UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

November 26, 2008

EPA-SAB-09-006

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

Subject: EPA's Strategic Research Directions 2008: An Advisory by the EPA Science Advisory Board

Dear Administrator Johnson:

In October 2007, the chartered EPA Science Advisory Board (SAB) initiated a series of interactions with EPA's Office of Research and Development (ORD) senior management and National Program Directors (NPD) to develop a better understanding of, and offer advice on, the strategic directions for EPA's research programs. This set of activities was 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 both to EPA's stated needs and the SAB's perspectives on the environmental challenges the Agency is likely to face in coming years.

The Agency asked the SAB to consider where EPA research should be as it plans its research for the next five years and beyond. 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 Board members discussed these strategic research descriptions in break-out sessions during the October 2007 SAB meeting. The SAB continued its discussions of EPA's research vision in several meetings. Though quite valuable, these sessions did not provide sufficient depth of information to allow the SAB to develop a detailed understanding of each research area or provide a full assessment of those programs.

However, the briefings and other interactions have provided the SAB with sufficient insight about current Agency plans to begin to develop broad strategic advice. The SAB plans to continue to conduct follow-up discussions with ORD, and possibly

other EPA scientists, on EPA's strategic research program directions and from time to time offer additional, more complete and detailed, advice.

The Agency's research and development program provides the scientific foundation and support for EPA's actions to carry out its mission to protect human health and the environment. Included in these activities are: i) conducting research and development to identify, understand, and solve current and future environmental problems; ii) providing 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 considering and preparing to deal with 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. In this Advisory, the SAB discusses and comments on the fundamental and overarching issues associated with these programs. More detailed comments are provided in the Appendix of this report.

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 16 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 reflects 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, the SAB believes 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 activities 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 restrictions, 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 and ecosystem 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 are important to understanding risks. Shifting locations of production within and 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 transport of pollutants, and movement of living organisms 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 or drought-stricken areas is leading governments and agencies to consider agreements for large-scale transfers of water from one watershed or 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 including research involving chemical mixtures.* EPA should continue to give primary emphasis to sensitive populations – this information will also provide critical data to protect the general population. In this sense,

sensitive populations refer to humans as well as to plant and animal populations, where the latter may be part of an interdependent ecological web. These studies will also help identify effective interventions when needed. Studies should also address the critical need for information on chemical mixtures that are reflective of actual situations in the world.

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. On the topic of environmental disasters, the SAB has recently sent you a separate self initiated report, which includes a number of research recommendations (SAB, 2008).

6) *Expand policy-relevant research on developing, testing and evaluating new and innovative alternatives to conventional command and control regulation*. There is a modest research literature on the relative advantages and disadvantages of different approaches in different contexts and on the development of new approaches. However, that literature is too small and insufficiently comprehensive given the importance of the issues that are at stake. Since existing programs are subject to review from time to time, and new issues such as the need to control of the emissions of greenhouse gases will likely arise in the future, the Agency would be well advised to build a vigorous research program that is focused on developing, testing and evaluating alternative strategies that might be able to more effectively and efficiently achieve future environmental goals.

7) *Improve dramatically the integration of economics and the decision and behavioral social sciences into research and policy development across the Agency*. The new research focus on ecosystem services is designed to provide inputs in a form that can be used in economic analysis and assessment of Agency programs. However, to be successful, evaluations of ecosystem services must build on an underpinning of solid ecological science, an area in which EPA has recently been dramatically reducing its research investments. The Agency will need to reverse this trend if the effort in ecosystem services is to meet its full potential. While the agency has reasonable staff resources in economics, and maintains some research on issues in environmental economics, its capability in the behavioral social sciences, and decision sciences, is so limited that it typically is not even in a position to ask the right questions. Given that risk perceptions and the behavioral response of members of the public are central to the design of many of the Agency's most important programs, the lack of staff resources and the absence of a coherent behavioral and sciences research program is a deficiency in urgent need of attention.

8) *Continue to work on improving the effective communication of research results to potential users both inside and outside the Agency*. The Agency has a variety of formal and informal strategies to move the results of its research into the hands of government and private decision makers, research groups in universities and the private sector, and the general public. Clearly if the results of EPA research are to have maximum value in promoting good environmental understanding, and informed decision making, these activities will require continued attention.

The SAB appreciates the very considerable assistance that it has received from Senior Staff in ORD, and the ongoing opportunity to work with the Agency in understanding and contributing to the improvement of its research vision. With a renewed commitment to reversing the recent trend of shrinking ORD research budgets, the SAB believes that EPA research will be able to address, well, the Agency's future needs for knowledge of human health, ecosystems, human behavior and the environment. In doing this, it should strive to build a broader and more forward-looking research program, and continue its efforts to break down barriers and promote greater strategic integration across its research programs. The SAB also believes that in this way, EPA research can set a high standard internationally for creative, forward looking, mission-motivated environmental research.

The SAB looks forward to your comments on its reflections on the EPA strategic research vision, and to its continued interactions with EPA on these critically important issues.

Sincerely,

/ Signed /

Dr. Deborah L. Swackhamer, Chair
Science Advisory Board

/ Signed /

Dr. M. Granger Morgan
Immediate Past 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.

U.S. Environmental Protection Agency
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EPA's Strategic Research Directions 2008: An SAB Advisory

1. Introduction

The EPA Science Advisory Board (SAB), senior managers of the 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 research program in October, 2007. This dialog has continued over several meetings since that time, and the parties intend that these discussions continue for at least the next several years. This interaction between the SAB and EPA is motivated by a desire to begin to think 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 in relation both to EPA's stated needs and the SAB's perspectives on the environmental challenges the Agency is likely to face in coming years.

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 perspectives on:

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 the SAB – EPA dialogue on strategic science planning for research be improved in the future?

Section 1 of this "enclosure to the letter to the Administrator" is this Introduction. Section 2 identifies EPA's 16 research areas as they were presented to the SAB during October 2007 and groups them according to how they were considered by the SAB at that meeting and since. In Section 3 the SAB offers its initial response 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 the SAB offers some suggestions for additional dialogue between the SAB and EPA on its strategic research vision**.** Finally, in the Enclosure, 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 during these initial interactions with ORD.

2. EPA Research Program Structure

The EPA Office of Research and Development (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). ORD also involved EPA's program and regional offices in this effort.

ORD research is intended to provide the scientific foundation to support EPA's mission by:

a) conducting research and development to identify, understand, and solve current and future environmental problems;

b) providing responsive technical support to EPA's Programs and Regions;

c) collaborating with EPA's scientific partners in academia, other agencies, state and tribal governments, private sector organizations, and nations; and

d) exercising leadership in addressing emerging environmental issues and advancing the science and technology of risk assessment and risk management.

For its interactions with the SAB, ORD structured its research program descriptions around sixteen 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. The sixteen specific research programs are listed in Table 1.

Because of an SAB request during the SAB-EPA interaction on the FY 2008 and 2009 research budgets, ORD moved toward discussing 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 in Table 1, ORD can identify and describe a number of linkages across research areas and they jointly plan some parts of this research across a variety of specific areas. In addition, EPA views the individual programs as being either **Program-Targeted Research** (e.g., Clean Air, Drinking Water, Water Quality, Land Preservation, Safe Pesticides 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).

Table 1. EPA Research Areas

SAB Grouping	ORD Research Areas
Technology	i) Land Preservation and Restoration ii) Nanotechnology iii) GEOSS / Advanced Monitoring Initiative
Economics and Sustainability	i) Economics and Decision Sciences ii) Technology for Sustainability
Ecosystems, Water and Security	i) Ecosystems Protection ii) Water Quality iii) Drinking Water iv) Homeland Security
Air and Global Change	i) Clean Air ii) Global Change
Human Health	i) Human Health ii) Computational Toxicology iii) Endocrine Disruptors iv) Human Health Risk Assessment v) Safe Pesticides and Products

3. Response to the Charge

3.1 General Comments

The SAB believes that EPA has made progress in identifying the strategic needs within its sixteen 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[1] 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" (NRC, 2008)[2].

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.

All of the Agency's current focal areas are individually important. However, if it is to be prepared to address future needs, EPA's research program should 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 addresses 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 (NRC, 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.

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[1]National Research Council, Evaluating Research Efficiency in the U.S. Environmental Protection Agency, Report of the Committee On Evaluating The Efficiency Of Research And Development Programs At The U.S. Environmental Protection Agency, 132pp, 2008.

[2]The NRC Committee also provided a framework for evaluating the efficiency of EPA research. The Committee identified two types of research efficiency. **Investment Efficiency** addresses three 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 that 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.

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, the SAB believes 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.**

   The Agency's Land Preservation area has historically focused on cleanup activities associated with contaminated sites, uncontrolled releases, spills, and leaking underground tanks. There are genuine, and considerable, needs associated with containing and removing contamination in the land environment, but while the Agency continues to address these issues, the Board believes that its focus should be broadened. For example, there is little research on land use topics such as measuring the benefits of Brownfields clean up and revitalization, urban sprawl and the built environment, and the multiple land sustainability issues that surround agriculture and biofuels.

   There have been recent efforts 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.

   Private actions associated with land use decisions, local and regional land use policies motivated by short-term commercial concerns (especially in coastal regions), water needs for residential and agriculture uses, bio-fuels as responses to shortfalls in conventional energy resources, globalization of the supply chain for increasing numbers of commodities and numerous other examples, illustrate choices made in response to the incentives provided by private markets and current regulations. Too often we learn the environmental consequences of these incentive structures only after problems have emerged. EPA's research in all media needs to better anticipate environmental and ecosystem costs and benefits of the incentives faced by independent individuals and organizations as they make decisions and drive developmental choices.

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.**

   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. 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.

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 next generation of environmental impact assessment tools, to anticipate 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.

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.

The growing globalization of the world's economy also presents challenges. When supply chains stretch to other parts of the world, especially into developing

countries, it becomes difficult to assure that environmental impacts are being adequately addressed. This can be further complicated by World Trade Organization (WTO) free-trade rules. There is a need for work on 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).

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

Expanding populations, depleted reserves of fossil ground water, and the growing impacts of climate change are making water supply an ever more pressing issue in a number of water-short or drought-stricken areas of the U.S. such as, Atlanta, Las Vegas, and Phoenix. This, in turn, is leading local government water management agencies to negotiate agreements for large-scale transfers of water from distant regions. The long-term ecosystem and ecosystem service impacts, and water quality 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. In addition, these impacts must also be understood in the context of climate change.

These first three items reflect problems that arise when many independent decisions are made by individuals and organizations that do not face prices, other incentives, or regulations that capture the externalities, full life cycle and longer term consequences of these decisions. Rather than dealing with the consequences piecemeal and after the fact, it would be wise for the Agency to begin to more systematically think about how it might become more anticipatory in addressing such issues.

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

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. While this has always been a key part of EPT's mission, new advanced experimental methods hold the potential to dramatically strengthen and support this effort.

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 effects on sensitive plant and animal populations, where these may be part of an interdependent ecological web, 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. While valuable, such work often fails to reflect the mixture of exposures that arise in the field.

Mixtures pose an enormous research challenge. Developing general ways to determine what combinations and in what concentrations are of greatest concerns is still largely unresolved problems. While the Agency has made some progress on mixtures of agents whose health or other effects are produced by common mechanisms (organophosphate pesticides, dioxin), these represent only part of the problem. Many mixtures to which people and ecosystems are exposed do not have common causal 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. While some brute force testing of specific mixtures is probably necessary, an expanded focus on developing more fundamental and generalizable strategies for addressing mixtures is clearly warranted.

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. 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.

The SAB has recently sent the Administrator a separate self initiated report, which includes a number of research recommendations that should allow the Agency to become better able to anticipate and respond to environmental

disasters. Rather than repeat those recommendations here readers are referred to the SAB report *An SAB Advisory: Preparing for Environmental Disasters* (EPA SAB, 2008).

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

Most of EPA's programs in environmental regulation and control operate under legislative mandates that stipulate specific strategies (use best available control technology; control to a specific emissions level per unit of activity; adopt a cap and trade regime; report all emissions to TRI; etc.). There is a modest research literature on the relative advantages and disadvantages of such different approaches in different contexts and on the development of new approaches. However, that literature is too small and insufficiently comprehensive given the importance of the issues that are at stake. Since existing programs are subject to review from time to time, and new problems such as control of the emissions of greenhouse gases will likely arise in the future, the Agency would be well advised to build a large and more vigorous research program that is focused on developing, testing and evaluating new alternative strategies that might be able to more effectively and efficiently achieve future environmental goals.

7) **Improve dramatically the integration of economics and the decision and behavioral social sciences into research and policy development across the Agency.**

The new research focus on ecosystem services is designed to provide inputs in a form that can be used in economic analysis and assessment of Agency programs. However, to be successful, evaluations of ecosystem services must build on an underpinning of solid ecological science, an area in which EPA has recently been dramatically reducing its research investments. The Agency will need to reverse this trend if the effort in ecosystem services is to meet its full potential. While the agency has reasonable staff resources in economics, and maintains some research on issues in environmental economics, its capability in the behavioral and decision sciences is so limited that it typically is not even in a position to ask the right questions. These are interdisciplinary fields of empirically based social science that have seen rapid development over the past few decades. They provide both valuable insight into how people think about issues of risk and how they frame and make decisions in the face of uncertainty. At least as important, they offer guidance on how best to design programs and messages to aid citizens and others in decision making. At its core, EPA makes decisions to protect human health and the environment based on knowledge in several technical areas relevant to risk assessment and risk reduction. To be effective, these decisions need to be informed by science that studies various environmental issues (domain knowledge), decision sciences that identify factual information from these domains that are critical to considering what actions should be taken, and knowledge from the behavioral social sciences that helps EPA to understand what

people perceive about this factual basis and how that relates to their goals regarding the problem or issue being addressed by the EPA.

Given that risk perceptions and the behavioral response of members of the public are central to the design of many of the Agency's most important programs, the lack of staff resources and the absence of a coherent research program is a deficiency in urgent need of attention. In the past, ORD teamed with the Decision and Management Science program at the National Science Foundation (NSF) to support some work in this area. In addition to hiring staff with expertise in this area, reestablishing that collaboration might be one strategy by which the Agency could move forward.

8) **Continue to work on improving the effective communication of research results to potential users both inside and outside the Agency.**

The Agency has a variety of formal and informal strategies to move the results of its research into the hands of government and private decision makers, research groups in universities, the private sector, and the general public. Clearly if the results of EPA research are to have maximum value in promoting good environmental understanding and informed decision making, these activities will require continued attention.

Communicating research results to the public, links closely to the issues discussed under 7 above, since the effectiveness of such communication can be considerably enhanced through the application of good modern empirical methods in communication design and evaluation.

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."

3.2 Human Resources for the Conduct of Science at EPA

In addition to asking the SAB for its views on research needs, EPA expressed an interest in the implications of workforce changes on the quality and responsiveness of the Agency's research programs. The question was primarily focused on strategic workforce planning, that is, how the skills available through the workforce might be adjusted to further evolve and improve the research program.

While expanding expertise into new areas is important, it is also important to ensure that many areas of existing expertise do not undergo erosion as staff turnover occurs from retirement and limited EPA investments in science staff, laboratory equipment, supplies,

travel and other things needed for researchers to be able to design and to carry out top flight research.

The SAB has discussed new areas of expertise that will be needed in several of its recent reviews of EPA research budgets. Areas of need range from emerging fields such as nanotechnology to existing fields in which the agency has insufficient expertise such as behavioral and decision sciences. Solving our environmental problems will require resources. However with many senior people in the existing workforce moving into retirement, there may also be opportunities to update the skill base with little increase in cost.

The EPA has long enjoyed a remarkably dedicated and highly 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, the SAB is concerned that too many of the scientists who are participating in these programs are losing interest when real opportunities and permanent, challenging jobs at the Agency do not become available or other more promising opportunities beckon from outside the Agency.

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.

When the SAB has raised such concerns in the past we have been told that all is well, and been given survey results to support this assertion. It is not our place to engage in an extended debate with Agency personnel on this matter. The SAB once again reports the impressions it has developed from its formal and informal interactions with staff at all levels across the EPA and with knowledgeable observers on the outside. 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 whether it sees opportunities for improving the research program's efficiency. Specifically, they asked the SAB to consider there are opportunities for greater coordination and synergy within ORD, across EPA, and across other organizations both inside and outside of government, and whether the SAB sees "themes" that could strengthen EPA's research strategy. The SAB has discussed a number of such themes in the paragraphs above.

The recent National Academy of Sciences' report, *Evaluating Research Efficiency in the US Environmental Protection Agency (NAS, 2008)* offers valuable suggestions on evaluating both investment efficiency and process efficiency for US EPA research programs. The SAB supports the findings of the NRC report and notes that the role of expert review by SAB is most helpful in evaluating investment 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.

EPA should be the leader in 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 into the water and air monitoring and treatment holds potential to 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 six 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 Regional offices, however, there is still an on-going need for the development of new monitoring strategies and tools. This parallels the opportunities in nanotechnology presented above.

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. EPA ORD should continue to 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. 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.

Of course, 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.

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 explore the possibility of developing 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 Environmental 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 Environmental Corps" might participate in EPA websites to give their advice on what EPA should be doing on various issues following a collaborative model of the sort illustrated by Wikipedia; and they might analyze EPA's data bases through competitions that reward the best ideas for new environmental science,

solutions, and technologies[3]. 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) Expansion and greater integration of behavioral and decision science into many ORD research programs

The SAB pointed out in point 7 of this advisory (see pages 9-10) that without a scientific understanding of human behavior and decision processes, the EPA 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

[3] See for example Don Tapscott and Anthony D. Williams, *Wikinomics : how mass collaboration changes everything*, Portfolio, New York, 351pp, 2008.

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 (what people eat, whether they can use protective clothing, etc.). 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 research and analytical results to people who must make decisions informed by 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 urgent need of an ambitious program of scientific research in the behavioral and decision 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. As noted above, it may be wise for EPA to partner with an agency such as NSF that has social science expertise in order to build this 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 has served 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 vulnerable to changes in regulatory priorities. Over the years the SAB has observed 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 consistent attention 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, might 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 annual review of 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 chartered 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 arranged for 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 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.

Specific research programs carried out by or for EPA, typically, do have an actual beginning and end. 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).

APPENDIX A

SAB Comments on EPA's Specific Research Areas

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1. Introduction

This Appendix contains specific comments of members of the EPA Science Advisory Board (SAB) Subgroups that were established by the SAB to evaluate and comment on each of the Office of Research and Development's (ORD) research program areas. General comments are contained in the SAB Advisory to which this Appendix is attached. The comments in this Appendix are the interim responses of the review Teams that evaluated the EPA strategic directions research materials during the meetings from October 2007 through July 2008. Sections 2.1 through 2.5 of this Appendix discuss the research areas within each team's primary purview, the key directions for the research in each of the specific research areas, and provide the SAB's initial comments on each of the specific research areas.

2. Comments on Specific EPA Research Programs

2.1 Technology Research Areas

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

2.1.1 Land Preservation & Restoration research supports the needs of the Office of Solid Waste and Emergency Response (OSWER) as it implements provisions of the Resource Conservation and Recovery Act (RCRA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Superfund Amendments and Reauthorization Act (SARA) in 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 Comments: 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 Life Cycle Analysis (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 Environmental Technology Validation (ETV) and Superfund Innovative Technology Evaluation (SITE) programs are essential to moving technology to commercialization and have involved substantial leveraging of limited EPA funds. The National Advisory Council on Environmental Policy and Technology (NACEPT) and other studies view these evaluation activities as having high value to private environmental technology organizations, and to the accomplishment of EPA's mission.

2.1.2 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 Comments: 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.

2.1.3 Global Earth Observation System of Systems (GEOSS)/Advanced Monitoring Initiative (AMI). 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 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 Multi-Year Plans (MYPs), and has good cross-agency (e.g. National Science Foundation) 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 directive?

2.2 Economics and Sustainability Research Areas

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.

Fundamentally, EPA makes decisions that are intended to protect human health and the environment from a suite of pollutants and behaviors that are addressed by nearly a dozen environmental laws. EPA makes choices about how to address a wide variety of environmentally linked risks based on knowledge and procedures in several areas. Choices inevitably call upon individuals to modify their behavior in regard to the issue. Informing EPA's decision-making requires several types of knowledge, i.e., **factual scientific and technical knowledge** about the risk issue and possible management approaches; **decision sciences knowledge** that identifies the scientific and technical information that is critical in evaluating possible actions to take to address the issue, and **social sciences knowledge** to determine people's perspectives in relation to how they see the key science as well as their desired outcomes associated with actions that might be taken to respond to the issue. Further, it is important that this aspect be started in the beginning of EPA evaluation efforts in support of decision-making and that the capability to do this be available to and used by all EPA Program Offices.

2.2.1 Economics and Decision Sciences. 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 Comments: The research plan for Economics and Decision Sciences follows closely the *Environmental Economics Research Strategy*. It identifies three major research areas (pp. 56-57):

- 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 Regulatory Impact Analyses (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 from its Committee 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 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 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.

2.2.2 **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 this 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 sustainability research program is focused on environmental dimensions of sustainability while recognizing that sustainable environmental outcomes are best achieved in a systems-based context." The resulting EPA research program is broader than the usual stove-piped media-focused program and it adopts 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 Comments: The ORD's research initiative in the 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 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 Attachment 1 to this Appendix).

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.

2.3 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.

2.3.1 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 Comments: 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 ecological conditions to goals 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 depend greatly on adding expertise in economics to the program. Decision support tools are also critical to the aspirations of this program; however, current activity in this area does not seem sufficient. ORD should invest 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. 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.

This new focus will also require support of the STAR grants program to be successful. ORD recognizes the importance of establishing research

partners in the broader research community to accomplish its challenging goals. The SAB believes that the elimination of the ERP-STAR program due to budget cuts 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.

2.3.2 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: 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 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 throughout this research area.

2.3.3 **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.

SAB Comments: 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 strategic direction should focus on the most important risks which could be non-regulatory. A watershed focus may provide the greatest opportunity for public health protection via prevention. More attention is needed for surface source water protection and distribution systems. Research on the protection of surface water sources of drinking water is at the intersection of the SDWA and CWA. Again, the "One

Hydrosphere" approach is suggested for EPA use in integrating its research on a variety of water issues.

2.3.4 **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 chemical, biological, and radiation (CBR) agents in both large outdoor areas and in water infrastructure.
- Improving the communication of risk and risk management options during a crisis.

SAB Comments: The SAB recognizes that the Homeland Security Research program began in a crisis mode and focused on getting as much done 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 as well. 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

that it involves new areas/opportunities with new resources.

2.4 Air and Global Change Research Areas

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

2.4.1 Clean Air Research 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 Comments: 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. Policy relevant research to support developing, testing and evaluating new and innovative 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.

2.4.2 Global Change Research 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 Comments: 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 increased 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. Greenhouse gases will inevitably become regulated. EPA should have a research portfolio now which assesses various policy actions and their cost-effectiveness for reducing greenhouse gas emissions (cap-and-trade, carbon tax, command-and-control, etc.). Various technologies could also be assessed for their cost-effectiveness.

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.

2.5 Human Health Research 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.

SAB General Comments for this Research Area. 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, and epigenetics should be included in assessment of human

health endpoints. This will require adequate numbers of individuals trained in epidemiology and public health.

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.

A critical evaluation of how new toxicological testing paradigm, including the *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.

There are several research areas that the Board believed were in need of greater emphasis. Briefly, they include:

- Long-term research to support the shift toward the new toxicity testing paradigm, such as the development of *in silico* methods to predict metabolism, addressing the issue of exposure duration in designing the high throughput tests, test strategies to ensure that novel agents from poorly studies chemical classes are adequately characterized, and epidemiological surveillance to support data interpretation;
- Research on methodologies for developing IRIS guidance levels (from non-apical endpoints) for chemicals that have sparse data sets.
- Work to evolve the Agency's hazard identification and dose response practices and Guidance guidelines to keep pace with the emergence of data from new types of toxicity tests.
- Epidemiological surveillance, particularly emphasizing the interactions of genes, lifestyle and environmental chemicals to gain a better understanding of "background additivity" and how to interpret results of the emerging high throughput tests.

These are further described in Attachment 1 to this Appendix.

2.5.1 **<u>Human Health</u>** 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 this program 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 focused on 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 Comments: 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 to 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 Attachment 1 to this Appendix. 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, this should be stated explicitly for the sake of transparency and clarity. This should be done both internally for organizing EPA efforts and during external evaluations. It is not clear whether the repackaging of the research portfolio presented by the Agency represents a shift in program focus away from some of the critical nearer term objectives.

2.5.2 **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 Comments: The SAB 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.

2.5.3 **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 Comments: 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.

2.5.4 Human Health Risk Assessment. This research program is at the forefront of applying quantitative methods advances to risk assessments (e.g., use of physiological based pharmacokinetic (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. Human Health Risk Assessment (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 Comments: The SAB recognizes that this as one of EPA's "bread and butter" research programs. The SAB 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 Reference Doses (RfDs) for chemicals with less than optimal data sets.

The SAB 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 reviewing research efficiencies to improve their ability to work with OMB in a more efficient manner. The SAB 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.

2.5.5 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 ecological systems, health protection.

ATTACHMENT 1: ADDITIONAL DISCUSSION

1. Detailed Recommendations Technology for Sustainability Research Program
(See Appendix A, Subsection 2.2.2, Page A-8)

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.

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. <u>Additional Research Topics For the Human Health Area</u>
(See Appendix A, Subsection 2.5, Page A-17 forward)

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) Long-Term 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) Research to Develop 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 SAB 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, 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.

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