



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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THE ADMINISTRATOR

Dr. M. Granger Morgan
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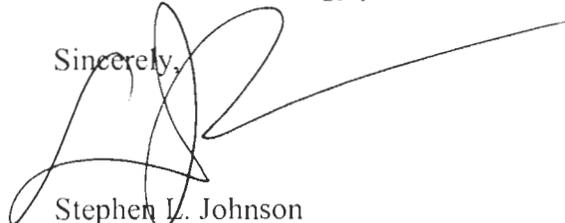
Dear Dr. Morgan:

I would like to thank you and the other members of the Science Advisory Board Executive Committee for your March 13, 2007, advisory report, *Comments on EPA's Strategic Research Directions and Research Budget for FY 2008* (EPA-SAB-07-004). This annual review is an instrumental component of the Agency's annual and multi-year priority setting and provides valuable guidance to the U.S. Environmental Protection Agency's Office of Research and Development as it continues to evolve its research program. I am pleased that the Board recognizes that EPA scientists are committed to sustaining a high-quality program of research.

This year, the SAB's review focused on strategic directions. As part of its review, the SAB identified four environmental challenge areas: climate change, sensitive populations, urban sprawl, and environmental disasters. EPA agrees that these are important issues and is committed to addressing cross-EPA and interagency research planning in these areas. The SAB also expressed concern about the downward trend in funding for several research program areas and the elimination of the economics and decision sciences research program within ORD. As you know, many considerations factor into funding decisions for all Agency programs. Accordingly, we must prioritize numerous Agency needs when developing the annual budget request to Congress. For the Science and Technology budget request, we are guided by the Agency's Strategic Plan and the decision supports needs of our program and regional offices. In this way, we can make the best use of our resources to support EPA's mission of protecting human health and the environment.

Thank you again for the SAB's advice on the strategic research directions and the Science and Technology component of EPA's FY 2008 President's Budget Request to Congress. We highly value your input and expertise. The Agency has prepared more detailed responses to the Boards findings and recommendations, which are enclosed. We look forward to continued discussions with the SAB on EPA's Science and Technology priorities and strategic directions.

Sincerely,


Stephen L. Johnson

Enclosure

**Response to the Science Advisory Board's Advisory on
*The U.S. Environmental Protection Agency's Strategic Research Directions
and Research Budget for Fiscal Year 2008 (EPA-SAB-07-004)***

The advisory report prepared by the Science Advisory Board titled *Comments on EPA's Strategic Research Directions and Research Budget for FY 2008: An Advisory Report of the U.S. Environmental Protection Agency Science Advisory Board* raises important issues concerning the U.S. Environmental Protection Agency's science and research activities. The Agency appreciates the expertise and perspective provided by the Board members. This annual review is an instrumental component of the Agency's annual and multi-year priority setting and provides valuable guidance as EPA's Office of Research and Development continues to evolve its research program. The Agency's interactions with the Board are a crucial element in EPA's ongoing efforts to inform its policies and decisions with the best available scientific information, and we remain committed to continued engagement with the Board on scientific issues and research directions.

This year's review had added value, as the SAB's annual advisory report also focused on the strategic directions of ORD's major research programs. In addition to reviewing ORD's individual research programs, as it has done routinely in the past, the Board also evaluated ORD's current and planned research program in four cross-program environmental challenge areas: climate change, sensitive populations, urban sprawl, and environmental disasters. The SAB expressed concern that cross-program strategic planning is still very limited. The SAB also expressed concern about decreased funding levels for ecosystems research and Science to Achieve Results extramural and fellowship programs, as well as the elimination of the economics and decision sciences research program within ORD. This year's response to the SAB's annual advisory report addresses ORD's strategic outlook, funding decisions, and other key issues raised in the SAB report.

Response to the SAB's Comments

Clean Air Research

EPA is pleased that the SAB expressed approval of the integration of the National Ambient Air Quality Standards and air toxics research programs and the requested budget increase in FY 2008. ORD's goal is to provide NAAQS and air toxics research in the context of an integrated air program. Regarding the SAB's caution that air toxics research should not be reduced in the combined program, given fiscal constraints, EPA hopes an integrated program will enable some research projects to address criteria pollutants and air toxics simultaneously. For example, since near-road activities (mobile sources) involve both NAAQS and air toxics, the goal of this research is to address exposure and related health concerns of both types of pollutants as part of this endeavor.

In its report, the SAB approves of EPA's focus on improved mechanistic understandings of the health effects of particulate matter. EPA is committed to addressing the prime issue of hazardous components and believes it must be done in the context of mechanistic studies if we are to identify the most active components or interactions within the particulate matter mix.

Regarding the SAB's approval of EPA's approach to understanding the relationship between particle composition and toxicity, EPA believes that there are likely substantial mixture effects. The program's FY 2008 integration is an attempt to develop an approach to this issue.

Additionally, regarding the SAB's support for the development of processing tools to understand how future changes in climate will alter air quality, EPA agrees that there is a relationship between climate and air quality. As new regulations (e.g. Clean Air Interstate Rule) begin to demonstrate results, it will be important to understand and better predict such changes and their impacts on human health and the environment.

EPA also agrees with the SAB's recommendation for further development of coupled land-surface, meteorological, and chemistry and transport models, which would allow comprehensive assessment of the consequences of the effect of land use and atmospheric composition changes on air quality. We are working with National Oceanic and Atmospheric Administration and National Aeronautics and Space Administration to make full use of as much data as possible (land use, meteorology, and satellite) to modify or conform air quality models to handle the additional complexity and to produce greater precision and accuracy.

Global Change Research

EPA concurs with the SAB's overall assessment of the Agency's global change research, although two items would benefit from clarification. The SAB is correct in stating that the primary focus of the program is on assessing the potential impacts of global change on air quality and water quality and on evaluating adaptation strategies for responding to global change. However, the SAB suggests that the program is currently unable to address the questions associated with the impacts of climate change on natural ecosystems. In fact, the program's focus on water quality includes studies of the effects of climate change on aquatic ecosystems (e.g. on ecosystem services) and the development of decision support tools for evaluating global change impacts and adaptation options in key watersheds. Studies of the potential impacts of climate change on terrestrial and marine ecosystems are also being carried out in other federal agencies that have mandates to focus on these systems. All of this work is coordinated and integrated through the interagency U.S. Climate Change Science Program, of which EPA is a member.

The SAB also notes the importance of modern methods of carbon capture and deep geological sequestration (Carbon Capture and Storage), since the Agency will likely be responsible for regulating some of the activities associated with these methods. In fact, EPA's Office of Air and Radiation, in partnership with the Office of Water, is beginning to examine these issues. The Agency's goal is to ensure that adequate knowledge is developed to support science-based regulation of CCS should the need arise.

Homeland Security

The SAB commented that there was a "lack of a compelling rationale for the Agency's overall portfolio of homeland security research." EPA's National Homeland Security Research Center developed its research portfolio based on research needs identified from the literature,

from stakeholders and experts, through coordination with federal agencies having homeland security responsibilities, and through requests from the customers of our research. The National Academies reviewed major portions of the program in 2003. NHSRC is currently developing its Strategic Multi-Year Plan, which will describe how the research portfolio is constructed, including the identification of key research questions and the process for prioritizing research needs.

The SAB also commented on what it believes is an ORD-wide lack of social science expertise and funding, including a lack of substantial behavioral science research support within NHSRC. NHSRC is currently developing a position paper that will identify homeland security social science research topics relevant to EPA's mission that fill important knowledge gaps, identify work in other research organizations already tackling these gaps, and describe what remaining research issues are relevant to NHSRC's mission.

Finally, the SAB commented that there is a "critical need for a plan for the disposal of infected animal carcasses, for which EPA has leadership responsibility among federal agencies. . . . EPA has thus far failed to provide scientifically sound guidance" To clarify, the U.S. Department of Agriculture is the lead federal agency for disposal of infected animal carcasses. USDA will coordinate with EPA on issues pertaining to EPA's mission – water, solid waste, the use of sterilants, and others. In addition, USDA may ask for assistance from EPA's on-scene coordinators to help manage an emergency. NHSRC, in support of USDA's lead role, is evaluating carcass management strategies, developing decontamination approaches for avian flu virus on surfaces, and participating with USDA and EPA's Office of Solid Waste in the preparation of a guidance document on safe disposal of contaminated animal carcasses.

Ecological Protection Research

We agree completely with the SAB's findings that high-quality research on ecosystem services requires a strong conceptual foundation implemented through core ecological science that incorporates both empirical observations and robust analytical frameworks. In this regard, it is important to clarify that *our primary research product is fundamentally ecological in nature*; that is, we propose to provide a biophysical description of how the distribution of ecosystem service endpoints change over space and time in response to stressors (e.g. pollution, climate change, demographic change, land cover change) and to decisions made at local, state, regional, and national levels (e.g. through alternative fuels policies, such as biofuels). Therefore, the Ecological Research Program has designed a program that will explicitly link and integrate products of our ecological focus with social and decision science, thereby enabling social preference and valuation. The ERP pioneered much of the early work in "alternative future scenarios," and in our new focus we are extending this concept of scenario building to include research to advance the "art of possible," that is, the kinds of services we could sustain if we took deliberate, proactive steps to enhance ecological structures, functions, and services, even within highly modified environments. We believe this approach is entirely in keeping with the SAB's recommendations for research that is systems-oriented and unconstrained by conventional "stove-pipes."

We have carefully designed a suite of products to keep our focus on the core ecological science while anticipating the needs of the Agency. These research outputs are metrics and dynamic maps, predictive models, management options, and decision support platforms.

With respect to the SAB findings regarding steep declines since 2003 in the Ecological Research Program budget, we agree that reductions, specifically to the Environmental Monitoring and Assessment Program, will reduce EPA's ability to contribute to long-term monitoring of the condition of critical ecosystems in the United States. We are pleased, however, that the program has had a substantial impact on the way managers inside and outside of the Agency think about environmental monitoring. As the Office of Water has adopted the EMAP principles, probability monitoring will hopefully be a longstanding tradition now in EPA and the states. We are continuing in-house research to further analyze existing EMAP data for the purpose of developing new stressor-response hypotheses and models. Further, EMAP scientists will be continuing their work with the Office of Water and will receive additional national scale data on a periodic basis to further their analyses.

Finally, with respect to the SAB's recommendation to reinstate Science to Achieve Results funding, the ERP has worked to leverage existing STAR research funds to the maximum extent possible and, in fact, is recognized for laying the foundation for much of the work in ecosystem services from which our in-house program will grow. STAR funding for extramural ecological research has exerted a powerful influence and capacity for training the next generation of environmental scientists.

Water Quality

The SAB supports the long-term goals of the Water Quality Research Program but expressed concern that "the technical skills, time, and money available to develop and implement total maximum daily loads appear to be a small fraction of what is required to achieve the goals of the program, and progress has seemed glacially slow to date." A very large part of reaching EPA's strategic goals depends on the ability to establish good TMDLs at the watershed level. Planned research will address various tools that can be used in decision making, relative to the types of management practices employed to control the contaminant of interest. We recognize the magnitude of the problem and plan to discuss committing more water quality resources to address this issue.

Drinking Water Research

We appreciate the SAB's suggestions on the strategic directions of the Drinking Water Research Program, and we recognize the need to sustain a core research program that addresses disinfection byproducts, arsenic, and other regulated contaminants in support of the periodic re-evaluation of the public health benefits of the standards. As part of the revision of the Multi-Year Plan, we are identifying interrelationships with other programs including homeland security (real-time detection of contaminants), water quality (source water protection, water reuse), human health (mode-of-action studies), endocrine disruptors (occurrence and treatment), global change (water quantity and quality implications), ecosystem services (source water protection, pathogen distribution), nanotechnology (fate and transport of nanoparticles), sustainability (water

use efficiency), computational toxicology (screening of chemical contaminants), resource conservation (disposal of residuals), air (source water quality, carbon sequestration), and so on, with the goal of promoting collaborative research and leveraging resources.

Research themes common to multiple programs include detection and control of pathogens and chemical contaminants. We are also aligning the program along five theme areas: Assessment Tools, Source Water (Water Resources), Treatment and Residuals Management, Distribution Systems and Storage, and Water Use/Health Outcomes. This reorganization will help to focus the research and allow for integration of topics such as infrastructure research, water reuse, global change, desalination, etc. Allocation of resources to meet all of the research needs is an ongoing challenge, and the Drinking Water Research Program is continuing to seek extramural research partners and collaborative opportunities.

Human Health Risk Assessment

The SAB provided constructive feedback on the Human Health Risk Assessment program. We appreciate that the SAB was very supportive of the direction for HHRA. The SAB supported the development of integrated science assessment documents as a major step forward in improving the process to provide the scientific underpinning for development of NAAQS. The SAB was strongly supportive of EPA's increasing efforts to develop Integrated Risk Information System and provisional peer-reviewed toxicity values. The SAB also was supportive of efforts to improve approaches for assessment of variability and uncertainty.

In addition, the SAB was not clear to what degree a few other topics were being addressed in EPA's HHRA program. These topics are as follows:

- Development of approaches to mine data and construct distributions to support the incorporation of variability into assessments;
- Development and use of probabilistic approaches in non-cancer assessments; and
- Development and application of methodologies for understanding human variability due to cumulative impact on endogenous biological processes and environmental exposures processes.

Each of these efforts is the topic of ongoing research and assessments and, in some cases, future research program planning. A few examples of ongoing efforts and plans are provided below to substantiate efforts on the contemporary risk assessment science topics raised by the SAB.

The National Center for Environmental Assessment, in collaboration with the National Center for Computational Toxicology, has efforts underway to develop and add to existing databases. These databases are to be used for Physiologically Based Pharmacokinetic modeling; they incorporate information about life stage and the impact of genetic polymorphism in activity and phenotype for phase 1 and phase 2 enzymatic metabolism. These efforts are included in the future performance commitments of the HHRA program.

In the case of probabilistic approaches, these efforts are included in a larger Agency effort under the aegis of the Risk Assessment Forum technical panel on probabilistic approaches for risk assessment. These probabilistic approaches have been applied in specific non-cancer assessments, such as for particulate matter. In addition, in the context of cross-ORD research planning, efforts include discussions of the use of the national probability sample obtained from the National Children's Study as a means to investigate uncertainty and variability in human environmental exposures and outcomes, using probabilistic and empirical approaches. This effort is being coordinated through the interagency steering committee for the NCS and is not a specific focus area of the HHRA but rather part of Human Health Research Program.

Regarding human variability and susceptibility and cumulative risk, the HHRA program has made significant contributions to both dose additive and effect additive modeling. These efforts include development of cumulative risk assessment guidance for assessing effects of exposures to mixtures and the applications of these approaches to assessments to classes of specific chemicals (e.g. polycyclic aromatic hydrocarbons, disinfection byproducts, and currently organotins).

Human Health Research

The main objective of EPA's HHRP is to reduce uncertainties in the extrapolations necessary for the risk assessment process by providing a greater understanding of the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to environmental toxicants. We concur with the SAB that decreases in budget may affect the capacity of the HHRP to address this objective, especially in certain key areas such as sensitive subpopulation research and the NCS. However, reductions in these areas generally reflect changes in EPA's capability to conduct exposure and longitudinal research involving children. EPA is committed to a viable program of fundamental research on the biological and exposure-related differences associated with age-related vulnerabilities to environmental stressors. A component of this research will involve the contribution that genetic polymorphisms play in the expression of toxicity by chemicals such as arsenic and in the genetic basis for asthma. EPA also has a grants program supporting human health research, including work on human variability.

A major component of the HHRP research program is cumulative risk, which includes research on chemical mixtures. While research on pesticide mixtures may decline in future years as these models mature into applicable tools, work on other chemical mixtures such as air and water pollutants will remain the same or increase. In addition, EPA will begin new efforts to understand potential interactions of several types of environmental stressors at the community level.

EPA remains committed to research on mode-of-action for use in regulatory decision making. This research is intended to provide methods, models, and data for direct use in risk assessments conducted by risk assessors in the Agency's program and regional offices. As indicated in the materials provided to the SAB, the need to develop new or emerging methods (e.g. genomics, proteomics), as compared to the application of those methods for risk assessment purposes, will tend to decrease over the next few years. MOA research will also focus on

identifying models and data that can be used by computational modelers to develop approaches for the prioritization of chemicals for screening and testing, as well as by risk assessors to support the application of default assumptions in the risk assessment process.

The SAB expressed support for the evolution of a program on indicators that would strengthen the linkages between source-exposure-dose-effect as articulated in EPA's Report on the Environment. A framework document identifying the research gaps in this area is being developed by EPA. Once the strategic direction for this program has been established, EPA intends to develop an implementation plan that will describe the types of exposures and endpoints that will be studied.

Contaminated Sites/Resource Conservation (Land Preservation and Restoration)

We appreciate the SAB's thoughtful comments on the future directions of the Land Research Program. The support for the shift into nanomaterial fate and transport issues and suggestions on urban sprawl as an emerging topic are appreciated. The program is moving from waste treatment to waste minimization/reuse research, and we will continue to shift in that direction in response to the SAB recommendations. Energy recovery is also an important issue that ORD is evaluating to determine its appropriate role. The Land Research Program is a problem-driven research program supporting the Office of Solid Waste and Emergency Response and the EPA regions' research needs. As such, it is also important that efforts are focused on the types of sites and problems that have higher risks, higher uncertainty, and/or higher impact in terms of the number of sites, proximity to people, or value/size of ecological resources. The research program focuses on the important issues of contaminated sediments, ground water contaminant transport and remediation, and site characterization. We will evaluate the issues of intensive agriculture and increases in coastal population, including whether it is appropriate to address them under the Land Research Program.

Nanotechnology

The Agency appreciates the SAB's feedback concerning its recent nanotechnology efforts. As a point of clarification, initially the Agency focused its nanotechnology grants (see the first paragraph of the Board's nanotechnology section) on the applications of nanotechnology for enhancing environmental and human health protection (e.g. more accurate, multi-analyte, rapid sensors; improved treatment and remediation technologies; reduction of pollution at the source from chemical and manufacturing processes; and improved environmentally benign techniques). Two years of effort were dedicated in these areas toward both increasing scientific understanding and spurring development in this field. After this period, EPA transitioned the emphasis of its program to the potential environmental and health implications of manufactured nanomaterials.

Regarding the SAB's discussion of particulate matter and engineered nanomaterials, the Agency is aware of the rich literature and research in this area and believes this information will prove useful to some extent. However, atmospheric particulate matter (primary and secondary particles) is composed of a heterogeneous mixture of compounds ranging in size and morphology. Engineered nanomaterials that may be emitted into ambient air from a facility will be much more homogeneous in size and morphology. In addition, tailoring these particles (by

functionalization, coating, surface chemistry, etc.) to achieve desired properties will result in novel compounds that are likely to be different from what we have experienced through ambient particulate matter. For these reasons, it is critical not to rely too heavily upon data and information gleaned from particulate matter studies; they should be used to provide clues about potential adverse health effect mechanisms, modes of deposition, and particle mobility, with the understanding that engineered nanoparticles may behave quite differently.

In FY 2007, EPA is beginning an in-house nanotechnology research effort to complement its extramural grants program on this topic. A focus of the program will be assessing the health, ecological, and environmental implications from exposure to engineered nanomaterials and their applications to manage their potentially adverse impacts. These data will inform EPA's regional and program offices' regulatory and other policy decisions. The program will also focus on developing and implementing a framework on how EPA should approach nanomaterials, including methods and tools that will allow the Agency to stay abreast of new and emerging nanomaterials and their applications with potential environmental implications.

Safe Pesticides/Safe Products Research

EPA appreciates the recommendations made by the SAB and concurs with its advice – not to shift resources supporting the development of data and models for the assessment of effects of pesticides and related chemicals on non-target species until the program's goals have been met.

Endocrine Disruptors

EPA appreciates the SAB's commendation of the research on Concentrated Animal Feeding Operations as being a best practice approach. The SAB discussed this effort as being conducted through the extramural STAR grants program. While EPA indeed used resources from increased Congressional appropriations in FY 2005 and FY 2006 for the STAR program, endocrine disruptors research (including CAFOs) is conducted through an integrated intramural program in ORD's Effects, Exposure, and Risk Management Laboratories. Furthermore, EPA anticipates that its intramural laboratories will be able to work cooperatively with some of the awardees from the STAR program.

The SAB acknowledged ORD's research that supports the Agency's Endocrine Disruptors Screening Program. It encouraged EPA to develop a strategy to "move away from apical multigenerational testing to newer and more-rapid approaches." EPA is conducting research to develop prioritization and screening approaches through the Endocrine Disruptors, Safe Pesticides/Safe Products, and Computational Toxicology Research Programs. The Computational Toxicology Program coordinates and collaborates some of its efforts through interagency agreements with the National Institute of Environmental Health Sciences and the National Genomics Research Center. Furthermore, through the U.S.-European Commission Biotechnology Task Force and other mechanisms, EPA is organizing and sponsoring joint workshops with the European Commission in these areas that are of mutual interest.

EPA agrees with the SAB that research in the area of cumulative and aggregate risk assessment is somewhat limited. However, several projects are ongoing in our laboratories that use rodent models to study the impacts of combinations of chemicals that interfere with either the thyroid or androgen systems, and the best approaches to predict these impacts are being determined. There are also a number of efforts in the field to study the impact of exposures to endocrine-active environmental mixtures. In addition to the research on CAFOs noted previously, multiple projects are looking at the impacts of endocrine activity in effluents from wastewater treatment plants and drinking water plants, and emissions from sources of combustion.

Science and Technology for Sustainability Research

We are pleased by the SAB endorsement of ORD's effort to establish a sustainability research program. This program aims to improve understanding of the earth's natural and man-made systems, assess threats to those systems, design and apply innovative and cost-effective industrial practices, and develop and apply new technologies and decision support tools. ORD's research strategy has been reviewed by the SAB, and we expect to finalize this strategy in the summer of 2007. Reflecting recommendations from the SAB, the strategy defines four implementing steps, one of which is to develop a Science and Technology for Sustainability research program. The STS Multi-Year Plan has been drafted and was reviewed by a Board of Scientific Counselors committee (spring 2007) as part of their evaluation of the precursor Pollution Prevention Program. These internal ORD planning activities, along with extensive outreach to EPA program offices and other federal agencies, will allow us to define an effective sustainability research program and allocate resources to implement it.

Conclusion

ORD continues to find the SAB's annual consultation on the President's budget request to be highly valuable. We appreciate the SAB's acknowledgement that EPA scientists are doing an outstanding job of sustaining a high-quality research program despite severe budget constraints. This year, the SAB also provided advice on the strategic directions of our major research programs. By examining EPA's efforts in four key cross-program environmental challenge areas, the Board noted that EPA needs to develop its research planning efforts in a way that increases coordination and collaboration across programs. EPA plans to take steps in this direction, and we look forward to continuing our collaboration. To further this collaboration, we look forward to meeting with the SAB in the coming months to continue our discussions of EPA's strategic directions for environmental research.