and for keeping ORD research forward looking.

The SAB and BOSC commend ORD's progress in undertaking this integrated planning and offer recommendations for strengthening the roadmaps and making them more consistent. Integration must be a key concern as ORD moves from research planning to research execution, and as it defines a process for providing research to decision makers that incorporates institutional learning about that process. Until progress is made or more information is available regarding those points, the SAB and BOSC cannot determine whether the integrated research described in the StRAPs will produce the results the EPA needs to advance solutions to the complex problems it faces.

Recommendation: Strengthen the roadmaps and make them more consistent with each other and with the StRAPs. Sections 5.1 through 5.4 of this report provide recommendations for revising and strengthening individual roadmaps. ORD has acknowledged that the draft roadmaps were at different stages of development and completion. In revising the roadmaps and StRAPs, the SAB and BOSC recommend that additional attention in each StRAP and roadmap be given to: (1) communicating a clear vision that lays out the key science needs and ORD's research niche *vis à vis* its research partners; (2) describing the current state of knowledge to provide baseline data in the research topic areas and where EPA's current projects fit; (3) describing other actors in the environmental protection scene and what

they contribute to the specific goals and objectives in the plans (there are frequent references to “partners,” but no definition of the term); (4) clarifying and making more consistent the reciprocal relationships between the sources of research and the targets (in many cases, one program says they are producing products for another, yet the target program is silent about those inputs); and (5) including in each StRAP a section along the lines of “Relationships to other StRAPs.”

Recommendation: Identify and communicate ORD research priorities in the roadmaps and commit ORD resources to them. Plans alone cannot guarantee that needed future integration across ORD program areas will occur. Given the planning necessary to conduct integrated research and the heavy demand on research resources to conduct the work, a data-driven prioritization of the questions ORD chooses to address is necessary. The roadmap mechanism appears appropriate for fostering integration across programs, but it must be clear who is the steward of priority topics in the roadmap and who implements and makes sure the research happens.

Recommendation: Acknowledge and plan for actual integration, which requires active collaboration from the onset. Attempts at cross-program integration are evident within the StRAPs and ORD briefing materials provided for the July 24-25, 2014 SAB-BOSC meeting. Whether these efforts develop the needed scientific knowledge to advance EPA’s ability to address complex problems depends on the implementation of these proposed linkages. Often, linkages and relationships proposed in strategic planning documents occur at only a superficial level – for example sharing final results only at the end of research projects. In other cases, one research program may independently produce research projects that are reported to be “relevant” to other research programs. To the extent that these linkages are of this superficial nature, they may not provide the needed scientific knowledge. However, if the proposed linkages are implemented in a meaningful, in-depth and ongoing manner, they should help provide the integrated scientific knowledge required by the agency.

To be most useful, cross-program integration should involve active collaborations from the outset of research projects – so that each project benefits from the combined expertise of multiple programs. The extent to which linkages reported in the StRAPs will promote truly integrated work is unclear. The StRAPs and briefing materials characterize cross-program linkages only in abstract terms, for example reporting broad research topics within each program that are relevant to other programs, or over which some type of otherwise unspecified interaction is planned. For example, page 8 in the SSWR StRAP states, “Watershed Sustainability has clear linkages to SHC through the EnviroAtlas and Report on the Environment, and to ACE, particularly in the realms of climate change and prediction and management of materials and waste.” It is unclear to what extent these “clear linkages” will include active cross-program collaborations, and how areas such as this will benefit from this integration.

Recommendation: Plan for the human resource and information needs required to carry out integrated research programs. The SAB and BOSC recommend that the EPA develop a long-term hiring and training plan (versus short-term hiring of postdocs or supporting external research) to better integrate behavioral science into their long term research. ORD should institute a formal means for broad communication and interaction among ORD technical staff to support its integrated research program. ORD would benefit from widespread use of the communities of practice approach undertaken by the computational toxicology program for sharing information and collaborating on environmental research.

Because transparency is identified as a core value in the EPA Strategic Plan and accessibility to intramural and extramural data and information is a key challenge, ORD would benefit from developing

state-of-the-art information management to provide the optimal interface(s) for the interdisciplinary scientists engaged in EPA research and the science products held or used by the agency programs. Development of overall strategic plan goals in the arena of information management science that serves and integrates the national research programs and cross cutting areas may help assure resources and commitment to this need.

Recommendation: Identify the criteria or a process for evaluating research “results that advance EPA’s ability to address complex problems.” There is a need for identification of criteria or a process for determining whether a product or research activity has been successful and advanced the EPA’s ability to address complex problems. Regulatory and research activities within the agency must, to be effective, continually absorb, synthesize, adapt, and use information from within and outside the agency. “Absorptive capacity” is known to vary greatly among organizations. ORD hears the needs identified by Program Offices and Regions, does research, and feeds information back to the offices and regions. The Program Offices and Regions translate the information into regulations and procedures and work with local authorities to protect human health and the environment. There is some recognition in research plans of the need for information loops rather than one-way transmission, but no consistent or systematic attention to this challenge.

In addition, ORD should more clearly define the success of research that meets community needs. In many places throughout the planning documents, tools to support communities are emphasized, but “community” is rarely defined with any precision, and “community engagement” is rarely operationalized into a coherent process.

Recommendation: Implement a process for identifying ORD cross-cutting research topics and managing their life cycle. The four cross-cutting research projects reviewed by the SAB and BOSC are all appropriate choices. At the July 24-25, 2014 meeting, ORD explained that the four current cross-cutting topics were developed in the following way. ORD convened its Executive Council whose members brainstormed topics and developed a “heat map” showing their relationship to ORD’s national research programs. ORD looked for research topics related to agency priorities where ORD could make a difference. The number of topics was capped at four to keep the planning and coordination efforts manageable. The SAB and BOSC note that the individual draft roadmaps did not include a description of this selection process.

Moving forward, it is not clear how current efforts will mature and be brought to closure or how future topics will be initiated. If there is no plan to initiate new cross-cutting projects, the four existing efforts, while highly meritorious, will not fully represent the diversity of integration challenges faced by the agency. If there is no plan for bringing the efforts to conclusion, then there is the danger of proliferation of the efforts, diluting their effectiveness.

As ORD considers future roadmaps, the SAB and BOSC recommend that it consider adding SHC as a cross-cutting topic. This topic, like Climate Change, is associated with its own research program, and is a topic central to the EPA’s protection of public health and welfare, worthy of a cross-cutting roadmap. Such an SHC roadmap would meet important needs to plan for involving communities and evaluating community engagement throughout ORD’s research programs.

5.5.1. Major themes and key recommendations for integration across ORD programs

- Identify and communicate ORD research priorities in the roadmaps and commit ORD resources to them.

- Acknowledge and plan for integration, which requires active collaboration and human and information resources.
- Implement a process for identifying ORD cross-cutting research topics and managing their life cycle, including criteria and processes for evaluating research “results that advance EPA's ability to address complex problems.” This process should include consideration of SHC as a possible future cross-cutting topic.

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APPENDIX A: CHARGE TO THE SAB AND THE BOSC

1. ORD's Strategic Directions

In 2011, a joint SAB/BOSC committee provided advice to ORD on strategic directions as ORD realigned its research into six integrated programs. The initial research plans guided ORD for 2012-2016. ORD is now beginning the development of Strategic Research Action Plans (StRAPs) to cover the period 2016 -2019 for the six programs:

Air, Climate and Energy
Safe and Sustainable Water Resources
Chemical Safety for Sustainability
Sustainable and Healthy Communities
Human Health Risk Assessment
Homeland Security

The update of these plans is in the formative stages, providing an opportunity to receive early input and insights from the Chartered SAB and the BOSC Executive Committee. ORD is preparing plans that aim to provide the science needed to meet EPA's priorities, as described in the new EPA Strategic Plan (2014-2018). Also, the ORD plans need to anticipate the science that will be needed for environmental protection for 2020 and beyond.

Charge Questions

- 1a.** Considering the proposed research directions and focus, how well is ORD as a whole poised to support EPA in meeting the goals of the EPA Strategic Plan?
- 1b.** What are the SAB/BOSC perspectives overall on the proposed research directions providing research to address environmental issues of 2020 and beyond?

2. Program Specific Charge Questions

In the first Charge questions above, ORD is asking the for SAB/BOSC's view on the ORD research program as a whole. Additionally, ORD asks for the SAB/BOSC's advice on strategic directions for each of the six research programs.

Charge Questions

- 2a.** How well will the research directions in each Early Draft StRAP (2016-2019) support EPA in achieving the relevant Agency objectives and cross-cutting strategies, as described in the EPA Strategic Plan (2014 -2018)?
- 2b.** What are the SAB/BOSC perspectives on the proposed research directions in each StRAP providing research to address environmental issues of 2020 and beyond?
- 2c.** For each program, do the presentations and plans indicate that ORD is designing for integration, where appropriate, on topics that are relevant to other research programs?

3. Air, Climate and Energy Charge Questions

The ACE Research Program includes a focus on the environmental impacts of energy production and use, including decisions regarding energy choices. Initially, ACE work addressed impacts of biofuels, as well as the development of models and decision tools that evaluate the outcomes of energy choices. The support to the biofuels program has diminished substantially. As we look to the future, we face a continually changing energy landscape, and an urgent need to anticipate the likely environmental impacts of an evolving mix of energy sources. The ACE Program wants to effectively target its resources to produce models and decision tools that illuminate environmental impacts and that will aid individuals, communities and governments in understanding the consequences of energy choices.

Charge Question

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

4. Sustainable and Healthy Communities

SHC has committed to integrating ecological and human health to better address issues of human and community well-being.

Charge Question

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

SHC's research and development on indicators and indices, ecosystem goods and services, and the EnviroAtlas make reference to specific health conditions such as asthma, but are largely oriented toward protection and promotion of more broadly-defined individual and community well-being.

Charge Question

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

As EPA moves to implement a sustainability paradigm, ORD's role is to conduct research that supports this paradigm. SHC's plan is to conduct research on sustainability using a systems-based approach and by using case studies to illustrate community-level sustainability.

Charge Question

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

5. Safe and Sustainable Water Resources

In many parts of the country, the quality and availability of fresh water is a serious concern, and one that will become even more challenging as the climate changes. Simultaneously, energy consumption

continues to rise. To meet the increasing energy demand, domestic energy consumption is increasing, and contributing to the increasing demand for water. Water is used to cool power plants, grow feedstock for and produce biofuels, and to extract oil and gas. Additionally, large amounts of energy are used to transport and treat water for human use. This "water energy nexus" is a significant challenge as we strive for more sustainable energy and water use. Many government agencies have roles to play in energy and water development and management in the US – including the Department of Energy, Department of the Interior, Department of Agriculture, US Geological Survey and others. EPA is particularly interested in moving toward a future in which communities could have "net zero" input and output of energy, water, nutrients, and other resources reclaimable from wastewater.

Charge Question

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

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

CSS research is conducted to provide the fundamental knowledge infrastructure and complex systems understanding required to predict potential impacts from use of manufactured chemicals and products, as well as to develop tools for rapid chemical evaluation and sustainable decisions. The CSS research program integrates advances in information technology, computational chemistry, and molecular biology to improve Agency prioritization of data requirements and science-based assessment of chemicals through signature research in Computational Toxicology. EPA investments in advanced chemical evaluation and sustainability analytics are providing decision support tools for high-throughput screening and efficient risk-based decisions. In addition, CSS research results are translated to provide solutions and technical support to our Agency partners and external stakeholders.

The HHRA program is focused on development of assessments to support Agency program decisions (i.e., Integrated Science Assessments, Integrated Risk Information System assessments, Provisional Peer Reviewed Toxicity Value assessments) and on development and application of new methods to improve risk assessments. The focus of the 2014 SAB/BOSC review is on the development and application of new methods for risk assessment, rather than on the assessment products (which are reviewed by SAB and other peer review panels).

Tailoring analytical assessment approaches to provide characterization of new endpoints as biotechnology advances requires development of new methods of dose-response analysis to transparently incorporate and integrate data across scientific disciplines and different experimental designs (e.g., epidemiology, controlled or clinical exposures, *in vitro* *I* *in vivo* *I* *ex vivo* toxicology). As our understanding of the key events for different diseases evolves, building bridges to systems biology requires construction of analytical methods that can incorporate data on biomarkers from various disease dimensions (e.g., early or late-stage) in various tissues (e.g., blood or liver) of different species, and the ability to incorporate high-throughput data and adverse outcome pathways (AOP) with different degrees of verification. To this end, the HHRA and CSS programs are collaborating to develop new science (CSS) and support and evaluate its application in various assessment products (HHRA).

Charge Questions

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

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

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

7. Homeland Security Charge Questions

In past years the HSRP conducted research primarily to support the Agency's responsibilities related to the terrorism portion of Homeland Security incidents. The Agency has broadened the definition of Homeland Security to include all hazards (e.g., natural disasters, industrial accidents) and the HSRP aims to be in line with this new direction. The revised StRAP applies the research in the all hazards framework and provides new strategic directions related to all hazards research.

Charge Question

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

While developing the 2016-2020 StRAP, the HSRP utilized a systems approach when constructing its research to support the Agency's responsibilities related to water security and resilience and indoor/outdoor cleanup. This systems thinking is incorporated into the research objectives, science challenges, and research topics and projects.

Charge Question

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

8. Roadmaps for Cross-cutting Issues

ORD's six research programs are designed to focus on six key Agency priority areas. Inevitably, significant environmental issues arise that cut across these six programs. For example, climate change, while an important component of the Air, Climate and Energy research program, is highly relevant to the other research programs.

Rather than create additional research programs for every cross-cutting issue, ORD is developing Roadmaps for climate change research, children's environmental health, nitrogen and co-pollutants, and environmental justice. They "map" out the ongoing and planned research from each StRAP. ORD intends that each Roadmap include: articulation of the problem and why this is an area where ORD can play a leadership role; identification of several relevant topics for research; description of research in the StRAPs (ongoing or planned) that will address the issue; and identification of scientific gaps in these cross cutting issues that will inform the national research programs in the development of the next StRAPs. As new, high priority, cross-cutting issues emerge, ORD expects

to use this approach to integrate existing research efforts and identify needed work. ORD notes that the Environmental Justice Roadmap is still in an early stage of development.

Charge Question

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

9. Integration across the Programs

In addition to cross cutting issues that are germane to most or all of the research programs, there are issues that are highly relevant to two or three of the programs. ORD is actively working to prevent research falling into six silos by strengthening ties across the programs. The alignment into six programs has been underway for two years and integration efforts between any two of the research programs are growing or are newly beginning. In some cases, integration requires formal planning while in others coordination and collaboration occurs in less formal ways as the research programs are planned and implemented. The goal is for integration across the programs to improve the science and better address environmental issues.

Charge Question

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

APPENDIX B: TECHNICAL COMMENTS ON CROSS-CUTTING TOPICS

B.1. Children's Environmental Health

Translational framework

- The following statement is vague and needs further development to be meaningful: “The second translational route lies through using knowledge of individual patterns of exposure and disease predisposition to develop community-based approaches to health promotion and risk management. Here, environmental health research and public policy can only fully empower communities to manage risks by providing a clear understanding of important exposures and where these can be locally controlled.”
- The statement “the framework presented in Fig. 2 facilitates translation of advances and findings in computational toxicology to information that can be directly used to support risk assessment for decision making and improved public health” seems to be overstated. Please elaborate to explain how.

Research area 1.

- Regarding “knowledge systems, the Roadmap states that “Integrated impact: Systems information across all levels of organization associated with development and childhood disease and wellbeing is incorporated into predictive modeling to inform Agency risk assessments and environmental programs.” This lofty goal needs to be more carefully outlined and developed.
- 1.2.1 Enzyme Ontogeny Databases (CSS) - Can this be elaborated to link to epidemiologic studies and risk assessments of children's environmental health questions?
- 1.3.3 Adverse Outcome Pathway Wiki (CSS) - It would be useful to consider how this is/may be applied outside ORD. Describe the stage of development of this concept across the four outcomes of interest and other outcomes.
- The tables present the EHC initiatives including research agendas and community engagement but they are lacking in any information regarding the National Institute of Child Health and Development and/or the Children's Health Study's research agendas.
- “EPA's Strategic Plan translates this fundamental knowledge to provide a systems understanding that is necessary to adequately protect the health of children.” Please explain how.

B.2. Nitrogen and Co-Pollutants

Gap analysis

- It is good to see frequent referral to gap analysis however, it is unclear how research priorities set based on the gap analysis. This should be clarified in the document. Research prioritization should be considered a “value of information assessment” (VOIA). That is, new monitoring/research should be undertaken if the value (for informing decisions) of the new data/research justifies funding the effort. In general, proposed ORD projects involve good science and good scientists, but that alone does not warrant funding. Funded projects should be restricted to those that provide the greatest information/knowledge gain, given ORD objectives which are aligned with direct support of the EPA's mission. In many cases, a VOIA can be undertaken using sensitivity analysis.

Use of modeling and measurement to support development of nitrogen water quality criteria.

- Research is needed to quantify the connection between a water quality criterion and a designated use; see Reckhow et al. (2005) for a discussion and example of this type of analysis. This will aid in the selection of nutrient criteria. The NRC (2001) depicted the linkages between a pollutant source and a designated use. A water quality criterion serves as an easily-measurable surrogate for the designated use. The closer the criterion is to the designated use (in the causal chain in the figure) the better the criterion is for assessing water quality standard compliance. The further the criterion from the designated use, the more hidden uncertainty that is present in determining compliance based on the criterion.

B.3. Climate Change

Revisions to the “Research Needs” listed in Appendix C

- The climate change topic is broad and the EPA research role is not well defined in the roadmap. Outlining a few basic components of research to inform future EPA decision making would be useful. The roadmap should more clearly identify its relationship to the EPA’s Climate Change Adaptation Plan. The roadmap should also more clearly communicate the rationales for the EPA program-identified “Research Needs” listed in Appendix C. This Appendix lists, for example, best practices for communities to adapt to and mitigate climate change. It was unclear, however, what would be scoped under this topic. The rationales for prioritizing some topics within the water-ecosystem-climate piece also need further explanation.

B.4. Environmental Justice

Community participation.

- Some possible research topics/approaches include:
 - Conduct community-based participatory research (CBPR) to identify factors that impact individual susceptibility and vulnerability, or an individual’s ability to effectively respond to environmental stressors;
 - Identify exposures and exposure interactions between sub-populations and how they relate to health disparities;
 - Identify cultural factors and factors related to those crossing U.S. borders, and the impacts on health disparities;
 - Develop mitigation strategies to improve public health within communities; and,
 - Develop simple, analytic decision support tools.