UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

[Date]

EPA-**SAB**-08-**xxx**

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Strategic Research Directions of the US EPA 2008: A Science Advisory Board Advisory Report

Dear Administrator Johnson:

The U.S. EPA Science Advisory Board (SAB) initiated a series of interactions with U.S. EPA Office of Research and Development (ORD) senior management and National Program Directors (NPD) to discuss the strategic directions for EPA's research programs during October, 2007. The discussions were motivated by a desire to move beyond the SAB's annual review of a single year's research program budget and to think more strategically about the Agency's overall research program in relation to EPA's own stated needs and also the SAB's own perspective on those needs. Specifically, the Agency asked the SAB to consider where EPA research should be in 2012 and beyond and what factors EPA should consider in order to reach that point.

To assist the SAB in its review, ORD prepared an overview of ORD's strategic research directions for each of its research areas and provided brief documents that summarized the strategic directions and current focus for each specific area. Additionally, EPA staff and SAB members discussed these strategic research descriptions in break-out sessions during the October 2007 SAB meeting. Though quite valuable, these sessions did not provide sufficient depth of information to allow the SAB to formulate a full understanding of each research area and to comment in detail on all the research program areas. Thus, the reflections in this document are a first response by the SAB to EPA's strategic research vision as articulated in that October meeting. In the future, the Board will continue to conduct follow-up discussions with ORD, and possibly other EPA scientists, on EPA's strategic research program directions. From time to time the SAB, at the request of EPA, may provide additional advice.

The Agency's research and development program provides the scientific foundation for EPA's actions in support its mission to protect human health and the environment. Included in these activities are: i) conduct of research and development to identify, understand, and solve current and future environmental problems; ii) provision of technical support to EPA's Programs and Regions; iii) collaboration with EPA's scientific partners in academia, other agencies, state and tribal governments, private sector organizations, and nations; and exercising leadership in addressing emerging environmental issues and advancing the science and technology of risk assessment and risk management.

ORD's research program structure contains sixteen (16) specific research areas. These program areas address EPA's science and technology needs in topics such as: human health; air and global change; economics and sustainability; environmental technology; ecosystems; water; and homeland security. These programs are listed and summarized in the Enclosure to this letter.

In this report, the Board focuses on fundamental and overarching issues. The SAB believes that EPA has made progress in identifying the strategic needs within its 16 focused research areas. Similarly the National Academy of Sciences has remarked on the importance to research efficiency of good planning and implementation, and concluded that "…EPA and its ORD have a sound strategic planning architecture that provides a multi-year basis for the annual assessment of progress and milestones for evaluating research programs, including their efficiency" (NAS, 2008). The SAB is pleased by the EPA's efforts to engage in a dialogue on strategic research planning. This willingness to engage the Board and others openly about research directions and strategies is laudable as EPA comes to grips with the need for major new science understandings to meet current environmental protection issues, as well as the emerging issues that will be a part of its mission in the future.

The Agency's current sixteen focal areas are important. However, if it is to be prepared to address future needs, EPA's research program will have to adopt a more integrated view, one that recognizes the inherent complexities and interconnections among human and ecological systems, gives greater consideration to feedbacks, and focuses on the relevant scales of each issue. In this context, it is clear that if the Agency is to truly protect the environment, it must undertake a larger program of research that goes beyond its immediate regulatory needs and address the broad array of environmental problems facing the nation.

Of course, focused research in support of current regulatory programs is needed. However, it appears to the SAB that a balanced program that has been recommended by the SAB and the National Academy of Sciences in a number of past reports (NAS, 2000; SAB, 2006; SAB 2007) is being lost as a result of constant pressures to address the near-term data needs of the Agency's operating programs in the face of ever more serious resource constraints.

Several changes are needed to address pressing environmental problems that do not fall neatly within existing regulatory mandates. Today these needs are only addressed within the

Agency's research plans in fragmentary ways, even though they are often interrelated. In its research programs, we believe that EPA should:

1) *Broaden the interpretation of "land preservation" to take a greater leadership role in future land-use decision making and in managing the consequences of bio-fuels, sprawl, green-field development, and the pressures of unconstrained coastal development*. This program has historically focused on cleanup activites associated with contaminated sites and releases. In addition, issues associated with the Resource Conservation Challenge have been a part of the program. Though latitude for change in this program may be limited by funding strictures, EPA should consider broadening the program to enable it to focus on issues that are key to the success of EPA's new Sustainability programs, including research to understand the environmental consequences of incentive structures associated with land use decisions.

2) *Expand the focus on the environmental consequences of new technologies to include a broader consideration of the life-cycle of new products and their globalization*. Understanding changes in where and how products are manufactured and in the types of products manufactured arfe important to understanding risks. Shifting locations of production within the U.S., outside the U.S., can present unique risks to the U.S. population (e.g., changed water and energy usage and availability, contaminated products, long-range trapsport of pollutants, and movement of living organizations to new locations of the world, to name a few). EPA must conduct research to better understand these issues and how they influence human health and the environment, as well as conduct research on the efficacy of alternative regulatory mechanisms for protecting human health and the environment in the face of these changes.

3) *Expand the analysis of water infrastructures, supply, demand and quality in light of changing socio-economic pressures and climate*. Increased water demand from expanding populations in water-short areas is leading agencies to consider agreements for large-scale transfers of water from one region to another. EPA needs to conduct research that will improve our understanding of ecosystem and service impacts associated with such transfers to be prepared to make informed decisions on water management issues in the future.

4) *Reinvigorate and modernize research on sensitive human and ecological populations*. EPA should continue to give primary emphasis to sensitive populations – this information will also provide critical data to protect the general populations. In this sense, sensitive populations refer to humans as well as to plant and animal populations. These studies will also help identify effective interventions when needed. Studies should also address the critical need for information on chemical mixtues that are reflective of actual situations in the world.

5) *Improve the science foundation needed to responsed to unexpected and emerging problems and environmental disasters*. Science and technology that is relevant to human health and the environment are expanding in terms of complexity and the pace of their development. EPA needs to develop creative mechanisms to provde the Agency access to this science within the constraints of its resources

6) *Expand policy relevant research on developing, testing and evaluating new and innovative alternatives to conventional command and control regulation*. Most EPA research programs focus on specific media and their efforts are driven by current regulatory strategies, mandates, and needs. In thinking of 2012 and beyond, the SAB believes that a broader and more systems-oriented approach to research will be needed to break out of existing "stove-piped" programs and to attend to the interrelated issues that are characteristic of the real world.

[DFO Created this concluding statement as a strawman] The SAB appreciates this opportunity to work with EPA in further expanding and interweaving the existing Agency research vision. With a renewed commitment to providing the resources necessary for the conduct of this forward looking research program, and with a commitment from the Agency to making the connections needed across its research efforts, the Board believes that EPA will be able to address the Agency's needs for knowledge of human health and the environment within the context of how they exist in the complex real world. With such a commitment, EPA can move further toward successful achievement of its mission to protect human health and the environment. The Board looks forward to your comments on its interim reflections on the EPA strategic research vision, and to its continued interactions with EPA on these critically important issues.

Sincerely,

Dr. M. Granger Morgan
Chair
Science Advisory Board

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), 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. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA website at http://www.epa.gov/sab.

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ENCLOSURE

ADVICE ON EPA'S STRATEGIC VISION FOR ENVIRONMENTAL RESEARCH – US EPA SCIENCE ADVISORY BOARD

1. Introduction

The U.S. EPA Science Advisory Board (SAB); senior managers of the U.S. EPA Office of Research and Development (ORD), and the ORD National Program Directors (NPD), began an evaluation and dialog on the strategic directions for EPA's sixteen (16) research programs during October, 2007. This dialog has continued over several meetings since that time, and the parties intend that these discussions continue indefinitely over time. This interaction between the SAB and EPA is motivated by a desire to move beyond thinking about EPA's strategic vision for research in a way that is broader than the view that can be obtained through the lens of each year's annual review of the EPA research program budget. Both the SAB and EPA want to engage and to think more strategically about the Agency's overall research program relatibr to EPA's own stated needs and also the SAB's own perspective on those needs.

In initiating this interaction, the EPA Assistant Administrator for Research and Development) asked the SAB to consider the strategic directions for EPA's 16 specific research areas and to provide its thoughts on the following:

a) Where EPA research should be in the next five years, i.e., 2012 and beyond in terms of:
   i. Research areas that will need continued emphasis;
   ii. Research areas that might need increased emphasis; and
   iii. Research areas that might be given decreased emphasis over the next several years.

b) What scientific factors EPA should consider to get to this point?
   i. Changes in "environmental science" itself;
   ii. Ways in which the workforce, and the skills available through the workforce, might be adjusted to further evolve and improve the research program (i.e., strategic workforce planning); and
   iii. Opportunities for efficiency
      - ♦ Are there areas with opportunities for greater coordination and synergy within ORD, across EPA, and across other organizations both inside and outside of government;
      - ♦ Are there other research "themes" that could strengthen EPA's research strategy (e.g., cross-cutting advice on sprawl, disasters, climate change); and
      - ♦ How might we improve the SAB – EPA dialogue on strategic science planning for the future?

Section 1 of this "Enclosure" is this Introduction. Section 2 identifies and summarizes the key components of EPA's 16 research areas. In Section 3 the SAB responds to the Agency's charge to the SAB for these interactions. Specifically, Section 3.1 offers general SAB comments on a number of overarching issues that emerged during its October 2007 discussions with EPA on its strategic research directions. In Section 3.2 the SAB comments on the human scientific resource needs of EPA, focusing on the problems of sustaining and renewing EPA's excellent and highly motivated scientific research staff. In Section 3.3 the SAB comments on strategies that ORD might consider in enhancing its research effectiveness and efficiency. In Section 3.4 of this advisory the SAB offers some suggestions for additional dialogue between the SAB and EPA on its Strategic Research Discussions**.** Finally, in Section 3.5 the SAB offers more specific comments on the current research program directions described in EPA's 16 strategic research area descriptions (SAB, 2007a). However, as noted above, these are preliminary comments because the depth with which the SAB was able to learn about each strategic research area was at best modest.

2. US EPA Research Program

The EPA Office of Research and Development's (ORD) began a new strategic planning effort during 2006 that involved ORD's National Program Directors (NPD), the ORD Executive Council (OEC) and the ORD Science Council (SC). The research areas are intended to provide the scientific foundation to support EPA's mission by: i) conducting research and development to identify, understand, and solve current and future environmental problems; ii) providing responsive technical support to EPA's Programs and Regions; iii) collaborating with EPA's scientific partners in academia, other agencies, state and tribal governments, private sector organizations, and nations; and iv) exercising leadership in addressing emerging environmental issues and advancing the science and technology of risk assessment and risk management.

ORD has structured its research program around sixteen (16) specific research areas. These program areas are summarized in a set of strategic documents that formed the information base for the SAB – EPA discussions during its October 2007 meeting. ORD's sixteen specific research programs are listed in Table 1.

Table 1. EPA Research Areas

Grouping	Research Area
a) Technology	i) Land Preservation and Restoration ii) Nanotechnology iii) GEOSS / Advanced Monitoring Initiative
b) Economics and Sustainability	i) Economics and Decision Sciences ii) Technology for Sustainability
c) Ecosystems, Water and Security	i) Ecosystems Protection ii) Water Quality iii) Drinking Water iv) Homeland Security

d) Air and Global Change	i) Clean Air ii) Global Change
e) Human Health	i) Human Health ii) Computational Toxicology iii) Endocrine Disruptors iv) Human Health Risk Assessment v) Safe Pesticides and Products

The SAB challenged ORD during the S AB-EPA interaction on the FY 2008 research budget to discuss examples of cross-cutting research (e.g., in cross cutting areas such as sprawl, climate change, sensitive populations, etc.). Though a cross-cutting view of these themes is not directly addressed in the descriptions listed above, ORD does think of the individual linkages across research areas and they jointly plan some parts of this research across a variety of specific areas. In addition, EPA views the inviduals programs as being either **Program-Targeted Research** (e.g., Clean Air, Drinking Water, Water Quality, Land Preservation, SafePesticides and Products, Homeland Security, Global Change, and GEOSS/AMI) or **Cross-Program Research** (e.g., Human Health, Computational Toxicology, Human Health Risk Assessment, Endocrine Disrupting Chemicals, Ecosystems, Economics and Decision Sciences, Science and Technology for Sustainability, and Nanotechnology).

3. Response to the Charge

3.1 General Comments: Moving to a more proactive and system-oriented research portfolio

In this report, the Board focuses on fundamental and overarching issues. The SAB believes that EPA has made progress in identifying the strategic needs within its 16 focused research areas. Similarly the National Academy of Sciences Committee on Evaluating the Efficiency of Research and Development at the U.S. Environmental Protection Agency has noted, "The key to research efficiency is good planning and implementation. EPA and its ORD have a sound strategic planning architecture that provides a multi-year basis for the annual assessment of progress and milestones for evaluating research programs, including their efficiency" (NAS, 2008)[1]. The SAB is pleased by the EPA's efforts to engage in a dialogue on strategic research planning. This willingness to engage the Board and others openly about research directions and strategies is laudable as EPA comes to grips with the need for major new science understandings to meet current environmental protection issues, as well as the emerging issues that will be a part of its mission in the future.

The Agency's current sixteen focal areas are important. However, if it is to be prepared to address future needs, EPA's research program will have to adopt a more integrated view, one that recognizes the inherent complexities and interconnections among human and ecological systems, gives greater consideration to feedbacks, and focuses on the relevant scales of each issue. In this context, it is clear that if the Agency is to truly protect the environment, it must undertake a larger program of research that goes beyond its immediate regulatory needs and address the broad array of environmental problems facing the nation.

Of course, focused research in support of current regulatory programs is needed. However, it appears to the SAB that a balanced program that has been recommended by the SAB and the National Academy of Sciences in a number of past reports (NAS, 2000; SAB, 2006; SAB 2007) is being lost as a result of constant pressures to address the near-term data needs of the Agency's operating programs in the face of ever more serious resource constraints.

Several changes are needed to address pressing environmental problems that do not fall neatly within existing regulatory mandates. Today these needs are only addressed within the Agency's research plans in fragmentary ways. In its research programs, we believe that EPA should:

[1] NAS also provided a framework for evaluating the efficiency of EPA research. NAS identifies two types of research efficiency. **Investment Efficiency** addresses theree questions: are the right investments being made, is the research being performed at a high level of quality, and are timely and effective adjustments being made in the multi-year course of the work to reflect new scientific information. NAS states that these questions are best evaluated by use of expert judgment not quantitative measures. **Process Efficiency** involves quantitative measures of inputs and outputs (e.g., publication rates, time required to conduct research, and percent of grants tht are peer-reviewed) and these can be measured in units such as dollars, hours and numbers. PART emphasizes Process Efficiency. Investment Efficiency is best judged by expert advice.

1) **Broaden the interpretation of "land preservation" to take a greater leadership role in future land-use decision making and in managing the consequences of bio-fuels, sprawl, green-field development, and the pressures of unconstrained coastal development.**

The Agency's Land Preservation area has historically focused on cleanup activities associated with contaminated sites, uncontrolled releases, spills, and leaking underground tanks. More recently efforts have been made to include waste minimization activities, mostly through the Resource Conservation Challenge (RCC), a voluntary partnering program aimed at helping companies and institutions overcome barriers to implementing waste minimization programs. This is a potentially valuable program, but it has not been systematically evaluated to assess its efficacy or to develop plans for improvement. This should be done.

Perhaps more than most of the other of the Agency's research programs, the Land Preservation area has less latitude in shifting its programs in response to suggested new directions. This is due principally to restricted uses of Superfund resources, but also the genuine, and considerable, needs associated with containing and removing contamination in the land environment. Still, the Board is concerned that new and broader issues that this area could also address are not being seriously considered. For example, there is little research on land use topics such as measuring the benefits of Brownfields cleanup and revitalization, urban sprawl and the built environment, and the multiple land sustainability issues that surround agriculture and biofuels. The Board urges that EPA carefully examine the complimentary nature of an expanded Land Use program and its nascent, but important, research program in Sustainability with a view toward recognizing opportunities for cross-disciplinary collaboration.

Private actions associated with land use decisions, globalization of the supply chain for increasing numbers of commodities, water needs for residential and agriculture uses, bio-fuels as responses to shortfalls in conventional energy resources, and numerous other examples illustrate choices made in response to the incentives provided by private markets and current regulations. Experience seems to suggest that we learn the environmental consequences of these incentive structures after problems have emerged. Organizing environmental research in all media so that it considers the task of measuring *ex ante* the environmental costs (or equivalently the benefits) of the available choice alternatives would require re-casting EPA's research activities. Under this approach EPA would connect the full environmental consequences to their sources as distinct private decisions. This organization would also provide an accounting system that is consistent with sustainability scoring.

2) **<u>Expand the focus on the environmental consequences of new technologies to include</u>**

A number of factors associated with product life cycles influence the types of risks that are emerging in the U.S. and worldwide, as well as how and why those risks emerge. It matters where products are manufactured and how they are manufactured. In addition, new technologies are emerging that will have to be considered in view of their own life cycles.

EPA needs to understand where things will be manufactured in the future. Thirty years ago, 80 percent of automobile-related manufacturing took place in less than 20 counties in the U.S. Today that number is less than 50 percent. Auto manufacturing left the Rustbelt and moved into the American southeast (a shift from Brownfields to Greenfields). Just-in-time inventory processes have dramatically increased the transportation-related impacts for the production life cycle, especially for high-weight, low value inputs. Thus, the location of production and any attendant risks has changed within the U.S.

There is also a need for attention to production activities outside U.S. borders. The increase of international trade has made it more important to think about how human health and the environment in the U.S. might be influenced by manufacturing outside our boarders. Productions processes for these products, and the products that result from international production processes, also matter. Risks from production and products need to be considered where things are produced outside our boarders as well as the risks associated with outside production and products once they are brought into the U.S.

Examples of US human health and environmental problems that can result, at least partially from pollution released in other countries, include not only global effects such as climate change and stratospheric ozone depletion, but also environmental transport of pollutants such as particulate matter and mercury. Additionally, transport of contaminants through products (e.g., lead in children's toys; pesticides in food products), and accidental or incidental transport of living organisms associated with increased global transportation (e.g., invasive species such as zebra mussels, disease vectors) can cause adverse effects to human health and the environment in the U.S.

ORD should develop mechanisms and devote resources to anticipating significant changes in the methods and locations of industrial production that could have impacts on EPA's mission and programs. Shifts in hydrocarbon synthesis (biofuels) are already on the radar screen but other changes loom large. Research is needed to better understand the effects of globalization on risks to human health and the environment in the US and elsewhere.

There is also a need for research on the efficacy of alternative regulatory mechanisms for protecting health and the environment. Some conventional regulatory approaches (e.g.,

pollution taxes, inspection systems) may be more difficult to implement outside US jurisdiction and may be limited by free-trade rules, suggesting that alternative approaches such as programs to assist non-US producers in developing or adopting more environmentally or health-friendly products and processes (e.g., ongoing US-China efforts, development of energy-star and other product standards) may be considered in addition to more conventional regulatory mechanisms.

Production locations and methods are not only changing for existing products, but new technologies are giving rise to new types of products that must be evaluated. For example, to continue to reduce the cost and size of computer chips, the semiconductor industry is exploring alternative production methods ranging from water-based lithography to the use of DNA and nano-scale quantum techniques to produce logic. Similar transitions are underway in the production of batteries as companies explore alternatives to lithium ion such as nano-phosphate. These shifts in industrial production methods could result in dramatic changes in material inputs, water and energy requirements, emissions, and end-of-life issues. When they happen, where, and how all need to be better understood by EPA

3) **Expand the analysis of water infrastructures, supply, demand and quality in light of changing socio-economic pressures and climate.**

Expanding populations in water-short areas of the U.S. (e.g., Atlanta, Las Vegas, and Phoenix) is increasing the demand for water. This, in turn, is leading local water management agencies to negotiate agreements for large-scale transfers of water from distant regions. The long-term ecosystem and ecosystem service impacts of such transfers have received little study. Because interest in inter-basin transfers of water is likely to grow in the future, an improved understanding of the ecosystem impacts associated with such transfers will be necessary to make informed decisions on regional and interstate water management/reuse as well as land uses which contribute to increased water demand.

4) **Reinvigorate and modernize research on sensitive human and ecological populations**.

The study and protection of sensitive populations (including plants, animal, and human) should continue to be a prime emphasis for the EPA. If the Agency protects those populations that may be the most susceptible to toxins and other stressors it will likely fulfill its primary mission of protecting the general population.

Sensitive human groups include populations at various stages of life (fetus, pregnant females, children, elderly, etc) and populations of individuals with specific diseases (such as asthma), specific genotypes, or specific exposures. Studies of these sensitive populations, not only provide critical data to protect the general population, but also

provide insight into what chemicals are toxic, their mechanism of action or pathways of toxicity, and potentially help to identify opportunities to protect these populations and the general population as a whole.

Studies of affects on sensitive plant and animal populations are also important. Such studies will also provide insight to mechanisms of action of environmental chemicals and possibly avenues of intervention (including nutrapharmaceuticals, nutrition, etc) when various species or ecosystems are at risk. The study of these sensitive plant and animal populations is also important in helping to understand the effects of population losses on the entire ecosystems. The study of sensitive populations must also consider how changes to sensitive ecosystems can affect the entire system.

Often, environmental research and environmental protection actions focus on single pollutants, species, or stressors. This is not reflective of actual situations in the world. Thus, there is also a critical need to develop models and approaches that examine human health and ecological effects of relevant chemical mixtures in the context of other exogenous and endogenous "background exposures" and to move away from the focus of intense scrutiny on narrowly conceived single agent scenarios. To do so will require the development of criteria for selecting the most relevant mixtures and for understanding how environmental exposures add to the existing burden of endogenous and other xenobiotic exposure to cause disease. While the Agency has made some progress on common mechanism mixtures (organophosphate pesticides, dioxin), these represent only a minor part of the problem. Further, most mixtures to which people and ecosystems are exposed will be dominated by mixtures that do not have common mechanisms; also exposures typically occur within the context of other xenobiotic and endogenous chemical stressors as well as non-chemical risk modifiers that can also change the effects resulting from such environmental mixture exposures.

5) **Improve the science foundation needed to respond to unexpected and emerging problems and environmental disasters.**

The science and technologies impinging on human health and environmental evaluations are exponentially expanding in terms of complexity and pace of development. Examples include the likely emergence of transforming sciences such as toxicogenomics and nanotechnology. Resource-limited organizations such as EPA will be increasingly challenged to develop creative mechanisms to provide the Agency access to this science within the realistic constraints of EPA human and budget resources.

6) Expand policy relevant research on developing, testing and evaluating new and innovative alternatives to conventional command and control regulation.

The first three of the above examples represent problems that arise from the many independent decisions made by individuals and organizations that do not face prices, other

incentives, or regulations that capture the full life cycle and longer term consequences of these decisions.

With a few exceptions, such as the new initiative in sustainability, most of EPA's current research programs are tied to specific media and their focus is driven by current regulatory strategies, statutory mandates and needs. The SAB understands the forces and budgetary limitations that have created this situation. However, in thinking about 2012 and beyond the SAB believes that a broader and more systems-oriented approach to research will be needed. Many of the elements of such a program already exist, but in the words of Administrator Johnson, currently the work is much too "stove-piped."

Over the coming months the SAB will work to develop more complete and balanced advice on what a more integrated and systems-oriented research portfolio might look like. At this stage we offer comments on a number of topics that emerged from our discussions with ORD in October 2007.

3.2 Human Resources for the Conduct of Science at EPA

EPA is interested in the implications of workforce changes on the quality and responsiveness of EPA's research programs. EPA's question is primarily focused on how the skills available through the workforce might be adjusted to further evolve and improve the research program (i.e., strategic workforce planning). The SAB notes that the issue is not just one of expanding expertise into new areas. Rather, there is a need to ensure that the existing expertise base does not undergo erosion as staff turnover from retirement and lack of EPA investments in science staff, and the laboratory equipment and supplies needed for researchers to be able to carry out research. The SAB recognizes that new issues will require new skills in the workforce and it has noted this in several of its recent reviews of EPA research budgets. Skill will be needed for many of the new emerging issues such as nanotechnology production and risk as well as in the specialties within the social sciences (e.g., human behavior, communications, and other). EPA is generally as aware of the new skills it will need as those who are on the SAB. In many ways, this issue is as much one of making the personnel resources available as it is in attracting and retaining those with new skills. Given that we are now at a point in which many in the existing workforce are moving into retirement, the time is good for making these changes. The Agency must also develop plans for transitional training for new employees to avoid repeating some of the current issues in the future.

There is an issue, though that must be addressed if EPA is to succeed in attracting and retaining the best and the brightest scientists. The EPA has long enjoyed a remarkably dedicated and high qualified scientific research staff. However, in our discussions with bench-level scientists during our October, 2007 visit to RTP, and in the individual interactions that members of the SAB have had in recent years with both junior and senior agency researchers, several

issues have emerged that deserve ongoing and expanded attention from EPA's senior managers. These include:

a) The erosion and/or disillusionment of senior staff. Continually shrinking research budgets have resulted in growing numbers of senior staff who are becoming disillusioned, and this risks loss of the high level of dedication that brought them to the agency in the first place.

b) Recruiting and retaining young talent. The agency has developed an outstanding program to attract postdoctoral scientists to the ORD labs, and an active program to recruit new young scientific staff. However, we are concerned that too many of the scientists who are participating in these programs are losing interest when real opportunities and permanent, challenging jobs are not available, and they are subsequently moving on to other careers.

c) Continuing Education and Training. The agency has long had formal and informal programs to support continued education, up to and including opportunities for MS-level scientists and engineers to pursue PhD studies. However, it is time to review and revitalize these activities.

With the exception of our recurrent recommendations to reverse the continued erosion of research budgets, the SAB is not close enough to the details of ORD operations to suggest specific strategies to address these issues. However we know enough about recent staffing trends to recommend that the issues of sustaining and strengthening ORD and the Agency's scientific human resources deserves continued and expanded attention.

3.3 Comments on Research Effectiveness and Efficiency

EPA asked the SAB for advice on the scientific factors that should be considered so that EPA can transition to its future program focus. Of interest to EPA in such advice was whether changes in "environmental" science itself would be important; if workforce issues such as skills available might need to be adjusted to further evolve and improve the research program (i.e., strategic workforce planning); and if there are opportunities for improving the research program's efficiency (e.g., are there opportunities for greater coordination and synergy within ORD, across EPA, and across other organizations both inside and outside of government; or are there other research "themes" that could strengthen EPA's research strategy (e.g., cross-cutting advice on sprawl, disasters, climate change).

The recent NAS report on Evaluating Research Efficiency in the US EPA offers valuable suggestions on evaluating both investment efficiency and process efficiency for US EPA research programs. The SAB supports the findings of the NAS report and notes tht the role of expert review by SAB is most helpful in evaluating investiment efficiency in research. In this regard, the SAB offers the following thoughts for consideration.

a) Strategies by which the EPA might make greater use of results from its own research program (we offer examples in sustainability and in nanotechnology) and relevant research from other organizations.

As a leading research agency, EPA should be the leader in the using its own research results. The following are examples of current opportunities:

i) The recent Agency and government-wide initiative on nanotechnology has provided significant research results demonstrating the properties of nanomaterials. Incorporation of these results in technology development activities in the water and air monitoring and treatment arenas could yield significantly improved process performance.

ii) The Technology for Sustainability Research Program has identified three interrelated ideas drawn from economics, social, and environmental realms. These have been translated into 6 program themes. Integration of the ideas and themes into other research programs will yield program results that reflect EPA's view of "… meeting basic environmental, economic, and social needs now and in the future without undermining the natural systems upon which life depends."

iii) The Ecosystem Research Program's new direction on assessing ecosystem services needs to be integrated into Agency Program offices and should help in prioritizing and evaluating the effectiveness of their activities.

iv) ORD has passed the tools developed in EMAP to the Program and Regions; yet there is an on-going need for the development of new monitoring strategies and tools. This parallels the opportunities in nanotechnology presented above.

As the leading organization for research efforts that are directed at EPA's specific mission areas that protect human health and the environment, EPA ORD should actively look for and use the relevant research results from other governmental and nongovernmental organizations in ways similar to that noted above for its own research results.

The SAB has noted on many occasions that other governmental and non-governmental organizations either fund or conduct research that can be useful in supporting EPA's mission achievement. To its credit, EPA has a long history of using such results to the extent that they are relevant to EPA's conduct of its own research and in considering the need for action on various environmental issues. However, as the SAB has remarked before, much of the research conducted by these outside organizations, though generally categorized as "environmental research" is not of the type that directly answers important questions that are relevant to EPA's specific mission.

EPA ORD is uniquely positioned to pursue the most relevant research to support the EPA mission. This is in fact the primary mission of ORD. That said, it is clear that there is much research being conducted outside of EPA that can be useful to EPA as it improves the understanding of components of problems that are a part of its mission. Thus, EPA should continue to "mine" these efforts for useful knowledge and procedures. However, EPA should enhance and improve this effort by instituting a systematic process that ensures that such research results are captured by EPA and used to support the Agency mission when it is appropriate for such uses. This systematic mining of others' research results can also identify opportunities for EPA collaboration and partnerships to leverage the use of EPA's own resources.

b) Strategies to engage citizens for data collection, and for computational resources for advanced modeling and analysis.

Communications is shifting from a one-to-many paradigm (i.e., the approach that dominated radio and television for decades) to a many-to-many, net-centric paradigm. Nicholas Negroponte, the Director of MIT's Media Lab, called this the move from "passive old media" to "interactive new media." Interconnected people now have the technological tools that allow users to generate and distribute their own content -- everything from computer code (Linux) to course curriculum (iTunes University). People can collaborate to make their content better (peer-to-peer design and development) and they can apply their collective wisdom to solving important scientific challenges.

To take advantage of these changes, ORD should develop a strategy to engage a new generation of "citizen scientists" to help the agency collect, analyze, and apply the results of these activities to environmental issues. In this, EPA could consider the integration of citizens and outside organizations into their "macroscope", possibly as a Citizen's Science Corps. In this manner, EPA could create opportunities for citizens to work as observers and participants in a variety of efforts that would be useful to EPA's achievement of its mission. Citizens could perform measurements, analyze data, and support efforts to attain environmental improvements. In addition to making direct observations; such a "Science Corps" could participate in EPA websites to give their advice on what EPA should be doing on various issues (e.g., Wikipedia); and they can analyze EPA's data bases through competitions that reward the best ideas for new environmental science, solutions, and technologies (reference *Wikinomics: How Mass Collaboration Changes Everything*, 2006). The Agency might, with some imaginative effort determine how it could turn a few million GPS-enabled cell phones with cameras into a participatory sensing system? EPA might consider using a virtual world like Second Life to test reactions to product labeling schemes or work on collaborative strategies to manage ecosystems?

An example of a successful venture in this area is the effort to link together America's 70 million bird watchers. Web-based systems like *Bird Source* and *Journey North* have allowed birders to share sitings and see new spatial patterns of migration never before possible. John Fitzpatrick, director of the Laboratory for Ornithology at Cornell, commented that, "We'll be able to count them, monitor them, and observe their population crashes, on a continental scale."

In addition, a few years ago, NASA found that people with a bit of training could identify craters on the surface of Mars and classify them by age (humans can still beat computers on many pattern recognition tasks). Instead of just borrowing computer power (SETI project) NASA borrowed the brains of thousands of people in what was called the Clickworker's Project. People did this for the challenge and learning experience, not for money.

More recently, thousands of people poured over satellite images trying to find the downed plane of pilot Steve Fossett (Help find Steve Fossett with Google Earth). A similar technique was used to search for Jim Gray, a Microsoft scientist who went missing on his sailboat off the coast of California.

c) <u>Expansion and greater integration of behavior and decision science into many ORD research programs</u>

Without a scientific understanding of human behavior, the Environmental Protection Agency cannot fulfill its responsibility to the American people.

An element of human judgment is part of every analysis that the Agency conducts. It is present in the definition of fundamental terms, such as risk, benefit, exposure, discount rate, and equity. It is present in the selection and weighting of data. It is present in the selection of values for sensitivity analyses and the assessment of scientific uncertainties. The roles of judgment and their limits have been studied extensively for some forty years. If that science is not reflected in EPA's analytical processes, then the results of those analyses are less than they should be and they are conveyed with greater confidence than is warranted. These are the issues that, in part, motivated OMB's Risk Assessment Bulletin. Although that effort was faulted as fundamentally flawed by the National Academy of Sciences and subsequently abandoned by OMB, the need for systematic treatment of scientific judgment remains.

Many EPA analyses attempt to assess processes that depend on human behavior. For example, the risks from toxic chemicals depend on exposure processes shaped by human behavior (e.g., what people eat, whether they can use protective clothing); they may also depend on the behavior of people who must maintain equipment, interpret malfunctions, issue warnings, and respond to cautions or evacuation orders. In the publicly available reports from two consultations, the SAB's Homeland Security Advisory Committee

raised serious questions about the behavioral realism of important programs that were sound in other ways. Unless EPA bases its analysis on social and behavioral science, its assumptions will be little more than guesswork.

The value of much of EPA's work depends on its ability to convey its results to people who must make decisions based on them. It is well established in the scientific literature that many technical issues are understood in different ways by expert and lay audiences. With scientifically sound communications, however, it is possible to make research results clear to those willing to attend to them. At one time, the Agency was a leader in scientifically sound communication. Today, however, EPA's communications are almost all improvised, without any rigorous analytical identification of its audiences' information needs or empirical evaluation of its effects. As a result, the Agency may not only fail to extract the full value of its research, but inadvertently misinform its audiences.

The Agency is in dire need of an ambitious program of scientific research in the social and behavioral sciences. At the moment, its ranks are so depleted that it has difficulty commissioning sound work from the outside, lacking staff with the expertise needed to evaluate proposals and products. There is no substitute for aggressive hiring, investment in dedicated STAR graduate fellowships, and extramural research to fulfill the most pressing gaps until EPA has created adequate intramural research programs. It may be wise for EPA to partner with an agency with social science expertise in order to build this program, as it did in the early days of its decision making program.

d) <u>An alternative organizational structure for EPA Research</u>

The Agency may wish to consider alternative models for the management of the activities pursued within its laboratory system. Historically EPA research has been organized according to media-specific, pollutant-specific, and problem-specific areas as well as the risk management paradigm (air, radiation, assessment, effects, toxicology, exposure, risk management, homeland security, etc.). Such a model serves the regulatory side of the Agency well, but makes it difficult to respond to modern environmental problems which are increasingly cross-media, systemic, and complex. A focus that is finely tuned to the regulatory side of the Agency also is sensitive to changes in regulatory priorities. Because of this the SAB has seen over the years a tendency for calls at EPA to shift away from existing research – research that may have taken several years to incorporate within plans and budgets – into new areas. This undermines the normal pursuit of research which almost always requires conduct over some protracted timeframe to reach successful conclusion. Alternative models that are more adaptive, multidisciplinary, and systems-oriented would allow the Agency to better anticipate new environmental challenges, and be less reactive. These would very likely permit cost and functional efficiencies to be gained, as well as create a more stable research environment within the research organization. The Board recognizes that a transition to an alternative model for management is a painstaking endeavor accompanied by a culture change and resistance

by some. The long term rewards, however, would be best for the protection of human health and the environment.

3.4 Moving Forward with the SAB – EPA Strategic Research Discussions

EPA asked how future SAB-to-EPA interactions on strategic science planning might be improved? Since 2005, the responsibility for reviewing the EPA research budget has been the responsibility of the Chartered Science Advisory Board. The SAB made the decision to move the review from an SAB subcommittee to the full Board because of its desire to reflect the importance of the review and because it allowed the Board to add to the number of individuals on the team that actually reviewed the report. It also permitted the span of expertise used in the review to be increased. The SAB believes that retaining this activity as a Chartered SAB responsibility will allow the improvements already gained from this change to be preserved and it will also allow the benefits to be increased in the future.

In its consideration of EPA's overall research picture, largely through the window of a budget review, the SAB has explored a variety of approaches to conduct the actual review and considered a variety of types of information that would help it in the conduct of these reviews. EPA and the SAB continue to work to identify an optimal set of background documents to be given to the SAB so that it can carry out a meaningful review of EPA's research budget. Over time the amount of documentation has decreased. The SAB believes that it should continue to work with EPA to refine the set of background documents necessary to allow a high quality review of EPA's research program portfolio.

In addition, the SAB and EPA have varied the specific organizations involved in the review from having the SAB interact with just ORD to having all the client offices participate in the discussions of research needs. This is because the span of activities conducted under the ORD research and development program overlaps with similar activities that are pursued by various program and regional offices. Thus, it has been the goal of the SAB and ORD to have regional and program offices all involved in the discussions so that the full science program would be a part of the discussions, not just that part carried out by ORD. At this point, the Program and Regional Offices are not participating in the interaction as fully as the SAB and ORD would like. The SAB believes that EPA's program and regional offices should be more involved in these discussions in the future. This is both so that the SAB can learn from programs and regions of how well their needs are being met by ORD and also because program and regional offices also conduct science activities that are of a similar nature to those conducted by ORD. To best provide advice to ORD on how its research efforts should evolve, it will be important to understand the full EPA science program and those components that are not under the direction of ORD.

The SAB has long thought that engaging in discussions of the overall research program over the long term was not as successful when done in association with discussions on EPA's

research budget. Generally, open discussion is restricted when it occurs as a part of the budget process because of rules that constrain the Agency's ability to thoroughly discuss how well a given budget meets the needs for conducting research that is identified in its long-term strategic planning. Thus, the SAB and ORD agreed to separate the two activities into a two-phased process in which the SAB and EPA are engaging in a continuing series of discussions of the strategic directions for EPA research so that the Board can better understand the overall directions of Agency research and how that might change. In addition, the SAB each February evaluates and advises the Administrator on the coming year's research budget in terms of how that budget will contribute to the Agency's accomplishment of the goals and objectives that are embodied in the longer term strategic directions for each research program. The SAB believes that continuing this separation, and pursuing discussions with EPA over time will contribute to better communications between the SAB and ORD on the overall research program. This will, in turn, provide a contextual basis for the SAB's use in advising EPA, and the U.S. Congress, on each year's budget.

The topics which come to the SAB for consideration and advice-giving differ from those sent to the ORD Board of Scientific Counselors (BOSC) and other advisory bodies. For example, SAB review topics tend more toward being peer reviews of scientific assessments or assessment methods than the actual conduct and progress on specific research programs – the latter usually being done by the BOSC. The SAB believes that deliberations on the adequacy and completeness of EPA research program strategies and budgets could be enhanced if it incorporates additional representation from other advisory bodies into its own reviews. The SAB will pursue this for future activities in these two areas.

One of the difficulties in evaluating research budgets and strategies from year to year comes from changes that EPA makes to the structure, nomenclature, and organization of its research programs. Thus, from one year to the next, the location of specific research topics might fall within different categories. Further, when considering resource levels allocated to specific programs, and to the component activities within given programs, it is important to have information on what resource levels are actually associated with each component and program from year to year. Without this, it is quite difficult to know how a program is progressing over time. In addition, resource allocations rarely are given, when they are given, on a consistent basis over a series of years (e.g., some years show budget levels while some show appropriated levels) and thus it is difficult to see resource trends over time. The SAB believes that its discussions on EPA research could be improved if it could be provided with a consistent set of resource numbers over a period of at least 5 years for specific programs and program components. Further, if requirements change in a way that causes programs, and their components, to be renamed from one year to the next, information should be provided that makes those changes clear.

Contrary to popular belief, specific research programs carried out by or for EPA do have an actual beginning and an actual ending. Often the end of an activity within an ORD research program signals the need for a follow-on action by a Program or Regional Office. The SAB

believes that improved consideration of EPA's research programs conducted by ORD could be gained from participation of Regional and Program Office personnel who could indicate how specific completed research activities are to be implemented in their own offices (e.g., the continuation of the EMAP is such an issue since it is being indicated by ORD now as an area where research has completed the development of a method/approach and that the benefits gained from information coming from implementation of those methods will now be the responsibility of other EPA offices. Knowing that such things will happen is important to the SAB as it develops its advice on ORD's research programs and budgets).

3.5 Commentary on EPA's Specific Research Areas

The key directions for each of these research areas are briefly summarized in the following paragraphs.

a) Land Preservation and Restoration:

- Develop sustainable planning criteria for land use plans, e.g., Brownfields.
- Evaluate alternative remediation technologies for contaminated sediments.
- Emphasize in situ treatments and PRBs for ground water protection, study the operation of landfills as bioreactors, and help assess asbestos risks.

b) Nanotechnology

- Understand sources, fate, transport, and exposure throughout the life-cycle of nanomaterials.
- Develop risk assessment and test methods.

c) GEOSS / Advanced Monitoring Initiative

- Transition from pilot projects to focusing on user needs, capacity building, and communities of practice.
- Develop best practices guide to forecast air quality and inform decision making.

d) Economics and Decision Sciences

- Develop risk assessment metrics that can be used for valuation purposes.
- Find ways to transfer air market mechanisms to other environmental issues.
- Advance computational tools to develop analytic models capable of evaluating policies on both micro- and macro-economic scales.

f) Technology for Sustainability

- Develop sustainability metrics to include in EPA's Report on the Environment, inform design and production, and evaluate innovative technologies.
- Provide decision support tools that address energy and environmental impacts, e.g., water and land use.
- Promote collaborative partnerships.

g) Ecosystems Protection

- Assess the benefits of ecosystem services to human well-being.
- Understand how policy and management choices affect the type, quality, and magnitude of services we receive from ecosystems.

h) Water Quality

- Support aquatic life guidelines and recreational water criteria, by studying the impact of stressors, including habitat alteration, nutrients, pathogens, and emerging contaminants.
- Improve watershed management by applying diagnostic tools to assess impairment and guide mitigation efforts to manage both point and non-point sources.

i) Drinking Water

- Develop sustainable source water protection approaches.
- Assess exposure to contaminants from water storage and distribution systems.
- Improve tools for characterizing and monitoring pathogens and biofilms, and develop methodologies for microbial risk assessment.
- Develop methodologies to quantify the impacts of SDWA rule implementation on public health outcomes.

j) Homeland Security

- Identify and validate methods to detect and quantify biological agents.
- Develop a methodology to assess microbial risks and risk-based advisory levels.
- Develop decontamination and disposal approaches for CBR agents in both large outdoor areas and in water infrastructure.
- Improve the communication of risk and risk management options during a crisis.

k) Clean Air

- Support the development and implementation of the NAAQS and other air quality regulations.
- Develop a multi-pollutant “one atmosphere” approach, focusing on identifying specific source-to-health-outcome linkages, e.g., near roadway exposures.
- Assess health and environmental improvements from past actions.

l) Global Change

- Continue to prepare the Synthesis and Assessment Products mandated by the Global Change Research Act.
- Refine the assessment of climate change on air quality in the U.S.
- Characterize the potential impacts of global change on water quality and aquatic ecosystems.

m) Human Health:

- Establish relationships between environmental decisions and changes in health indicators.
- Focus on characterizing toxicity pathways for dose-response and extrapolation models for risk assessment.

n) Computational Toxicology

- Provide predictive models for screening and testing of chemicals to improve source-to-outcome linkages.
- Develop new approaches and technologies to better predict a chemical's hazard, and identify toxicity testing priorities.
- Develop new systems biology models, such as the virtual liver.

o) Endocrine Disruptors

- Complete development of protocols for EDC screening and testing assays.
- Improve understanding of EDCs' mechanisms of action, dose response, and cumulative risk issues.
- Develop exposure assessment and risk management tools to characterize and reduce exposure to EDCs.

p) Human Health Risk Assessment

- Continue to support IRIS profiles, PPRTVs, and other priority assessments.
- Develop methods, models, and guidance for improved health risk assessments.
- Conduct integrated science assessments for ambient air pollutants.

q) Safe Pesticides and Products

- Develop predictive tools for chemical prioritization and testing requirements, and enhanced interpretation of exposure and toxicity studies.
- Develop mathematical models for integrating dose-response and habitat relationships for wildlife population and plant communities.
- Develop approaches to assess allergenicity potential from GM crops and to assess the risks of gene flow from GM crops.

a) Technology Research Comments

For the purposes of these discussions between the SAB and ORD, the Technology Research Area includes: i) Land Preservation and Restoration, ii) Nanotechnology, and the iii) Global Earth Observation System of Systems/Advanced Monitoring Initiative (GEOSS/AMI). Each of these programs has attributes the SAB believes represent the evolution and revolution changes in the environmental arena. Research activities in the Land Preservation and Restoration Program have evolved from the traditional studies on hazardous waste treatment and management to Brownfields cleanup and revitalization. The Nanotechnology Research and GEOSS/AMI represent strategic research initiatives

on, respectively, the implications of modern technology and on innovative uses of data to support EPA's mission.

i) **Land Preservation & Restoration** research supports the research needs of RRA, CERCLA, and the Office of Solid Waste and Emergency Response (OSWER) on the detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances in the environment. The purpose of the research program is to provide more cost-effective tools, models, and methods to support decisions on land restoration, materials management, and reuse/land revitalization (SAB, 2007a).

The key directions of ORD's current research program in this area include (Teichman, 2007a):

- Development of sustainable planning criteria for land use plans, e.g., Brownfields.
- Evaluation of alternative remediation technologies for contaminated sediments.
- *In situ* treatments and permeable reactive barriers for ground water protection, study of the operation of landfills as bioreactors, and assessment of asbestos risks.

SAB Comment: The Agency's Land Preservation area has historically focused on cleanup activities associated with contaminated sites, uncontrolled releases, spills, and leaking underground tanks. More recently efforts have been made to include waste minimization activities, mostly through the Resource Conservation Challenge (RCC), a voluntary partnering program aimed at helping companies and institutions overcome barriers to implementing waste minimization programs. This is a potentially valuable program, but it needs to be systematically evaluated to assess its efficacy or to develop plans for improvement.

The Board recognizes that there are emerging environmental research needs that fall within the purview of this technology area that should be explored. Generally, these research needs fall within the well-recognized field of Land Use and include, but are not limited to, measuring the environmental and economic benefits of Brownfields cleanup and revitalization, documenting the multiple environmental challenges associated with urban sprawl and the built environment, clarifying the complex relationship between agriculture, biofuels, and environmental protection, and improvements in the rigor of LCA for use in land use remediation and protection. The Board urges the EPA to examine more closely the complimentary nature of an expanded Land Use program and its nascent, but important, research program in Sustainability with a view toward recognizing opportunities for cross-disciplinary collaboration.

The EPA ETV and SITE programs are essential to moving technology to commercialization and have involved substantial leveraging of limited EPA funds. NACEPT and other studies view these evaluation activities as having high value to private environmental technology organizations.

ii) **Nanotechnology Research** addresses the environmental protection challenge of ensuring "…that, as nanotechnology develops and engineered nanomaterials are manufactured and used, unintended consequences of exposures to humans and ecosystems are prevented or minimized. In addition, knowledge concerning how best to apply products of this emerging technology to detect, monitor, prevent, control, and clean up pollution is also needed." In this regard, EPA has developed a research portfolio by working with others including federal agencies, industry, academia, and non-governmental organizations to ensure research gaps are covered, critical issues are addressed, and information is communicated to all interested parties." (SAB, 2007a).

The key directions of ORD's current research program in this area include (Teichman, 2007a):

- Understanding sources, fate, transport, and exposure throughout the life-cycle of nanomaterials.
- Developing risk assessment and test methods.

SAB Comment: The Agency's Nanotechnology research program appears to be well integrated into the broader National Nanotechnology Initiative, a positive development, and has shown that it can reach out to the broader international community as well as the manufacturing companies themselves. The ORD program on nanomaterials has been formulated strategically, considering EPA needs and with an eye towards leveraging and potential future regulatory decisions. There is involvement with many external groups. EPA has given careful attention to building on areas of internal expertise such as fate and transport, ecological assessment, and small particle inhalation. The program integrates activities at the international, national, and cross-agency levels. An important, unaddressed challenge is the implication of mixtures and environmental transformations of nanomaterials and other contaminants.

iii) Global Earth Observation System of Systems/Advanced Monitoring Initiative. EPA's GEOSS/AMI program grew from recognition that the goals of the US EPA's 2006-2011 strategic plan (US EPA, 2006a) and those of the GEOSS were mutually reinforcing. GEOSS envisions a future in which "…decisions and actions are informed by coordinated, comprehensive, and sustained Earth observations and information." GEOSS intends to integrate "…multiple Earth observation systems (networks, databases) and using computer modeling and

decision support tools to help revolutionize our understanding of Earth's complex processes." EPA activity in this multi-agency program began with its participation in groups leading the effort to plan and support GEOSS and with its own Advanced Monitoring Initiative that is aimed at showing some major tangible results by September 2008. EPA's efforts involve 34 projects in four areas (Air Quality Forecasting/Assessment and Decision-making for Human Health; Coastal/Source Water Quality and Decision-making for Human Health; Integrated Air-Water-Land-Biota Decision-making for Healthy Communities and Ecosystems; and Information Technology/Information Management (SAB, 2007a).

The key directions of ORD's current research program in this area include (Teichman, 2007a):

- Transition from pilot projects to focusing on user needs, capacity building, and communities of practice.
- Develop best practices guide to forecast air quality and inform decision making.

SAB Comment: The GEOSS/AMI initiative is well-conceived and planned. It has a strong cross-media focus, especially for air and water, supports the goals of multiple MYPs, and has good cross-agency (e.g. NSF) connections. Some of the benefits of GEOSS are that it develops a technologically collaborative culture, creates an understanding of the need to plan for such collaboration, and, done right, it will work itself out of business. To accelerate and further the development of this technologically collaborative culture, the Agency should select a few high impact projects,such as the Chesapeake Bay and Mississippi River, for demonstration during the next phase of this program.

At this early stage the Board supports GEOSS/AMI, but with two caveats:

- There is a need to guard against moving toward a "data-rich/information poor" state, and
- Parallel concerns about the need for evaluating data quality and uncertainty exist.

One potential application of GEOSS/AMI in relation to Homeland Security would be to organize the data from multiple labs from multiple samples from multiple field teams of the air, water, and land. However, without additional integration with economics and decision sciences, it would become just another store house of data, without much assessment. By adding the components of cost benefit analyses, compliance/ and participation behavior, it would be possible to determine if allowing the public back into an contaminated area, but restricting

their exposure through protective actions such as interdiction of crops would be adequately protective of public health and would be publicly acceptable.

As a specific example, there are a number of protective actions which have been discussed involving milk which had been contaminated with a short lived radionuclide Would it be acceptable to use the milk to make cheese since the aging process would allow radioactive decay to take place? Could it be turned into powdered milk for consumption after 10 half-lives? What would the public's reaction to this milk be? By integrating economics and decision sciences with geo-mapped land use areas, it would be possible to make some better assumptions about public acceptance.

Another specific example would be to allow people to return to their homes following an incident involving deposition of a hazardous substance in their neighborhood, but not allow them to consume vegetables from their backyard garden, and require them to wipe their pet's feet every time the pet enters the house after running around on the lawn. Would people comply with this direction?

b) <u>Economics and Sustainability Research Areas</u>

For the purposes of these discussions between the SAB and ORD, the Economics and Sustainability Research Area includes: i) Economics and Decision Sciences, and ii) Technology for Sustainability.

i) **<u>Economics and Decision Sciences.</u>** This research program area is managed by the EPA National Center for Environmental Economics (NCEE) which plans the research component of its program in cooperation with the Office of Research and Development. This "**…**research is designed to improve our understanding of human and organizational environmental behavior and preferences, which is critical for improving EPA's decision-making, cost-benefit analyses, and implementation strategies."...This research program "…focuses on how people value their health and the environment; corporate and consumer environmental behavior; and market mechanisms and incentives (SAB, 2007a).

The key directions of NCEE's current research program in this area, include (Teichman, 2007a):

- Developing risk assessment metrics that can be used for valuation purposes;
- Finding ways to transfer air market mechanisms to other environmental issues; and
- Developing advanced computational tools needed to support analytic models capable of evaluating policies on both micro- and macro-economic scales.

SAB Comment: The research plan for EDS follows closely the *Environmental Economics Research Strategy*. It identifies three major research areas (pp. 56-57):[2]

- health benefits valuation (both mortality and morbidity),
- ecological benefits valuation, and
- treatment of uncertainty.

It also proposes research in three additional areas: environmental justice, costs and benefits of climate change, and compliance/participation behavior.

The health valuation research is designed to improve the estimation of costs and benefits of EPA actions, primarily for use in RIAs and related assessments. An extensive literature exists on the valuation of mortality risks (i.e., estimating the value of a statistical life (VSL)), and the proposed research appears to be aimed at refining those estimates to provide estimates that vary with factors such as income, age, and health status. While more information on this topic would clearly be valuable, before investing significant additional resources in VSL estimation by sub-group, the SAB urges the Agency to consider how the new information will be used in benefits assessment to ensure that the research results are policy-relevant.

The SAB applauds the research direction related to ecological benefits valuation. Since this work requires extensive integration of ecological and economic analysis, the SAB urges the Agency to extend this research area to include participation from other program areas. Note that meaningful ecological benefits valuation requires more than applying an average value estimate (e.g., the "value of a hectare of wetlands") to an estimate of environmental effect (e.g., hectares of wetlands preserved). Rather, it requires a meaningful assessment of the value of a policy-driven change in ecosystem services that reflects important bio-physical and socio-economic characteristics of the impacted ecosystem and population. Research in this area should build on results of the recent SAB project on valuing the Protection of ecological systems and services (CVPESS).

The EDS strategy focuses almost exclusively on economics, particularly measuring costs and benefits, with little attention to other behavioral and decision science issues (other than the proposed work on compliance/participation in voluntary programs). Yet, behavior of firms and individuals drives environmental performance. This behavior is in response to policy-induced incentives, as well as cognitive and decision-making processes employed by individuals. The SAB

[2] Note that these three areas are not the same as the three "bullets" on the overview slides by Kevin Teichman. We did not feel that the bullets on the slide accurately captured the main components of the research strategy proposed for EDS.

urges EPA to expand the EDS research strategy to include research focused on these issues. This could include work on the incentives and likely effectiveness of alternative policy approaches (evaluated relative to specific policy contexts), business management decisions, information processing, technology/product adoption (including consumer behavior), and risk and other communication strategies.

As a practical example, with the growing emphasis on energy conservation, a market for compact fluorescent lamps (CFLs) has been stimulated. It is common to see CFLs in mass distribution markets, such as most major department stores. However, CFLs contain mercury which is released if the bulb is accidentally broken. It may be necessary to consider whether regulation is needed to require locations that sell CFLs to institute "take-back" programs. What incentives will inspire the public to return the bulbs rather than put them into the normal household waste stream?

More generally, the EDS research strategy should be broadened to identify and include links with other program areas. The current strategy is defined more from a disciplinary than a problem-oriented perspective. For nearly all of the EDS research areas, closer interaction with other program areas would be fruitful. Specific examples include revitalization of contaminated lands (with land preservation), effectiveness of TMDLs (with water), and managing water quantity (with water and global change).

Finally, the EDS research strategy seems to be driven to a large extent by short-term national assessment needs, most notably for RIAs. This is likely to become even more pronounced now that EDS has moved from ORD to the EPA National Center for Environmental Economics (NCEE) and its budget has been sharply reduced. The SAB urges the Agency to broaden its research agenda to contribute to improvements in other decision contexts (e.g., regional planning applications and site-specific decisions) and to look beyond the short-term in identifying research priorities.

ii) **Technology for Sustainability** research has emerged as the new emphasis for programs that originated at EPA under the concepts of pollution prevention in the early 1990's. According to EPA, in this context, "sustainability" refers to "…meeting the needs of the present without compromising the ability of future generations to meet their own needs. From a public policy perspective, sustainability means meeting basic environmental, economic, and social needs now, and in the future, without undermining the natural systems upon which life depends." Sustainability goes "…beyond traditional end-of-pipe control strategies and embraces system-based, long-term solutions." Early efforts under Pollution Prevention and New Technologies aimed to provide "…tools and technologies that

advanced the idea of environmental systems management while preventing and controlling pollution and reducing risks to human health and ecosystems originating from multiple economic sectors.

Strategic directions for the STS research program begin with the notion that sustainability "…must combine interrelated ideas drawn from economic, social and environmental realms" – often thought of as the "Three Pillars of Sustainability." Given EPA's narrowly focused mission, the EPA STS research program is focused on environmental dimension of sustainability while recognizing that sustainable environmental outcomes are best achieved in a systems-based context." The resulting EPA research program is broader than normal "stove-piped media-focused programs to a focus that is multimedia and systems wide. EPA's sustainability research program has six themes: 1) Natural Resource Protection, 2) Non-renewable Resource Conservation; 3) Long-term Chemical and Biological Impacts; 4) Human-built Systems and Land Use; 5) Economics and Human Behavior; and 6) Information and Decision-making (SAB, 2007a).

The key directions of ORD's current sustainability research program include (Teichman, 2007a)**:**

- Development of sustainability metrics for use in EPA's Report on the Environment, informing design and production, and evaluating innovative technologies.
- Provide decision support tools to address energy and environmental impacts, e.g., water and land use.
- Promote collaborative partnerships.

SAB Comment: The ORD's research initiative in area of sustainability is an important and timely step forward. The SAB supports ORD's research efforts to develop metrics and tools to advance the Agency's ability to achieve protection of human health and the environment through sustainable practices. The SAB believes the "6 Themes of Environmental Sustainability" identified as the framework for this research are appropriate and important areas upon which to focus. Additionally, EPA's intent to work on sustainability metrics, decision support tools and innovative technologies expressed in the long-term goals statements seems to capture the broad categories of tools and techniques in which the agency should be working. That said the review team felt that the written description provided to the SAB on the intended research actions under the long-term goals did not clearly link to the 6 themes for sustainability. The agency representatives did note that their forthcoming research strategy document will show this linkage. A post meeting, inspection of the June 13, 2007 draft of the strategic research strategy draft contains a table (5.1) on page 43 which gives some

indication of linkages between the 6 themes and the 3 long-term goals. A table such as this with some more details on research projects would have been helped to clarify these linkages in the information provided for this current discussion. The SAB looks forward to seeing those linkages further developed in the final Sustainability Research Strategy.

In conclusion, the SAB suggests that the agency allow itself wide latitude in the way it approaches sustainability research since this new systems-based approach to environmental protection will require a fundamental departure from the current stove-pipe single-media based regulatory framework. The SAB recommends the following (expanded details for each of these recommendations are included in Appendix A of this Advisory).

Recommendations

- Clearly define the intended audience(s)
- Behavior and decision science research is needed
- Establish (or clearly define) linkage to other Research areas and programs
- Go beyond Technology – green chemistry and pollution prevention
- LCA tools don't incorporate directly what matters to people so they can't incorporate value or benefits
- Need for a clear definition of the sustainable condition or future state the agency desires to maintain or achieve.
- Explore developing a bridge between risk and performance to achieve sustainability.

c) Ecosystems, Water and Security Research Areas

For the purposes of these discussions between the SAB and ORD, the Ecosystems, Water and Security Research Area includes: a) Ecosystem Protection, b) Water Quality, c) Drinking Water, and d) Homeland Security.

i) **Ecosystem Protection.** The Ecological Research Program (ERP) is taking a new strategic direction that is intended to fill the need "… for better understanding the implications of human impacts on ecosystems and the resources they provide." This new program direction recognizes that even though, "The nation's health, security, economic potential, and much of its culture are directly and intimately tied to ecosystem characteristics and quality"[,] environmental policy "…decisions have failed to take these relationships into account." The redirected ERP intends to build on past research efforts in ecosystem monitoring, restoration, and functions, to develop operational methods to incorporate quantitative information on ecosystems services into decision making routines. Using internal resources, and a suite of unique partnerships with outside organizations (academia, NGOs,

other governmental agencies, etc.), the ERP will conduct research designed to "…answer multiple questions about ecosystem services. … and develop multiple measures of services, including biophysical and monetary measures, to estimate incremental changes to ecosystem services, as well as suites of 'bundled' services associated with land, air, and water systems over explicitly defined spatial and temporal scales." The "…goal is to inform a wide range of issues related to questions of social choice, with a special focus on informing trade-offs among ecosystem services provided under alternative management and policy decisions." ERP, through its own work and that of its partners, will create products in four categories: 1) measurements and dynamic maps of ecosystem services; 2) predictive models relating to the response of stressors; 3) tools for analysis of management options; and 4) decision support tools (SAB, 2007a). Approaches developed by ORD to monitor ecosystem conditions (e.g., Environmental Monitoring and Assessment Program-EMAP) will now be passed to the Program and Regional Offices to implement.

The key directions of ORD's current ecosystems research program, include (Teichman, 2007a):

- Assessing the benefits of ecosystem services to human well-being, and
- Understanding how policy and management choices affect the type, quality, and magnitude of services we receive from ecosystems.

SAB Comment: The SAB noted the changes from the historically, diverse research program in this area to one that is refocused on ecosystem services. The SAB believes that ORD has a strong vision of where it is going in this area; however, that vision is not yet integrated across EPA Research and EPA Program Offices. Additionally, even though ORD has passed the tools developed in EMAP to the Program and Regional Offices for implementation, the SAB believes that there continues to be a need to link conditions to goals through and that there is a need for additional development of monitoring systems, especially for some of the contemplated trading systems that involve ecosystem services. Success in this research area will be enhanced if EPA adds expertise in economics to the program. Decision support tools are also critical to this program. ORD should invests in system support science more heavily in the future given that it will benefit Ecosystems Research as well as several other programs. ORD has a history of taking the outcomes from their research and helping to infuse those results into EPA practice. This will be very important for research on ecosystem services. An ecosystem services perspective will require staff with a holistic perspective and this perspective must be communicated to user communities. This new focus will also require support of the STAR grants program to be successful. The opportunity to think at the strategic level instead of just focusing on the "issue of

the week" is important to getting these new programs on a strong footing. Integrating across diverse scales is important.

Several National Program areas have responsibilities for water-related research areas, including Water Quality, Drinking Water, Ecosystems, Global Change, and Sustainability. While there are structures in place to encourage and facilitate interactions among the research programs and the program offices, these arrangements are not always effective in communicating when ORD's effort is to end and OW's effort is to begin.

The Office of Research and Development recognizes the importance of establishing research partners in the broader research community to accomplish its challenging goals. However, it is disappointing that the ERP-STAR program will not continue to be vehicle for collaboration with universities due to budget cuts. The SAB believes that this is a strategic error.

The ERP description reports that the EMAP program (a status and trend program) has been transferred to the Water Quality Program for technical support and to the Program Offices for survey monitoring and assessment. In light of the SAB's criticism of the Report on the Environment 2007 for not including long-term trend information and little trend analysis for indicators questions arises in my mind 1) does the Water Quality Program have the capability to provide technical assistance needed, 2) and do the Program Offices have the capability to implement the survey monitoring and assessment need to generate indicator trend data and analysis for future Reports on the Environment.

[At the Board's Reqpuest ORD has Commented Regarding Advice on its Ecosystems Research Program:

The report states that the ecosystems research needs to be better integrated into the work of the PEA program Offices and that a shared vision has yet to emerge. The SAB proposes that an entity be identified to facilitate the integration and to help shape the outcomes of ths research program. ORD does not dispute the need for stronger ties between the ecosystem research program and our colleagues iin the Program Offices. While we appreciate the SAB's willingness to become an active facilitator for this effort, we believe that this function is better managed internally within EPA. One of the NPD's functions is to ensure good ORD/Program Office coordination. ORD believes it is best to rely on the Eco NPD to ensure that the ecosystems research program is better integrated into the work of the Program Offices.

The SAB states that several research areas have responsibilities for water-related research, including Water Quality, Drinking Water, Ecosytemes, Global Change, and Sustainability. ORD recognizes that there are overlapping responsibility areas between multi-year plans. ORD has mechanisms in place to

encourage and facilitate interactions among the research programs to ensure that research activities are coordinated. In addition, ORD is undertaking a review of its multi-year plan categories, andis considering options for merging some plans. One objective in merging the plans is to address the concerns raised by the SAB. The SAB may want to share in its report its thoughts on this effort and its contribution to mitigating their concern about program overlap.]

ii) **Water Quality** research supports EPA's Office of Water and Regional Offices in implementation of the Clean Water Act (CWA). The restructured water quality research program (WQRP) consolidates past work done under a separate goal into three remaining goals that focus on: 1) Water Quality Integrity Research - research in support of aquatic life guideline revisions, recreational water criteria, emerging contaminants, nutrients, biocriteria, stream biota, and biological condition gradients for Tiered Aquatic Life Uses; 2) Watershed Management Research - research in support of Total Maximum daily Load allocation processes; and 3) Infrastructure Research - research on innovative solutions to manage the nation's aging water and wastewater infrastructure (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Supporting development of aquatic life guidelines and recreational water criteria, by studying the impact of stressors, including habitat alteration, nutrients, pathogens, and emerging contaminants.
- Improving watershed management by applying diagnostic tools to assess impairment and guide mitigation efforts to manage both point and non-point sources.

SAB Comments: The SAB believes that EPA must begin to actively integrate its research and programs for water quality and drinking water. A holistic "Clean Water" program should be pursued analogous to the way in which research is now pursued as a "one atmosphere" concept in the air medium. More work is needed in watershed management, infrastructure, and integrated criteria development (across biological, chemical and physical criteria). Research is also needed on modeling, monitoring, and measurement to support water quality decision making. Climate change, and the relationship of water quality to land use practices, must be incorporated through out this research area.

iii) **Drinking Water** research is "…an applied research program designed to develop new scientific data, models, innovative methods, and cost-effective technologies for characterizing and managing the quality and sustainability of drinking water resources in support of EPA's goal of 'Clean and Safe Water.'" "The Drinking Water Research Program (DWRP) is moving towards an integrated framework for

addressing drinking water issues in the context of the water cycle." Major themes in the DWRP are in the areas of 1) Assessment Tools; 2) Source Water/Water Resources; 3) Treatment/Residuals; 4) Distribution/Storage/Infrastructure; and 5) Water Use/Health Outcomes. Increased emphasis is being placed on source water protection and sustainability; water distribution/storage systems/infra-structure; microbial risk associated with pathogen exposure; and health outcomes" (SAB, 2007a).

The key directions of ORD's current research program in this area, include (ORD, 2007a):

- Develop sustainable source water protection approaches.
- Assess exposure to contaminants from water storage and distribution systems.
- Improve tools for characterizing and monitoring pathogens and biofilms, and develop methodologies for microbial risk assessment.
- Develop methodologies to quantify the impacts of SDWA rule implementation on public health outcomes.

[At the Board's Reqpuest ORD has Commented Regarding Advice on its Drinking Water Research Program: The SAB noted that for Drinking Water Research "most attention is on total coliform and CCL research with groundwater source protection getting some attention. More attention is needed for surface source water protection and distribution systems." The SAB may have gotten the incorrect impression that most of the attention is on TCR and CCL because of comments made by the NPD at the strategic directions meeting when she explained that t the regulatory drivers for the research program are TCR, CCL, and UIC – this was not to imply that most of the research attention is on TCR and CCL. The Drinking Water Reserch Program has substantively increased emphasis on source water protection and distribution systems (e.g., a recent initiative on infrastructure). ORD suggests tht this section be reframed as follows: "Members noted that the regulatory drivers for Drinking Water Research are the revision of the total coliform rule (and potential distribution system rule), CCL3, and the proposed rule for geologic sequestration under the UIC program. Research on protection of surface water soruces of drinking water is at the intersection of SDWA and CWA. More attention is needed on both surface source water protection and distribution systems. Again, the One Hydrosphere approach is suggested for EPA to use in integrating its research on a variety of water issues.]

SAB Comment: Members noted that for Drinking Water Research most attention is on total coliform and CCL research with groundwater source protection getting some attention. It is understood that these priorities are driven by the regulatory drivers of the Total Coliform Rule, the Candidate Contaminant List (CCL), and Underground Injection Control (UIC, geologic carbon sequestration). While the

regulatory drivers are important, the future sstrategic direction should focus on the most important risks which could be non-regulatory. A watershed focus may provide the greatest opportunity for pubic health protection via prevention. More attention is needed for surface source water protection and distribution systems. Again, the "One Hydrosphere" approach is suggested for EPA use in integrating its research on a variety of water issues.

iv) **Homeland Security** responsibilities of EPA include: 1) the protection of water systems in general and for detecting and recovering from terrorist attacks affecting water systems; 2) decontaminating buildings and outdoor areas impacted by a terrorist attack; and 3) developing a nationwide laboratory network to support routine monitoring and response requirements. The EPA Homeland Security Research Program "…is currently conducting a year-long exercise to align the program more closely with these responsibilities. The original Homeland Security Research Program covered broad emergency response issues; however, the realigned research program will focus primarily on terrorist attacks. Even so, "…the program will continue to nurture research collaborations with the broader scientific community, seeking supplemental expertise, fostering valuable collaborations and leveraging of additional resources. In addition, although research products will be planned to meet the needs of Agency customers, ORD will conduct research that benefits multiple EPA programs and other Federal agencies as much as possible." Goals focus on developing 1) "…products and expertise to improve protection from and the capability to respond to terrorist attacks on the nation's water and wastewater infrastructure" and 2) "…products and expertise to improve the capability to respond to terrorist attacks affecting buildings and the outdoor environment." Behavioral research program requirements are still being explored in a white paper being developed by EPA on homeland security-related research needs in the behavioral sciences (e.g., risk communication and perception during crises) (SAB, 2007a).

The key directions of ORD's current homeland security research include (Teichman, 2007a):

- Identifying and validating methods to detect and quantify biological agents.
- Developing a methodology to assess microbial risks and risk-based advisory levels.
- Developing decontamination and disposal approaches for CBR agents in both large outdoor areas and in water infrastructure.
- Improving the communication of risk and risk management options during a crisis.

SAB Comment: The SAB recognizes that the Homeland Security Research program began in a crisis mode and focused on getting as much as possible as

quickly as possible. The need now is to become more strategic and to define program boundaries so that this strategic focus has a goal. Even though the strategic directions state the intent to focus only on terrorism, EPA must think beyond terrorism and conduct research to enhance responses to natural disasters. EPA also needs to think about how to increase collaborative research with other agencies and other stakeholders as well as to obtain more collaboration within EPA. A cross-cutting issue is the need to coordinate with others to better define EPA's niche in the response area and how that influences research needs. Important research areas identified include: risk communications; detection methods for contamination, decontamination, disposal and outdoor exposure. Issues such as determining "how much clean up is necessary" have social research needs beyond communications.

EPA should ensure that it integrates the work and lessons learned from others, including:

- Other countries (UK, Canada, Australia)
- Other federal agencies (DoD, USDA, CDC, DHS, DOE),
- Multiple EPA offices (ORD, OW; other multi-year plans),
- The States, and
- Involves new areas/opportunities with new resources.

[At the Board's Reqpuest ORD has Commented Regarding Advice on its Homeland Security Research Program:: The SAB writes n the Homeland Security section tht "There is an appearance that the Program and the NHSRC are doing same or similar work. EPA needs to clarify how work of the two organizations work together and not in duplication." The NHSRC is responsible for planning and implementing EPA's Homeland Security Research Program, and the program and regional offices use ORD products in their operations. For example, ORD has developed over 80 provisionary advisory levels (PAL) for selected toxic industrial chemicals and warfare agents for acute, short-term, and chronic exposure conditions. We suggest that the SAB delete or expand upon and clarify this comment.]

d) <u>Air and Global Change Research Areas</u>

For the purposes of these discussions between the SAB and ORD, the Air and Global Change Research Area includes: a) Clean Air, and Global Change.

i) **<u>Clean Air Research</u>** provides research results needed to develop and implement the National Ambient Air Quality Standards (NAAQS) – primarily particulate matter (PM) and ozone as high risk pollutants. Secondarily it also provides research for Hazardous Air Pollutant (HAP) management. Clean Air Research

(CAR) has been restructured over the last several years into an integrated program in contrast to the previous research program that focused on individual pollutants. Ultimately the research program will provide information that allows EPA to adopt a multi-pollutant program that will lead to targeted control of emissions products that most affect human health. Long-term goals for the CAR fall into five thematic areas.

- Theme 1 supports the development of NAAQS and other air quality regulations;
- Theme 2 supports implementation of air pollution regulations;
- Theme 3 develops a multi-pollutant approach to research;
- Theme 4 identifies specific source-to-health linkages using 'near roadway' as the prototype; and
- Theme 5 assesses health and environmental improvements due to past regulatory actions (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Support the development and implementation of the NAAQS and other air quality regulations.
- Develop a multi-pollutant "one atmosphere" approach, focusing on identifying specific source-to-health-outcome linkages, e.g., near roadway exposures.
- Assess health and environmental improvements from past actions

SAB Comment: As noted above, the Clean Air Research Program identified three key directions for their research agenda. The SAB agrees that all of these meet the criteria of being high priority research areas and are particularly supportive of the more holistic systems approach that the "one atmosphere" concept encompasses. In addition, we believe it is also important for ORD to maintain a robust research program on air toxics, and on air quality in indoor environments, which are critical for human exposure. In addition to these current focus areas, the SAB agrees that research on interactions of global change and air quality is an important new priority for both the Clean Air and Global Change programs. Further, the SAB believes significant societal benefits would result from increased research on the global mass balance of mercury and its fate and transport. Research to develop and assess alternative policy approaches (e.g., marketable permit systems for multimedia pollutants, effectiveness of various types of voluntary instruments, etc.) would also yield high social returns.

ii) **Global Change research at EPA is a part of the interagency U.S. Climate Change** Science Program (CCSP) mandated by the Global Change Research Act

of 1990. "The primary focus of ORD's Global Program is on the assessment of the potential consequences of global change (particularly climate variability and change) on air quality, water quality/aquatic ecosystems, and human health. Results of the program's assessments are used to investigate adaptation options that improve society's ability to effectively respond to the risks and opportunities presented by global change. The program emphasis is shifting toward developing decision support tools to help managers consider global change during the decision making process (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Continue to prepare the Synthesis and Assessment Products mandated by the Global Change Research Act.
- Refine the assessment of climate change *on* air quality in the U.S.
- Characterize the potential impacts of global change on water quality and aquatic ecosystems.

SAB Comment: The first key direction is largely driven by regulatory requirements whereas the second two areas are more anticipatory in nature. There seems to be very strong collaboration between the global change program and other research areas such as the water quality research, ecosystems protection, and clean air. There also appears to be a very healthy view concerning coordination of research efforts with other agencies. One area that could yield high returns from a focused research program is the development of guidance concerning mitigation and adaptation strategies, particularly with respect to the additional environmental benefits (or costs) these strategies might have (e.g., a practice that sequesters carbon in agricultural soils might also generate increase nutrient runoff). A second key direction of high importance is research on the design and development of policy instruments to implement greenhouse gas reductions cost-effectively.

Relative to reducing the nation's greenhouse gas emissions, Carbon Capture and Sequestration (CCS) is thought to be mandatory for the use of coal in the future. CCS is a major research area in which EPA will likely be involved in regulating and permitting carbon dioxide geological sequestration, but also in encouraging and leading research and demonstration efforts (especially in view of the recent cancellation of the Future-Gen project, the only major CCS demonstration project in the country to date). At the present time, EPA has taken a rather narrow view of its charge in this area to be limited to protection of groundwater quality under the Clean Water Act. SAB recommends that ORD begin partnering with DOE to provide risk assessments, encourage demonstration projects, and estimate leakages to the atmosphere. This should be a high national priority and EPA should play a prominent role."

e) Human Health Area

For the purposes of these discussions between the SAB and ORD, the Human Health Research Area includes: a) Human Health, b) Computational Toxicology, c) Endocrine Disruptors, d) Human Health Risk Assessment, and the e) Safe Pesticides and Safe Products.

[*At the Board's Reqpuest ORD has Commented Regarding Advice on its Human Health Research Program: The grouping of research areas for review presents a challenge. For example, both the SP2 and EDC programs have ecological as well as human health components. During the February 28 meeting, ORD will present a new framework for ORD research that may be useful in future SAB reviews.]*

i) **SAB General comments on Human Health.** Research directed at human health impacts should encompass a broad perspective to include public health approaches, exposure assessment, and epidemiology. Potential gene-environment interactions, including lifestyle, the built environment, diet, drug, and other xenobiotic exposures, should be included in assessment of human health endpoints. This will require adequate numbers of individuals trained in epidemiology and public health.

A critical evaluation of how new toxicological testing paradigms, including in vitro and in vivo approaches, can support risk assessment and ultimately risk based decision-making should be conducted within the next five years. This dialogue should include industry, NGOs, the public, and international groups in making this evaluation.

The Agency has put forward an impressive array of research objectives to support long term needs in human health assessment, including an increased emphasis on research to support the new toxicity testing paradigm. The SAB notes that there are some important areas of research that were not included in the materials received by the Board for its October 2007 meeting. Still, the research portfolio presented had few items where efforts may be decreased, and these were already noted by the agency. Therefore the additional research areas identified below and discussed in Appendix A would ideally be accomplished with the infusion of funding. Only one long term goal was identified as an objective that could be de-emphasized. The Board did not have enough time to make any firm recommendations on prioritizing this research.

The following outlines important areas of research that could be given increased emphasis in the general research area of human health, and then briefly comments on research by individual groups or laboratories as described in the October 2 presentation by Dr. Kevin Teichman.

- Research to Support Toxicity Testing Paradigm Shift. These include:
  - Predicting metabolism
  - Addressing exposure duration
  - Addressing novel agents
  - Epidemiologic surveillance

- Research to Develop Numerical (IRIS) Guidance Levels for Chemicals with Limited Apical Endpoint Test Data.
- Evolving Agency Hazard Identification and Dose Response Practice and Guidance as New Test Data Emerge.
- Epidemiological Research: Surveillance, Understanding Gene-Lifestyle-Environment Interactions.

ii) **Human Health** research provides fundamental information to improve our understanding of and to predict levels of human health effects associated with environmental agents that are managed through a variety of statutory mandates. Research themes in the HHRP focus on: 1) developing data, methods and models for risk assessment; 2) research to characterize aggregate and cumulative risk; 3) research on susceptible subpopulations; and 4) research to evaluate the public health impact of environmental decisions. Historically, Human health research has th biological mechanism of toxicity, cumulative effects associated with exposures, understanding susceptible subpopulations, the internal factors associated with vulnerability, life stages in relation to vulnerability, and the evaluation of public health outcomes. A recent NAS report (NAS, 2007) has made it clear that additional emphasis is needed on the development of new ways to characterize and predict toxicity. In addition, EPA's desire to continue to improve its "Report on the Environment" requires research for evaluating the effectiveness of decisions targeting public health (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Establish relationships between environmental decisions and changes in health indicators.
- Focus on characterizing toxicity pathways for dose-response and extrapolation models for risk assessment.

SAB Comment: Long term research focused on both of the key research directions is needed but should not sacrifice critical research efforts addressing sensitive populations and understanding their vulnerability. The main goals for the new initiative in toxicity testing approach are expected to achieve results in the 10 to 20 year time frame. Nearer term, research outputs are needed to support

program office needs in cumulative and aggregate risk assessment, and support characterizations of human susceptibility and variability to develop more scientific approaches for modeling dose response relationships. Also, methods are needed to take existing test data to the next step to enable better predictions especially for chemicals with non-apical endpoint data or limited data sets, as discussed in Appendix A. Community level risk assessment can better direct regulatory focus and depending on the nature of the assessment tool provide a conduit for stakeholder involvement in decision-making. There is an increasing need for tools that can be used by communities. On the ground for particular problems, collaborations between an EPA Region and local authorities in both risk assessment and risk management aspects can be important, but on a research level tools developed by agency would help facilitate efforts in the field.

To the extent that the program is continuing to support methods to characterize variability, susceptibility and cumulative risk, it should be explicitly noted for transparency and clarity, both internally in organizing efforts and for external evaluations. It is not clear whether the repackaging of the research portfolio presented by the Agency, actually, represents a shift in program focus away from some of the critical nearer term objectives.

iii) **Computational Toxicology** research develops enhanced tools for prioritization of hazards, and improved methods for quantitative risk assessment. Traditional methods can not keep pace with the current demands for hazard and risk evaluations, thus methods employing modern tools of molecular biology, information management, and computational models are being developed to identify, characterize hazard and risk quicker, cheaper and in a more scientifically robust way. Objectives of the program are to improve our understanding of the link between chemical sources and adverse health outcomes; to provide predictive models for screening and testing; and to improve quantitative risk assessment by providing a better understanding of basic mechanisms and their underlying biology (SAB, 2007a).

The key directions of ORD's current research program in this area include (Teichman, 2007a):

- Provide predictive models for screening and testing of chemicals to improve source-to-outcome linkages.
- Develop new approaches and technologies to better predict a chemical's hazard, and identify toxicity testing priorities.
- Develop new systems biology models, such as the virtual liver.

SAB Comment: The Board believes that this program continues to be headed in the right direction. The objectives of providing predictive models for screening

and testing chemicals, developing new approaches and technologies for predicting chemical hazard and testing priorities and developing new systems biology models such as the virtual liver are reasonable objectives to advance toxicity testing and predictive biology within the agency. Ultimately, a large research effort will be needed to fully realize the NAS toxicity testing vision so that the testing strategy can serve as the basis for most agency assessments. This can not be accomplished by elements reflected in the current research strategy. The Computational Toxicology Research Program is taking the first steps to build capacity and collaborations and to lay down initial work for proof of concept. The Board heard about the Agency's efforts to ensure that data supporting the work of the Program was publicly available on-line and the SAB compliments the Program for overcoming the obstacles to make this happen.

iv) **Endocrine Disruptors** research improves our understanding of chemicals that interact with the endocrine system. Research has been conducted to: 1) develop methods, models and measures for understanding and managing risks from endocrine disrupting chemicals (EDCs); 2) apply these methods to determine the extent of endocrine disruptor impacts to humans and wildlife; and 3) support the EPA screening and testing program on EDCs mandated by the Food Quality Protection Act and the Safe Drinking Water Act Amendments. Over the last five years, the program has increased its emphasis on research to characterize sources and occurrences of EDCs (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Complete development of protocols for EDC screening and testing assays.
- Improve understanding of EDCs' mechanisms of action, dose response, and cumulative risk issues.
- Develop exposure assessment and risk management tools to characterize and reduce exposure to EDCs.

SAB Comment: This program has been focused on completing the screening and testing assays, and is well along in this effort. The SAB agrees with the phase down for Tier I test development and suggests a greater attention to support hazard identification and explore how dose response can be characterized based on less than ideal data sets. The SAB also suggests exploring methods for estrogen and androgen compounds considering "background" exposures and exploring cumulative risk assessment approaches given background levels. The Agency might explore developing TEF approaches for several classes of compounds.

v) **Human Health Risk Assessment.** This research program is at the forefront of applying quantitative methods advances to risk assessments (e.g., use of PBPK

models to reduce uncertainty in risk extrapolations or to replace default uncertainty factors). The program maintains its leadership role in incorporating mode of action evaluations to support decision-making. Products of the program include IRIS assessments, Integrated Science Assessments (ISAs), and other assessments that respond directly to Program Office needs and are primary considerations in Agency actions to protect human health and the environment. HHRA also incorporates contemporary science advances into agency practice to improve risk assessment methods, models, and guidance for other EPA offices (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Continue to support IRIS profiles, PPRTVs, and other priority assessments.
- Develop methods, models, and guidance for improved health risk assessments.
- Conduct integrated science assessments for ambient air pollutants.

SAB Comment: The SAB recognizes that this as one of EPA's "bread and butter" research programs. The Board supports the three objectives in this research area and notes that there is an opportunity for developing and incorporating new approaches for sparse data sets to expand the capacity to develop guidance values. Staff in this research program should therefore collaborate closely with those in the Human Health Research program in these efforts. In addition, to have better assurance that sensitive populations are adequately addressed, collaboration between these programs is also needed to develop a better understanding of how to approach the use of variability assumptions in risk assessment. EPA should also consider better integration of HHRA with its Endocrine Disruptor Program to develop RfDs for chemicals with less than optimal data sets.

The Board notes its concern with delays and challenges posed by OMB reviews. The SAB encourages the EPA to make use of suggestions provided in the recent NAS document (NAS 2008) on revieweing research efficiencies to improve their ability to work with OMB in a more efficient manner. The Board's sense is that OMB has a very limited scientific review capacity and EPA needs to find improved ways of addressing these delays. One way is to work with OMB to develop a sufficient level of comfort so that OMB will increasingly rely on EPA's own document review processes.

vi) **Safe Pesticides and Products** research supports the problem-driven science needs of EPA's Pesticides and Toxic Substances programs. Safe Pesticides and Safe Products research tends to focus on high priority science needs that are not addressed by other research programs and work on both human health issues and ecological issues. The program's long-term goals focus on: 1) developing

methods, models and data as the scientific foundation for prioritizing test requirements, enhancing data interpretation, and improving decision-making; 2) developing probabilistic risk assessments focused on natural populations of birds, fish, other wildlife, and plants; and 3) conducting research to provide the scientific foundations for decision-making on biotechnology products (SAB, 2007a).

The key directions of ORD's current research program in this area, include (Teichman, 2007a):

- Develop predictive tools for chemical prioritization and testing requirements, and enhanced interpretation of exposure and toxicity studies.
- Develop mathematical models for integrating dose-response and habitat relationships for wildlife population and plant communities.
- Develop approaches to assess allergenicity potential from GM crops and to assess the risks of gene flow from GM crops.

SAB Comment: The SAB believes that this research area has reasonable objectives. However, there is a need for greater emphasis on toxicity tools to enable migration to safer products based on human, as well as ecologicl systems health protection.

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APPENDIX A: DETAILED RECOMMENDATIONS

1. Detailed Recommendations Technology for Sustainability Research Program (See Report Part 6 number 2 b, Page 27)

a) Clearly define the intended audience(s): It appeared to the review team that the ultimate objective of this research is to develop improved information, tools and approaches that will lead to changes in behavior. The intended audience or audiences (e.g., Agency, firms, and individuals) from which such behavior change is expected is not clear and needs to be more explicit. For example, who are EPA's "clients" as mentioned in paragraph 5 under section "Making a Difference"?

b) Behavior and decision science research is needed: The concept of sustainable development has an implicit element of people or organizations making decisions that lead to behaving in a manor such that their actions do not diminish environmental conditions resulting in either current impacts to human health or the environment nor reduce opportunities for use of that environment by future generations. Therefore, the area of behavioral and decision sciences should play an important role in helping EPA develop tools and information to aid such sustainable practice by individuals and organizations. The current research strategy does not reflect a focus on behavioral or decision science and the designers should revisit this area for research opportunities. Although the agency is planning to work on decision support tools such as life-cycle assessment (LCA) this is not the same as research on how and why people or organizations make decisions with regard to sustainability. Such behavioral research should not only address whether behavior is elicited but also if once elicited it is leads to positive improvements.

c) Establish (or clearly define) linkage to other Research areas and programs: Sustainability as a research area is truly cross-cutting at it core. Although the research strategy overview provided to the SAB indicates a degree of cross linkage in planning with other ORD areas, the SAB recommends a systematic and thorough planning effort that cross-links sustainability research with other programs. Examples of opportunities for such cross planning include:

- Revitalization of contaminated lands (economics and Land restoration)
- Effectiveness of TMDLs (economics and water)
- Managing water quantity (water-Global change- sustainability)

In addition, the agency should be taking a fresh page on this research. Don't just repackage former areas such as "land preservation" go beyond land contamination to management to avoid reduction in ecological services and or other human health services

d) Go beyond Technology – green chemistry and pollution prevention: E.g. Research on Smart growth; sustainable cities I am not sure what we want to say on this topic so appreciate if others could add their thoughts

e) LCA tools don't incorporate directly what matters to people so they can't incorporate value or benefits.

The review team also supports EPA's move towards taking a "systems" approach to environmental management. To this we note ORD's interest in focusing on tools based on LCA techniques. The review group cautions that the typical system boundaries and the inputs and out-puts of such analysis do not include any consideration of the benefits or the costs associated with the process or system under review. LCA as currently practiced is an excellent planning and design aid to manage raw material consumption, energy, hazard and waste production but it should not be relied on for integrated management decisions or balancing trade-offs among benefits without further development. It would be exciting and important if the agency can identify opportunities to integrate or couple LCA, and similar tools, with economic or valuation techniques.

f) Need for a clear definition of the sustainable condition or future state the agency desires to maintain or achieve. Sustainability, or its stated operational objective, sustainable development, has a variety of meanings depending on the audience that considers the term. Therefore, it seems essential that the agency start its sustainability effort by defining in specific systems terms the operating condition it plans to protect or restore. For example, water quality is generally defined in terms of expected or designated uses such as fishable, swimable or drinkable. If such conditions were attained, would EPA deem these systems to be sustainable? If so, what metric would the agency use to track sustainability? To the degree that the agency can specifically define the acceptable operating conditions for any specific environmental regime, it will assist itself in identifying sustainable metrics and designing sustainability tools to support sustainable practice for that regime. The definition of an environmental regime is itself in question. Historically one might that appropriate regimes are air, water and land, but if one attempts to manage a river or a lake, sustainable outcomes will not be achieved if the interfaces of land and air with that water body are not part of the management strategy and design of sustainable practices. The SAB does not suggest that this will be easy, or even how this might be done, but EPA should work diligently to do a conceptual mapping or otherwise the breakthrough expected from the sustainability research will not yield the needed behavioral changes that achieve sustainable conditions.

There may be value for EPA if it were to develop a vision of sustainable conditions in collaboration with other agencies that have complimentary responsibilities for land (e.g. USDA/NRCS), and water (e.g. USGS and ACOE).

g) Explore developing a bridge between risk and performance to achieve sustainability: The risk assessment paradigm is a core management conceptualization for EPA, and for that matter most of the entities it regulates. If the Agency plans to lead the nation to a higher state of environmental management performance, then it must build a bridge of understanding between the risks associated with the stressors it manages and how they link to functional process and the benefits associated with those processes. So in ecological terms this would mean linking chemical, physical or biological stressor loads to predicted adverse ecological responses in functional ecological processes which are ultimately linked to the ecological services humans enjoy from a landscape. If the agency succeeds in establishing this analytical chain then it can test and understand the implications of risk management to ecological performance sustainability. This would suggest the agency should be trying to move beyond the management of individual agents to the management of environmental regimes or landscapes (e.g. lakes, rivers, forests, cities etc.) based on their actual condition or performance.

The Agency should test the assumption that following a risk assessment/risk reduction strategy can lead to defining sustainability tools and achieve sustainable practices. The SAB believes that sustainability is tied to an expected set of performance criteria and the absence of unacceptable risk or risk reduction to acceptable levels is no guarantee of a sustainable outcome. The extreme but very real example of controlling ecological risks by removing the forest to get to the underlying contaminated soil highlights a use of risk assessment that is not framed in a sustainability context. If the Agency wants to achieve sustainable management of contaminated sites it will need to put risk projections into the context of actual ecological conditions which should be held up against a definition or set of design criteria of sustainable condition for the ecological habitat in question. Clearly, this means that data collected on sites must include data on ecological conditions and not just levels of contamination. This example is intended to illustrate the need to understand how the risk paradigm aligns with the type of decisions to be made, and that the current practice used to conduct regulatory reviews and reach decisions (e.g. data we collect) may need to evolve within the policy context of sustainability rather than risk control.

2. Additional Research Topics For the Human Health Area

(See Report Part 6 number 5, Page 35 - 36)

What follows outlines important areas of research that could be given increased emphasis in the general research area of human health, and then briefly comments on research by individual groups or laboratories as described in the October 2 Compilation and captured in bullets in Deputy Assistant Administrator Teichman's presentation.

a) Research to Support Toxicity Testing Paradigm Shift. In support of the new toxicity testing initiative, various areas for increased emphasis were noted. These include:

- *Predicting metabolism:* Development of strategies to support identification and characterization of possible active metabolites in humans and breakdown products. This is a critical area for research because failure to miss important metabolites can lead to missing toxic activities and under-predicting human risk.

- *Addressing exposure duration:* Rapid high throughput tests of exposed cells and cell components will eventually be used to shed light on the consequence of complex, long term human exposures – by their nature reflecting real life exposure of cells at various ages to a wide spectrum of various endogenous and exogenous chemicals.

- *Addressing novel agents:* An understanding of the extent that the tests capture the behavior of agents that fall outside the chemical sets used to develop the assays, and approaches to address novel agents will be needed.

- *Epidemiologic surveillance*: A critical piece for predicting human toxicity from high throughput test results for a chemical exposure will be an understanding of other exogeneous and endogenous exposures that perturb the same toxicological process, the degree of human exposures to them, and the variable human responses to such exposures. Research is needed to support the development of human surveillance strategies to provide the needed human data to interpret high throughput findings.

The NAS (2007) *Toxicity Testing* report notes these and a variety of other research areas that require attention in order to support the development of toxicity test batteries for wide use - to address the large number of environmental chemicals that are not now tested for lack of resources and rapid methods. The NAS envisioned a large scale research venture over many years to bring the testing vision to fruition, involving an NTP-like effort in terms of scale. The Agency's impressive but necessarily modest effort to move forward and gain experience and capacity in the area is noted. As the Agency by itself and in collaboration with other Federal agencies and institutions makes progress in its research, it is encouraged to turn frequently to the scientific community through the SAB and other scientific expert groups to optimize its research effort in this area.

b) Resarch to Development of Numerical (IRIS) Guidance Levels for Chemicals with Limited Apical Endpoint Test Data. Chemicals go uncharacterized because data from classical toxicity test results (e.g., long term bioassays) are not available. In some cases, in vitro and metabolic studies and other data would enable the prediction of toxicity endpoints and levels. One example where the Agency does make quantitative activity estimates and estimates risk in the absence of full bioassay data is dioxin-like compounds based on toxic equivalency factors. Research is needed to support the application of this approach to other chemical classes. In the long term approaches will be needed to develop guidance levels based on data emerging from the toxicity testing vision discussed above. Nearer term, research can enable the Agency to move forward on chemicals using short term in vivo and in vitro data and structure activity

relationships. This kind of information can be quite valuable in supporting green chemistry and other initiatives aimed at moving toward using less toxic materials.

c) Evolving Agency Hazard Identification and Dose Response Practice and Guidance as New Test Data Emerge. Clearly there is a need to evolve risk assessment techniques and practice as the practice of toxicity testing changes. With the exception of pesticides, there are significantly fewer chronic studies being performed today than twenty years ago. REACH promises to produce large volumes of toxicity data, but many chemicals are likely to have non-classical toxicity tests, particularly given the REACH guidance to where possible minimize the use of animals. Agency guidance and practice needs to evolve to take advantage of the available toxicity data, particular in cases where chemicals go uncharacterized. While the *Carcinogen Guidelines* and *Supplemental Guidance* did advance over previous versions, they were long in coming, and the International Agency for Research in Cancer has now developed guidance that is considered by some to be more up to date. There is a research component to develop new practice – new methods need to be developed to capitalize on findings, and sensitivity and specificity of the new approaches need to be understood in a general sense. It is recognized that development and incorporation of new approaches to chemical hazard and dose response prediction are challenges for a variety of practical reasons. Predictability of agency response to particular types of test data, consistency across chemicals in methods of analysis, and the need for researchers to have the skill set and understanding to replicate analyses all come into play in maintaining the status quo. On the other hand when there are exposures to apparently toxic agents that go uncharacterized and are not included in risk assessments, or better replacement chemicals are harder to identify, or agency assessments appear out of step with the science, opportunities for better decision-making are lost and agency credibility suffers.

d) Epidemiological Research: Surveillance, Understanding Gene-Lifestyle-Environment Interactions. The Board saw in-house capacity in the area of epidemiologic research limited to a few specialized areas. Most of the long term research is “bottom up” in nature, with the long term goal of inferring risks and effects in individuals from mechanistic understanding and data. “Top down” look at exposures and disease can be used to quantitatively generate as well as check hypotheses. It can also help to develop more scientifically rigorous basis for individual variability assumptions used in dose response analyses. Also, as in the first bullet above, epidemiologic understanding of endogenous and exogenous exposures and health status should prove critical in applying the results of high throughput screening to individuals and populations. Molecular epidemiology is key to identifying relationships between specific diseases and genes. Disease pathways can be discovered through associations between genes in susceptible individuals and diseases. An understanding of background processes and exposures is also critical to understanding the potential for linear dose response relationships due to “background additivity. The Board supports the partnerships EPA has developed with agencies such as CDC in health tracking and biomonitoring, as well

as the extramural research conducted to support the assessment of the criteria air pollutants and cumulative risk assessment. Still, greater in-house capacity including at a senior level could provide a public health and epidemiologic perspective to the research program and potentially synergize activities in the toxicity testing initiative.