

**Summary Minutes of the US Environmental Protection Agency
Science Advisory Board Meeting
October 3 to 5, 2007**

Meeting Location:

Marriott Hotel at Research Triangle Park, NC
4700 Guardian Drive
Durham, NC 27703

1. Purpose of the Meeting: The Meeting was held to discuss EPA's strategic research directions with representatives of the EPA Office of Research and Development (ORD), to conduct quality reviews of three draft SAB reports, and to discuss potential plans for upcoming SAB meetings in December 2007 and February 2008. The meeting agenda is in Attachment A. The Board Roster is in Attachment B. The *Federal Register* announcement for the meeting is in Attachment C. Attachment D is the sign-in log for the meeting (physical file only).

2. Members Participating in the Meeting:

Dr. M. Granger Morgan, Chair	Dr. James Bus
Dr. Gregory Biddinger	Dr. Maureen Cropper
Dr. Virginia Dale	Dr. Rogene Henderson
Dr. James Johnson	Dr. Agnes Kane
Dr. Cathy Kling	Dr. George Lambert
Dr. Michael McFarland	Dr. Judy Meyer
Dr. Jana Milford	Dr. Steve Roberts
Dr. Kathleen Segerson	Dr. Phil Singer
Dr. Kristin Shrader-Frechette	Dr. Deborah Swackhamer
Dr. Thomas Theis	Dr. Lauren Zeise
Dr. Steve Heeringa (FIFRA SAP Liaison)	

3. MEETING SUMMARY – Day 1 -Wednesday, October 3, 2007

a) Convene the Meeting

Mr. Thomas Miller, SAB Designated Federal Officer, convened the meeting at 11:00 a.m. noting that the SAB is a federal advisory committee chartered under the Federal Advisory Committee Act and is empowered by law to provide advice to the USEPA Administrator. The SAB follows procedures as require by FACA (including the requirements for open meetings, for maintaining records of deliberations, and for making available to the public, summaries of the meetings. Persons from the public have the right to provide information for the Board's consideration through written comments and by being allowed to make brief oral statements at meetings if appropriate. Mr. Miller reminded all that SAB Members are required to comply with Federal ethics and conflict-of-interest laws. SAB staff review relevant information provide by Members and others to ensure that SAB panels reflect appropriate balance and to guard against Member COI and bias. Two Appearance issues were reported by Members and those Members asked

to be recused during the portion of the meeting that gave rise to the appearance of impartiality issues (see more at the discussion on Ethylene Oxide).

Mr. Miller then turned then asked SAB Office Director, Dr. Vanessa Vu, to make her opening remarks for the meeting. Dr. Vu. welcomed Members and others to the meeting, noted items on the agenda, and then asked Dr. M. Granger Morgan, Chair, US EPA Science Advisory Board, to carry out the agenda.

Dr. Morgan welcomed members, agency representatives and the public to the meeting and provided an overview of the agenda for the meeting.

b) Updates on Members' Activities on Environmental Disasters

Dr. Morgan stated that the SAB's advice to the Administrator was beginning to take final form and noted his desire to ensure that the advice would have an appropriate tone and that he also wants to be sure that the Agency's current day-to-day activity and experience are with environmental response and disasters is acknowledged.

Members commented that, for the report, an explanatory text box should mention: i) EPA's historical experience with oil and hazardous materials releases under the National Contingency Plan, ii) that the day to day procedures for oil and hazardous materials response approaches are integrated into responses to the larger, highly visible, Incidents of National Significance; iii) that the current research focus in support of Homeland Security (e.g., building decontamination and water system surveillance systems) is only part of the overall science needs which include things such as, social science research, monitoring protocol development, data management techniques, rapid risk assessment approaches, and risk communications research.

Action: Dr. Dale agreed to provide some wording on broader issues to put into the "Box." Dr. Bus will provide some language to help ensure that the advice conveys the idea that learning from other organizations' experience will be important for EPA. It would be inappropriate to give an idea that only things developed by EPA would satisfy the need the SAB sees.

Members believe that the "influence diagram" to be included as Figure 1 could have additional items added, e.g., Human Health, and it could also be helped with some additional broader needs **which Dr. Dale will provide.**

Members considered stating what some of the best practices might be based on the presentations the SAB received in December 2006. However, because SAB discussions focused on a small group of organizations who told of their experiences, and because many others have their own experiences that were not part of our discussions members decided to only discuss those that were raised at the December 2006 meeting as examples, and not "best practices."

Shelter in Place is a better example of a "rapid communication response to an approaching toxic cloud" than the current example of seeking higher ground.

The current draft language suggests establishing a small interdisciplinary advisory group (possibly 5) to identify and assess potential environmental disasters. Additional expertise is likely needed, thus the number of advisers might need to be greater. For example, it might be necessary to have additional social scientists beyond those in the risk communications area.

Dr. Morgan reemphasized his desire to be fair to EPA and to recognize its expertise and experience in the release area over a multi-decadal time frame. It will be important to make sure the advice is quite clear about contextual issues associated with any deficiency that the SAB might want to point out (i.e., stating that the need might differ depending on the scale of the event – the need might be less pressing for day-to-day releases that are usually responded to by local authorities -with EPA’s knowledge and assistance as needed – and more pressing for those responses that require more resources because of their size, scale, and characteristics of the threat itself that overwhelm the local, single agency response that is most prevalent).

The SAB EEC has looked at some aspects of EPA emergency response in the past. In those interactions with EPA, and in the Board’s own interactions with those from outside groups, the issue of trust in first responders is a major issue. Trust building prior to a response is critical.

Members also noted the importance of rapid assessment of what has been released, its quantity, and the risk associated with the released agent. They also reemphasized the idea that the type of monitoring and assessment, and reporting on the results, could be permitted to vary as an event goes forward in time. For example, earlier monitoring may not need to be of as high a quality as later monitoring and it certainly needs to be available more quickly and in clear terms that those at risk can understand.

Members were asked to provide additional thoughts to Dr. Morgan so that he can develop a draft for further Board consideration.

c) Quality Review of the SAB Draft Report on Hypoxia in the Northern Gulf of Mexico

Members conducted a quality review of the draft report *Hypoxia in the Northern Gulf of Mexico: An Update by the EPA Science Advisory Board* (see on the SAB Website at http://www.epa.gov/sab/pdf/8-30-07_hap_draft.pdf and in Attachment E of the physical file for these minutes). The EPA charge to the Hypoxia Advisory Panel is in Attachment F and the charge for an SAB quality review is in Attachment G.

Dr. Virginia Dale, Chair of the Hypoxia Advisory Panel (HAP) briefed the Board on the review and its key findings as an introduction to the topic. The HAP was made up of a diverse group of experts. In association with the Board’s quality review of the draft report it was reviewed by four outside experts and the results of their review was given to Board members for their information while they conducted that quality review of the draft. There was extensive comment from the public through out the period during which

the HAP did its work. Dr. Dale noted that the report provides advice that goes beyond science and provides advice that is at the interface of science assessment and policy-making. The advice represents the best professional judgment of the HAP after considering the available background information, including that provided in public comments.

Written comments that were provided by Board members prior to the meeting are in Attachment H1. Comments from outside external experts are in Attachment H2. No person or organization from the public asked for time to make oral comments to the SAB on this topic.

Dr. Morgan thanked Dr. Dale and noted that the report represents an enormous effort. Dr. Morgan asked Board Members if they wanted to emphasize or discuss any of their written comments on the draft report. Members commented on a number of issues as noted below:

- i) The need for a report like this derives from EPA's historical pollutant-specific approach to such problems. The panel did well in dealing with the issue in an integrated fashion. Even so, there is still more than can be done to treat the topic in a holistic manner (e.g., the short-term remedy proposed for agricultural nitrogen runoff needs to recognize that there is an impact to the "calories" supplied to the world from a change and to the costs of food). Also, because the nitrogen cycle is already perturbed, additional remedies for the hypoxia problem could cause problems elsewhere, e.g., in terms of nitrogenous greenhouse gas generation. The full nitrogen cycle needs consideration. There are benefits to discussing a wider set of problems.
- ii) The report produced valuable insights. It is important to recognize that there is a trade-off between point source controls and non-point source control (i.e., removing nutrients from water means more may be placed on the land in the form of biosolids).
- iii) There was little empirical work available on things like subsidies versus command and control, though a report is about to come from USDA Economic Research Service on some parts of this issue.
- iv) The relationship between phosphorous levels and the size of the hypoxic zone is uncertain. The promise of cellulosic bio-fuels is at least ten years off and may be beyond the tipping point noted in the report.
- v) The SAB's advice needs to be clear so that we do not advise in a way that merely transfers the problem from the water medium to air.
- vi) There has been only a brief time for the public to respond to the draft report reviewed by EPA.
- vii) The adaptive management approach that recognizes that we do not yet fully understand the system is good. However, for such an approach we need measures for pollutant flux in streams and the effects to the Gulf. Some information needs are more important to adaptive management than others. We may want the report to say more about the relationship

- between adequate monitoring and the ability to use adaptive management approaches.
- viii) Many recommendations sound like policy prescriptions. This is especially so in the Executive Summary where the vagueness contributes to this tone. It is possible to rephrase some policy prescriptions to make them less policy directive. For example, statements could be made in terms of how existing policy targets are influenced by changes suggested in the report. This could decrease the impression that the report is too policy oriented.
 - ix) Some of the recommendations are responsibilities of states or even USDA even though they might not help EPA deal with hypoxia itself.

Dr. Dale responded to some questions directly and stated that other comments could be accommodated with edits to the draft report. She emphasized that the report did take a systems view; however, the system focused on was hypoxia in the northern Gulf of Mexico, a system which itself is embedded within larger systems. Language could be added to the report recognizing this link to a bigger view. As to EPA's ability to implement the recommendations alone, the report was requested by a multi-agency task force, so the recommendations are applicable beyond EPA.

Dr. Morgan noted that there have been many public comments on the draft report and while some have clearly been dealt with by the Panel, it is not clear whether all have been. In addition, the Board has asked for several important clarifications which need to be considered by the Board after being accomplished by the HAP. Therefore he asked members if the report should be granted conditional approval now with final judgment to be granted by several Vectors or whether approval should be deferred until after the Board reviewed changes to the draft report by the HAP. Members agreed that it would be best for the SAB to take a look at the revised document before granting approval.

The following action was directed by the Board:

- i) The Hypoxia Advisory Panel will convene by telephone conference meeting in November to discuss public and SAB comments on the report.
- ii) The public comment period will remain open during October 2007 as this meeting is arranged.
- iii) At the HAP meeting, public and SAB comments will be discussed and the Panel will decide on whether and how the comments are to be addressed.
- iv) The document will undergo final clarifying edits.
- v) The revised document will be sent to the SAB and made available for public inspection at the same time.
- vi) It would be valuable for comments received to be categorized into meaningful groups and an indication made to the SAB on the disposition of these categories of questions.
- vii) The following Vectors were identified to help the Board determine how its comments on the draft have been handled: Dr. James Galloway, Dr. Mike McFarland, and Dr. Thomas Theis. Dr. Granger Morgan will also look at the next draft prior to its coming to the next SAB meeting.

- viii) The objective will be for the SAB to conduct a final, and reasonably brief, final review of the edited report at its November or December 2007 meeting.

d) Visit to the EPA Laboratory at Research Triangle Park, NC

Members then visited the EPA Office of Research and Development laboratories at Research Triangle Park, NC for an informal poster session and individual discussions with ORD researchers on recent research projects conducted by EPA. This visit ended at approximately 5:30 p.m. and the first day's activities were then adjourned.

4. MEETING SUMMARY – Day 2 –Thursday, October 4, 2007

a) Strategic Research Directions for the US Environmental Protection Agency

Dr. Morgan introduced the topic noting that the purpose of the day's interactions with ORD on EPA's research directions was to allow for free discussions of the range of research and development needed to put the U.S. in a good position to face the environmental challenges over the next five to ten years. In general, we are thinking about the kind of scientific understanding that will be needed to accomplish EPA's mission during that time. Dr. Morgan stated that it was not our intention during this meeting to conduct a review of budgeted resources that are applied to specific projects within each of the research programs that EPA will discuss with the Board. That time will come during the usual February budget review meeting.

i) Dr. George Gray, Assistant Administrator for Research and Development

Dr. Morgan introduced Dr. George Gray, Assistant Administrator for Research and Development at the US EPA, who participated by telephone. Dr. Gray noted that he was optimistic that the dialogue among Board Members and ORD Program Directors would be an effective way to improve the understanding of the major research needs at the EPA. The near-term pressures to develop a February report on each year's budget for specific research programs has not provided ample opportunity to provide the SAB with a full picture of how these frequently changing short term needs relate to the overall strategy for research in each program. This meeting's interaction should help ORD in providing that view. Dr. Gray stated that he would appreciate the SAB's thoughts on:

- areas that might need increased or decreased emphasis for the next 5 years;
- ways in which the workforce, and the skills available through the workforce, might be adjusted to further evolve and improve the research program;
- areas where there is opportunity for greater coordination and synergy within ORD, across EPA and across others inside and outside government to obtain science to support agency goals;
- whether there are other themes that could strengthen EPA's research strategy (e.g., cross-cutting advice on sprawl, environmental disasters, climate change, etc. would be helpful); and
- how we might improve our dialogue on strategic planning for the future.

Dr. Morgan thanked Dr. Gray for his comments which will help to frame the Board's discussions. Dr. Morgan noted that the previous day's visit to the laboratory had given Members an important opportunity to meet with specific researchers and to discuss their science projects. The gains from such informal discussions and touring the laboratory provided useful insights from those conducting the research and the interactions were very useful. He recommended such informal visits for ORD senior management as a way to gain such insights and to help build morale. Dr. Gray noted that he does this from time to time and he too recognizes the value of connecting with those doing the research in that way.

ii) **Dr. Kevin Teichman, Strategic Research Directions**

Dr. Teichman gave an overview of the strategic directions of EPA's research programs (see Attachment I). ORD began a new strategic planning effort in 2006 which will now make it easier to discuss the direction of EPA research with the Board in a non-budget environment. In getting to this point, the ORD Executive Council (OEC) was briefed by the ORD National Program Directors (NPD) on their proposed strategic directions for research in December 2006. In January, 2007 the OEC met to discuss the research directions proposed by the NPDs and to synthesize the directions. NPDs then worked with the ORD Science Council (SC) to discuss the synthesis and in February 2007 ORD interacted with the SAB during its review of the 2008 research budget and for the first time began to discuss the budget within the context of these larger strategic directions. In June, 2007, SAB and ORD agreed to an approach that would allow for the Board to consider the strategic research directions outside the budget review process. This new approach should move the SAB closer to achieving the goals it had in mind (i.e., providing strategic advice on the EPA research program) when it moved the "research budget review" from a standing committee to the Board itself.

Dr. Teichman stated that the ORD Mission is to provide the scientific foundation to support EPA's mission by:

- Conducting research and development to identify, understand, and solve current and future environmental problems.
- Providing responsive technical support to EPA's Programs and Regions
- Collaborating with our scientific partners in academia, other agencies, state and tribal governments, private sector organizations, and nations.
- Exercising leadership in addressing emerging environmental issues and advancing the science and technology of risk assessment and risk management.

Last year, the SAB challenged ORD to discuss examples of cross-cutting research during the research budget review by asking for information on several broad themes that it thought were important (sprawl, climate change, sensitive populations, etc.). Though time pressures then made the ORD response less complete than it wished, we did get a start on such a view. Now, ORD has provided strategic information on 16 research programs prior to support the strategic discussions that both the Board and EPA wish to hold on the EPA research programs. Though a cross-cutting view of these themes is not directly addressed in the descriptions, ORD has itself begun to think of the individual

programs, and to plan these programs in a way that does recognize and build on the types of linkages that the SAB had in mind when it challenged EPA to think of cross-cutting themes during that earlier review of the budget. In ORD's current strategic thinking, we consider that of the 16 strategic research areas, eight are predominantly targeted to specific operating programs and eight have broader cross-cutting applicability. The 16 research areas are categorized in the following manner:

Cross-Program Research

Human Health
 Computational Toxicology
 Human Health Risk Assessment
 Endocrine Disrupting Chemicals
 Ecosystems
 Economics and Decision Sciences
 Science and Technology for Sustainability
 Nanotechnology

Program-Targeted Research

Air
 Drinking Water
 Water Quality
 Land Preservation and Restoration
 Safe Pesticides and Products
 Homeland Security
 Global Change
 GEOSS/AMI

Dr. Teichman then highlighted the Key Directions for each of these Research Areas. Details for each of the Research Areas are included in the background information provided by ORD prior to the meeting (see [Attachment J – Compilation of EPA ORD Research Program Descriptions](#) and on the SAB Website at http://www.epa.gov/sab/pdf/compilation_of_epa_ord_res_prog_descrip.pdf). For the areas identified as Cross-Program Research, Key Directions included:

Human Health Research

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

Computational Toxicology

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

Human Health Risk Assessment

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

Endocrine Disruptors

- Complete development of protocols for EDC screening and testing assays.
- Improve understanding of EDCs' mechanisms of action, dose response, and cumulative risk issues.

- Develop exposure assessment and risk management tools to characterize and reduce exposure to EDCs.

Ecosystems Protection Research

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

Economics and Decision Sciences (OPEI)

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

Sustainability

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

Nanotechnology

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

For the areas identified as Program-Targeted Research, Key Directions included:

Clean Air Research

- 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.

Drinking Water

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

Water Quality

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

Land Preservation & Restoration

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

Safe Pesticides and Safe Products

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

Homeland Security

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

Global Change

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

GEOSS/AMI

- 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.

Dr. Teichman restated the needs of ORD from this review that were identified earlier by Dr. Gray in his introductory remarks. The ORD Charge asks:

- **Where ORD research should be in 2012 and beyond?**
 - Areas for continued emphasis
 - Areas for increased emphasis
 - Areas for decreased emphasis

- **What scientific factors should ORD consider to get there?**
 - Evolving science
 - Strategic workforce planning
 - Efficiency opportunities

Comments and questions from SAB Members included:

- It is difficult to discuss the future of research without talking of budgets. For example, NRC’s recent toxicity testing vision recommends setting up an institute to pursue the research. That will take money. However, for today, we are going to focus on the overall research needs. Later we will think about how the needs might be achieved.
- Some areas appear to overlap – how is that communicated in the strategic planning? Dr. Teichman stated that the NPDs deal with that issue not as overlap, but as points where programs meet. NPDs think about and plan these linkage points as opportunities to gain synergy between two or more research areas.
- In our specific breakout groups, members should discuss the research needs and not worry so much about where they fit. It should be left to ORD to fit the needs into their programs and to link the needs as appropriate.
- EPA’s move forward in the sustainability area is laudable. It would seem to be important when thinking about sustainability to have an objective in sight. What is a “sustainable world?” With a vision of what that “sustainable world” might be, you can better plan specific research areas, as well as the points where one area links to another. Dr. Teichman noted that though it is not yet clear, we are thinking about this question.
- Because the labs control how the dollars actually get expended, what mechanism is used by the NPDs to influence those spending decisions to ensure that the overall goals of each research area are met? Dr. Teichman noted that NPD roles and responsibilities are new and developing. The research program that is implemented is decided through discussions among a number of ORD groups. The Executive Council, which is made up of ORD Senior Management, sets the overall strategic goals and provides some broad allocation of resources. The NPDs consider these broad goals and work with others to identify the strategic research needs and how to get the most from the targeted resource. The National Lab and Center Directors then decide how they can attain the goals and who does the various pieces. So it is somewhat a cooperative approach to applying the resource even though actual spending decisions occur at the Lab and Center level.
- The Air program has recently gone to a “one air” approach. It is probably time to take a “one hydrosphere” approach in the water area (drinking water plus water quality).
- There is a perception that EPA’s activities impede, or at least make it more difficult for business to be profitable. The agency thus has an image problem.

Communicating ORD's strategic vision will be important to helping people understand EPA's role and to demonstrating the value that achieving EPA's mission of protecting human health and the environment brings.

iii) **Morning Break-out Sessions**

Dr. Morgan pointed out that many of the EPA Regional Scientists/Regional Science Liaisons, as well as researchers from the local ORD Lab's were observing the day's proceedings. He invited all present to select a break-out session to attend and he encouraged them to actively participate in the discussions and not to be content with just observing. He then asked the persons in attendance to identify themselves so that the richness of the group could be appreciated. Those present did so (See Attachment D for a list of persons responding).

Dr. Morgan led a discussion of the break-out assignments for the members and Leaders were designated to capture the major points for each session and to lead the writing efforts for each group. Those appointed were:

Human Health	Drs. Bus and Zeise
Ecosystems, Water and Security	Drs. Dale and Singer
Economics and Sustainability	Drs. Biddinger and Segerson
Air and Global Climate Change	Drs. Milford and Morgan
Technology	Drs. McFarland and Theis

The intention for the break-out sessions is to think broadly about the next decade or so of science needs. It would be useful to:

- take the key issues (and the individual write-ups as background information) and consider whether these are the most pressing environmental needs in each research area, and to
- think about influences of cross-cutting issues on these needs and the reverse

Members, agency representatives and those observing then went to their specific break-out locations and discussed the research areas. The morning sessions focused on the following Research Areas:

- 1) **Human Health Research**: SAB Break-Out Group: Drs. James Bus and Lauren Zeise (Group Leaders); Dr. Steve Heeringa, Dr. Rogene Henderson, Dr. Agnes Kane, Dr. Kristin Shrader-Frechette, Dr. George Lambert. DFO: Dr. Sue Shallal and Dr. Vivian Turner. ORD National Program Directors: Dr. Hugh Tilson, Dr. Jerry Blancato, Dr. Elaine Francis

Research Areas Discussed:

Human Health Research; Computational Toxicology Research; Endocrine Disruptors Research

- 2) **Ecosystems, Water and Security** SAB Break-Out Group: Dr. Virginia Dale and Dr. Philip Singer (Group Leaders) Dr. James Johnson, Dr. Mike McFarland, Dr. Judy Meyer, Dr. Deborah Swackhamer, Dr. Granger Morgan. DFO: Dr. Thomas Armitage and Dr. Vivian Turner. ORD National Program Directors: Dr. Greg Sayles, Dr. Chuck Noss

Research Areas Discussed: Homeland Security, Water Quality

- 3) **Economics and Sustainability** SAB Break-Out Group Dr. Gregory Biddinger and Dr. Kathy Segerson (Group Leaders) Dr. Cathy Kling, Dr. Jana Milford, Dr. Thomas Theis. DFO: Dr. Holly Stallworth. NCEE and ORD National Program Directors: Dr. Al McGartland, NCEE and Dr. Gordan Evans, ORD

Research Areas Discussed: Economics and Decision Sciences, Sustainability

iv) **Afternoon Break-out Sessions**

The afternoon sessions continued two of the morning sessions and added two new topics.

- 4) **Human Health Research**:
SAB Break-Out Group: Drs. James Bus and Lauren Zeise (Group Leaders); Dr. Steve Heeringa, Dr. Rogene Henderson, Dr. Agnes Kane, Dr. Kristin Shrader-Frechette, Dr. George Lambert. DFO: Dr. Sue Shallal and Dr. Vivian Turner. ORD National Program Directors: Dr. Hugh Tilson, Dr. Jerry Blancato, Dr. Elaine Francis

Research Areas Discussed:
Human Health Research; Computational Toxicology Research; Endocrine Disruptors Research

- 5) **Ecosystems, Water and Security**
SAB Break-Out Group: Dr. Virginia Dale and Dr. Philip Singer (Group Leaders) Dr. James Johnson, Dr. Mike McFarland, Dr. Judy Meyer, Dr. Deborah Swackhamer, Dr. Granger Morgan. DFO: Dr. Thomas Armitage. ORD National Program Directors: Dr. Greg Sayles, Dr. Chuck Noss

Research Areas Discussed: Homeland Security Research, Water Quality Research

- 6) **Air and Global Climate Change- Triangle Room**
SAB Break-Out Group: Dr. Jana Milford and Dr. Granger Morgan (Group Leaders); Rogene Henderson, Dr. Cathy Kling. DFO: Dr. Holly Stallworth. ORD National Program Directors: Dr. Joel Scheraga and Dr. Dan Costa

Research Areas Discussed: Global Change Research; Clean Air Research

- 7) **Technology:** SAB Break-Out Group Dr. James Johnson, Dr. Mike McFarland, Dr. Thomas Theis. DFO: Dr. Anthony Maciorowski and Mr. Tom Miller. ORD National Program Directors: Dr. Randy Wentzel, Dr. Nora Savage, Dr. Ed Washburn

Research Areas Discussed: Land Preservation; Nanotechnology, Global Earth Observation System of Systems/Advanced Monitoring Initiative

v) **Plenary Session - One**

Group Leaders summarized the discussions from the individual break-out groups. These are to be synthesized into brief written pieces that should be sent to the Chair and the DFO for compilation into written advice to the Agency.

1) **Ecosystems, Water, and Security Research**

For the Ecosystems Protection Research Area members noted a change from the historically, diverse research in this area to one that is refocused on ecosystem services. Members believe 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. There is an opportunity for someone to facilitate this integration and to help shape the outcomes of this program. Members noted the continuing need to link conditions to goals through continued development of monitoring systems, especially for some of the contemplated trading systems that involve ecosystem services. Success in this research area will be enhanced if EPA adds expertise in economics to the program. ORD has a history of taking the outcomes from their research and helping to infuse those results into EPA practice. This will be very important for research on ecosystem services. An ecosystem services perspective will require staff with a holistic perspective and this perspective must be communicated to user communities. This new focus will also require support of the STAR grants program to be successful. The opportunity to think at the strategic level instead of just focusing on the issue of the week is important to getting these new programs on a strong footing. Integrating across diverse scales is important.

Members noted that the Homeland Security Research program began in a crisis mode and focused on getting as much as possible as quickly as possible. The need now is to become more strategic and to define program boundaries so that this strategic focus has a goal. EPA must think beyond terrorism and conduct research to enhance responses to natural disasters. EPA also needs to think about how to increase collaborative research with other agencies and other stakeholders as well as to obtain more collaboration within EPA. A cross-cutting issue is the need to coordinate with others to better define EPA's niche in the response area

and how that influences research needs. Important research areas identified include: risk communications; detection methods for contamination, decontamination, disposal and outdoor exposure. Issues such as determining “how much clean up is necessary” have social research needs beyond communications.

For Water Quality Research members noted 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.

Members noted that for Drinking Water Research most attention is on total coliform and CCL research with groundwater source protection getting some attention. More attention is needed for surface source water protection and distribution systems. Again, the “One Hydrosphere” approach is suggested for EPA use in integrating its research on a variety of water issues.

2) Human Health Research

Members believed that EPA’s strategy is moving in the right direction for many issues. Members noted the publication of a major new NAS report on toxicology testing, *Toxicity Testing in the Twenty-first Century: A Vision and a Strategy* and their belief that the report which is setting the paradigm for use of “omics” testing will have profound influences on EPA’s future toxicology research, future toxicology testing, and for developing data for use in risk assessment. Members stated that EPA human health researchers recognize the implications of this new report on their research directions. The field is becoming much more complex than in the past. EPA will need to be positioned to integrate the knowledge and methods from these new fields as it becomes available. It is important that EPA develop new ways to collaborate with other agencies and non-governmental entities to pull this science together for use in achieving the EPA mission. It is not clear how this can be done, but exploration of ways should begin – perhaps use of CRADAs can help.

Members also noted that additional emphasis is needed in public health, surveillance and epidemiology so that these new *in vitro* screens can be used in strengthening that work. More emphasis is needed on metabolism, acute to chronic prediction, and whether the new paradigm fits for novel pollutants that are being introduced into the environment (e.g., nanotechnologies and products).

Members stated that for many chemicals, there is little *in vivo* study data available for developing IRIS values. For these, mechanistic information could be used to

move forward. This would at least allow some conclusions on the likelihood of certain effects at certain levels of exposure. This is within the Human Health Risk Assessment Research Area.

Particularly difficult research issues remain in predicting metals risk and in making chronic risk predictions with only acute data available. Access to key federal databases will grow in importance (HANES, National Children's Study). Additional in-house epidemiology and public health expertise is needed to work with agency toxicologists and risk assessors if EPA is to evaluate outcomes from research and policies targeting risk reduction. Better exposure information will also be necessary. International contributions in human health research will be important for EPA to integrate into its practice. Concern was noted in the change in the Human Health Research Area from four to two goals. It will be important for program materials to be clear that certain significant issues are not dropped from the research program as a result of this change (e.g., susceptible populations).

3) Economics and Sustainability

Members noted several cross-cutting issues, including: clarification of the nature of behavioral change research needed; the need for work on affecting change and measures of effectiveness of changes made; and the need to establish explicit links between behavioral research and other research and operating programs (e.g., land and water protection, global change, TMDLs, etc.).

For Economics and Decision Sciences members believe there is a need for research to clarify the ways in which research can study how risk assessment metrics and benefits valuation can be put on a consistent basis; the need for research on incentive effects of different policy instruments in a variety of policy contexts; the need for discussion of decision-science research needs; and the need for behavioral research beyond just economics.

Members applauded the focus on Science and Technology for Sustainability but believe the development of metrics will be difficult and that some goals could give an overly reduced perspective on the topic. Members pointed to the need for a clear definition of sustainable conditions to be achieved in order for metrics to be developed. Members agree with the importance of partnerships and collaboration with others inside and outside EPA to the hoped for success of the program. The sustainability themes in the background document are good, however, the research agenda does not go very far in demonstrating how these fit into the research agenda. Research needs to go beyond "green technologies" to smart growth, sustainable cities, etc. Members suggested EPA explore the development of bridging from risk to performance concepts (e.g., how we go from ecological risk to ecosystem function to ecosystem services). Members noted that new systems and technologies can be developed but they are only

useful to the extent that people's behavior changes and the new things are adopted.

4) Air and Global Change Research

Members noted the significance and importance of the long-standing Clean Air Research program which was combined into a one-air concept from earlier separate NAAQS and Hazardous Air Pollutant research programs. They endorsed the currently planned work on mechanisms, particulate matter effects, and atmospheric pathways. Members recognized the new way of framing source to health issues (e.g., near-roadway effects) and its relation to accounting for where effects originate. They would like to see more on local and neighborhood components including exposure, as well as a better understanding of emissions and how emissions might be forecast.

For Global Change Research, Members suggested adding efforts on policy design (research to compare alternative policy instruments) and guidance on mitigation technologies. They noted the continuing need for global mass-balance research for mercury. Members believed EPA did a good job in discussing collaboration and integration with others in their air research program background information (with the possible exception of greenhouse gases).

5) Technology Research

In the Land Preservation Research area, Members noted their impression that this long-standing program has been historically constrained and influenced by limits imposed on the use of Superfund resources. The EPA principles and the intended outcome of the Agency's voluntary Resource Conservation Challenge (RCC) concept must be considered in developing this research program. There are no metrics available to judge the RCC's effectiveness, thus work to begin developing metrics is encouraged. EPA could merge the RCC concept with its sustainability concept, and if this is done, there would be a need for greater emphasis of land use in sustainability. Significant cross-fertilization opportunities exist if this is done.

For Nanotechnology Research, EPA has done an excellent job in merging their work into the National Nanotechnology Initiative (NNI) which currently seems to have an environmental fate and transport focus. It is not too soon to begin to think beyond this fate and transport focus to research that will be needed later (e.g., health effects). A focus on environmentally benign products and processes might be useful. Integrating EPA's focus with that of the international community is important because our products must remain competitive in the international arena. Given the horrendously large task involved in looking at toxicity and risk for these products, and the rapidity with which the technology is developing through innovation, it will be difficult for EPA to keep up with developments in this field. But, this work must proceed. Members recognized

that EPA works with small companies to ensure the companies provide the right information for use in evaluating effects. Even so, thinking of these evaluations in the classical mode may not allow EPA to keep up with the task. Thus, the new toxicology vision of the NAS might become important to evaluating nanotechnology processes and products.

Members noted that they had little to disagree with in the cross-media focus of the EPA portion of the Global Earth Observation System of Systems/Advanced Monitoring Initiative (GEOSS/AMI) portion of the research program. Members noted though that it is important for the Agency to ensure that they do not run the program in a manner that provides too much data and too little information.

Cross-Cutting Issue – Long-Term versus Short-Term Science Needs: Members discussed a persistent cross-cutting issue that continues to impede the ability of the EPA research program to conduct the forward-looking research that provides knowledge, techniques, and technologies necessary for developing innovative solutions to current problems, as well as emerging environmental challenges. The topic was clearly shown in the break-out discussions on water issues. There is a long-standing tension between Regional and Program Office short-term needs and long-term science needs that are a critical part of EPA's research program. The SAB, as well as the National Academy of Sciences, has discussed this issue for many years though the terminology has evolved over time. Whether the terminology assigns research components to categories articulated as core, basic, fundamental, or cross-cutting research, as contrasted to applied, program-driven, or targeted program research, the issue is the same – how can ORD provide for today's Regional and Program Office needs for data and technical assistance and at the same time continue to push the frontiers of environmental science forward so that EPA can meet its mission needs in the future?

Members agreed that this is a problem with many components, some of which are strategic in nature and others are related to resource limitations that form barriers to implementing even the best of strategic science plans. Further, there remains an impression that, even though it has a laudable goal of program accountability, the PART process has contributed to both strategic planning and budget decisions that favor the short-run over the long-run. The SAB has noted its view of how PART might influence this issue in its budget commentary for several years now and for the current discussion of strategic research directions does not see the need to say more about PART, rather the SAB will, instead, focus on the general issue of long-term versus short-term science needs.

The meeting was adjourned for the day at 4:45 p.m.

5. MEETING SUMMARY – Day 3 - Friday, October 5, 2007

a) Plenary Session – Two

Dr. Kevin Teichman thanked the Members for their open discussions during the previous day. He also provided feedback on the comments made by Break-out Group Lead Discussants at the conclusion of day two. He stated that he was pleased with the discussions. He believes that the SAB response to the overall charge for the meeting, i.e., “what did you think of ORD’s strategic directions,” is that ORD’s strategic directions are not off course. The SAB did offer some additions that would supplement the current directions (e.g., in the area of ecosystems services, even though one member stated that the strategy is the “most visionary thing I saw” there is a tension with providing near-term support to the Office of Water. In “policy design” ORD’s risk management research should focus on more than “end-of-pipe” controls, and in Decision Sciences there is a need for risk communications research).

Dr. Teichman reflected on the “creative tension” issue noted by the Board. To begin with, he introduced a way of thinking about EPA science and research. Though somewhat artificial, for conceptual purposes he suggested that EPA-research should be thought of as a subset of “science” and that good research is what develops products that help EPA apply good science approaches to policy-development. Just as in academia where one desires scientists who can both deliver powerful lectures and conduct excellent research, EPA wants scientists who are both leaders in their fields and responsive to Program and Regional Office science needs. ORD must respond to many different needs and clients. That said, ORD is not a job-shop because that would rapidly lead EPA to lose its research edge and not provide the latest science to inform EPA policies. To ensure that ORD continues to maintain its edge, the organization follows promotional policies for its scientists that mirror those in academia in regard to the pursuit of science, but because ORD serves EPA’s science needs, the pursuit of science is directed toward areas that support EPA’s mission. A good example of how this works is in the area of the Environmental Monitoring and Assessment Program (EMAP) where ORD, and its partners, developed statistically rigorous approaches to assessing ecological conditions, demonstrated their proof-of-concept, and transitioned the program to others to use in performing the monitoring function and to conducting specific environmental assessments. ORD is now moving on to Ecosystem Services as a focal area to allow it to help inform the next generation of policy development.

Dr. Teichman then listed a number of things that he had heard in each area as the leaders did their report on each research areas. He also responded to some of the research-area-specific comments from these leaders.

- a) For Ecosystems he heard that: the approach had not yet been communicated to Program Offices; there is a greater role for economists to help people understand ecological benefits; STAR funding is needed and this needs to expand to global change; and more case studies of greater diversity are needed and the results need to be shared with programs and regions.

- b) For Homeland Security he heard that it is now time to move from the crisis mode of reacting to program needs to one driven by a strategic approach; risk communications needs to be informed by more research; clean-up levels need to be informed by research on human behavior; the indoor focus needs to be supplemented by outdoor needs – especially in the area of clean up levels; and there is a need for more planning and collaboration with stakeholders.
- c) For Water Quality there is support for integrated watershed management research; need for more emphasis on infrastructure; and a need for more emphasis on models as they inform management decisions.
- d) For Drinking Water there is a need for emphasis on distribution systems and source water system protection, and that climate change needs to be integrated across the Drinking Water and Water Quality areas and with other agencies.
- e) For Human Health there is a recognition that the NAS report on the new toxicology vision has changed the way the research program will be pursued and it will affect the skill-mix needed by EPA to move forward effectively in this area; there was little said on the “accountability” issue of using research to show how it affects health changes; heard that there is a need for more public health and epidemiology research; and increased emphasis on acute to chronic predictors.
- f) For Human Health Risk Assessment the slow pace of the IRIS program was noted and ORD is working to improve the pace of those assessments; he did not hear about the new ISA process relative to the old Air Quality Criteria Document approach.
- g) For Economics there is a need for behavior change research to be emphasized; it is not clear whose behavior change was to be the focus; and research is needed on decision sciences.
- h) For Sustainability the goal of developing metrics is a lofty goal but it will be difficult to develop; life cycle assessment does not capture what people value; there is a need to link sustainability to other programs; the six themes were appreciated by the Board but linking them into the research agenda seemed to be lacking; there is a need to go beyond green technology; and we should link risk to function to performance and service.
- i) For Clean Air there is a need to continue work on mechanisms and pathways; work at local scales should be enhanced; and emissions characterization for Indoor Air is important to residual risk assessment. He heard nothing on indoor air.
- j) For Global Change there is a need for more emphasis on global change on air itself and EPA’s program responsibilities; and there is a need for work to support policy design and mitigation and adaptation technologies. For Mercury there continues to be a need for global mass-balance research.
- k) For Land Preservation there is a need for metrics for the RCC and RCC needs more prominence in the program; there is a possibility of combining this concept with “sustainability”.
- l) For Nanotechnology the Board recognized the strong collaborative nature with other agencies and suggested that it was time for research to go beyond fate and transport to toxicity issues. The Board suggested the need for

designing in environmental and health concerns up front as opposed to trying to do evaluations of risk later.

- m) For GEOSS/AMI the Board also recognized that this was another area with good cross-agency activity and cautioned against having a data rich environment that did not provide useful information.
- n) For Pesticides and Products and Endocrine Disruptors research, the Board has been silent so far.

Dr. Morgan thanked Dr. Teichman for his feedback and asked for additional reflections from the SAB Members. Members noted:

- a) The Board had also noted that the research transferred to NCEE still left decision sciences uncovered and even with the science program they describe there remains some SAB concern that important research won't be conducted.
- b) The built environment issue is an important area for research in the Sustainability and the Land Protection area. Current focus is on tools not on land use issues *per se*. Dr. Teichman noted that there are four MYPs in the Sustainability area and they might have more on that. Mr. Hecht noted that the strategic plan is cross-cutting and address the six areas where we feel EPA has the most impact but it is not intended to be exhaustive on each of the themes. More will be coming forth to guide the program over time.
- c) The SAB comment on "behavior" really is more focused on studies that observe human behavior and learn from that and not on the discussion point that questioned whose behavior was the target of change from the activities discussed.

Action Item: Dr. Morgan asked the group leaders to compile their thoughts into a **write up** of several hundred words on each cluster of Research Areas. The focus of these pieces should be on the appropriateness of each research area's key directions, on other needs that you see as appropriate, and if you wish, on areas where less attention might be directed. It would also be appropriate to comment on cross-cutting advice. These write-ups should be sent to the SAB DFO who will compile a first draft for the Chair.

Dr. Morgan stated that to ensure that the Board had not misunderstood any of the issues presented that he would like to send a committee draft to Dr. Teichman for reaction before it becomes a final report. The SAB also envisions the likelihood of making the process of considering the strategic directions of ORD research an iterative process that will probably involve additional dialogue between specific smaller SAB groups and specific agency NPDs and others on individual or related groups of research program areas. Dr. Swackhamer was asked to draft some wording on the long-term versus short-term issue.

Dr. Morgan thanked Dr. Teichman and the other EPA ORD and Regional Scientists for their participation in the discussions over the last day and one-half and noted that the session had been quite valuable to the Board. He noted that this focus on strategic directions for EPA research would help the Board's annual review of the EPA research

budget. He committed to continue to pursue additional discussions in smaller groups of Board members with a variety of EPA representatives.

b) **Upcoming SAB Activities**

Dr. Vu discussed the planned December meeting of the Board. Agenda items include the completion of the quality review for the Hypoxia report and possibly two other SAB draft reports; wrap up of the environmental disasters advisory; continuation of the advisory on strategic research directions; and further planning for the possible project on future environmental challenges. Dr. Vu also briefed the Members on the full Operating Plan for FY 2008 (see Attachment K – physical file only).

Action: The Designated Federal Officer was directed to survey the Board to confirm availability for the December 6-7, 2007 date for the next meeting. November 29, 30, 2007 was also to be considered.

Discussion of Possible Project on Environmental Challenges: Dr. Vu reminded the Members that Board had originally placed a meeting on the calendar for May 2008 that would have explored the influence of SAB advice (and potentially other advisory committee advice) on EPA science over the last 30 years. Subsequently, the Board decided that the topic should be recast, possibly looking at environmental science challenges for the next 10 to 20 years, and scheduled for completion by mid-2009. Working out the details for this project was left for a future meeting. Dr. Vu noted that the task would be daunting but that it could be done if Members were willing to take it on knowing the amount of their own time that it would require.

Dr. Morgan suggested that a less daunting effort might lead to the same outcome, i.e., hold a “workshop” during December 2008 to consolidate our thinking on future environmental challenges using as background:

- a) Information gathered from this meeting, and other recent meetings relative to strategic research directions;
- b) Information from additional efforts during calendar year 2008 – possibly by engaging the SAB Standing Committees;
- c) Information from a number of commissioned papers to be developed by some notable thinkers in environmental sciences; and
- d) Information to be derived from panels on human health and environmental change.

Such an approach would provide flexibility for a broader variety of views to be placed on the table (from the outside people brought in) and it would not be as burdensome on Board members. A Steering Committee could help to design the project.

Members were in favor of a 2008 event to reflect on 30 years of outside advice and to hold a workshop that would develop a proceedings or a report from the SAB on what was

gleaned from the workshop on future environmental challenges. The outcome of the workshop would determine whether a formal report to the Administrator was merited or not.

A handout from Dr. Steve Heeringa was distributed to update Members on the activities of the FIFRA Scientific Advisory Panel's recent activities (see Attachment L).

c) **Quality Review of the SAB Draft -- Advisory on EPA's Issues in Valuing Mortality Risk Reduction**

Members conducted a quality review of the draft *Advisory on EPA's Issues in Valuing Mortality Risk Reduction* (see on the SAB Website at http://www.epa.gov/sab/pdf/9-4-07_draft_advisory_val_mortality_risk_reduc_mc_hs.pdf and in Attachment M of the physical file to these minutes). A compilation of SAB member comments provided prior to the meeting are in Attachment N and the charge for an SAB quality review is in Attachment G.

Dr. Maureen Cropper, Chair of the Panel briefed the Board on the background for the review and its key findings. Dr. Morgan thanked Dr. Cropper and asked Board Members if they wanted to emphasize or discuss any of their written comments on the draft report. Members commented on a number of issues and one paragraph was suggested as an addition to the document as follows:

In closing we remind the Agency, that there is a much larger normative element in the selection of VSL for regulatory evaluation and analysis than arises for many of the other issues with which the Science Advisory Board deals. For example, while there is no denying the reality of income effects, it is a policy judgment, not a scientific question, whether the same VSL should be employed in all regulatory decisions across a society or different values should be chosen depending upon the preferences and income of the population affected by a specific regulation.

Dr. Cropper agreed to add the paragraph and to respond to the Members' written comments with edits to the draft advisory.

A motion to accept the report contingent upon the minor edits being made as noted in the Members' comments was made and seconded. Dr. Morgan called the motion to a vote and it was approved with no dissent.

d) **Quality Review of the SAB Draft -- Review of the ORD Draft Assessment Entitled, 'Evaluation of the carcinogenicity of Ethylene Oxide'**

Members conducted a quality review of the draft report *Review of the ORD Draft Assessment Entitled, 'Evaluation of the carcinogenicity of Ethylene Oxide'* (see at http://www.epa.gov/sab/pdf/ethylene_oxide_final_review_draft_report_8-30-07.pdf and in Attachment O of the physical file to these minutes). The EPA charge to the Panel is in Attachment P and the charge for an SAB quality review is in Attachment G. Two Board Members, Dr. Bus and Dr. Biddinger, asked to be recused from participating in the

review of this draft report because of the interests of their employers. The members were excused from the discussions and they joined the audience for the duration of the discussion.

Dr. Steve Roberts, Chair of the Ethylene Oxide Advisory Panel briefed the Board on the review and its key findings. Members emphasized several issues from their written comments (see Attachment Q), including:

- i) the discussion of uncertainty needs to be clarified and the contributions in the Appendices in this regard should be highlighted in the introduction (it might even be worthwhile to craft these items into a published work);
- ii) the topic is controversial and the focus on epidemiology could be broadened to include mechanisms, biomarkers, etc., other potential hazards associated with ethylene oxide, etc.;
- iii) it might be good to add more on what specific data would be needed to obtain a better carcinogenicity analysis;
- iv) the document needs a better discussion of weak association versus weak risk, one does not necessarily lead to the other;

Dr. Roberts did not anticipate any difficulties in responding to the comments of the SAB members. In response to Dr. White of EPA, Dr. Roberts noted that regarding the use of linear versus non-linear risk extrapolation approaches, the panel members did not all agree on one over the other. What emerged was advice from the panel stating that EPA should use both extrapolation methods, but the Panel did not specify which one should be preferred. Board Members agreed that it was appropriate to ask for both to give a better sense of uncertainty to decision makers. The Board also noted that it was appropriate to defer to EPA on which approach it preferred.

Dr. Morgan thanked Dr. Roberts and introduced Dr. Jane Teta, Principal Scientist, Exponent, Inc., who made an oral statement on behalf of the American Chemistry Council (see Attachment R).

A motion was made and seconded to conditionally approve the report subject to edits being made consistent with the Board's comments and discussion. The edits are to be returned to Drs. Henderson, Kane, and Zeise serving as Vectors to determine when the conditions are met prior to being forwarded to the Administrator. Dr. Morgan called for a vote on the motion and it was passed without dissent.

e) **Closing Comments and Action Items:**

Dr. Vu recapped the meeting outcome as follows:

- i) The 2008 Operating Plan has the Board's approval to implement;
- ii) Staff will assemble and engage a Steering Committee to further develop the issue of a December 2008 Science Challenges workshop;

- iii) Staff will facilitate the continued edits to the environmental disasters commentary and drafting of the advisory on the EPA strategic research directions;
- iv) Staff will survey Members for a final December meeting date;
- v) Staff will schedule additional telephone conference meetings as necessary to conduct quality reviews or other planning activities; and
- vi) Staff will facilitate the planning of the February 2008 research budget review. The hope is that the results of this meeting will permit a streamlined process for conducting the review.
- vii) Members having ideas for additional information that would improve the effectiveness and efficiency of the February 2008 Research budget review should send their ideas to the DFO for compiling and follow up.
- viii) Staff should provide the recent NAS report on Toxicity Testing to Members.
- ix) Staff should contact AAAS to request that they (Dr. Kei Koizumi) participate in the February 2008 SAB meeting by giving an overview presentation on the Federal research budget.

The Designated Federal Officer adjourned the meeting at 11:00 a.m.

Respectfully submitted by:

Certified as true:

/ Signed /

/ Signed /

Thomas O. Miller
 Designated Federal Officer
 US EPA Science Advisory Board

Dr. M. Granger Morgan
 Chair
 US EPA Science Advisory Board

Attachments

<u>Attachment</u>	<u>Title</u>
A	Agenda
B	Roster
C	FRN
D	Sign in sheets – physical file only
E	Draft Report: <i>Hypoxia in the Northern Gulf of Mexico: An Update by the EPA Science Advisory Board</i>
F	Hypoxia Charge from the EPA
G	Quality Review Charge
H1	Compilation of Member Comments on the Draft Hypoxia Report
H2	Compilation of Outside Experts' comments on the Draft Hypoxia Report
I	Strategic Research Directions presentation by Dr. Kevin Teichman
J	Compilation of EPA ORD Research Program Descriptions
K	Memo from Dr. Vu: SAB Staff Office Update for Oct. 3-5, 2007 Meeting
L	Dr. Heeringa's updates on the activities of the FIFRA SAP (physical file only)
M	Draft <i>SAB Advisory on EPA's Issues in Valuing Mortality Risk Reduction</i>
N	Compilation of Member comments on Mortality Risk Reduction Draft
O	Draft Report: <i>Review of the ORD Draft Assessment Entitled, 'Evaluation of the carcinogenicity of Ethylene Oxide'</i>
P	Request for SAB review of the Draft Ethylene Oxide Carcinogenicity Assessment
Q	Compilation of Member Comments on the Draft SAB EtO Report
R	SAB Meeting Comments on EtO by Dr. Jane Teta, Exponent, Inc. and the American Chemistry Council

**US Environmental Protection Agency
Science Advisory Board Meeting**

October 3 to 5, 2007

Meeting Location:

Marriott at Research Triangle Park
4700 Guardian Drive
Durham, NC 27703
Phone: (919) 941-6200

Wednesday, October 3, 2007

11:00 a.m.	Convene the Meeting:	Mr. Thomas O. Miller Designated Federal Officer US EPA SAB
11:05 a.m.	Welcome and Remarks, SAB Office Director	Dr. Vanessa Vu Director, EPA SAB Staff Office
11:10 a.m.	Introductory Remarks - Science Advisory Board Chair	Dr. M. Granger Morgan Chair, EPA SAB
11:15 a.m.	Updates and Discussion of Comments on Environmental Disasters	The Chair The Board
12:15 p.m.	Lunch	
1:30 p.m.	Quality Review of the SAB Draft Report on Hypoxia	The Board
{ Phone Lines Available }	<ul style="list-style-type: none"> a) Public Comments (written only) b) Board Comments (compiled) 	
3:30 p.m.	Visit to the US EPA Research Triangle Park Laboratory	The Board
5:30 p.m.	Adjourn for the Day (time approximate)	

Thursday, October 4, 2007**8:30 a.m. Re-Convene the Meeting****Thomas O. Miller**
Designated Federal Officer
US EPA SAB**Introductory Remarks of the Chair****Dr. M. Granger Morgan**
Chair, EPA SAB**8:45 a.m. Strategic Directions for Research at the
US EPA****The Board**
Dr. George Gray
Assistant Administrator for
Research and Development
(by telephone)**{ Phone
Lines
Available } – Plenary Session****Dr. Kevin Teichman**
ORD Acting Deputy
Assistant Administrator for
Science
**ORD National Program
Directors****10:30 a.m. A. Morning Breakout Sessions
Raleigh Room****The Board**
EPA Representatives

- 1. Human Health:**
 - a) Human Health Research**
(Dr. Hugh Tilson, ORD)
 - b) Computational Toxicology**
(Dr. Jerry Blancato, ORD)
 - c) Endocrine Disruptors**
(Dr. Elaine Francis, ORD)

SAB Break-Out Group:
Dr. James Bus
Dr. Steve Heeringa
Dr. Rogene Henderson
Dr. Agnes Kane
Dr. Dr. Steve Roberts
Dr. Kristin Shrader-Frechette
Dr. Lauren Zeise
Dr. George Lambert**10:30 a.m. 2. Ecosystems, Water and Security
Durham Room**

- a) Homeland Security**
(Dr. Greg Sayles, ORD)
- b) Water Quality**
(Dr. Chuck Noss, ORD)

SAB Break-Out Group:
Dr. Virginia Dale
Dr. James Johnson
Dr. Mike McFarland
Dr. Judy Meyer
Dr. Philip Singer
Dr. Deborah Swackhamer
Dr. Granger Morgan

- 10:30 a.m. 3. Economics and Sustainability**
 Triangle Room
- a) Economics & Decision Sciences**
 (Dr. Al McGartland, NCEE)
- b) Sustainability**
 (Dr. Gordan Evans, ORD)
- SAB Break-Out Group**
 Dr. Gregory Biddinger
 Dr. Cathy Kling
 Dr. Jana Milford
 Dr. Kathy Segerson
 Dr. Thomas Theis
- 12:30 p.m. Working Lunch**
 (Break to pick up lunch and return to
 breakout rooms)
- 1:00 p.m. B. Afternoon Breakout Sessions**
- 1. Human Health- Raleigh Room**
- a) Human Health Risk Assessment**
 (Dr. John Vandenberg, ORD)
- b) Safe Pesticides and Safe Products**
 (Dr. Elaine Francis, ORD)
- SAB Break-Out Group**
 Dr. James Bus
 Dr. Steve Heeringa
 Dr. Agnes Kane
 Dr. Dr. Steve Roberts
 Dr. Kristin Shrader-Frechette
 Dr. Lauren Zeise
 Dr. George Lambert
- 1:00 p.m. 2. Ecosystems and Water –Durham Room**
- a) Drinking Water**
 (Dr. Audrey Levine)
- b) Ecosystems Protection Research**
 (Dr. Rick Linthurst)
- SAB Break-Out Group**
 Dr. Greg Biddinger
 Dr. Virginia Dale
 Dr. Judy Meyer
 Dr. Kathy Segerson
 Dr. Phil Singer
 Dr. Deborah Swackhamer
- 1:00 p.m. 3. Air and Global Climate Change-
 Triangle Room**
- a) Global Change**
 (Dr. Joel Scheraga)
- b) Clean Air Research**
 (Dr. Dan Costa)
- SAB Break-Out Group**
 Dr. Rogene Henderson
 Dr. Cathy Kling
 Dr. Jana Milford
 Dr. Granger Morgan
- 1:00 p.m. 4. Technology- Salon A/B/C**
- a) Land Preservation**
 (Dr. Randy Wentsel)
- b) Nanotechnology**
- SAB Break-Out Group**
 Dr. James Johnson
 Dr. Mike McFarland
 Dr. Thomas Theis

(Dr. Nora Savage)

c) **GEOSS/AMI**

(Dr. Ed Washburn)

3:15 p.m. Break**3:30 p.m. Reconvene in Plenary****{ Phone
Lines
Available }****The Board
EPA Representatives****4:45 p.m. Adjourn for the Day****Friday, October 5, 2007****8:00 a.m. Re-Convene the Meeting****Dr. M. Granger Morgan
Chair, EPA SAB****8:15 a.m. Strategic Directions for Research at the
US EPA – Continue the Plenary Session
(if needed)****The Board
EPA Representatives****10:00 a.m. Quality Reviews****{ Phone Lines
Available }**

- 1) **Draft *SAB Advisory on EPA's
Issues in Valuing Mortality Risk
Reduction***
 - a) **Public Comments (None)**
 - b) **Board Comments (Compiled)**

**The Board
Dr. Maureen Cropper**

- 2) **Draft *Review of the ORD draft
assessment entitled, "Evaluation of
the Carcinogenicity of Ethylene
Oxide"***
 - a) **Public Comments (one request)**
 - b) **Board Comments (Compiled)**

**The Board
Dr. Steve Roberts**

11:30 a.m. Upcoming SAB Activities:

- a) **Operating Plan 2008**
 - i) **Science Challenges**
- b) **Future Meetings:**
 - i) **December 2007 Meeting**
 - ii) **Calendar Year 2008
Meetings**

**Dr. Vanessa Vu
The Board****12:30 p.m. Adjourn the Meeting****The DFO**

ATTACHMENT C

Group
Envsubset/DC/USEPA/
US@EPA

To "Federal Register SCIENCE ADVISORY BOARD" <epa-sab@lists.epa.gov>

08/30/2007 12:04 PM

cc

Please respond to
Group Envsubset/DC/USEPA/US@EPA

Subje [epa-sab] Science Advisory Board Staff Office;
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ENVIRONMENTAL PROTECTION AGENCY
[FRL-8462-5]

Science Advisory Board Staff Office; Notification of a Meeting of
the Science Advisory Board

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public face-to-face meeting of the chartered SAB to: (1) Discuss strategic research directions for the U.S. Environmental Protection Agency; (2) complete its discussions of science use in disaster response programs; (3) conduct a quality review of the draft SAB report Advisory on Factors Influencing Hypoxia in the Gulf of Mexico; and (4) conduct a quality review of the draft SAB report Review of EPA's Draft Evaluation of the Carcinogenicity of Ethylene Oxide: A Report of the U.S. EPA Science Advisory Board.

DATES: The meeting dates are Wednesday, October 3, 2007, from 8:30 a.m. to 5:30 p.m. through Friday, October 5, 2007, from 8:30 a.m. to not later than 2 p.m. (Eastern Time).

Location: The meeting will be held in Research Triangle Park, NC. The location will be announced on the SAB Web site as soon as possible.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain additional information about this meeting may contact Dr. Angela Nugent by mail address given below; by telephone at (202) 343-9981; by fax at (202) 233-0643; or e-mail at:

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nugent.angela@epa.gov or by contacting Mr. Thomas O. Miller, Designated Federal Officer (DFO), by mail at the address given below; by telephone at (202) 343-9982; by fax at: (202) 233-0643; or e-mail at:

millier.tom@epa.gov. The SAB mailing address is: U.S. EPA, Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. General information about the SAB, as well as any updates concerning the meeting announced in this notice, may be found on the SAB Web site at: http://www.epa.gov/sab.

SUPPLEMENTARY INFORMATION: The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: (a) SAB Quality Review of the Draft Committee Report Factors Influencing Hypoxia in the Gulf of Mexico. The Chartered Science Advisory Board will conduct a quality review of the draft report of its Hypoxia Advisory Panel at its meeting on October 3-5, 2007. Specific times will be provided in the meeting agenda that will be placed on the SAB Web site prior to the meeting (http://www.epa.gov/sab). EPA's Office of Water requested that the SAB develop a report that evaluates the state-of-the-science regarding the causes and extent of hypoxia in the Gulf of Mexico, as well as the scientific basis of possible management options in the Mississippi River Basin. In response to EPA's request, the SAB Staff Office formed the SAB Hypoxia Advisory Panel. That Panel held several meetings to discuss the issue and has now completed its draft report to the EPA Administrator. Federal Register notices were published announcing each of the Hypoxia Advisory Panel meetings (see 71 FR 8578-8580; 71 FR 45543-45544; 71 FR 66329-66330; 71 FR 55786-55787; 71 FR 59107 and 71 FR 77743-77744). Background on the Panel and this review is available on the SAB Web site at: http://www.epa.gov/sab/panels/hypoxia_adv_panel.htm.

(b) EPA Strategic Research Directions: The Agency has asked the Science Advisory Board for advice on the strategic directions for its research program for the next five to fifteen years. This activity complements the annual SAB review of EPA's research budget, and permits a more critical evaluation of research programs than is possible during the research budget review. It will also give EPA additional time to incorporate SAB advice into the longer term research planning process that informs each year's budget preparation activity. The Agency charge asks for advice on the alignment of EPA research and development program directions with the strategic priorities identified by EPA's operating programs and Regional Offices; coordination of research planning within ORD and across EPA; coordination of research planning with environmental science programs of other government agencies; and whether EPA research is positioned to provide critical scientific support to EPA and the nation on emerging issues. The SAB will discuss EPA research program directions with EPA representatives on October 4 and 5, 2007. Specific information on the structure and schedule for these discussions will be provided by the meeting agenda that will be available on the SAB Web site prior to the meeting (http://www.epa.gov/sab).

(c) Science in Emergency Response. The SAB is exploring the use of science in preparing for and responding to environmental disasters. The SAB held a meeting on this topic on December 12-14, 2006 during which non-EPA experts discussed their experiences with disaster preparedness and response (71 FR 67566). The SAB continued its discussions of science in emergency response during its June 19-20, 2007 meeting (see 72 FR 27308). The SAB is currently drafting advisory comments to the

Administrator as a result of these discussions. Final discussions of those comments will be held during the SAB meeting on October 3-5, 2007. Specific times will be provided in the meeting agenda that will be placed on the SAB Web site prior to the meeting (<http://www.epa.gov/sab>).

Additional information is available on the SAB Web Site for the December 2006 meeting at:

<http://www.epa.gov/sab/agendas.htm>, and for the June 19-20, 2007 SAB meeting at: <http://www.epa.gov/sab/07agendas/>

(d) SAB Quality Review of Review of EPA's Draft Evaluation of the Carcinogenicity of Ethylene Oxide: A Report of the U.S. EPA Science Advisory Board. The Chartered Science Advisory Board will conduct a quality review of the draft report of its Ethylene Oxide Review Panel on October 3-5, 2007. Specific times will be provided in the meeting agenda that will be placed on the SAB Web Site prior to the meeting (<http://www.epa.gov/sab>). EPA's Office of Research and Development (ORD) requested that the SAB review its draft document entitled Evaluation of the Carcinogenicity of Ethylene Oxide that was prepared by the National Center for Environmental Assessment (NCEA). In response to EPA's request, the SAB Staff Office formed the SAB Ethylene Oxide Review Panel. That Panel held several meetings to discuss the issue and has now completed its draft report to the EPA Administrator. Federal Register notices were published announcing each of the Ethylene Oxide Review Panel's meetings (see 71 FR 10500, 71 FR 66328, 72 FR 20538). Background on the Panel and this review is available on the SAB Web Site at: http://www.epa.gov/sab/panels/ethylene_oxide_rev_panel.htm.

Availability of Meeting Materials: Materials in support of this meeting will be placed on the SAB Web Site at <http://www.epa.gov/sab> in advance of this meeting.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the SAB to consider during the advisory process. Oral Statements: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes per speaker, with no more than one hour for all speakers. Interested parties should contact Dr. Angela Nugent by mail at the EPA SAB Staff Office, (1400F), U.S. EPA, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by telephone at (202) 343-9981; by fax at (202) 233-0643; or by e-mail at: <mailto:nugent.angela@epa.gov> <<mailto:nugent.angela@epa.gov>> Mr. Thomas Miller, DFO, at the contact information provided above, by September 21, 2007, to be placed on the public speaker list for the October 3-5, 2007 meeting. A telephone conference line will be available for those portions of the meeting during which the SAB is conducting quality reviews of draft committee reports. Information on the call in procedures and numbers can be obtained by calling the EPA SAB Staff Office at (202) 343-9999. Written Statements: Written statements should be received in the SAB Staff Office by September 27, 2007, so that the information may be made available to the SAB for their consideration prior to this meeting. Written statements should be supplied in the following formats: one hard copy with original signature, and one electronic copy via e-mail to: <mailto:nugent.angela@epa.gov> and

miller.tom@epa.gov (acceptable file

format: Adobe Acrobat PDF,

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WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

Meeting Accommodations: For information on access or services for individuals with disabilities, please contact Mr. Thomas Miller at (202) 343-9982, or e-mail at miller.tom@epa.gov.

To request accommodation of a disability, please contact Mr. Miller, preferably at

least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: August 24, 2007.

Anthony Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E7-17197 Filed 8-29-07; 8:45 am]

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ATTACHMENT B

**U.S. Environmental Protection Agency
Science Advisory Board
Roster
October 3-5, 2007**

CHAIR

Dr. M. Granger Morgan, Lord Chair Professor in Engineering; Professor and Department Head, Department of Engineering and Public Policy, Carnegie Mellon University, Pittsburgh, PA

SAB MEMBERS

Dr. Gregory Biddinger, Coordinator, Natural Land Management Programs, Toxicology and Environmental Sciences, ExxonMobil Biomedical Sciences, Houston, TX

Dr. James Bus, Director of External Technology, Toxicology and Environmental Research and Consulting, The Dow Chemical Company, Midland, MI

Dr. Maureen L. Cropper, Professor, Department of Economics, University of Maryland, College Park, MD

Dr. Virginia Dale, Corporate Fellow, Environmental Sciences Division, Oak Ridge National Laboratory, Oak Ridge, TN

Dr. Stephen Heeringa, Research Scientist and Director, Statistical Design Group, Institute for Social Research, University of Michigan, Ann Arbor, MI.

Dr. Rogene Henderson, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. James H. Johnson, Professor and Dean, College of Engineering, Architecture & Computer Sciences, Howard University, Washington, DC

Dr. Agnes Kane, Professor and Chair, Department of Pathology and Laboratory Medicine, Brown University, Providence, RI

Dr. Catherine Kling, Professor, Department of Economics, Iowa State University, Ames, IA

Dr. George Lambert, Associate Professor of Pediatrics, Director, Center for Childhood Neurotoxicology, Robert Wood Johnson Medical School-UMDNJ, Belle Mead, NJ

Dr. Michael J. McFarland, Associate Professor, Department of Civil and

Environmental Engineering, Utah State University, Logan, UT

Dr. Judith L. Meyer, Distinguished Research Professor Emeritus, Institute of Ecology, University of Georgia, Lopez Island, WA

Dr. Jana Milford, Associate Professor, Department of Mechanical Engineering, University of Colorado, Boulder, CO

Dr. Stephen M. Roberts, Professor, Department of Physiological Sciences, Director, Center for Environmental and Human Toxicology, University of Florida, Gainesville, FL

Dr. Kathleen Segerson, Professor, Department of Economics, University of Connecticut, Storrs, CT

Dr. Kristin Shrader-Frechette, O'Neil Professor of Philosophy, Department of Biological Sciences and Philosophy Department, University of Notre Dame, Notre Dame, IN

Dr. Philip Singer, Professor, Department of Environmental Sciences and Engineering, School of Public Health, University of North Carolina, Chapel Hill, NC

Dr. Deborah Swackhamer, Interim Director and Professor, Institute on the Environment, University of Minnesota, St. Paul, MN

Dr. Thomas L. Theis, Director, Institute for Environmental Science and Policy, University of Illinois at Chicago, Chicago, IL

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

SCIENCE ADVISORY BOARD STAFF

Mr. Thomas Miller, Designated Federal Officer, 1200 Pennsylvania Avenue, NW 1400F, Washington, DC, 20460, Phone: 202-343-9982, Fax: 202-233-0643, (miller.tom@epa.gov)

EPA Science Advisory Board Hypoxia Advisory Panel

Charge to the Panel

Background

EPA participates with other Federal agencies, state and tribes in the Mississippi River/Gulf of Mexico Watershed Nutrient Task Force. In 2001, the Task Force released the *Action Plan for Reducing, Mitigating and Controlling Hypoxia in the Northern Gulf of Mexico* (or *Action Plan*).¹ This *Action Plan* was informed by the underlying science described in *An Integrated Assessment of Hypoxia in the Northern Gulf of Mexico* (or *Integrated Assessment*)² developed by the National Science and Technology Council, Committee on Environment and Natural Resources. Six technical reports³ provided the scientific foundation for the *Integrated Assessment*. The aforementioned documents provide a comprehensive summary of the state-of-the-science for the Gulf of Mexico hypoxic zone through about the year 2000. Since then, scientific literature and understanding regarding the Gulf of Mexico and the Basin has advanced.

EPA's Office of Water has requested that the SAB develop a report that evaluates the current state-of-the-science regarding the causes and extent of hypoxia in the Gulf of Mexico, as well as the scientific basis of possible management options in the Mississippi River Basin. Background materials for this evaluation include: the *Action Plan*; *Integrated Assessment*; six technical documents prepared in 2000; a bibliography of scientific articles primarily related to the science of hypoxia in the Gulf published subsequent to the 2000 *Integrated Assessment*; a summary from the Management Action Reassessment Team (MART) of federal programs to increase watershed planning, reduce loadings from agricultural lands and encourage better land use practices; and available information from USDA's ongoing Conservation Effects Assessment Project (CEAP) program. In addition to the documents cited above, the Panel will review current research activities pertinent to this evaluation, including findings from scientific symposia sponsored by the Task Force. To capture recent advances in our scientific understanding of hypoxia, the causes and potential solutions, the Task Force has sponsored three scientific symposia, and is sponsoring a fourth symposium, including:

- A. Upper Basin Science Symposium, September 26 - 28, 2005, Ames, IA;
- B. Gulf Hypoxia Science Symposium, April 25 - 27, 2006, New Orleans, LA;
- C. Lower Basin Science Symposium, June 1 - 2, 2006, New Orleans, LA;
- D. Sources, Fate and Transport Symposium, November 7-9, 2006, Minneapolis, MN.

The SAB may incorporate other relevant publications and information based on the expertise of its members .

The SAB is asked to develop a report that addresses the state of the science of hypoxia as well as the scientific basis for mitigating hypoxia through management options. The SAB is asked to

focus particular attention on scientific advances since 2000 that may have increased understanding and options in three general areas.

- 1. Characterization the Cause(s) of Hypoxia.** The physical, biological and chemical processes that affect the development, persistence and extent of hypoxia in the northern Gulf of Mexico.
- 2. Characterization of Nutrient Fate, Transport and Sources.** Nutrient loadings, fate, transport and sources in the Mississippi River that impact Gulf Hypoxia.
- 3. Scientific Basis for Goals and Management Options.** The scientific basis for, and recommended revisions to, the goals proposed in the Action Plan; and the scientific basis for the efficacy of recommended management actions to reduce nutrient flux from point and nonpoint sources.

In addressing the state of the science, the SAB is asked to focus on the strengths and limitations of the science in managing the Gulf hypoxia problem, including available data, models and model results and uncertainty. The SAB is asked to pay particular attention to any new information that has emerged since or was not adequately considered in the last *Integrated Assessment*. EPA, in conjunction with its federal, state, and tribal partners will consider the SAB's advice and recommendations as future revisions to the *Action Plan* are developed.

Questions for the State-of-the-Science Evaluation

1. Characterization of Hypoxia – The development, persistence and areal extent of hypoxia is thought to result from interactions in physical, chemical and biological oceanographic processes along the northern Gulf continental shelf; and changes in the Mississippi River Basin that affect nutrient loads and fresh water flow.

A. Address the state-of-the-science and the importance of various processes in the formation of hypoxia in the Gulf of Mexico. These issues include:

- i. increased volume or funneling of fresh water discharges from the Mississippi River;
- ii. changes in hydrologic or geomorphic processes in the Gulf of Mexico and the Mississippi River Basin;
- iii. increased nutrient loads due to coastal wetlands losses, upwelling or increased loadings from the Mississippi River Basin;
- iv. increased stratification, and seasonal changes in magnitude and spatial distribution of stratification and nutrient concentrations in the Gulf;
- v. temporal and spatial changes in nutrient limitation or co-limitation, for nitrogen or phosphorus, as significant factors in the development of the hypoxic zone;
- vi. the implications of reduction of phosphorus or nitrogen without concomitant reduction of the other.

B. Comment on the state of the science for characterizing the onset, volume, extent and duration of the hypoxic zone.

2. Characterization of Nutrient Fate, Transport and Sources: Nutrient loads, concentrations, speciation, seasonality and biogeochemical recycling processes have been suggested as important causal factors in the development and persistence of hypoxia in the Gulf. The *Integrated Assessment* (CENR 2000) presented information on the geographic locations of nutrient loads to the Gulf and the human and natural activities that contribute nutrient loadings.

- A. Given the available literature and information (especially since 2000), data and models on the loads, fate and transport and effects of nutrients, evaluate the importance of various processes in nutrient delivery and effects. These may include:
 - i. the pertinent temporal (annual and seasonal) characteristics of nutrient loads/fluxes throughout the Mississippi River basin and, ultimately, to the Gulf of Mexico;
 - ii. the ability to determine an accurate mass balance of the nutrient loads throughout the basin;
 - iii. nutrient transport processes (fate/transport, sources/sinks, transformations, etc.) through the basin, the deltaic zone, and into the Gulf.
- B. Given the available literature and information (especially since 2000) on nutrient sources and delivery within and from the basin, evaluate capabilities to:
 - i. predict nutrient delivery to the Gulf, using currently available scientific tools and models;
 - ii. route nutrients from their various sources and account for the transport processes throughout the basin and deltaic zone, using currently available scientific tools and models.

3. Scientific Basis for Goals and Management Options. The Task Force has stated goals of reducing the 5-year running average areal extent of the Gulf of Mexico hypoxic zone to less than 5,000 square kilometers by the year 2015, improving water quality within the basin and protecting the communities and economic conditions within the basin. Additionally, nutrient loads from various sources in the Mississippi River Basin have been suggested as the major driver for the formation, extent and duration of the Gulf hypoxic zone.

- A. Are these goals supported by present scientific knowledge and understanding of the hypoxic zone, nutrient loads, fate and transport, sources and control options?
 - i. Based on the current state-of- the-science, should the reduction goal for the size of the hypoxia zone be revised?
 - ii. Based on the current state-of-the-science, can the areal extent of Gulf hypoxia be reduced while also protecting water quality and social welfare in the basin?
- B. Based on the current state-of- the-science, what level of reduction in causal agents (nutrients/discharge) will be needed to achieve the current reduction goal for the size of the hypoxic zone?
- C. Given the available literature and information (especially since 2000) on technologies and practices to reduce nutrient loss from agriculture, runoff from other nonpoint sources and point source discharges, discuss options (and combinations of options) for reducing nutrient flux in terms of cost, feasibility and any other social welfare considerations. These options may include:

- i. the most effective agricultural practices, considering maintenance of soil sustainability and avoiding unintended negative environmental consequences
- ii. the most effective actions for other nonpoint sources
- iii. the most effective technologies for industrial and municipal point sources

In all three areas, please address research and information gaps (expanded monitoring, documentation of sources and management practices, effects of practices, further model development and validation, etc.) that should be addressed prior to the next 5-year review.

^{1/} Available at <http://www.epa.gov/msbasin/taskforce/actionplan.htm>

^{2/} Available at http://www.nos.noaa.gov/products/hypox_finalfront.pdf

^{3/} Available at http://www.nos.noaa.gov/products/pubs_hypox.html

ATTACHMENT H2

Expert Comments on “Science Advisory Board Hypoxia Panel Draft Advisory Report”

(Draft September 12, 2007)

1. **Dr. Madhu Khanna, University of Illinois, Department of Agricultural and Consumer Economics:**

Thank you for sending me the report by the SAB Hypoxia Committee and for the opportunity to review it. I am attaching my review comments as well as a recent paper of mine that might be of interest to the committee. It examines the economic costs/benefits of various policies for large scale nitrogen reduction. Please let me know if any further information is needed from me

Sincerely

I am very impressed by the quality of the report prepared by the committee. The report is comprehensive, up to date in terms of incorporating the latest scientific findings and balanced in terms of its recommendations. My comments are limited to some of the sections that I felt qualified to review, such as those addressing cost-effectiveness and environmental implications of alternative approaches for pollution control and the effectiveness of existing policies in inducing environmentally friendly changes (Sections 4.4 and 4.5). I have a few comments that the committee might consider for inclusion in the report for completeness.

- a) In Section 4.4.2 it might be useful to have some discussion on the effectiveness of land retirement programs vs. working land programs for conservation. While the CRP has been and continues to be the largest conservation program in terms of acreage and funding, there is an increasing emphasis on working land programs such as the Conservation Security Program. The CRP uses an Environmental Benefits Index that aims to target enrollment towards areas with high environmental benefits and lower costs and compensates farmers to retire their land from crop production. In contrast, the CSP pays farmers for ongoing stewardship practices rather than just for newly adopted practices. This raises issues of additional benefits achieved. Mechanisms used for targeting CSP enrollment are not as clearly defined and there is no emphasis on competitive bidding for enrollment in these working land programs.
- b) The work of CEAP which is seeking to provide nation-wide estimates of benefits of conservation programs should provide valuable findings. However, it needs to be supplemented with economic analysis at a similar scale to determine the costs of alternative conservation practices and help identify where conservation programs should be targeted to have the maximum impact on the hypoxic zone. I am not sure to what extent that is currently happening.

- c) As pointed out in Section 4.4.4 existing crop subsidies create counter incentives to conservation. It might also be worth emphasizing the point made in lines 38-41 that replacing crop subsidies by subsidies that reward environmentally friendly actions could lead to a double dividend in terms of improved environmental outcomes and increased social welfare (because they reduce the need for distortionary income and commodity taxes to finance the crop subsidies). I am attaching a paper under second submission to the *American Journal of Agricultural Economics*, which uses a stylized general equilibrium model to show the magnitude of the welfare gains possible even with the fairly large reductions in nitrogen use/loadings (40-50%) suggested by this panel report as needed to contain the hypoxic zone.
- d) Page 190, lines 16-26. It might be mentioned here that some of the reasons for low rates of adoption of precision technologies has been the high fixed costs of adoption and uncertainties of crop prices and yields. Farmers are therefore likely to have high option values for investing in such technologies. Moreover, the economic returns from adoption are likely to vary spatially depending on the heterogeneity in soil conditions. Thus cost-share subsidies may need to be high enough to cover option values and vary spatially to create sufficient incentives for adoption. Such subsidies may also need to be supplemented by revenue insurance programs to overcome the risks of adoption. Please see the following papers for more discussion of these issues:

Khanna, M., M. Isik, and A. Winter-Nelson, "Investment in Site-Specific Crop Management under Uncertainty: Implications for Nitrate Pollution Control and Environmental Policy," *Agricultural Economics*, 24 (1): 9-21, December 2000.

Khanna, M., "Sequential Adoption of Site-Specific Technologies and its Implications for Nitrogen Productivity: A Double Selectivity Model," *American Journal of Agricultural Economics*, 83: 35-51, February 2001.

Isik, M. and M. Khanna, "Variable Rate Nitrogen Application under Uncertainty: Implications for Profitability and Nitrogen Use," *Journal of Agricultural and Resource Economics*, 27 (1): 61-76, July 2002.

Isik, M. and M. Khanna, "Stochastic Technology, Risk Preferences and Adoption of Site-specific Technologies," *American Journal of Agricultural Economics*, 85 (2): 305-317, May 2003.

2. Dr. William J. Wiseman, Jr., National Science Foundation:

Congratulations on a nicely written document. It was interesting to read! The science in the areas where I have expertise is essentially correct. My comments are more indicative of areas that might benefit from clarification than correction. I have also indicated some editorial glitches that I caught. There were others that I did not indicate, because the text was sufficiently far from my knowledge base and the usage might be appropriate. I hope that a proper editor goes over this before release.

Thank you for inviting me to read this document and comment upon it.

Review of the Draft Report of the EPA Science Advisory Board Hypoxia Advisory Panel

This report represents a prodigious effort by the panel members. It reads well and represents an objective summary of the state of the science, at least for the portions within my expertise, and makes well-founded recommendations for future activity. My principal concern is that, given the present federal and state budgets, it may not be politically possible to address each recommendation immediately. It would seem to be most helpful if the panel could prioritize their recommendations to indicate which activities and actions have the most need for immediate implementation and which offer the greatest potential for improved understanding for the investment.

Throughout the document, there are numerous references to the plume, as well as to a coastal current. It would be helpful to have a clear definition of what the panel considers to be the limits of the plume. There are many different definitions in the literature.

On page 21, equation 1 does not clearly separate surface and body sources and sinks of oxygen. Term 6 is a surface source/sink only, while term 8 is a body source of oxygen. Term 7 involves both body and surface sinks. This could be made clearer.

In the key findings, on page 31, the second bullet suggests retrospective and prognostic modeling studies of altered flow diversions. It might be useful to include scenarios of altered nutrient supply to the associated river mouths, as well. This would be useful to suggest whether hypoxia truly is a recent problem, as well as to indicate the interactions of river flow diversions and altered management scenarios in the MRB.

Bullet 4 on the same page emphasizes the importance of understanding the controls on vertical mixing in the NGOM. Lateral mixing processes may be equally important. Equation 1 on page 21 suggests that alongshore and cross-shore dispersion coefficients are of equal magnitude. This is, I believe, not yet demonstrated and likely untrue. While some important processes associated with cross-shore dispersion may, ultimately, be captured by models, it is unclear that present models do this well. Thus, the effects of these processes must still be parameterized. Our understanding of these processes does not allow this parameterization to be performed with any confidence at this time.

The following is a list of editorial comments or minor questions.

P(age)1, L(ine)6: To my knowledge, the areal extent of the full hypoxic region has not been mapped with sufficient frequency to understand its temporal variability. The few times that it has been mapped more than once per year, the maximum extent was in late summer and there are physical and biological reasons to expect this to be the time of greatest extent. This implies that the observed extent of the hypoxic zone each year is only a conservative estimate of its maximum. The areal extent may be larger.

P5,L42 thru P6, L4: Because human responses are unpredictable, care must be exercised throughout to speak only of scenario modeling, rather than predictions.

P11,L2 change 'Unites' to 'United'.

P11,L4: change 'Two thirds' to 'Roughly two thirds'. The correct percentages are presented later in the document.

P19,L35 & 36: 'sufficient oxygen', sufficient for what?

P20, Key findings lines 1 & 2: 'data are consistent with increased hypoxia' refers to what aspects of hypoxia? Rates of occurrence? Duration? Minimum oxygen levels?

P21,L19 & 35: line 19 ignores the important dependence of mixing on time.

P25,L15: Maps of observed surface salinity and satellite images of chlorophyll and SST show the same distinct plumes, e.g. figure 9 of the report. This is not just a modeling result.

P27,L21: change 'theseis' to 'these'.

P33,L18: remove the carriage return that puts 'figure 7' on the next line.

P34,L19: 'Near inshore' makes no sense. Either nearshore or inshore is, I believe, intended.

P38, first line in box: change 'events in throughout' to 'events in'.

P39,L45 thru P40,L30: these lines are redundant with line 13 thru 43 on page 39.

P44, L30: 20076 should be 2006 or 2007.

P44,L32: I do not find a reference for Dagg et al. with a date of 2006 in the references.

P47,L19: change 'biologically' to 'biological'.

P49,L1: change 'productivity that have' to 'productivity have'.

P56,L1: Again, it is not clear that July is always the time of maximum extent of hypoxia, although it is when we have the most data.

P84, second line in box: change 'river' to 'rivers'.

P92,L19: change 'would' to 'would be'.

P124,L2 & 3: Monitoring at appropriate intensities is recommended. These intensities and durations are not defined. One important message from long-term monitoring sites is that the strongest signal following modifications to a region may be a transient with a duration of many years. It might be good to indicate that these monitoring efforts must continue for extended periods to allow discernment of the true long-term effects.

P156,L39: change 'loss nitrate' to 'loss of nitrate'.

P158,L16 thru 30: change 'NO3' to 'NO₃' everywhere for consistency with the preceding text.

P171,L9: change 'AFOs' to 'AFO'.

P172,L3: change 'place in at' to 'place at'.

P176, line 8 in the box: change 'co-sighting' to 'co-siting'.

P149,L1: What is the 51st state?

P205,L12: 'use less' to 'use is less'

3. Dr. Walter Dodds, Kansas State University, Division of Biology:

Review of EPA-Science Advisory Board Report on Gulf Hypoxia by Walter Dodds

The review generally addresses the original charge questions asked by the EPA. It is very thorough, and deals with many of the issues that will be required to control the size of the zone of hypoxia. The Advisory Board is to be commended for such a comprehensive and broad scope report dealing with the many potential issues involved with this complex problem. I have only a few major concerns.

My first concern is the rationale for linking the size of the hypoxic zone target reductions to the amount of total N and P reduction. The models for N have been published elsewhere but should be reproduced in the report along with an error analysis indicating the likelihood of obtaining the stated reduction goals. Straight regression models for TN and TP resulted in r^2 values of 0.27 and 0.60 respectively (Turner et al. 2006). This indicates substantial unaccounted for variance. The mechanistic models do better for total N loading (Scavia et al. 2003). Still, given the high variance, the potential for error should be calculated. Unrealistic expectations that a 45% decrease in TN load will decrease the hypoxic zone to 1/4th the size could ultimately lead to disappointment. Clear explanation of why reduction in the size of the zone is not strictly proportional to reduced nutrient loads would be helpful to the case for load reductions of this magnitude.

Related to the above concern is the method used to set the TP load reduction. Limited reasoning is given for reducing the total loading of TP 45%. Given that TN and TP

loading values are very close to the Redfield ratio recently, equal percentage reductions could be warranted, but this point should be made clearly. Better yet, unpublished materials by Scavia should be presented (maybe they will be out in time for the final report?). Given that models of phytoplankton production predict interactions of N and P that increase yield, if it is easier to lower one or the other more than 45%, the recommendation maybe should be phrased as “at least 45%”. If total N and total P data are available historically, then maybe the ratio of loading that was present before the hypoxic zone should be the target unless mechanistic models suggest otherwise. The case for a stoichiometric approach has been made strongly with regard to this issue (Dodds, W. K. 2006. Nutrients and the "Dead Zone": Ecological stoichiometry and depressed dissolved oxygen in the northern Gulf of Mexico. *Frontiers in Ecology and the Environment* 4:211-217). DIN:SRP data available historically could be used to estimate TN:TP (albeit with a good bit of error). Please note that the plots in the Dodds reference were not corrected by the journal as per request and a correction was published online for members or is available at <http://www.k-state.edu/doddslab/journalarts/dodds%20free%202006.pdf>

I am not thrilled by the statement on page 36 that N and P limitations tend to be confirmed by SRP:DIN. The relative degree of N and P limitation can be calculated from bioassays, and the data can be used to create ratios of N and P limitation. This approach to calculating degree of N limitation from a complete bioassay design has been published (Dodds, W. K., E. Martí, J. L. Tank, J. Pontius, S. K. Hamilton, N. B. Grimm, W. B. Bowden, W. H. McDowell, B. J. Peterson, H. M. Valett, J. R. Webster and S. Gregory. 2004. Carbon and nitrogen stoichiometry and nitrogen cycling rates in streams. *Oecologia* 140:458-467). I agree with the related statements that a more complete mechanistic understanding of how N and P is transported into the NGOM is necessary as are more detailed bioassays.

My third concern involves a control option that I did not see discussed. Restoring the length of stream channels to historic levels could potentially have a positive impact. The report acknowledges the importance of in-stream nitrogen removal as determined by the SPARROW and RIV-N model (albeit with large ranges). The effect of removal is a function of length of stream channel. Streams have a sinuosity of roughly 1.6, so channelization could decrease stream length by roughly 1/3. This could substantially influence the amount of removal and restoring natural stream geomorphology could assist with removal (Bernot, M. J. and W. K. Dodds. 2005. Nitrogen retention, removal, and saturation in lotic ecosystems. *Ecosystems* 8:442-453). This restoration of stream length could also improve phosphorus retention.

Page 40 repeats an entire paragraph from the previous page.

Some of the specific research recommendations could be construed as self serving for members of the panel and I hope that research funding in the recommended areas is ultimately open competition and subject to peer review (e.g. EPA STAR grants). The report could even suggest this to maximize the perception of unbiased participation.

4. Dr. Mark Alley, Virginia Tech, Department of Crop and Soil Environmental Sciences

Review Report, “Hypoxia in the Northern Gulf of Mexico: An Update by the EPA Science Advisory Board.

Prepared by Mark Alley, Dept. of Crop and Soil Environmental Sciences, Virginia Tech, Blacksburg, VA 24061, September 18, 2007

The report is comprehensive and exhaustive in its coverage of the hypoxia problem and recommendations for reducing the impacted area in the Northern Gulf of Mexico. In reading this report, I think that it would make an excellent “text” for an inter-disciplinary course on water quality and land use, with particular emphasis on agricultural issues related to N and P. I offer the following specific comments for consideration by the committee.

Pages 98-99:

Recommendation: “Sustainability of soils in the MARB must be fully addressed by measurement of changes in soil N pools as a result of new management systems....N mass balances.”

Comment: No new management system is recommended, nor is research recommended to develop new management systems. Research on changes in soil N pools will definitely increase the understanding of N transformations and loss. I would propose that research with changes in N pools associated with different tillage systems, especially those that increase surface residue, and reduce fuel and machinery cost while increasing soil organic matter, would be most useful.

Page 134:

Topic: “nutrient management is more cost-effective at low levels of N loss reduction”

Comment: Nutrient management needs to be defined in this context. Is it a comprehensive plan that is verified for implementation, or is this discussion referring to the writing of nutrient management plans, and then assuming in a model that a certain reduction has occurred?

Page 135:

Topic: Increased enrollment in CRP reduces nitrate flux at a cost of xxx dollars

Comment: Is this cost only the cost of program payments and reduction in crop subsidy? Past programs that have taken large amounts of land out of production have resulted in major economic losses to towns in certain regions, and such costs are real to those communities. While there is no doubt that putting land in properly managed CRP reduces sediment and nutrient losses, clarification of what is included in these costs will help readers determine if this is a viable strategy for all areas, or just some areas.

Page 135 and 137:

Topic: Fertilizer tax discussion

Comment: There is no mention of how any type of fertilizer tax would affect our place in global markets and the WTO. We are importing large amounts of fertilizer N, probably over 50% of total N needs, and we have had anti-dumping tariffs on Russian and Ukraine produced ammonium nitrate and urea for the past several years. Some comment as to the implications of taxing nutrients, especially imported nutrients, on our (U.S.) trade policy is warranted, even if there would be no effect.

Page 138:

Topic: “transition from corn to perennial crops could benefit farmers.”

Comment: I agree with the premise, but some support is needed, especially in a section dealing with social welfare. In fact, if the benefits to farmers were really great, we would see a conversion happening, as opposed to the transition that has occurred from more complex rotations in the past to the current corn-soybean system. Please comment on possible benefits to farmers.

Pages 151-152:

Topic: Discussion of taxes on nutrients.

Comment: Would nutrients in manures and legumes (net N fixation) also be taxed to change behavior? Not certain that legume N should be taxed, but N and P in manure has been a major environmental problem in localized areas, and should be considered for taxation if it is felt that taxing fertilizer might change behavior.

Page 156:

Topic: Ag drainage and bio-reactors

Comment: No mention is made of costs associated with controlling losses prior to getting into the tile. Such costs are needed in order to compare the cost of the bio-reactors to better nutrient management, if it is possible. This is an interesting technology and deserves discussion, but is it potentially cost effective compared to preventing losses to the tile.

Page 169:

Topic: Changing cropping systems to include more perennials

Comment: Nutrient pollution reduction with increased perennials in the cropping system is a clear concept. However, equipment and labor considerations to bring more perennials, and generally more livestock, into the farming system need to be investigated for economic viability. Also, what types of policies and incentives will be needed to make this happen. There are reasons why fewer farms have livestock and associated perennials today than 50 years ago, and these reasons need to be assessed under our current economic conditions.

Page 174:

Topic: “reducing surface runoff losses of P via conservation tillage can enhance nitrate leaching.”

Comment: While this is true in some cases, I do not think that such a broad general statement can be made. In particular, where no-till, especially continuous no-till, or conservation tillage is resulting in increases in soil organic matter, then N will be sequestered in the organic matter. At some point, the system will reach equilibrium, but during the buildup period of soil organic matter, leaching may not be increased. With the major benefits of reduced sediment and P loss with no-tillage and strip tillage, the statement in the document should not leave the impression that nitrate leaching is always increased with conservation or no-tillage.

Page 175:

Topic: Line 25 “energy rich” referring to ash.

Comment: Should this be “P rich ash”?

Page 176:

Topic: “Increases in N fertilizer prices” and thus increased value of manure will create more opportunities for moving manure.

Comment: The increased cost of diesel fuel to haul manure has offset much of the increased value of the nutrients. Also, increased energy costs for processing manure will also offset increased nutrient values to some extent, and this will vary with region and local situations.

Page 178-182:

Topic: “Nitrogen application timing”

Comment: Much discussion is given to fall versus spring N applications, and justifiably so, given the large amounts of fall N applications and losses associated with these applications. However, more discussion should focus on split N applications for at-planting versus side-dress applications as the system is moving to more UAN solution and urea fertilizers that offer more flexibility than anhydrous.

Page 181, line 6: 1.2 to 1.8 cm not mm

Page 181:

Comment: Tile drained lands are wetter in spring and thus make spring anhydrous application difficult, especially when trying to complete timely planting. These lands may be most amendable to a split at-planting and side-dress application, although growers have great concern about being able to make the side-dress N application. Some discussion of these factors by individuals from the area would be helpful, and I think address grower and dealer concerns about how to make the change from fall applied anhydrous to spring and summer applications.

Page 183:

Line 9: “yield response to N on a site- and season-specific basis”

Page 183:

Line 27: Sawyer and Randall reference is 2005 in the text but 2007 in the reference list.

Page 184:

Line 12: I agree that high yields are necessary for efficient use of all resources. Thus, I think that some reference should be made for the need to have total crop production systems with proper genetic selection, plant populations, and pest control in conjunction with “balanced fertilization” to optimize nutrient use at each specific site.

Page 185:

Line 29: Karlen et al. 2005 is not in the reference list. The statement being supported by this reference is very interesting, and I wanted to check the reference. I am not certain what is meant by “it could also increase grower risk, especially when above-normal rainfall occurs shortly after the side-dress N is applied.” Is the implication that the side-dress N could be moved directly into tile drains? Please clarify because in most situations I would expect heavy rain to move side-dress N downward, and possibly increase denitrification losses if soils are saturated. But given high evapotranspiration at side-dress time and rapid corn growth, I would expect greater losses from all preplant applications of N in tile-drained fields simply because more N is being applied earlier in the season. However, I can understand the direct movement into the tile drains in soils with good structure and macropores, but the implication that losses could be greater with side-dress split applications is not what I would expect.

Page 185:

Comment: Paragraph is devoted to “controlled release fertilizers” which is very appropriate. However, a paragraph should also be given to “stabilized” fertilizers, i.e. nitrification inhibitors and urease inhibitors, especially with the increase in urea and UAN use in the region.

Page 186:

Lines 2-10: Very good discussion.

Page 186:

Lines 12-29: There is no mention of tillage in this paragraph. This is a very important discussion and given the discussion in the previous paragraph, I think that the tillage method(s) used in the study discussed should be given. Also, was the tillage method used in the study representative of broad areas in crop production.

Page 189:

Comment: Lines 13-14: “The effects of tillage are not clear” More discussion is needed on this point. In many climates, continuous no-till clearly increases soil organic matter. However, in colder climates with high soil organic matter levels naturally, this may not be the case. The authors might clarify if this is what is being implied, especially in the northern part of the Mississippi River basin. This paragraph is very important and I think adding more discussion of tillage systems and N fertilizer influence on soil organic matter within different types of tillage could increase the value of this section.

Page 190:

Comment: Lines 16-26: The discussion of technology costs, economic returns, and cost-share programs is very important to this section on precision agriculture. However, changes in fertilizer prices have been so rapid this past year, i.e. from \$0.30 / lb of N to \$0.45 to \$0.50 per pound of N, the cost benefit ratio has changed, and some of the technologies are more cost effective than this discussion might lead readers to believe. Possibly should update with current prices for N and for technology.

However, the major point that I suggest needs to be added to this section concerns the grower's perception of paying for technology to get the N rate "optimized" at each location in the field. From a research and environmental standpoint, getting the rate "optimized" reduces potential N loss (good for the environment) and minimizes cost of N fertilizer. However, growers understand that N is required for corn to grow well and produce economic yields. Growers generally know that the amount needed in various fields is different, and even within fields, the optimum amount differs. So the question for the grower is, "do I spend money for technology to optimize the rate (without a guarantee), or do I spend money for N fertilizer?" The point is that paying for the technology increases grower risk, as opposed to purchasing fertilizer N with the same amount of money per acre. This is one of the reasons for the reluctance to adopt some of these technologies.

The other part of this discussion about optimum rates is that the cost of being wrong with regard to N rate, is greater than ever in today's environment. Over fertilization costs are greater due to the high cost of N. However, under fertilization with yield loss is greater because of the higher value of the grain. Thus, there are incentives to optimize rates, and with decreased technology costs, I think that some of these precision tools may be more widely used if grain prices stay and high and N fertilizer prices remain high.

The preceding paragraph may or may not be useful for this publication, but I simply offer it as some reflections on working with growers and students to develop efficient production programs.

Page 192

Comment: There is no discussion of the need to update soil test P calibrations. I have seen Antonio Mallarino's work in Iowa updating P soil test calibrations, but I am not certain if similar work has been done in other states in the basin. If not, then it is a need to get the calibrations and recommendations up to date for optimizing P fertilization.

Page 194

Comment: Are the variable rate manure applications being done because of "permit" limitations for livestock operations, i.e. continue to apply P on land close to facility, as opposed to optimizing the use of the nutrients for increasing crop yields?

Page 194

Comment: Lines 19-22: This sentence deserves a paragraph in order to increase the emphasis. Many nutrient management plans have been written but not implemented

and/or updated. This is very important and should be a stand alone paragraph with suggestions as to how plan implementation can be increased! I would share suggestions if I had any really good ideas on this!

Page 195-196

Comments: Recommendations are good. However, no mention is made of need for considering the influence of tillage systems on optimizing N rates, and fuel and machinery costs are causing major changes in tillage systems.

Discussion of adoption of conservation practices (page 196) – I suggest that it is important to consider that “costs” are viewed differently by different growers, and the views of costs depend on labor availability, farm organization and financial situation, as well as interest in technology. Thus adoption of conservation practices, as well as other technologies, will always be a very individual situation, unless the cost:benefit ratio is overwhelming to move to the new technology. For example, the benefits of using “Roundup-Ready” soybeans were so great, that adoption occurred rapidly, even with technology fees. We do not have such examples for nutrient management and fertilizer use, but we need to look for those targets (as the authors have mentioned in other sections) for the greatest benefits.

Page 201

Comments: Line 18: Please check this number. I do not believe that we currently can project that 70% of all domestic corn production will be used for ethanol. For example, wheat prices are currently “buying” acres that will come from corn in the southeast and western reaches of the corn belt. Perhaps the study cited concludes that 70% is the correct number, but it seems high to me.

Page 207

Comment: Line 27-28: “requires greater conservation, more no-till production and increased use of cover crops.”

Page 208

Comment: Lines 15-17: Even with 2 year planting incentives, until processing plants develop a market, i.e. establish prices, for switchgrass, it is a very poor business decision for growers to plant this crop on more than just a few acres to learn production techniques. Since the fermentation processes are not commercialized at this point, there is a lot of uncertainty around this crop.

ATTACHMENT G

CHARGE TO THE SCIENCE ADVISORY BOARD FOR REVIEWING DRAFT SAB PANEL REPORTS

The quality review process for draft SAB reports is intended to carry out the Board's required review and approval function for all SAB reports to the Administrator as addressed by FACA, EPA policies, and the SAB Charter. It ensures that specific SAB Committee/Panel reports are clear and not ambiguous or inconsistent. The Board review is **not a re-review** of the issues discussed by the expert committee/panel that conducted the review and drafted the report. Substantive issues in draft and final reports are the purview of the experts who conducted the SAB's specific review and authored the draft report. However, the exposition of the expert conclusions conveyed in the final SAB report is a primary concern of the Board, as is the content of the jointly authored Letter to the Administrator. The Charge to the Board in reviewing the draft is to determine whether:

- a) the original charge questions to the SAB Standing or Ad Hoc Committee/Panel were adequately addressed in the draft report;
- b) the draft report is clear and logical; and
- c) the conclusions drawn, and/or recommendations made, are supported by information in the body of the draft SAB report.

Those conducting quality reviews are also asked to be alert to technical errors, or omissions, that they note during their review; however, Board Members are not responsible for identifying all errors and omissions that might exist and their ultimate approval does not certify that a report contains no such issues.

The outcome of a quality review is a final disposition decision on a draft SAB report. That decision is reflected in the minutes of the public quality review of the report and that record becomes guidance for any final edits or revisions needed in the draft report. Revisions are the responsibility of the Chair of the drafting panel/committee and final approval is conveyed by the SAB Chair's authorization to sign the report's transmittal letter to the Administrator. On occasion, one or more Board vettors may be assigned to assist the SAB Chair, and the Expert Panel Chair, in the final edits and conditions of the Board are met by the final report to the Administrator.

Comments of the EPA Science Advisory Board on the Draft Report: Hypoxia in the Gulf of Mexico

(October 2, 2007)

1. Dr. James Galloway

- a) Does the draft report adequately address the original charge questions asked by EPA?
Noting that there were no specific 'charge questions', but rather a listing of things to address under three general topics, it is my assessment that the panel did address the things there were asked to address. It would be helpful however if the Executive Summary was organized in such a way as to put specific findings/conclusions/recommendations to specific items in the charge.
- b) Is the report clear and logical?
The report is clear and logical, and very detailed—the authors are to be commended. It does stress however the need for a well organized Executive Summary and a letter to the Administrator that identifies the most important recommendations. Specifically, the letter to the Administrator should specify the top 3-4 conclusions of the panel. This will not only be useful to the Administrator but will give the panel members the opportunity to work these through in their own minds. In this regard, the letter directs the Administrator to the Executive Summary of the Advisory for specific findings and recommendations. However, it appears that the Summary lists things that need to be done (all important) but does not indicate what the most important actions are. It would be very helpful if the panel could identify the top 3-4 things that need to be done and the order that they should be done in. Then identify the next top 3-4 things, etc.
- c) Are the conclusions drawn, and/or recommendations made in the report, supported by information in the body of the draft SAB report? The conclusions/recommendations are supported by information in the report, and in the documents that the report references.
- d) Are there technical errors in, or omissions from the report?
There do not appear to be major errors of statement or omission in the report. I do have the following comments:

Page 3, line 17: I would encourage the panel to choose a word other than 'ballpark' when saying what specific percentages of the N and P fluxes come from point sources.

Page 6, line 12: I would avoid using the word 'reduced' when discussing chemicals unless the exchange of electrons is involved.

Section 4.4, Cost-Effective Approaches for Non-point Source Control: For each approach in this section it is important to ask the following question: Is the N that is not being released to the waters, being lost to other systems with the consequence of not removing reactive N from environmental systems but rather just re-distributing it.

2. Dr. Rogene Henderson:

The report is on a topic outside my field, so I only reviewed the Executive Summary and the front material. I briefly scanned the comments of the outside reviewers. I thought the executive summary was a clearly written document that I enjoyed reading. I appreciated the extensive glossary of terms and acronyms in the front material. The conclusions and recommendations of

the group appeared to be reasonable and logical. The charge questions as described in the submittal letter were addressed. This report may turn out to be one of the classic reports from the SAB.

3. Dr. Tom Theis:

This is a comprehensive report on the causes, impacts, and potential remedies available for the hypoxic zone in the Gulf of Mexico. The report itself is embedded within, and is a logical product of, EPA's classical approach to environmental management, which favors chemical-by-chemical, media-by-media, and problem-by-problem assessments. This approach is engendered by most of the Agency's enabling legislation, and is the classical way in which its regulatory functions are carried out. Still, to its credit, the report goes considerably further than this by examining the hypoxia problem as a series of processes in which a suite of interrelated physical and chemical factors, and several chemical species, are involved.

The Panel may wish to consider the following thoughts as they prepare the final draft:

- The report is organized around 43 “key findings” and 91 “recommendations”, a large number as befits its comprehensive nature. But not all of the recommendations are of equal importance, and a great many are better directed at other agencies (in particular the USDA, but also many State agricultural agencies). The usefulness of the document could be improved considerably by prioritizing the recommendations, and identifying those that might be implemented by the Agency in the short term through its regulatory authority, and those that will take longer either because the knowledge base is insufficient, societal management institutions are not yet mature enough, or cooperative actions are the best way to proceed.
- As best I can determine all but one of the charge questions is answered. That one (III.C.iii.), requests that the Panel address the most effective technologies for point source controls on nutrients. The Panel's answer refers to the need to further analyze the costs and feasibility of tightened limits, and mentions only biological nutrient removal, and “enhanced nutrient removal” technologies (section 4.5.8). Given that several findings and recommendations are made regarding the need for better point source controls, the level of the analysis in the report that this charge question requests is modest and lacks the detail that is prevalent throughout most other sections in support of other charge questions.
- Given the scope of the report, and the significant role of non-point nutrient sources, it is surprising that it makes no mention of one of the Agency's main tools for controlling them, the Total Maximum Daily Load (TMDL) program, an approach that is mandated by the Clean Water Act. This is especially odd since the report reviews very thoroughly the components that comprise the TMDL process: monitoring, water quality modeling, computation of loads, and implementation of Best Management Practices (BMPs), many of which are also reviewed in the report. It is true that the TMDL process has a distinctly local focus (on watersheds), and as far as I know the Gulf hypoxic zone is not a listed impaired water body (although other oceanic waters are listed). TMDL was not specifically designed to manage a water body the impairment of which is the result of the combined effects of many smaller watersheds. However the methodology is certainly applicable, the regulatory authority is present, and the goals of the program are consistent with the needs identified in the report. TMDL alone is probably not sufficient to address

the hypoxia problem, but together with other approaches suggested (for example market-based tools), it may be an important part of a collection of tools for achieving desired reductions in nutrient loads to the Gulf. In any case its absence from such a comprehensive report would seem to be a significant omission.

- The report contains quite a bit of information, and in general presents it in a very organized way. It reading it, though, one oddity is the inconsistent use of mathematical notation. There are two very complex PDEs (in that their application is complex) on page 21, but not a single chemical reaction anywhere in the report in spite of the fact that transformations among chemical forms and species are central to understanding the complexity of the hypoxia problem. This omission is especially hard to understand in light of the great pains that are taken to explain the complexities of hypoxia in the MARB. For instance the glossary explains that the atmosphere contains 78.09% N₂ and 20.95% O₂, rather elementary facts for a science-based report, but glosses over the subtleties of nitrification, denitrification, and phosphate cycling to name a few.
- The report, in at least two places (p. 7, p. 224), refers to the application of market-based trading programs as a means of reducing compliance costs of nutrient controls. While this may be the end result, since presumably technical and organizational innovation will be spurred, it is not guaranteed (for instance if water quality “caps” are inadequate or lowered too rapidly). In any market-based scheme there will be some “winners” and some “losers”, with the aimed for result that the overall costs are spread out in a more efficient way than other approaches (e.g. command-and-control methods). I believe a more accurate depiction of trading schemes is that they “levelize” costs.
- Ultimately, upsets of the order of those that have occurred for the earth’s nutrient cycles, especially for nitrogen, presents society with many, often unpalatable, conundrums and trade-offs. The somewhat hidden assumption of the Panel is that all that it is possible to do to reverse the extent of the hypoxia problem must be done, and hence concludes that specific reduction goals should be set and means taken to reach them. As suggested above, one consequence of the problem-specific focus is that well-meaning recommendations for improvement may exacerbate other problems that have not been comprehensively considered. Most of the recommendations in the report for reducing the severity of the hypoxia problem are aimed at either reducing nutrient loads to the MARB, or increasing rates of denitrification. The consequences for related environmental, social, or economic systems have, in general, not been adequately addressed by the Panel. A few examples. (1) One suite of recommendations is aimed at reducing loads of fertilizer on agricultural lands, and planting alternative, less N-demanding crops, but consideration of potential parallel impacts on national and global dietary needs is not considered. (2) The report spends less than a page on the well-known production of nitrous oxide from denitrification, yet makes several recommendations to increase rates of denitrification (e.g. through restoration or development of wetlands), noting that the amounts of N₂O are anticipated to be a small percentage of total nitrate reduced. No analysis of the impact of increased amounts (not rates) of N₂O on global warming appears to have been considered (i.e. small yields, but the potential for overall increased production of a powerful greenhouse gas). (3) The report does consider the consequences of national energy policies, in the form of biofuels, on hypoxia and recommends that cellulosic crops (such as switchgrass) be cultivated. Yet there is no wider, life cycle based, analysis of the impacts of the processing of such feedstocks into biofuels, most of which rely on chemically-intensive methods. Further, the short and long term consequences on the agricultural community of widespread and rapid transition from traditional row crops to a

“new” crop such as switchgrass may be considerable, with consequences ranging from the creation of new markets to as yet unknown responses of farmers to its cultivation (e.g. they may add fertilizer anyway if even modest improvements in yield result).

4. Dr. Jana Milford

This is an impressive report that responds well to the charge questions asked by EPA. The report is very well written and the conclusions are generally well supported.

I have a few comments for consideration by the Hypoxia review panel.

p. 6. I wish the panel would explain in the executive summary about what it means by “the system moves to a point of no return.” Although it’s explained better later in the report, at this point this is a vague, if dire-sounding phrase.

p. 8. The panel recommends “incentives for conversion to cellulosic perennials ... as a cellulosic source for biofuels.” This recommendation seems to put the cart in front of the horse, since as yet, cellulosic biofuels are not thought to be commercially viable on a wide scale. Perhaps the recommendation could be modified to suggest that further development of the technology to produce cellulosic biofuels be encouraged, and point out that even when cellulosic biofuels are commercially viable, incentives may be needed to encourage production of ceullosic perennials.

pp. 196-198. I wish the panel would include some additional discussion of NH_x emissions to air and not just omit this discussion because these emissions represent only “a recycling of nitrogen within the basin.” I would argue that if followed by conversion to ammonium nitrate or sulfate, emissions to air can lead to significant long-distance transport and contributions to reactive nitrogen deposition in other sensitive areas besides the Gulf. At the least, reductions in air emissions of NH_x should be mentioned as co-benefits of reducing agricultural inputs of nitrogen, and the panel should flag any strategies it recommends for reducing N discharges to water that might increase discharges to air.

pp. 197-198. The discussion of NO_x emissions from electricity generation seems somewhat dated, because it doesn’t acknowledge the additional emissions reductions from this sector that will be required under the Clean Air Interstate Rule, which include year-round reductions in 23 states and the District of Columbia.

p. 201. Given the rapid pace of change in the biofuel industry, the report should consider updating references to projections for increased ethanol production and corn acreage. At the least, the report needs to say when the 263% rise in ethanol production is expected to occur by, and likewise when the 7.3 million ha increase in corn acreage is expected to occur by.

p. 215. Table 18. I believe more of the listed agricultural management options have benefits for air quality than are indicated in this table. Reductions in NH_x or N₂O emissions associated with many of these options should be identified as having air quality benefits.

5. Dr. Kristin Shrader-Frechette

9-23-07 Comments by Kristin Shrader-Frechette on EPA Hypoxia Study

While the hypoxia study, overall, is very well done and very readable, four amendments would probably make it a stronger study.

Proposed amendment 1: Because the definition of “biosolids” in the glossary on p. xv contains a major value judgment and begs a controversial scientific question about harms associated with biosolids, the word “harmless” should be removed from line 3 of the definition. See rationale below.

Proposed amendment 2: Because the definition of “biosolids” in the glossary on p. xv contains a second value judgment and begs a second controversial scientific question about whether they should be used as fertilizer, the third sentence of the definition should be cut because it claims that when treated, such biosolids can be applied as fertilizer.

Rationale for amendments 1-2:

(A) Using the word “harmless” in the glossary, to describe biosolids, is inconsistent, given that EPA itself says the sludge is not harmless. EPA says dioxins in the treated biosolids, for example, cause a small, but measurable, increase in cancers among farm families. (<http://yosemite.epa.gov/opaOpenDocument/admpress.nsf/b1ab9f485b098972852562e7004dc686/209dab87e1b0a8b785256dc20050c977?>).

(B) Because the document affirms (p. 3) that most (54%) non-point sources of N are from fertilizer, and (p. 3) that hypoxia reduction is at odds with many current agricultural and energy policies, the glossary and document probably should not beg any related value or policy questions (such as that the sludge is harmless, or that it can be safely applied as fertilizer), especially when the questions are matters of scientific controversy.

(C) Although in 2003, the EPA concluded that using sewage sludge as fertilizer caused few adverse health effects and declined to impose regulations on the practice, researchers have complained both about undesirable chemicals and about pathogens in the waste. University of Georgia microbiologist David Lewis showed in 2002, in a British medical journal, that 25 percent of individuals surveyed (who lived within a half mile of sewage sludge used as fertilizer) experienced eye, lung, skin and other irritations, including Staphylococcus aureus infections. The study showed that although modern treatment can eliminate 95 percent of pathogens, enough pathogens remained in class B sludge to pose a health risk. In 2002, the National Research Council also concluded that there may be public health risks from using processed sewage sludge – biosolids -- as commercial fertilizers.

Proposed amendment 3: Since the document affirms (p. 3) that most (54%) non-point sources of N are from fertilizer, it might be good if the 5 significant opportunities for N reduction, mentioned on p. 6 mentioned fertilizer specifically.

Proposed amendment 4: Although the report warns (p. 8) that action on hypoxia lags behind the science; (p. 52) that there is evidence of a dangerous regime shift in the Gulf; (p. 16) that the ultimate goal of the study is mitigation and control to reduce hypoxia; (p. 8) that scientists and policymakers must confront the conflicts causing hypoxia – nevertheless the vagueness and generality of the recommendations on pp. 5-8 of the executive summary do not encourage action as much as they ought. To be more effective, in achieving the admitted goals of the study and in

addressing the severity of the hypoxia problem, the report might benefit from 5 organizational improvements. These include (i) giving a full list of bulleted or numbered recommendations, either in the executive summary, or in an entire chapter at the end, as most National Academy reports do; (ii) organizing the recommendations, so that action proposals and research proposals are listed together; (iii) rewriting the recommendations so that they are more specific, empirical, and action oriented; (iv) rewriting them so that they include who or what group might be responsible for implementing or initiating the actions; (v) rewriting the recommendations so that there is more emphasis on the adaptive management discussed on pp. 121 ff. Otherwise, the recommendations might not be as clear as possible and might not promote needed action.

This bulleting, gathering, and rewriting of specific, empirical recommendations could build on the recommendations already given, e.g., on pp. 52, 55, 98, 107-108, 119-120, 124-5, 133-4, 143-144, 152-4, 157, 162, 175-6, 195-6, 199, 201, 209-10.

6. **Dr. Granger Morgan:**

The report is clear and well written. It is directly responsive to all the charge questions. My congratulations and thanks to all who are responsible for this impressive effort.

Many issues are identified for which scientific understanding is still not complete and various recommendations are made for research to make that understanding more complete. However, EPA's ultimate concern should be managing the problem of hypoxia. In that regard, it is not always clear to me which of the recommended research efforts, if satisfactorily undertaken, have a high probability of supporting improved management activities, and which do not. If some differentiation is possible that would be good – otherwise there is the risk that research might become a substitute for action. The recommendation (pg 120) that "model selection should depend on the question(s) being asked," is very good. The same philosophy should be applied to the prioritization of research.

The report talks of a "state change" in the Northern Gulf, but does not articulate very clearly what exactly has changed. Some more concrete explanation of what has changed would help. The report suggests that there will likely be hysteresis in the system. It is clear to me why this is important but as a non-expert reader it is not clear to me what the mechanisms causing hysteresis are likely to be.

The recommendations supporting an adaptive approach are very sensible, especially if it is undertaken with adequate instrumentation and observation of the system that allows ongoing improvement in models and understanding – this because it is unlikely that all of the uncertainties will be resolved through research on the time scale over which the management problem must be addressed. It is not clear to me that the need for adequate instrumentation and measurement as a corollary to successful adaptive management is sufficiently emphasized.

The two bulleted recommendations on page 131 which state needed reductions should take the form "a reduction of at least X is needed in order to meet the established target of Y." Otherwise they read like the SAB is making a policy recommendation which is not its appropriate role.

I don't understand why *shallower* tile depth *reduces* drainage flow in tile systems (pp 155-157). Is this because spacing is taken as constant and becomes too wide to collect all surface input as depth gets shallower? An explanatory sentence would be nice.

Add "are needed" in the final recommendation on bioenergy. More fundamentally, bio-energy production can reduce volume but in general it does not eliminate, indeed it concentrates, N and P in the residual.

Page 199 the recommendation is missing the word "should".

On page 223 I am troubled by the response to IIIA that the "...goal will need to be extended beyond 2015...". I would think it better to say "...that either a much more aggressive set of control strategies will need to be adopted or the goal will need to be extended beyond 2015..." I am concerned about the SAB straying too far into policy making.

Top of page 224 "...recommends a minimum target of 45% reduction..." Don't you need some language about an adaptive approach in that recommendation? I don't think you are saying get -45% and the problem will be solved but rather, aim for a big cut and then start adjusting policy on the basis of what one sees as the process proceeds.

Given the various public comments about "voluntary approaches" and the fact that there is now a small literature on the effectiveness of such approaches (including the recent RFF study), should the panel consider saying something about this?

Several of the comments above, if adopted, should also be reflected into the summary material at the start of the report.

While it gets mentioned a few times, there is very little discussion of how climate change may impact this problem. The time scale on which the hypoxia problem is being addressed is comparable to the time scale on which significant climate change will occur. A bit more focus on the implications of climate change (frequency, intensity and distribution of precipitation, soil moisture, etc.) would be well advised. Also, when the SAB visited region 6 and received briefings on the work on coastal wetland restoration it appeared that EPA was not factoring potentially large climate-induced sea-level rise into their thinking. The committee might consider whether this is an issue that could also be important for this problem.

7. Dr. Valerie Thomas:

Here are my comments on the Draft Hypoxia Report.

Overall a truly strong report. There are some inconsistencies, as detailed below:

p. 138. The summary statement on the potential to protect social welfare while reducing Hypoxia isn't completely consistent with the detailed discussion. The detailed discussion, on p. 137 lines 31-40, and before, says that the Integrated Assessment remains the most complete coverage and suggests that benefits exceed costs, even with only some of the co-benefits included. So it is surprising to read, on p. 138 lines 12-13 that that "there is great uncertainty of whether the goal can be achieved while protecting social welfare in the Basin." The paragraph that follows is consistent with the detailed discussion, that is "while we cannot definitively say that we can achieve the 5000 km² goal while maintaining social welfare, there is evidence to suggest that it is feasible to do so." I suggest that lines 12-13 on p. 138 be cut; that removes the inconsistency.

p. 143. Key findings. "Due to inadequate research funding... there is currently inadequate scientific basis to know with assurance whether the goal of a 5-year running average of 5000 km² for the hypoxic zone can be achieved while maintaining social welfare in the Basin." Again, this

statement is more negative than the evidence reviewed in the body of the report. Moreover, this statement and much of the preceding section could be interpreted to suggest that the panel's interest in more research funding is resulting in an exaggeration of the social welfare issue. None of the evidence presented in the body of the report suggests that maintaining social welfare will be impossible. A better sentence would be something like this: "The evidence strongly suggests that social welfare in the basin can be maintained while achieving the goal of a 5-year running average of 5000 km² for the hypoxic zone." See also the response to the charge question on page p. 223, lines 36-39, where there is an excellent statement; the body of the report needs to be brought into conformity with the response to the charge question.

pp. 145-146. Very nice discussion of voluntary measures.

pp. 168-169. Key Findings. Perennials. The draft states that use of perennials would result in significant N and P reductions. However, the preceding text, while mentioning that perennials are more efficient users of N, doesn't mention the P implications of a switch to perennials. More importantly, the text does not seem to include any references that directly support the N or P benefits of perennials. I don't doubt that the benefits are real. But since a switch to perennials would be a major change for the Basin, the recommendation should be strongly supported by references to the peer-reviewed literature.

p. 172 line 3. Remove the word "are"

p. 175. Line 4. Change "affect" to "effect". Line 44: change "in" to "is".

p. 176. Key Findings. The key findings section says that "co-siting with biofuel production facilities... will likely create the economies of scale and alternative technologies for manure management more feasible." This finding is not supported in the text; the text says the opposite: on p. 173 lines 23-30 the text says that co-locating AFOs with corn production "may exacerbate the accumulation of manure-based nutrient." The finding is also inconsistent with the finding on p. 210. (Also, note that the quoted sentence from the findings is not a grammatically correct, and that "sighting" should be changed to "siting." Further, the last bullet point isn't a complete sentence; something like "should be provided" needs to be added.) Overall, this section is not as well written as others; it is not tightly argued; the conclusions are not well-supported by the text.

p. 199. Atmospheric Deposition. Excellent section. (Also, the recommendation needs the word "should" before "be incorporated".)

p. 201. Excellent section on sewage treatment plants.

p. 223, lines 36-39: "social welfare can be protected by choosing policies that incorporate targeting." This statement in the charge question responses is an accurate reflection of the evidence discussed in the body of the report; it is a more accurate reflection than the statements on this topic on pp. 138 and 143.

STRATEGIC RESEARCH DIRECTIONS

*Presentation to the
EPA Science Advisory Board
Executive Committee*

*Kevin Y. Teichman, Ph.D.
Acting Deputy Assistant Administrator for Science*



Context and Approach

Context

- Last year, ORD began a new strategic planning effort.
- After the FY 2008 budget review, we agreed to talk about strategic directions in a non-budget environment.

Approach

- Board has received NPD 5-pagers.
- We have grouped research areas in break-out sessions.
- Board and NPDs will engage in dialogue on strategic directions.

How We Got Here: ORD Strategic Planning

- December 14-15, 2006 briefing of Executive Council (EC) by National Program Directors on proposed strategic directions for research.
- January 8, 2007 meeting of the EC to discuss December meeting presentations and synthesize integrated strategic directions.
- January 17, 2007 joint meeting of the EC and Science Council (SC – includes NPDs) to discuss initial EC synthesis of NPD strategic directions.
- January 18, 2007 EC meeting to begin implementation of strategic directions for research programs.
- February 22, 2007 SAB review of ORD's FY 2008 proposed budget and strategic directions.
- June 20, 2007 SAB and ORD agree on revised approach to discussing strategic directions.

ORD's Mission

- Provide the scientific foundation to support EPA's mission by:
 - Conducting *research and development* to identify, understand, and solve current and future environmental problems.
 - Providing *responsive technical support* to EPA's Programs and Regions.
 - *Collaborating with our scientific partners* in academia and other agencies, state and tribal governments, private sector organizations, and nations.
 - *Exercising leadership* in addressing emerging environmental issues and advancing the science and technology of risk assessment and risk management.

Format of NPD Write-Ups

- Program Context
 - Background information
- Strategic Directions, Science Challenges, and Research Needs
 - Agency drivers
 - External drivers
 - Evolving science
- ORD's Current and Future Research Directions
 - Where are we now and where do we need to go
- Making a Difference
 - Research products
 - Use by decision makers
 - Environmental outcomes

EPA Research Areas

Cross-Program Research

- Human Health
- Computational Toxicology
- Human Health Risk Assessment
- Endocrine Disrupting Chemicals
- Ecosystems
- Economics and Decision Sciences
- Science and Technology for Sustainability
- Nanotechnology

Program-Targeted Research

- Air
- Drinking Water
- Water Quality
- Land Preservation and Restoration
- Safe Pesticides and Products
- Homeland Security
- Global Change
- GEOS/AMI

Key Directions

Human Health Research

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

Computational Toxicology

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

Key Directions

Human Health Risk Assessment

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

Endocrine Disruptors

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

Key Directions

Ecosystems Protection Research

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

Economics and Decision Sciences (OPEI)

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

Key Directions

Sustainability

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

Nanotechnology

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

Key Directions

Clean Air Research

- 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.

Global Change

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

Key Directions

Drinking Water

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

Water Quality

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

Key Directions

Land Preservation & Restoration

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

Safe Pesticides and Safe Products

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

Key Directions

Homeland Security

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

GEOSS/AMI

- 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.

Effective Use of Plenary Sessions

- First Plenary (this morning)
 - Been there, done that.
- Second Plenary (this afternoon)
 - Board rapporteurs share 2-3 highlights of strategic directions for each research area.
- Third Plenary (tomorrow morning)
 - Unconstrained by EPA's traditional budget categories, what strategic research needs are missing/under-emphasized in ORD's research program?

Summary

- ORD has spent the past year considering our programs' strategic directions.
- The Board has always provided valuable advice in budget reviews . . .
- However, today we ask you to put budgets aside and think strategically.
- While the 5-pagers represent our current best thinking, they are intended to promote and not constrain discussion.
- We look forward to a fruitful series of discussions that will inform the strategic directions of ORD's research program.

Charge to the Bright Brigade

- **Where we should be in 2012 and beyond?**
 - Areas for continued emphasis
 - Areas for increased emphasis
 - Areas for decreased emphasis

- **What scientific factors should we consider to get there?**
 - Evolving science
 - Strategic workforce planning
 - Efficiency opportunities

9-4-07 Science Advisory Board (SAB) Draft Advisory on EPA's Issues in Valuing Mortality Risk Reduction

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
EPA SCIENCE ADVISORY BOARD

DATE

EPA-SAB-xxxxxxx

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

Re: SAB Advisory on EPA's Issues in Valuing Mortality Risk Reduction

Dear Administrator Johnson,

The EPA National Center for Environmental Economics (NCEE) requested the Science Advisory Board's advice on how the Agency should use meta-analysis to combine estimates of the value of reducing mortality risks (i.e., estimates of the Value of a Statistical Life (VSL)). The NCEE also asked the SAB for advice on how the Agency should incorporate information on remaining life expectancy when valuing reductions in risk of death. To respond to this advisory request, the SAB's Environmental Economics Advisory Committee (EEAC) was augmented with SAB chartered members as well as members of the Advisory Council on Clean Air Compliance Analysis. The SAB Panel reviewed two NCEE papers on these subjects: *Report of the EPA Workgroup on VSL Meta Analysis*, and *Willingness to Pay for Environmental Health Risk Reductions When There are Varying Degrees of Life Expectancy: A White Paper*.

In answer to the meta-analysis charge questions, the SAB does not believe that meta-regression—a particular form of meta-analysis—is an appropriate way to combine VSL estimates for use in policy analyses. The SAB does, however, agree that meta-regression is a useful statistical technique for identifying various aspects of study design or population characteristics that are associated with differences in VSL estimates. Once important sample characteristics, model and estimation factors affecting the VSL have been identified, the Agency must determine a set of criteria for what constitutes a set of acceptable empirical studies of the VSL. The SAB urges the Agency to establish such criteria. The Agency must also determine

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1 which studies are appropriate for estimating the VSL in a specific policy context, depending on
2 the nature of the risk addressed by a policy and the population affected. Once these criteria have
3 been determined, and an acceptable sample of VSL estimates from the literature has been
4 formed, appropriate statistical techniques can be used to combine these estimates. Two that have
5 been used to weight individual study estimates include the random effects and the empirical
6 Bayes estimator.

7
8 In addition, the SAB believes that both stated preference and revealed preference studies
9 should be considered in valuing mortality risks and that weight should be given to each of them
10 in proportion to how well they each address the policy question at hand. Both approaches have
11 strengths and weaknesses in a particular context, and, as a result, we do not believe that the
12 Agency should rely exclusively on one or the other in all contexts. Furthermore, the SAB
13 believes that the Agency should make needed adjustments when using VSL estimates from the
14 literature and consider reasonable priors regarding the magnitude of the VSL when including or
15 excluding the results from previous studies.

16
17 Regarding the role of life expectancy in valuing mortality risks, the Committee notes that
18 economic theory, in general, places no restrictions on the relationship between the VSL and
19 remaining life expectancy: the VSL may increase, decrease or remain constant as life
20 expectancy decreases. The relationship between the VSL and life expectancy is therefore an
21 empirical matter. In practice, because life expectancy is difficult to observe, the Agency will
22 have to relate the VSL to factors related to life expectancy—namely age and health status.
23 Although the literature on the relationship between age and the VSL is growing, the Committee
24 does not believe that it is sufficiently robust to allow the Agency to use a VSL that varies with
25 age. The Committee also believes that the use of a constant Value of a Statistical Life Year
26 (VSLY), which assumes that the VSL is strictly proportional to remaining life expectancy, is
27 unwarranted. If there is insufficient information to indicate that the VSL declines with age, there
28 is not sufficient information to indicate that the VSL is strictly proportional to remaining life
29 expectancy. Thus, the SAB recommends that at present the Agency use an age-independent
30 VSL to value mortality risk reductions. However, we also urge the Agency to report the age
31 distribution of statistical lives saved and the average remaining life expectancies of persons in
32 each age group.

33
34 The SAB urges the Agency to fund more research on empirical estimates of the VSL.
35 Reductions in risk of death constitute the majority of benefits from air pollution and drinking
36 water regulations. Accurately estimating the value of these benefits is crucial to promoting
37 efficient environmental policy, both now and in the future.

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Thank you for the opportunity to provide advice on this important and timely topic. The SAB looks forward to receiving your response to this advisory.

Sincerely,

Dr. M. Granger Morgan
Chair
EPA Science Advisory Board

Dr. Maureen Cropper
Chair
Environmental Economics Advisory
Committee

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory committee 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. Mention of trade names or commercial products does not constitute a recommendation for use. Reports of the EPA SAB are posted at: <http://www.epa.gov/sab>.

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Roster

U.S. Environmental Protection Agency

Science Advisory Board

Advisory on

EPA's Issues in Valuing Mortality Risk Reduction

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3

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6

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9

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Introduction

Reductions in mortality risk constitute the largest quantifiable category of benefits for many EPA rules and regulations. As such, mortality risk valuation estimates are an important input to the Agency's benefit cost analysis. The EPA uses a value of statistical life (VSL) to express the benefits of mortality risk reductions in monetary terms for use in cost-benefit analyses of its rules and regulations. EPA has used the same central default value (adjusted for inflation) in its primary analyses since 1999 when the Agency updated its *Guidelines for Preparing Economic Analyses* (2000). Prior to the release of the Guidelines, EPA sought advice from the Science Advisory Board on the appropriateness of this estimate and its derivation. In 2000, EPA also consulted with the SAB on the appropriateness of making adjustments to VSL estimates to capture risk and population characteristics associated with fatal cancer risks (*An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Cancer Risk Reductions*, #EPA-SAB-EEAC-00-013, July 27, 2000.). Again in 2004, the SAB's Environmental Economics Advisory Committee (EEAC) held a consultation to respond to the National Center for Environmental Economics' (NCEE) charge questions on meta-analysis and valuing mortality risk reductions. In 2006, the EEAC, augmented with economists from the chartered SAB and the Advisory Council on Clean Air Compliance Analysis, met to discuss specific charge questions related to two NCEE papers: *Report of the EPA Workgroup on VSL Meta Analysis*, and *Willingness to Pay for Environmental Health Risk Reductions When There are Varying Degrees of Life Expectancy: A White Paper*. Both of these papers may be found at <http://yosemite.epa.gov/EE/epa/eerm.nsf/vwRepNumLookup/>.

NCEE's charge questions and the Panel's responses are provided below.

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Meta-analysis of Mortality Risk Valuation Estimates: Charge Questions and Responses

- 1. In light of the workgroup's findings, what approach or approaches are the most scientifically appropriate to derive summary estimates of mortality risk valuation for use in environmental policy analysis? Should meta-regression techniques be applied to selected estimates or are other methods (e.g., fitting distributions) more appropriate? Please specify which methods, aside from or in addition to meta-regression techniques the Agency should explore.*

We believe that, once EPA has assembled a set of studies that are applicable to the population affected by a regulation and that meet appropriate criteria for a well-executed study, it is appropriate to combine these using meta-analysis. For example, the VSL estimates could be combined using a random effects estimator, in which individual VSL estimates are weighted in inverse proportion to their variance. We do not, however, believe that meta-regression—a particular form of meta-analysis—is an appropriate way to combine VSL estimates for use in policy analysis, or to perform benefits transfer, for reasons described below. Meta-regression is, however, a useful technique for understanding what factors may explain variation in VSL estimates across studies.

A meta-regression, in which the characteristics of study participants (e.g., percent female, percent over 65) and study design (e.g., does an hedonic wage study control for a worker's industry) are used as covariates is useful in understanding what factors affect empirical estimates of the VSL. It can be thought of as an empirical literature review which may highlight factors affecting the VSL that would not otherwise be detected. By highlighting correlates of the VSL, meta-regression may suggest features of study design for which criteria should be established. For example, it might be determined that an acceptable hedonic wage study must control for the worker's industry at the 2-digit level because this has a significant effect on the VSL estimate obtained in an hedonic wage study

It is, however, another matter to treat a meta-regression as a reduced-form model that can be used for obtaining the VSL for a given sub-population or the VSL conditional on an appropriate study design. To illustrate, a meta-regression may control for the functional form of the dependent variable in an hedonic wage regression by setting a dummy variable equal to 1 if the dependent variable is the log of wage rather than the wage. If researchers believe that the appropriate form of the equation is to use the log of the wage, this should be one criterion for an acceptable study and only studies satisfying the criterion should be combined in the meta-analysis. Setting the dummy equal to 1 in the meta-regression is not equivalent to altering the functional form of the underlying studies.

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Similar problems exist when population characteristics in the meta-regression are used for benefits transfer. Suppose that one of the covariates on the RHS of a meta-regression is the proportion of the study sample over 65. It is one thing for estimates of the VSL across studies to show that this coefficient is negative and statistically significant, suggesting that the VSL is lower for persons over 65, and another to set this variable equal to 1 to compute the VSL for persons over the age of 65. The latter treats the meta-regression as a reduced-form model that can be used for benefits transfer. If the meta-regression suggests that age is important, EPA should use the results of studies that control for age, and other factors that are correlated with age, using individual data. These factors (e.g., wealth and income) are controlled for imperfectly in a meta-regression in which the population characteristics are summarized by an aggregate number for each study. The results of various studies may be combined in a structural model, but this is not what is happening in a meta-regression.

How should studies be combined if not using meta-regression? A weighting scheme needs to be selected for calculating a central estimate from the selected study results. One possibility is to combine the estimates in inverse proportion to their variance, i.e., to use a random effects estimator. Another approach would be to use an empirical Bayes estimator (Kochi, Hubbell and Kramer 2006) which weights individual study estimates using measures of between as well as within study variability. Other approaches may also be appropriate depending on the nature of the data and the policy application context. The analyst should explain the rationale for the selected approach.

When studies are combined to inform a particular regulation, it is imperative that (a) the studies pertain to the population affected by the regulation; and (b) that the studies satisfy appropriate criteria regarding their design. We urge EPA to establish such criteria. For example, EPA may wish to specify criteria to minimize the possibility that fatal job risk in an hedonic wage study is correlated with the error term (i.e., that fatal risk is endogenous), which would cause estimates of the VSL to be biased.² In combining studies we do not recommend the use of quality weights, other than the 0-1 weights that are implicit in deciding which studies are of sufficiently high quality to be included in the meta-analysis. Although, in principle, there is no reason why weights should not vary between 0 and 1, in practice determining these weights is likely to be difficult. In the interests of transparency, we urge that a set of criteria for acceptable studies be established and then applied to the literature.

Formulating a list of criteria for an acceptable study and applying them to the literature will necessarily involve expert judgment. Expert elicitation is also useful in determining whether it is appropriate to transfer a VSL estimate in the literature to a specific policy context. The Panel does not, however, recommend expert elicitation for combining estimates from the

²/ Fatal risk may be correlated with the error term in an hedonic wage study for several reasons: unobserved worker characteristics may be correlated with fatal job risk if more able workers choose safer jobs; or objective risk may be mismeasured (Black et al. 2003).

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literature that are amenable to quantitative assessment with meta-analysis techniques. EPA should not directly elicit appropriate VSL values from experts, asking them, for example, to specify a range of acceptable VSL values and/or a mean value based on their knowledge of the literature, if there are published estimates of sufficient number and quality to support a meta-analysis. This requires that the expert combine mentally the results of dozens of studies, and one loses transparency in the process.

- 2. Using the approach identified above, what measures/estimates should be combined? VSL estimates? The coefficient on fatal risk? Other? How should the Agency select the measures to be combined? Should a single, preferred estimate be selected from each study or should all estimates be included?*

We believe that a meta-analysis (e.g., a random effects estimator) should be used to pool VSL estimates from acceptable studies that pertain to the population affected by a regulation. The Panel recommends that only one estimate should be selected from a study that reports several models all estimated from the same dataset. Which estimate should be selected when a study reports several estimates of the VSL depends on the set of criteria that the Agency establishes to determine what is an acceptable study. For example, if different models use different sets of covariates, the Agency should select the model with the preferred set of covariates.

- 3. Should original studies be required to use a common empirical specification (functional form and choice of covariates) in order to be included in a meta-analysis? What data are required of the original studies to be included?*

For compensating wage studies, the Panel recommends that original studies report the results of a common specification of the compensating wage regression, in addition to the author(s)' own specifications. The compensating wage study report or article should also report the estimate of the VSL calculated by the authors and its standard error—the latter being essential for creating the weights to be deployed in the meta-analysis—and ample details on how exactly both were calculated.

We recommend that the compensating wage studies ultimately to be included in a meta-analysis:

- provide information on the source of data on risk to include both information on the death statistics as well as how that data is converted to a risk rate, worker pay (including whether the workers are paid an hourly rate) and worker characteristics;
- include codes for creating the sample used for the compensating wage regressions and for transforming variables;

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- report detailed statistics on risk, such as mean, mode, minimum/maximum rates and standard deviation and average pay for the sample;
- explain whether the author(s) did or did not include non-fatal risks in the compensating wage regression, in addition to the fatal risks variable
- explain whether the sample contains only union workers, or if union membership was controlled for in the regression
- explain whether high-risk workers (e.g., police officers, firefighters, etc.) are included or excluded from the sample
- explain clearly whether the researcher(s) included a quadratic term in risk, and interactions between risk and other variables, in the regression
- explain clearly all covariates included in the regressions. For example, if a set of dummy variables are included for the industry and occupation of the worker, details should be provided on each category included in the model.

For selecting stated preference studies, we recommend that the answers to the following questions be included:

- Was the study a (i) contingent valuation survey, (ii) conjoint choice experiments, or (iii) another type of hypothetical valuation exercise?
- What was the mode of administration of the survey?
- What was the sampling frame? Was a specific population targeted, or was the sample supposed to mirror the general population?
- What was the age of the respondents, split by gender, income, education, health status (if available)?
- What was the type of risk reduction respondents were to value in the SP study? (Was it a reduction in the risk of dying for all causes? Cardiovascular/respiratory causes? Road-traffic accidents?)
- Was the risk reduction immediate and incurred over the next year, or was it delayed into the future?
- Were respondents asked to consider a private risk reduction or one delivered by a public program? What was the payment vehicle (e.g., out-of-pocket costs of medical treatment, taxes, increases in the prices of products or the cost of living)?
- Was the payment one-time or an annual payment to be repeated each year for a number of years? How many years?
- Did each respondent have to value more than one risk reduction in the survey?
- Was the size of the (annual) risk reduction varied across respondents in the study? If so, (i) report the min, max and average risk reductions used in the study, and (ii) did WTP pass the scope test?

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4. *Given the various approaches used in the literature, what is the most scientifically appropriate measure to derive when combining estimates from multiple studies? A single central point estimate, a single distribution, or a range of estimates in economic analyses? How can such a measure best reflect the uncertainty and variability in mortality risk valuation estimates?*

Meta-analysis should be used to provide a description of the probability distribution of the estimates. The resulting probability distribution can be used for uncertainty analysis, and the expected value and other relevant point estimates (e.g., median, 5th and 95th percentiles) can be drawn from it.

5. *How should stated preference studies and revealed preference studies be considered together in a scientifically appropriate method to derive summary estimates of mortality risk valuation?*

The Panel believes that both stated preference (SP) and revealed preference (RP) studies should be considered in valuing mortality risks and that weight should be given to each of them in proportion to how well they each address the policy question at hand. For example, we may have greater confidence in the mean estimates from the wage-risk studies, but they are limited to a working age population and an on-the-job risk context. For some EPA policy questions, SP studies may be a better match to the policy question, such as for an elderly population and an illness-related risk context, although we may have less confidence in the specific mean results from the SP studies. This implies some weighting based on analyst judgment is necessary. We elaborate below on the fact that the two types of studies may, in practice, measure different concepts. We also discuss the strengths and weaknesses of each approach.

Revealed preference (RP) studies, such as compensating wage studies, measure the rate of substitution between risk and wealth. Stated preference (SP) studies measure ex ante willingness to pay for a discrete risk change and can involve changes in other aspects of a respondent's health conditions, such as a period of morbidity or a latency period for a fatal disease. This additional information presented as part of the stated preference questions may influence the measures of ex ante willingness to pay. The mechanism offered for reducing the risk may be a plan or a policy that may also influence the responses and thus the estimated willingness to pay. All of these factors affect comparability among VSL estimates from SP and wage hedonic studies.

Both RP and SP studies rely on several important maintained assumptions. Some economists prefer the SP framework because it is possible to describe the circumstances giving rise to the risk and the health outcomes involved that more closely correspond to the actual expected benefits of environmental regulations. However, other economists are skeptical of

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whether respondents treat the choice situations presented as “real” in the sense that the choices made correspond to what actually would happen if the same individual confronted an actual choice. In addition, some SP studies have demonstrated respondents’ difficulty in providing consistent answers to valuation questions, especially those involving small probabilities of serious outcomes. RP studies on the other hand rest on the maintained hypothesis that individuals correctly perceive risks as the researcher measures them—for example, that parents correctly perceive the reduction in risk of death from a child wearing a helmet when riding a bicycle. The assumption that people have good quantitative estimates of small risks has little empirical support. It is also the case that compensating wage studies must infer the VSL by controlling for many other factors that affect wages, such as worker ability and risk of nonfatal injury, which may be measured inaccurately but also may be correlated with risk of fatal injury on the job. Because different economists weight SP and RP advantages and disadvantages differently, there is no professional consensus about these methodological alternatives. Thus we do not recommend that the Agency rely exclusively on either SP or RP studies, but rather give some consideration to results from both types of studies.

6. *How should the Agency use studies based on specific sub-samples (e.g., elderly) in developing summary estimates of mortality valuation estimates for environmental policy analysis?*

As the Panel noted in answering Life Expectancy Charge Questions 1 and 2, EPA should aim to distinguish the VSL according to age and, possibly, health status, the empirical correlates of life expectancy. This implies that separate meta-analyses would be performed for studies of different populations, for example, persons 30-65 and persons 65 and over if sufficient numbers of such studies are available. However, it is an empirical question as to what population subgroups may have significantly different valuations for mortality risk reductions. Identifying such subgroups should be based on empirical evidence, not assumption. Meta-analyses may be helpful in identifying population characteristics that are important when determining whether a study’s results are applicable for a particular policy analysis.

7. *Most studies that combine estimates adjust the data from the original studies to some extent. For example, some studies adjust for after-tax wages, whereas others do not. Is there a set of such modifications that the SAB-EEAC believes to be critical when deriving summary estimates from the literature? Are there some data modifications that are generally incompatible with a sound approach to synthesizing existing estimates? What are the implications for interpreting results?*

In synthesizing estimates from multiple studies, it is important to adjust as well as possible for differences among the studies, especially for differences in the monetary units used

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in the studies. Such adjustments can be made to studies before including their estimates in a meta-analysis.

One adjustment that can and should be made is to adjust for monetary inflation between studies by converting all nominal monetary values into real values. Because there is uncertainty about the best estimate of inflation over a period (reflected, for example, in different measures such as the various consumer price indices and the GDP deflator), the best adjustment is not clear. However, if one relies only on relatively recent studies (that are likely to be most relevant to the evaluation of current policy), differences between the alternative indices are likely to be modest and contribute little to uncertainty about the appropriate valuation compared with other factors. Similarly, if valuation estimates using other currencies are included, it is necessary to adjust for the purchasing power of the currencies (again, uncertainty about the best conversion rate is not likely to be a major concern). In the case of wages, differences in fringe benefit provisions across countries may be pronounced and must also be considered.

Other adjustments that are in principle desirable are more difficult to make, and so the Panel recognizes our current empirical abilities may not permit these adjustments. One is to adjust for differences in real income and wealth between study populations. Since the value of reducing mortality risk increases with income and wealth, differences in these factors are expected to yield differences in estimated valuation. However, the appropriate magnitude of adjustment is not clear, because of uncertainty about the value(s) of the income elasticity and very little empirical evidence concerning the relationship between wealth and mortality valuation.

A second potential adjustment is to convert all estimates into marginal changes in consumer income (net of taxes and benefits). In hedonic-wage studies, workers' choices are in principle driven by comparing the total incremental compensation with the total incremental risk between jobs, where total compensation includes wages, health insurance, retirement income, compensation conditional on injury, and other benefits, all evaluated post tax. In stated-preference studies, respondents are likely to view payments as coming from post-tax income (in principle, respondents may be asked about payments that would be made using either pre- or post-tax income; this detail is usually not specified but may be inferred from question wording). Adjustment for these factors is difficult because of variation in marginal tax rates and benefit schedules across populations, and so the Panel does not view it as critical, but suggests that research attention be directed toward determining whether such adjustments can be made.

8. *What reporting and other protocols should the researchers conducting the combination study follow? How should the analysis handle zero or negative mortality risk valuation estimates from studies that otherwise meet its selection criteria for inclusion?*

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The purpose of the combination study should be clearly defined. For what population is the study attempting to combine estimates? There should also be an explicit description of the rules for the inclusion and exclusion of items in the combination study, and of the search rule by which the candidate studies were identified in the first place.

There should be systematic coding of important features of the items included in the combination study, for example the metric in which wages are expressed, the metric for risk itself, the other variables included in models involving VSL, and the populations for which VSL was evaluated.

In general, the preferred approach for selecting studies is based on study design criteria, not study results, but there may be limited circumstances when it is appropriate to exclude studies based on results. One of these is a finding of statistically significant negative values for mortality risk reduction (implying the population would prefer a shorter lifespan to a longer one—an implausible result for anything but extreme circumstances). Obtaining statistically insignificant results, implying zero value for an incremental risk reduction, is on the other hand, a theoretically plausible result and is not sufficient reason for exclusion of a study. Implausibly high valuations may raise concerns about study design problems that may not have been identified, but it is very difficult to determine a criterion for exclusion based on “high” results. A preferable approach would be to include an analysis of the effects of outliers on the estimates of mean values and some eventual judgment about how much weight may be appropriate to give the outliers.

9. *What future research or additional data would offer the most improvement in the Agency's ability to derive summary estimates of mortality risk valuation for environmental policy analyses over the short run? What longer-term research is most needed for improved summary mortality risk valuation estimates?*

- Fund more studies that will examine how the VSL varies with age and health status, the empirical correlates of life expectancy.
- Fund more studies that will shed light on the relationship between wealth and mortality valuation (income elasticity of VSL).
- Reanalyze the Pope et al. data to determine whether the impact of air pollution on mortality varies with age, rather than using a constant proportional hazard model).
- Attempt to improve hedonic wage estimates of the value of mortality risk reductions. Existing estimates, as pointed out by Dan Black and co-authors, suffer from omitted variable bias problems and problems of measurement error (in measuring risk of death), which cause estimates of the VSL to be biased.
- Consider combining RP and SP estimates using a structural approach, as in Smith, Pattanayak and Van Houtven (2006).

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- Fund studies to clarify the relationship between: (a) private willingness to pay to reduce own mortality risk (e.g., a private good), (b) private willingness to pay for programs that reduce mortality risk in the community (e.g., a public good) that may incorporate altruistic preferences, and (c) social preferences over programs that reduce mortality risk to people with different characteristics or risks from different sources. Some studies of each of these concepts have been published, but the literature is insufficient to identify possible systematic differences among results and to judge their relevance for EPA decisions.

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Life Expectancy and Mortality Risk Valuation: Charge Questions³ and Responses

1. *What is the most appropriate methodology to use when valuing changes in mortality risk for persons with different remaining life expectancies? Is it appropriate to use a standard VSL to value reductions in mortality risk when information on remaining life expectancy is not available?*
2. *It is anticipated that EPA will need to issue rules affecting persons who differ in their remaining life expectancies in a relatively short time-frame. What does existing research imply about approaches to valuing mortality risk when people have life expectancies of varying lengths? How applicable and relevant is the existing literature and how does the existing theoretical and empirical literature inform these issues?*

According to standard welfare economics the value of a reduction in mortality risk (e.g., in the probability of dying over a stated period) is what a person is willing to pay for it. This amount may be affected by a person's remaining life expectancy, but theory (e.g., the lifecycle consumption model with uncertain lifetime) has little to say about the relationship between willingness to pay (WTP) and remaining life expectancy. Under specific assumptions, the lifecycle model predicts WTP for mortality risk reduction to be first increasing with age and then decreasing with age (an inverted U shape over the adult lifespan). Only in very special cases can it be said that WTP should be an increasing function of remaining life expectancy.⁴ However, there are offsetting influences and it is not possible to predict based on theoretical analysis alone whether WTP is increasing, decreasing, or unchanged over a person's lifetime.

The relationship between WTP for mortality risk changes and remaining life expectancy is, therefore, an empirical matter. Unfortunately, this relationship is difficult to measure since remaining life expectancy is not observable while an individual is still alive. Individuals could be asked in a stated preference study what they would pay to reduce their probability of dying, *assuming different life expectancies*. However, this is a difficult question. In revealed and stated preference studies all that can be observed *ex ante* are correlates of life expectancy: viz., age and health status. So, one could try to measure how WTP varies with age and health status.

This suggests that EPA may, in principle, want to allow WTP to vary with age and health status. It is, however, the Panel's judgment that the empirical literature is not advanced enough at present to provide clear guidance as to how age and health status affect WTP for changes in

^{3/} In some cases, the charge questions were slightly revised to better reflect the Agency's intent, as discussed with the National Center for Environmental Economics.

^{4/} The Appendix to this report discusses the implications of the life-cycle model with uncertain lifetime for the value of mortality risk reductions, explaining that, in general, theory places no restriction on the relationship between WTP and age or remaining life expectancy.

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mortality risk.

Krupnick (2007) and Aldy and Viscusi (2007) provide recent summaries of the empirical literature on age and the VSL. Aldy and Viscusi (2007) focus on revealed preference studies while Krupnick (2007) summarizes the stated preference literature. Aldy and Viscusi (2007) review compensating wage studies by Smith et al. (2004), Kniesner et al. (2006) and Aldy and Viscusi (2006).⁵ Smith et al. (2004) find that the VSL is higher for workers aged 61-65 than for younger workers. Kniesner et al. find a VSL declines slightly after age 50 and then reaches a plateau, whereas Aldy and Viscusi (2006) find a significantly lower VSL for workers 55-62 than for younger workers. Krupnick (2007) reviews 35 studies, 20 of which find some evidence of the VSL declining with age and 15 of which do not. He concludes that, "Thus, considering the weight of the evidence, the implication is that for countries that apply a single VSL to adults of all ages, there is insufficient information and consensus to make a reasoned decision to switch to using either different VSLs for different ages (in a private good context) or a VSLEY, which imposes a linear (discounted) relationship between life-years remaining and the VSL." The Panel agrees with this statement.

We suggest that EPA should, at present, use an age-independent VSL to value mortality risk reductions according to the conventional paradigm. However, we also urge the Agency to report the age distribution of statistical lives saved and the average remaining life expectancies of persons in each age group.

- 3. Are there other areas of the literature that should be examined and how would they inform this issue in the short term (i.e., less than 6 months)?*

The Panel agrees that the White Paper by Dockins, Maguire, and Simon covered the appropriate literature.

- 4. What type of long-term research can inform these issues?*

The Panel agrees that willingness to pay for risk reduction is likely to be affected by remaining life expectancy, which is related to both age and baseline health status. The existing evidence on these relationships is weak and occasionally contradictory. The Panel recommends that additional research be funded to improve these estimates.

- 5. What paradigms should be considered in valuing changes in mortality risk for person with different life expectancies? How will these paradigms inform us in the short term?*

⁵ Although many compensating wage studies interact worker age with fatality risk, they do not measure risk of death by age. Aldy and Viscusi (2007) note that these early studies may therefore yield biased estimates of how the VSL changes with age.

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One paradigm that is commonly used to allow remaining life expectancy to affect the value of a reduction in mortality risk is the *Value of a Statistical Life Year (VSLY)*. As applied in practice, the VSLY assumes that the value of mortality risk reductions is proportional to remaining life expectancy (or discounted remaining life expectancy) and uses this assumption to calculate a value per life year saved. More specifically, the VSLY is derived by dividing the VSL by the discounted expected number of life years remaining for the average individual studied. This approach assumes that the VSL is the sum of the present value of each life year (the VSLY) weighted by the probability that an individual survives to that year, which is equivalent to assuming that the value of each remaining life year is constant.⁶ The resulting VSLY is then applied to the expected number of discounted life years saved by the regulation (i.e., to the predicted increase in discounted life expectancy).

This procedure is difficult to justify on either theoretical or empirical grounds, if the appropriate valuation concept is what a person would pay to reduce his own risk of dying. There is no empirical evidence to suggest that the VSLY is constant, or that the VSL declines in proportion to remaining life expectancy, which the constant VSLY implies. (See answer to charge question 1.) To apply the VSLY correctly would require first estimating how the VSLY varies with age. If this can be done, it would be simpler to use an age-adjusted VSL than using an age-adjusted VSL to calculate and age-adjusted VSLY.

6. *More generally, based on the economics literature, under what conditions is it most important to provide information on life expectancy and baseline risks as part of an economic analysis of environmental policy? If the information cannot be incorporated directly into monetized benefits estimates, how might it best be provided as a supplemental analysis?*

In general, the measure of benefits based on WTP should reflect the WTP of the population that is affected by the change. The central VSL EPA has used in their most recent RIAs (PM and ozone NAAQS) is a midpoint between \$1 million and \$10 million. The former is the lower interquartile estimate from Mrozek and Taylor (2002)'s meta-analysis and the latter is the upper interquartile estimate from Viscusi and Aldy (2003)'s meta-analysis. The Agency notes that the midpoint (\$5.5 million in 1999 dollars and 1990 income levels) is very similar to the mean estimate from the Kochi et al. (2006) meta-analysis, which also included stated preference studies. The wage studies obviously reflect a population of working individuals,

⁶ Formally, the approach assumes that the VSL at age j is, $VSL_j = \sum_{t=j}^T q_{j,t} (1 + \delta)^{j-t} VSLY$, where $q_{j,t}$ is the probability that an individual at age j survives to age t and δ is the discount rate. VSLY can be factored out of this expression, and $\sum_{t=j}^T q_{j,t} (1 + \delta)^{j-t}$ is discounted remaining life expectancy.

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which implies at least some minimal health status (i.e., healthy enough to work) and a specific age distribution (i.e., working age adults) with an associated average life expectancy (estimated to be 35 years). If the population most affected by an EPA regulation or policy change differs from the population represented in these studies, then the WTP estimates generated by these studies may be a biased estimated of the true WTP of the affected population. *Whenever* this is the case, it will be important to provide information on the life expectancy and baseline risk⁷ of the affected population as part of an economic analysis of the policy.

Unfortunately, the current economics literature does not provide convincing evidence regarding the direction of the bias that would exist if the baseline risk and life expectancy of the affected population differ from those of the population included in the WTP studies, i.e., there is mixed evidence on whether increases in baseline risk or reductions in life expectancy increase or decrease WTP estimates (see discussion of other charge questions). Nonetheless, it is important to include these characteristics of the affected population for two reasons: (1) to highlight the potential for bias, even if it is not possible to predict its direction, and (2) to highlight the fact that the policy is likely to affect certain sub-populations disproportionately. While this latter information may not be formally incorporated into the benefit-cost analysis (e.g., by providing WTP estimates that are specific to affected sub-populations), it would provide the basis for an equity assessment, which in many cases is required by statute, executive order, or agency policy. Information about disproportionate impacts can be important input into policy decisions.

The information about baseline risk and life expectancy is most useful if provided in the form of a distribution (rather than simply an average) across the affected population. This is particularly true when the distribution is bi-modal. A bi-modal distribution would exist, for example, in cases where the very young and the very old are susceptible to pollution effects.

⁷ Strictly speaking, the term baseline risk refers to the survival curves of the members of the population affected by the regulation.

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Appendix to Life Expectancy Charge Questions

This Appendix consists of two parts. The first describes the concept of a survival curve and its relationship to life expectancy. The second presents the life-cycle consumption saving model with uncertain lifetime, which forms the theoretical basis for examining the relationship between the Value of a Statistical Life, age and remaining life expectancy.

Survival Curves and Life Expectancy

The effects of an environmental intervention on mortality risk can be summarized using survival curves. Survival curves can be constructed for an individual or a population. An individual survival curve plots the probability that an individual is still alive as a function of her age (or calendar date). A population survival curve plots the fraction of people who are still alive as a function of date. A survival curve can be constructed beginning at any age or date and slopes downward (or is constant) everywhere. A steeper downward slope corresponds to greater mortality risk. The area under an individual's survival curve equals his remaining life expectancy.

Any pattern of change in mortality risk over time can be characterized as a shift in the survival curve. For example, a one year reduction in mortality risk (e.g., from reducing exposure to an acutely lethal pollutant such as carbon monoxide) flattens the survival curve for that year and hence increases its height for later time periods. A risk reduction having only delayed effects (e.g., reducing exposure to a pollutant that causes cancer to develop after a latency period) has no effect on the curve for the time between the change in exposure and the end of the latency period but flattens the curve and increases its height for subsequent periods. Any change in the survival curve produces a unique expected number of life years saved or lost (the change in the area under the curve).

What is typically valued in empirical studies is a change in the probability of dying over the coming year. As explained above, a reduction in the probability of dying over the coming year raises the individual's survival curve for all future years and thereby increases his life expectancy. The next section discusses how a rational, expected-utility maximizing individual would value this change in the context of the life-cycle consumption saving model.

Implications of the Life-Cycle Model for Age and the VSL

This section uses the life-cycle model with uncertain lifetime to derive WTP for a change in the conditional probability of dying at any age (Cropper and Sussman, 1990; Cropper and Freeman, 1991) and to examine how this might vary with age and remaining life expectancy. The model assumes that at age j the individual chooses his future consumption stream to maximize expected lifetime utility,

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$$V_j = \sum_{t=j}^T q_{j,t} (1 + \delta)^{j-t} U_t(C_t) \quad (1)$$

where V_j is the present value of expected utility of lifetime consumption, $U_t(C_t)$ is utility of consumption at age t , $q_{j,t}$ is the probability that the individual survives to age t , given that he is alive at age j , and δ is the subjective rate of time preference. We assume that (1) is maximized subject to a budget constraint that allows the individual to invest in annuities and to borrow via life-insured loans (Yaari, 1965). This is equivalent to assuming that the present value of expected consumption equals the present value of expected earnings plus initial wealth,

$$\sum_{t=j}^T q_{j,t} (1+r)^{j-t} C_t = \sum_{t=j}^T q_{j,t} (1+r)^{j-t} y_t + W_j, \quad (2)$$

where r is the riskless rate of interest, y_t is income at time t and W_j is initial wealth.

Now consider a program that alters D_k , the conditional probability of dying at age k , given that the individual survives to that age. Since $q_{j,t} = (1-D_j)(1-D_{j+1}) \dots (1-D_{t-1})$, any program that alters D_k will necessarily alter the probability of surviving to all future ages. For small changes in D_k , willingness to pay may be written as the product of the rate at which the individual is willing to trade wealth W_j for a change in D_k , which we term $VSL_{j,k}$, times the size of the change in D_k ,

$$WTP_{j,k} = - \frac{dV_j / dD_k}{dV_j / dW_j} dD_k \equiv VSL_{j,k} dD_k. \quad (3)$$

Applying the Envelope Theorem to the Lagrangian function formed by (1) and (2), the rate at which the individual substitutes current wealth for D_k may be written (Cropper and Sussman, 1990) as:

$$VSL_{j,k} = \frac{1}{1-D_k} \sum_{t=k+1}^T q_{j,t} [(1+\delta)^{j-t} U_t(C_t) \lambda_j^{-1} + (1+r)^{j-t} (y_t - C_t)]. \quad (4)$$

Equation (4) says that the value of a change in the probability of dying at age k equals the loss in expected utility from age $k+1$ onward, converted to dollars by dividing by the marginal utility of income (λ_j). Added to this is the effect of a change in D_k on the budget constraint. Cropper and

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Sussman (1990) show that, by substituting first-order conditions for utility maximization into (4) and rearranging terms, the VSL at age j for a risk reduction at age j equals

$$VSL_{j,j} = \frac{1}{1-D_j} \sum_{t=j+1}^T q_{j,t} (1+r)^{j-t} [U_t(C_t)/U'_t(C_t) + y_t - C_t]. \quad (5)$$

If the individual does not have access to fair annuities, but can save at the riskless rate r (i.e., he can never be a net borrower), then the expression in (5) holds without the last two terms inside the brackets.

It is $VSL_{j,j}$ that is estimated in compensating wage studies. Most stated preference studies measure (3) (with $j=k$). The question is how (5) changes with j . If $U_t(C) = U(C)$ for all t , and $r = \delta$, then C_t is constant for all t . In the case in which the individual can save at rate r (but never be a net borrower), the term in brackets is constant and $VSL_{j,j}$ becomes

$$VSL_{j,j} = \frac{1}{1-D_j} \sum_{t=j+1}^T q_{j,t} (1+r)^{j-t} [U(C)/U'(C)]. \quad (6)$$

In this special case, if $(1-D_j)^{-1}$ is close to 1, $VSL_{j,j}$ is likely to decline with age, j . Since

$$\sum_{t=j+1}^T q_{j,t} (1+r)^{j-t}$$

represents discounted remaining life expectancy, $VSL_{j,j}$ is approximately proportional to discounted remaining life expectancy, which would justify the use of a constant VSLEY. Equation (6) is, however, a very special case.

In general, as equation (5) demonstrates, one cannot make any statement regarding how $VSL_{j,j}$ varies with age j . This depends entirely on the pattern of consumption and utility of consumption over the lifecycle.

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Compilation of EPA ORD Research Program Descriptions
(October 2, 2007)

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1. Human Health

a) HUMAN HEALTH RESEARCH (MYP) (Hugh Tilson)

1. Program Context

In 1997, the National Research Council (NRC) published a report entitled *Building a Foundation for Sound Environmental Decisions* indicating that the Environmental Protection Agency (the Agency) should develop a research program to provide a fundamental understanding of key biological and exposure-related processes in order to forge basic scientific capabilities and methods that can be applied to a wide variety of environmental problems. In response to the NRC recommendation, the Agency established the Human Health Research Program (HHRP) in the Office of Research and Development (ORD). Overarching themes for the HHRP were developed following an Agency-wide meeting of Program and Regional Office scientists and staff and ORD scientists and managers. These themes included research to: 1) improve the scientific foundation of human health risk assessment and 2) enable evaluation of public health outcomes. It also determined that the former theme would emphasize three topics, including 1) harmonizing approaches to cancer and non-cancer risk assessment, 2) assessing aggregate and cumulative risk, and 3) evaluating risks for susceptible and highly-exposed subpopulations. The strategic direction of the HHRP was subsequently documented in the *Human Health Research Strategy* published in 2003. A Multi-Year Plan (MYP) describing the research themes and projected outputs for a 3-5 year period was published in 2003 and updated in 2006. Research in the HHRP supports data needs arising from the Agency's risk assessment process (Human Health Risk Assessment Program), as well as fundamental information gaps in problem-driven MYPs (Air, Drinking Water, Endocrine Disruptors, Safe Pesticides/Safe Products).

There have been several shifts in scientific and programmatic emphasis in the HHRP since 2003. In 2005, the Agency published the *Cancer Risk Assessment Guidelines* which emphasized the importance of using mechanistic information to establish the human relevancy (biological plausibility) of toxicological models. Based on this guidance, the HHRP increased its efforts to develop principles for the use of mechanistic information and dose-response models to reduce the dependence on default assumptions in risk assessment. Research from 2003-2006 that was focused on issues related to aggregate exposures and chemical mixtures has matured; subsequent research has emphasized tools and approaches to support cumulative risk assessment. From 2003-2006, research on susceptible subpopulations focused on how external (i.e., diet, preexisting disease) and internal (genetics, age) factors contributed to selective vulnerability. Research since 2006 has focused on the role of life-stage as a key determinant of vulnerability. There was little research on the topic of evaluation of public health outcomes during the period from 2003-2006. Since that time, two demonstration projects were funded to assess the impact of drinking water regulations related to microbial pathogens and the cumulative impact of air pollution reduction programs on environmental public health indicators for children and older individuals.

2. Strategic Directions, Science Challenges, and Research Needs

Two recently published documents articulate the scientific challenges for the HHRP in the next 10-15 years.

A. The NRC recently published a report *Toxicity Testing in the Twenty First Century: A Vision and Strategy* which describes the research needed to develop approaches to chemical toxicity characterization and prediction. Developing cost-effective approaches to prioritize chemicals for screening and testing continues to be a high priority for Program and Regional

Offices. There is a widely recognized need to reduce the number of animals used in testing, reduce the overall cost and time required to characterize each chemical, and increase the level of mechanistic understanding of chemical toxicity. Recently, ORD formed a *Future of Toxicology Working Group* which has been tasked with identifying how ORD intends to respond to the research needs mentioned in the NRC report. As noted in the NRC report, approaches for future toxicity determination will occur in four stages, including characterization of chemical properties related to environmental distribution, exposure risk, physico-chemical properties, and metabolism; toxicity pathway characterization to determine which biological changes activated by a chemical are associated with deleterious effects; targeted testing to relate *in vitro* effects to *in vivo* conditions; and dose-response and extrapolation modeling to perform low dose extrapolation. Scientific challenges associated with this approach include the need to:

- Obtain comprehensive knowledge of how chemicals interact with potential target sites;
- Develop quantitative bioassays to measure those interactions;
- Develop approaches to evaluate chemical effects during different stages of development;
- Develop approaches to evaluate potential interaction of chemicals in mixtures;
- Develop approaches to characterize potential exposure-to-effect linkages;
- Develop approaches that can evaluate impact of genetic polymorphisms in testing; and
- Develop models to predict effects for screening and testing.

These challenges will undoubtedly drive research in many of ORD's research programs and the HHRP will play a significant role given its current capacity to address many of these challenges.

B. Over the last several years, there has been increased interest in assessing the effectiveness the Agency's regulatory and non-regulatory decisions. In that regard, several knowledge gaps, uncertainties, limitations, and scientific challenges were identified in the 2003 and Draft 2007 Reports on the Environment (ROEs). The ROEs noted that the science underlying the Agency's key public health functions (e.g., describe, explain, predict, and evaluate) must be strengthened before it can begin to evaluate effectiveness of its environmental decisions. The ROE identified several gaps/limitations:

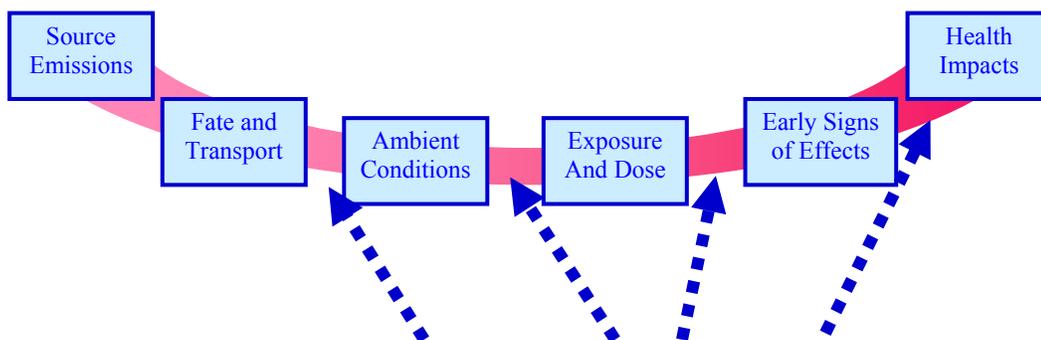
- The need to establish the necessary degree of predictive validity between indicators of each component of the source-exposure-dose-health continuum and the use of these indicators to demonstrate the impact of decision-making;
- The need to develop and evaluate methodologies for understanding the contribution of non- chemical risk factors to a given health condition;
- The need to evaluate susceptible and vulnerable subpopulations, such as children and the elderly;
- The need to evaluate aggregate and cumulative risks; and
- The need to build collaborations with other federal agencies and non-governmental bodies to collect health surveillance and exposure data at national and sub-national levels.

The ROE also noted that determining the effectiveness of environmental decisions is contingent on identifying the extent of human exposures and developing measurements of health outcomes, including potentially environmentally related neurodevelopmental disorders, neurodegenerative diseases associated with aging, diabetes, reproductive disease, and renal disease.

3. ORD's Current and Future Research Directions

The main objective of the current HHRP (FY 07 enacted budget) is to reduce uncertainties associated with the risk assessment process by providing a greater understanding of exposures to environmental stressors and the basic biological changes that follow. The HHRP develops the methods, models and data to reduce uncertainty in the "critical links" across the exposure-to-effect paradigm. The research program has four Long-Term Goals (LTGs).

Human Health Research Program



Human health research develops the methods, models, & data to reduce uncertainty in the 'critical links' across the source-to-exposure-to-effect paradigm

LTG 1 Risk assessors/risk managers use ORD's methods, models and data to reduce uncertainty in the risk assessment process. Under this LTG, the HHRP conducts research to provide new methods for hazard identification and testing, including the use of stem cells for cross species extrapolation and hazard identification and developing proteomic and genomic methods for screening and testing. This research also focuses on developing source-to-effect models for risk assessment. Two major projects under way are developing a biologically based dose-response model for arsenic and linking exposure, internal dose, and health effects data for the pyrethroid insecticides. Research on arsenic is critical for defining its mode of action (MOA) for low-dose extrapolation. The pyrethroid project is critical for the pending cumulative risk assessment of these insecticides by OPPTS. HHRP develops principles for the use of mechanistic data to reduce uncertainties in extrapolation (animal-to-human, *in vitro*-to-*in vivo*, high-to-low dose) in risk assessments, as well as providing MOA data to inform the choice of dose-response models for risk assessments. This research focuses on identifying key toxicity pathways or potential MOAs for prototypic classes of chemicals or generic modes of toxic action. Mechanistic data are produced to resolve data gaps identified by the Agency's risk assessors (National Center for Environmental Assessment) and to support regulatory decisions by Program and Regional Offices.

LTG 2 Risk assessors/risk managers use ORD's methods, models and data to characterize aggregate and cumulative risk. Under this LTG, the HHRP conducts extramural and intramural research to develop and interpret biomarkers for risk assessment of multiple environmental stressors, including pulmonary biomarkers for exposure to mixtures of air

pollutants, measurement studies to relate biomarkers to documented exposure of multiple environmental stressors, models to predict and interpret the results of biomonitoring studies, and studies to understand inter- and intrapersonal variability of biomarkers. The HHRP also develops and maintains exposure-related databases and develops probabilistic exposure and dose models for cumulative risk. The HHRP has provided exposure, dose, and MOA data and statistical approaches in support of the cumulative risk assessment for carbamates and is working with OPPTS to develop source-to-effect models for the FY11 cumulative risk assessment of pyrethroids. Research under this LTG 2 also focuses on developing the tools and framework to assess chemical and non-chemical stressors at the community level. HHRP research develops principles for the assessment of cumulative risk by the Agency's risk assessors and Program and Regional Offices.

LTG 3 Risk assessors/risk managers use ORD's methods, models and data to provide adequate protection for susceptible subpopulations. The primary focus of research of this LTG is on the influence of life stage on exposure and responsiveness to environmental agents. Research under this LTG is studying the long-term health effects (cardiovascular disease, obesity) of developmental exposures and evaluating the differential exposure and biological sensitivity of older individuals to environmental agents. LTG 3 supports work to develop tools for characterizing real world exposure for vulnerable populations, which includes conducting laboratory and chamber studies to test exposure hypotheses and understand factors influencing exposure, observational studies to characterize factors influencing exposures, and field studies to characterize the presence and magnitude of pollutants in children's environment. This LTG supports the Agency's contribution to the National Children's Study and research to determine the differential vulnerability of native populations. Children's Centers supported by the extramural program focus on the influence of environmental factors on neurodevelopmental disorders, asthma, and growth/development in children. The HHRP also develops animal models to assess the causes and exacerbation of asthma in susceptible subpopulations and the relationship between exposure to molds, allergenicity, and asthma, especially in children. HHRP develops data to protect the health of vulnerable populations such as children during the risk assessment process.

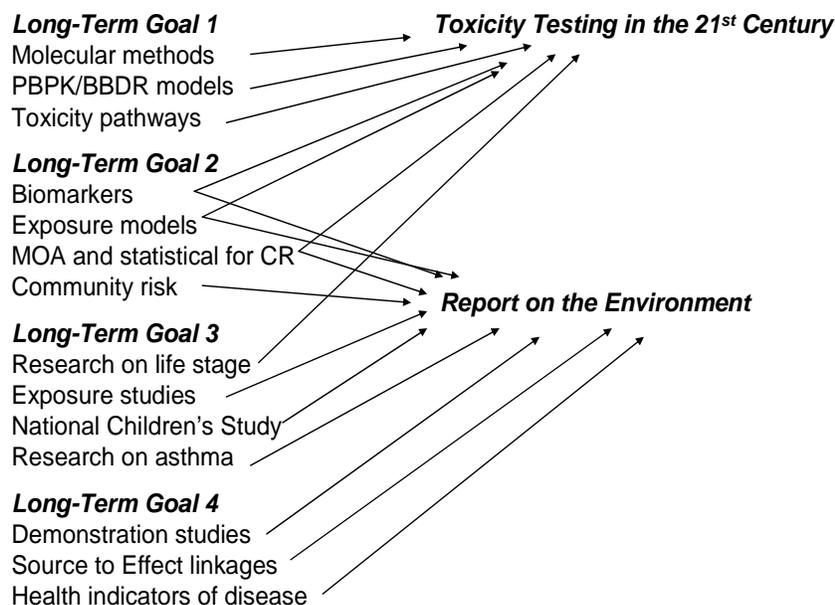
LTG 4 Risk assessors/risk managers use ORD's methods, models and data to evaluate the public health impact of environmental decisions. The HHRP supports demonstration projects to assess the impact of drinking water regulations related to microbial pathogens and the cumulative impact of air pollution reduction programs on environmental public health indicators for children and older individuals. The program is now developing approaches that link source-exposure-effects to evaluate impact of regulatory decisions in accordance with recommendations from the ROEs.

HHRP will transition from the current four LTGs to a program addressing scientific challenges discussed in the NRC report on *Toxicity Testing in the 21st Century* and the 2003 and Draft 2007 ROE (see figure on next page). Much of the research in LTG 1 (i.e., developing molecular methods, biologically based dose-response models, identifying toxicity pathways) is consistent with the scientific needs discussed in the NRC report. Much of the research currently in LTG 2 will inform both areas, driving the development of 1) biomarkers of exposure and effect for both testing and developing source to effect linkages, 2) exposure and dose models to provide the context for the NRC toxicity testing model and the critical link between source and effect, and 3) MOA and statistical models for cumulative risk for testing and assessing risk management decisions. Fundamental research to determine the influence of life stage on sensitivity to environmental agents also addresses research needs indicated in the NRC report. Developing linkages between source-to-exposure-to-effect as articulated in the ROEs is consistent with ongoing research to develop predictive biomarkers for cumulative risk, exposure and dose models,

community risk, the National Children's Study, research on asthma, and research currently covered under LTG 4.

Moving the HHRP from its current state to one that addresses research needs described by the NRC report and the ROE will take place over the next 2-3 years. The reorientation of the HHRP will be documented after the next review of the HHRP by the Board of Scientific Counselors (BOSC) in 2008 and in the next revision of the HHRP MYP scheduled for 2009. Guidance for research at the project level related to the NRC report will be primarily based on deliberations of ORD's *Future of Toxicology Working Group*. Guidance for research related to the ROE will depend on the outcome of two impending workshops, i.e., Public Health Applications of Human Biomonitoring to be held September 24-25, 2007, and Assessing Public Health Impacts of Risk Management Decision to be held January 14-15, 2008. The development of annual outputs and delineation of annual performance goals will evolve following discussion with the relevant Program and Region Offices, as well as the HHRP Research Coordination Team and documented in the next revision of the HHRP MYP.

ORD is in the right place to pursue the research needs indicated in the NRC report and the ROE. The Agency, the National Toxicology Program, and the National Institutes of Health Genomics Center of the National Human Genome Research Institute are establishing a Memorandum of Understanding (MOU) that will guide the evolution of a detailed research strategy to move toxicology to a predictive science based on relevant tools of modern molecular biology and chemistry. Research supported by LTG 1 of the HHRP and ORD's National Center for Computational Toxicology is already addressing many of the research needs articulated by the NRC and is contributing to the application of methods and models for human health risk assessment. With regard to research associated with the ROE, the Agency has already developed a MOU with the Centers for Disease Control and Prevention (CDC). CDC is developing a national environmental public health tracking network to develop and evaluate public health actions to prevent or control chronic and acute diseases that can be linked to hazards in the



environment. At present, the Agency and the CDC are working together to develop an on-going assessment of environmental and data health needs, discuss future pilot projects to examine specific data sets, and exchange information on data standards and technology. That CDC will play a significant role in working with the Agency to develop a research program addressing research needs mentioned in the ROE at upcoming workshops on public health applications of biomonitoring data and assessing public health impacts of risk management decisions. While CDC's mission is essentially to develop tracking systems for data, ORD is in a unique position to demonstrate the linkages from source-to-exposure-to-effects necessary to interpret biomonitoring data that can be used to assess the impact of environmental decision-making.

4. Making a Difference

ORD will work with other federal partners to implement technologies that allow for collection of quantitative data at the cellular and molecular level, develop reliable extrapolation models based on the rodent/human/*in vitro*/*in vitro* parallelogram, and develop robust *in vitro* models that incorporate broad metabolic capability and development stage. This research contributes directly to the need to develop approaches to facilitate prioritization of chemicals for screening and testing. HHRP research will also contribute to the development of biologically based dose response models linked with current exposure and dose models that could be used for future Agency risk assessments.

ORD's HHRP will identify a suite of biologically interpretable indicators for health effects and chemical classes of regulatory importance that could be used in temporal context at the regional and national level. HHRP will collaborate with Federal partners such as CDC to implement a tracking system that captures health and biomonitoring information for a more inclusive list of diseases and interpretable battery of endpoints for environmental stressors over time at the national and regional level. HHRP research will also contribute to generic approaches for assessment community risk. This research will contribute directly to the ability of the Agency to determine how its regulatory decisions protect human health.

b) COMPUTATIONAL TOXICOLOGY (Framework) (Jerry Blancato)

1. Program Context

The main objectives of the CTRP are to develop enhanced tools for prioritization of hazard, and improved methods of quantitative risk assessment, respectively. It is well recognized that the traditional approaches for chemical hazard and risk are not capable of keeping pace with the increasing demands being placed upon multiple Program Offices. Thus, the vision of the program is that the modern tools of molecular biology, information management, and computational models will become pervasive in risk assessments being conducted by the Agency so that we increase the efficiency and effectiveness of those activities. This area of science is expected to result in several approaches to make identification and characterization of hazard and risk faster, cheaper, and more scientifically robust. Ultimately this work will lessen the total reliance on animal studies by systematically using in-vitro and in-silico derived information with a more limited set of in-vivo studies to help assess risk. This work will also be a big step forward in establishing molecular based mechanisms of toxicity which will replace current default assumptions in risk assessments and better characterize sensitive sub-populations. These characterizations will be based on actual mechanisms of toxicity rather than default binning based on age or gender alone.

The program has evolved over several years at ORD. Work in this area has been going on for some time. In 2002 the development of a formal program was started. The initial impetus was a Congressionally ordered redirection of funds to develop alternative methods to reduce the use of animals in toxicity studies. The value of these approaches was quickly realized and the impetus was expanded to the realm discussed in the previous paragraph. [A Framework for a Computational Toxicology Research Program](#) was published in 2003 in which the goals and objective of the program were developed and articulated. The National Center for Computational Toxicology (NCCT) was formed in 2005 to provide a cadre of expertise to development the computational backbone for the program.

2. Strategic Directions, Science Challenges, and Research Needs

The strategic objectives of the CTRP are to improve understanding of the linkages between the source of a chemical in the environment 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 underlying biology. The Agency and the risk assessment community are faced with the enormous challenge of testing thousands of chemicals and exposures with limited funds and time and to also reduce the use of and reliance on animal testing. Traditional toxicology methods have typically tested single or few chemicals at a time at significant costs, high or limited doses and have required long times to gather and interpret the results for risk assessment. Clearly the science needs to be developed for faster and reliable testing that can also test more and more realistic exposure scenarios. In fact, The National Research Council (NRC) published a report *Toxicity Testing in the Twenty First Century: A Vision and Strategy* which describes the research needed to develop approaches to chemical toxicity characterization and prediction. Developing cost-effective approaches to prioritize chemicals for screening and testing continues to be a high priority for Program and Regional Offices. Example specific questions include:

How can more chemicals be prioritized and ultimately tested?

How can molecular studies be done to help better understand underlying mechanisms and thus reduce uncertainty?

How do xenobiotic induced effects interact with underlying genetic predisposition and underlying disease? Can genetic variability be quantified?

Better understand how risk develops and changes at different life-stages?

3. ORD's Current and Future Research Directions

The research in the CTRP is organized around 3 Long Term Goals (LTGs) which are:

Long-Term Goal 1 -: *EPA risk assessors use improved methods and tools to better understand and describe linkages across the source to outcome paradigm*

Long-Term Goal 2 - *EPA Program Offices use advanced hazard characterization tools to prioritize and screen chemicals for toxicological evaluation*

Long-Term Goal 3 - *EPA risk assessors and regulators use new models based on the latest science to reduce uncertainties in dose-response assessment, cross-species extrapolation, and quantitative risk assessment.*

Research is addressing those goals in three key areas, areas, information technology, chemical prioritization and categorization, and systems biology models. The work is summarized and outlined here:

Information Technology: New technologies are needed to mine existing data for patterns to place chemicals of unknown hazards appropriately in the context of existing data. In addition, new technologies will allow the integration of data from different domains of toxicology with and newer “omics” data.

DSSTox: In FY07/08, the ongoing DSSTox project will reach coverage of over 9,000 unique chemicals as it expands its efforts to structure annotate and extract summary toxicity data content from old and new sources of toxicity data, performing stringent chemical information quality review, involving source experts in primary documentation and data summarization, and publishing these as independent, standardized DSSTox data file modules. FY09 will witness expanding involvement with the ToxCast™, NTP HTS data generation efforts, and collaborations with European counterparts. The DSSTox project will be an important structure-annotated summary toxicity data conduit to the NCCT ACToR system as well as PubChem.

ACToR: A data management system (ACToR, Aggregated Computational Toxicology Resource) is being developed to handle the needs of the computational toxicology program, including ToxCast™, DSSTox and the Virtual Liver. This system will consist of several databases and computer applications for data access and analysis. During 07-08, we will develop databases to hold chemical structure, HTS and other assay data, experimental design information, in vivo toxicology data and genomics meta data. The system will be populated with data from the ToxCast™ Phase I experiments, ToxRefDB (defined below under the ToxCast™ program), DSSTox, and from other EPA and external data sources. It will be accessible inside the EPA via a web interface. In conjunction with the Office of the Science Advisor and OEI, a genomics data repository will be developed using the FDA-developed ArrayTrack system that will improve data security and data sharing capabilities. In FY09 and beyond, the ACToR system will begin to integrate other types of quantitative biological and toxicological data on chemicals. A version of the system will be made available on the external web site for use by outside researchers. A second version will house CBI data used in OPPT and other officers. Additionally, we will build

interfaces to the data system to allow direct access by data analysis tools for modeling, simulation and statistical analysis.

Chemical Prioritization and Categorization Tools: Having the capability to predict which chemicals are in greatest need of toxicology testing, and what endpoints would be the most important to examine, is a pressing problem for multiple regulatory offices in EPA..

ToxCast™. ToxCast™ is a multi-component program launched in FY07 following the establishment of an IAG with the NIH National Chemical Genomics Center and the awarding of nine research contracts for high throughput screening. The long term goal is to deliver a toolbox of high through put screening assays for use in predicting the types of toxicity likely to be induced in traditional animal toxicology studies. In Phase I, proof of concept fingerprints of biological activity associated with differing toxicological profiles for 320 pesticidal actives are being obtained and compared to known chemically induced phenotypes. In FY08, ToxRefDB, the supporting relational repository of traditional mammalian pesticide registration study outcomes created in partnership with OPP, will be completed. In FY09 and beyond, plans are to begin Phase II of ToxCast™ that will profile the activities of target groups of chemicals such as the anti-microbials the pesticidal inerts and the high production volume chemicals. With successful completion of Phases I and II, ToxCast™ technologies can be applied to chemicals of concern to EPA program offices.

Molecular Modeling to Predict and Understand Chemical Toxicity The focus of this program is computational modeling the interactions of environmentally relevant chemicals and biomolecular targets, in order to aid in the evaluation of the risks posed by these chemicals. Currently the focus has been on the binding to nuclear receptors. By FY 2009 the focus will shift towards the consideration of other interaction targets in biological macromolecules such as cofactor binding sites in receptors and enzymes that play a role in reactive processes. These additional targets will become part of a library of targets available for an activity screen.

Systems Biology Models: Modeling now plays a crucial role in practically all areas of biological research. Systems models integrate information at all levels of organization and aid in bridging the source-to-outcome paradigm and in conducting quantitative risk assessments.

The Virtual Liver. This project was initiated in FY07 as a joint effort of NCCT, NHEERL, NERL and NCEA. The goal is to create a network of internet based resources for use in understanding and predicting chemically induced liver toxicity. During FY 07/08 the Virtual Liver will focus on a computational systems model of the early molecular response to xenobiotic exposure in hepatocytes that act thru activation of a variety of nuclear receptors. The Virtual Liver will be developed as a flexible and extensible software architecture consisting of a hepatic knowledgebase (HepatoCyc), a biological network inference tool (HepatoMap) and a systems modeling and simulation tool (HepatoSim). In FY09 and beyond, the Virtual Liver will be extended to model hepatocellular fate as a function of molecular perturbations induced by xenobiotic exposure. The tentative biological use-case will include xenobiotic-induced hepatocellular proliferation (e.g. caused by phenobarbital) with supporting in vivo rat/mouse experimental data on large-scale gene-expression, proteins, metabolites and quantitative liver histopathology. Ultimately we expect this project to impact our understanding of susceptible subpopulations as we provide models that incorporate various environmental and genetic aspects of inter-individual differences. In the future the virtual liver serves as a template for such development in other tissues and organs. It is expected that the path for other tissues and organs in the future will be shorter and easier as a result of the virtual liver development.

Life Stage Models. A biologically based model to estimate exposure throughout lactation and early post-weaning period is under development, with particular emphasis on compounds with longer half-lives such as PFOA. In collaboration with NCEA, age-specific physiological parameters databases are being developed and will be prepared for posting to the internet. In FY09, the one generation model will be extended to incorporate PBPK aspects and further benchmarked against data for specific chemicals. Comparisons will be made with the current risk assessment approach using external measures of maternal exposure.

Susceptible Subpopulations. FY07-09 work in the area of susceptibility will focus on analysis of data collected as part of the Mechanistic Indicators of Childhood Asthma (MICA) study (an HSD/NHEERL lead CompTox New Start). Advanced statistical and machine learning methods will be applied in combination with mechanistic information to evaluate multiple types of biomarker data collected in MICA. As we move into FY08-09, the focus will shift toward developing methods and tools to link gene expression and SNP data with environmental and behavioral variables and application of a systems biology approach to provide mechanistic-based guidance for empirical analyses and to identify data gaps for future studies.

Statistical Methodology for Estimating Parameters in PBPK/PD Models. The International Workshop on Uncertainty and Variability in PBPK Models took place in FY07 and a summary has been published in Toxicological Sciences. More detailed white papers covering statistical methodology, PBPK model development, and approaches to assessing variability and uncertainty in PBPK models in risk assessment are also being prepared for publication in FY08. An additional paper on assessing parameter identifiability in PBPK models is under development. Work is beginning on approaches for using parallel computing to speed up computations, which should lead to a useable software framework in FY08. In FY09 we will apply the approach (e.g., pyrethroids for the OPP cumulative risk assessment).

Improving Dose-Response Analysis to Reduce Uncertainty in Risk Assessment. The goal of this project, which was initiated in FY07, is to establish standards of practice for incorporating mode of action descriptions into quantitative models of dose-response. The U.S. EPA's Guidelines for Carcinogen Risk Assessment state that biologically based models for dose-response are the preferred method for low dose extrapolation. This preference is motivated by the reduction in uncertainty obtained when default assumptions used for dose-response modeling are replaced by accurate descriptions of the mode of action. Mode of action information will be incorporated into quantitative models to predict dose-response behaviors for the carcinogenic effects of arsenic and formaldehyde. Relatively rich databases are available for these chemicals and they are of regulatory interest. Endpoints of regulatory concern and the key datasets on the respective modes of action for these chemicals will be identified. Appropriate research will be conducted to fill datagaps. Close interaction between NCCT, NHEERL, NCEA and relevant program offices will be critical to ensure both the scientific rigor of the models and their suitability for use in regulatory actions. Products will be delivered based on regulatory timelines.

Metabonomics. The user-accessible ORD Metabonomics Facility, located in NERL/Athens will continue to be focused on advancing the use of metabonomics and metabolism for identifying biomarkers of exposure, reconstructing exposures, and providing high quality data and scientific knowledge that will improve future exposure assessments. NERL is initiating an Implementation Planning process for Computational Toxicology that will identify and prioritize the specific research activities that will be planned and conducted for the period FY08-FY12

Why ORD?

ORD has the expertise and experience to conduct this work. ORD is one of the leading organizations at applying new methodologies to the risk assessment process. While health based

research organizations and the pharmaceutical industry have already laid a ground work for using computational biology to study the underlying molecular mechanisms of disease and prioritizing drug actions ORD is at the forefront of applying these techniques and knowledge gained to understanding toxicity and better interpreting the drivers of risk. Further this work will help the Agency and risk assessment community reduce some of the uncertainties in risk assessment and to make more sound predictions faster and cheaper than by current methods. Over the last several years, ORD has embarked on a great deal of this research to help change how toxicity testing is performed and how the results are applied to risk assessment. Many of the important thrust areas recommended in the recent NRC report are well underway at ORD. Given the wide expertise within ORD and the responsibility for and experience in conducting risk assessments for the nation ORD is in prime position to apply the fruits of this research. The work is being done with wide collaborative efforts both inside and outside the Agency. Nine expert firms are working on the ToxCast™ project. The virtual liver project involves a large number of experts from within ORD and is being expanded to include University and other federal researchers. Further support will come from firms that are expert in biologic computing. We have set up several communities of practice in areas of ORD research with members from diverse organizations within and outside the Federal government. ORD and OPP are collaborating with OECD in several areas as well.

4. Making a Difference

Some anticipated key accomplishments in 2008 and beyond

Increased development of in-vitro and in-silico methods to identify and quantify toxicity pathways for exogenous chemicals, with special emphasis on nuclear receptor mediated cellular events.

2008: Biologically based model of prostate androgen dependent gene regulation incorporating genomics data resulting in a better basis for understanding risk for chemicals affecting this organ.

2008: Evaluation of modeled dosimetry for rat fetus and pup for a series of compounds selected on the basis of possessing varying degrees of biological persistence and lactational transfer to inform the uncertainty in use of maternal exposure dose in risk assessments

2008: Assist with the development of procedures and capabilities for deriving chemical signatures for predicting toxicity outcomes from the complete profile of [Distributed Structure-Searchable Toxicity \(DSSTox\)](#) data files. This will be of direct positive impact to the IRIS and other risk assessment processes.

2008: Publication of the results of Phase I (initial proof of concept) of the ToxCast™ program, and launch of Phase II (signature extension and validation). ToxCast™ will provide a major new way to prioritize chemicals benefiting the Agency and others and of immediate help to the Office of Pesticide Programs.

2008 and beyond: pharmacodynamic and pharmacokinetic models better describing pathways of toxicity and relationship to environmentally relevant exposure levels for arsenic as a prototype for how multiple modes of postulated action can be empirically examined and computationally modeled.

2009 begin Phase II of ToxCast that will profile the activities of target groups of chemicals such as the anti-microbials the pesticidal inerts and the high production volume chemicals.

2010 and beyond: with successful completion of Phases I and II, ToxCast technologies can be applied to chemicals of concern to EPA program offices.

2011: Development of virtual liver a multi-scale, computational model of the liver that incorporates anatomical and biochemical information relevant to toxicological mechanisms and responses

c) ENDOCRINE DISRUPTORS RESEARCH (MYP) (Elaine Francis)

1. Program Context

It has been suggested that humans and domestic and wildlife species have suffered adverse health consequences resulting from exposure to chemicals in the environment that interact with the endocrine system. However, considerable uncertainty exists regarding the relationship(s) between adverse health outcomes and exposure to environmental contaminants. For example, despite the identified potential hazard, we know little about specific toxicity pathways that lead to neither the identified effects nor the factors influencing environmental exposures and the environmental concentrations of endocrine disrupting chemicals (EDCs) that would be required to induce effects at the population level. Nevertheless, it is known that the normal functions of all organ systems are regulated by endocrine factors and small disturbances in endocrine function, especially during certain stages of the life cycle such as development, pregnancy and lactation, can lead to profound and lasting effects. Research on endocrine disruptors was first identified as one of the six high-priority topics in the ORD Strategic Plan in 1996. This was based upon recognition of: 1) *the potential scope of the problem*, 2) *the possibility of serious effects on the health of populations*, 3) *the persistence of some endocrine-disrupting agents in the environment*, and 4) *the widespread global concern about the fate and transport over national borders*.

The Endocrine Disruptors Research Program (EDRP) is providing the Agency with the scientific information it needs to reduce or prevent unreasonable risks to humans and wildlife from exposures to individual pesticides and toxic chemicals and environmental mixtures of chemicals that interfere with the function of the endocrine system. For over a decade, the EDRP has been conducting research to: 1) develop methods, models, and measures to provide a better understanding of the science underlying the effects, exposure, assessment, and management of endocrine disruptors; 2) apply the methods models and measure, we and others have developed to determine the extent of the impact of endocrine disruptors on humans, wildlife and the environment; and 3) support the Agency's screening and testing program that was mandated in 1996 by the Food Quality Protection Act (FQPPA) and Safe Drinking Water Act Amendments (SDWAA). There has been a transition of the EDRP over the last five years from focusing on effects research to supporting more research on characterizing sources and occurrences of EDCs.

2. Strategic Directions, Science Challenges, and Research Needs

The highest priority for the EDRP is the completion of the development of protocols for the assays critical to the Agency's Endocrine Disruptors Research Program (EDSP). Over the last ten years the program has conducted the underlying research, developed and standardized protocols, prepared background materials for transfer, briefed Agency advisory committees, participated on international committees on harmonization of protocols, and/or participated in validation of 18 different *in vitro* and *in vivo* assays for the development and implementation of the Agency's two tiered Endocrine Disruptors Screening Assay (EDSP). Collectively this part of the EDRP is leading to the development of protocols critical to the success of the Agency in fulfilling its Congressional mandates to develop and implement a screening and testing program. After the development, standardization and validation, these screening and testing protocols will be used not only by the USEPA to require the testing of chemicals, but also internationally through the Organization for Economic Cooperation and Development's (OECD) test guidelines program and possibly by other regulatory agencies. The process to develop and implement screening and testing program has had a high profile and the products are closely scrutinized by the US Congress, stakeholders, and the scientific community within the US and internationally.

As data begin to be submitted to the Agency through the EDSP, OPPTS needs to be able to interpret the findings and integrate them into assessments. There are a number of scientific uncertainties for which research is still needed. For example:

understanding of how EDCs elicit toxicity through receptor-based interactions, membrane receptors, enzyme alterations, and other non-nuclear receptor-based pathways, **particularly at the low end of the dose-response curve** is especially relevant to evaluating effects at ambient environmental levels of exposure will lead to improved methods to interpret data and, thus, improved risk assessments.

determining the degree to which the effects of EDCs with defined mechanisms/modes of action (MOAs) can be extrapolated across classes of vertebrates. This research is needed to: 1) reduce the uncertainty associated with extrapolating effects of chemicals across species, and 2) understand the degree to which quantitative extrapolation is defensible/possible, comparative toxicological studies using chemicals with well-defined MOAs are necessary. Of significance, the development of approaches to evaluate and conduct inter-species extrapolation research should ultimately help reduce uncertainties in both human health and ecological risk assessments and reduce the number of animals needed for testing.

developing approaches to assess exposures to mixtures of EDCs. The current Agency default for predicting the effects of mixtures is to assume dose addition. There is a critical need to determine if this assumption accurately predicts the empirical effects of mixtures of endocrine disruptors, with similar and with different mechanisms of action. Furthermore, it is critical to develop approaches to facilitate incorporation of these data into risk assessments.

determining the critical factors that account for exposures during development resulting in toxicities occurring later in life (e.g. windows of vulnerability, developmental tissue dosimetry, modes of action). Development is a period when hormone-mediated changes in gene expression can have permanent consequences that may not be apparent until later in life because functional changes do not occur until puberty or adulthood and during which extraordinary changes occur.

developing biomarkers and the next generation of assays for screening chemicals for their potential endocrine disruption. There is a need to take advantage of the tremendous growth in the development of newer molecular approaches and develop predictive biomarkers and the next generation of assays for possible use in subsequent rounds of EDSP. The main advantage of these assays is that they often take less time to evaluate chemicals for their ability to interact with the endocrine system, cost less than other more conventional assays and test, and reduce (and in some cases eliminate) the use of whole animals. These latter elements are consistent with the recently issued NAS report on recommendations for a new testing paradigm in the 21st century.

What are the major sources and environmental fates of EDCs? How can unreasonable risks be managed? There is a need to develop chemical and molecular indicators of exposure on the highest priority endocrine-active chemicals. There are a number of existing risk management tools that possibly could be applied to reduce exposures to EDCs. If technologies exist that can be applied to major sources of exposure, the impact could potentially be a major reduction of EDC release to the environment.

One of the biggest unanswered questions that exists with EDCs is to what extent do they impact humans, wildlife and the environment. **Determine the extent to which human development/reproduction is being adversely affected by exposure to EDCs.** Given that development and reproduction appear to be highly sensitive endpoints in laboratory animal and wildlife studies and that there are reported alterations in particular endpoints (e.g., hypospadias, cryptorchidism, sperm quality), if any adverse effects are to be found, then evaluating these endpoints in humans appears to be logical. **Characterize the occurrence and effects of endocrine active compounds in environmental media and develop management approaches to mitigate unreasonable risks.** It is important to understand the extent of EDC exposures and the factors influencing the source-to-exposure-to-dose relationships in order to develop effective risk management strategies. Gaining improved understanding regarding the fate and transport processes, the interactions of EDCs from the source to the receptor, and collecting high quality exposure data for the development of multimedia, multi-pathway models are critical for ecological and human health risk assessments. Application of biological indicators of exposure to the study of components of mixtures offers the potential to validate and refine these models.

3. ORD's Current and Future Research Directions

Long Term Goal 1: Reduction in uncertainty regarding the effects, exposure, assessment, and management of endocrine disruptors so that EPA has a sound scientific foundation for environmental decision-making. Previously, ORD's research determined classes of chemicals that act as endocrine disruptors and their potencies. Having characterized modes of action, research is focused on the shape of the dose-response curve for specific modes of action and the development of approaches for assessing cumulative risk and extrapolating results across species. ORD is finalizing the next generation of assays to be used by the Agency's EDSP. To accomplish these goals and consistent with recommendations made by the Subcommittee of the BOSC, ORD is incorporating the new technologies broadly described as "genomics" or '-omics.' Also previously, ORD's research developed and evaluated through laboratory and small scale pilot field studies, molecular indicators of exposure and analytical methods for detecting certain EDCs in environmental samples. ORD is now focusing on applying its efforts to identify the key factors that influence human exposures to EDCs and major sources of EDCs entering the environment, such as from wastewater treatment plants (WWTPs), concentrated animal feeding operations (CAFOs), and drinking water treatment plants. ORD is also developing tools for risk reduction and mitigation strategies.

Long Term Goal 2: Determination of the extent of the impact of endocrine disruptors on humans, wildlife, and the environment to better inform the federal and scientific communities. This work focuses on application of ORD's research, in partnership with grantees and other federal agencies, in using the methods, models, and tools developed under LTG 1 and elsewhere to characterize the impact of environmental mixtures of EDCs on environmental media and aquatic organisms. Potential sources of EDCs to be examined include WWTPs, CAFOs, and drinking water plants. The EDRP is also supporting the completion of five epidemiology studies initiated through an interagency request for applications to characterize the effects of EDCs on human development and reproduction.

Long Term Goal 3: OPPTS is using endocrine disruptors screening and testing assays developed by ORD to create validated methods that evaluate the potential for chemicals to cause endocrine-mediated effects in order to reduce or prevent risks to humans and wildlife from exposure to endocrine disrupting chemicals. Earlier ORD research has led to the development of standardized protocols for all of the *in vitro* and *in vivo* assays identified by OPPTS as viable candidates in their Tier 1 screening battery and the mammalian and invertebrate tests for Tier 2. ORD now is focusing on finishing the Tier 2 assays in the amphibian and fish

models. Once this research is completed this LTG will be considered as being met and any further research on developing the next generation of EDSP assays will be conducted under LTG 1.

4. Making a Difference

LTG 1 Outcomes: OPPTS and other Program Offices, Regions, and outside EPA organizations are using data from ORD's EDRP to evaluate manufacturers' data submitted to the Agency through EDSP and/or from other sources, and develop integrated risk assessments on EDCs. Furthermore, the tools and data developed will be applied in field studies by EPA and/or others to determine the levels of exposure to EDCs in environmental media and the extent to which and efficacy with which they could be reduced or eliminated (e.g., LTG 2). A few examples of specific products include:

- Characterizing the shape of the dose-response curve especially at environmentally relevant levels of exposure
- Developing an approach for utilizing genomics data in EPA risk assessments^{1,2}
- Developing frameworks for: cross-species models of TH and aromatase disruption for more accurate extrapolation from animals to humans; improved linkages between TH alterations in short term screens and adverse outcomes; characterization of impact of EDCs on toxicity pathways associated with neuroendocrine regulation of puberty and of epigenetic mechanisms of transgenerational transmission of EDC induced reproductive tract lesions³
- Developing new analytical and biologically-based methods for characterizing EDC exposures and bioinformatic approaches for prioritizing environmental monitoring study designs.
- Continued training/transfer of DNA-assay & further application, e.g. characterize impact of CAFOs, endocrine-active pharmaceuticals in WWTPs on fish populations^{1,2}

LTG 2 Outcomes: ORD's are leveraged with those of other organizations (consistent with recommendations of the Subcommittee of the BOSC) to characterize the impact of EDCs on the environment, wildlife, and humans. A few examples of specific products include:

- Through cross-Laboratory/Center efforts, developing/applying new analytical and *in vitro* methods and other tools to evaluate environmental samples (e.g., effluences from CAFOs, WWTPs, industrial discharge, drinking water treatment plants, biosolids, combustion byproducts for endocrine activity and determine their potential impact on fish, wildlife and human health using a combination of laboratory and field studies; determining the efficacy of operations to reduce EDCs – will contribute to site-specific risk assessments and development of risk management options
- Providing a better understanding of the potential impact of certain EDCs on human development/reproduction²-completion of five epidemiology studies funded through interagency solicitation

LTG 3 Outcomes: ORD is developing, standardizing, and finalizing assays that OPPTS and/or other national and/or international organizations will validate for screening and testing of chemicals for endocrine activity in the US and/or internationally. A few examples of specific products include:

- Finalization of methods for EDC effects on amphibian and fish development, growth, & reproduction in whole animals & abbreviated assay based on molecular/biochemical endpoints⁴
 - Finalize development of comprehensive battery of assays with recombinant receptors and steroidogenic enzymes and EDC-responsive gene expression assays in stable cells lines from several classes of vertebrates for chemical prioritization and screening⁴
-

- Enhanced in utero lactational protocols that would include addressing gaps in the areas of exposures to mixtures and dose response in low dose region⁴
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¹ consistent with BOSC recommendations

² of value to broader regulatory and scientific communities

³ providing OPPTS with tools to evaluate EDSP data and integrate into risk assessments

⁴ may become incorporated into EDSP &/or international (OECD) testing guidelines/approaches

d) HUMAN HEALTH RISK ASSESSMENT (MYP) (John Vandenberg)

1. Program Context

The HHRA program plays a unique role in serving the needs of the EPA programs and regions through incorporating, integrating and coordinating the use of scientific information as a foundation for regulatory decision-making. The products of the program i.e., Integrated Risk Information System (IRIS) assessments, Integrated Science Assessments (ISA) for major air pollutants, and other assessments (e.g., World Trade Center) are directly responsive to program needs and are primary considerations in Agency actions to protect human health and the environment. In partnership with the ORD laboratories, and benefiting from the research products from many other ORD multi-year plans (MYP), the HHRA program is at the forefront of applying quantitative methods advances to risk assessment, such as the use of PBPK models to reduce uncertainty in risk extrapolations and to replace default uncertainty factors. The HHRA program also maintains a leadership role in incorporating mode of action (MoA) evaluations to support EPA decision-making, as emphasized in the EPA 2005 Cancer Guidelines and Early-Life Supplemental Guidance and used in recent assessments to evaluate the relevance of animal tumors to humans and the associated dose-response relationships.

EPA's National Center for Environmental Assessment (NCEA) consolidated its program in 2003 to focus on health risk assessment activities in support of the core mission of the agency to protect public health and the environment. The Human Health Risk Assessment Program (HHRA) was formed to develop and apply new methods in state-of-the-art health risk assessments through a more integrated and focused program. The HHRA Multi-Year Plan was recently developed to serve as the strategic plan for implementing the new annual and longer-term performance goals of the program.

2. Strategic Directions, Science Challenges, and Research Needs

The program is strategically designed around three long-term goals (LTG) which together represent the development and application of state-of-the-science information in health risk assessments.

LTG1: Integrated Risk Information System (IRIS) and other priority health hazard assessments: Agency, state and local risk assessors use the state-of-the-science health hazard assessment information provided on priority substances in their decisions and actions to protect human health from risks posed by environmental pollutants.

LTG 2: State-of-the-science risk assessment models, methods, and guidance: EPA programs, states and other risk assessors use the risk assessment models, methods, and guidance provided to enhance, through the incorporation of contemporary scientific advances, the quality and objectivity of their assessments and decision-making on environmental health risks.

LTG 3: Integrated Science Assessments (ISAs; formerly know as Air Quality Criteria Documents): ISAs are updated to reflect the best available scientific information on identifiable effects on public health and the environment outcomes from exposure to the criteria pollutants. This information is used by the EPA Office of Air and Radiation in their review of the National Ambient Air Quality Standards (NAAQs) to protect public health and the environment with an adequate margin of safety.

What are the scientific challenges for the research program in the next 5-10 years?

Of central importance to environmental health decision making is the need to better quantify risks and characterize uncertainty at the exposure levels generally experienced in real world situations by large numbers of people, including susceptible populations. This public health protection objective cannot be fully achieved based on evidence from humans, due in part to ethical, logistical and statistical constraints. Decisions can be informed, however, through extrapolation from available *in vitro*, *in vivo*, epidemiological and other data, including emerging evidence from new approaches such as genomics analyses. These extrapolations include between animals and humans, from high to low dose, between routes of exposure, and among individual humans, including susceptible populations. Research to inform risk decisions can be broken down along these extrapolation components and the numerous factors that contribute to the variability and uncertainty in each component. For instance, high to low dose extrapolation can be informed by understanding such factors as the relevance of high dose mode of action to low doses. Primary research on these components is undertaken by the ORD laboratories under various MYPs, and is a primary consideration of the ORD Human Health Research Program. HHRA MYP LTG 2 acts to incorporate these data and analyses, along with other published literature, into EPA risk assessment practices and outputs. These efforts are focused on addressing critical linkages in the risk assessment process between the exposure-to-outcome continuum.

What are the drivers prompting these challenges?

Although non-regulatory, IRIS and other assessments developed under LTG 1 support environmental decision making and may serve as a basis for other activities such as resource prioritization. The hazard characterization and dose-response assessments provided by IRIS constitute the first two steps in the NAS (1983) risk assessment paradigm, the other steps being exposure assessment and risk characterization. In the Agency context, IRIS toxicity values resulting from the dose-response assessment (e.g., reference values, cancer slope factors) can be combined with site-specific exposure estimates (e.g., exposure to the chemical in food, in drinking water, in soil at a waste site, in air near an incinerator) to provide a risk estimate for the situation of interest. In doing so, the “health hazard assessment” information provided by IRIS contributes to a fuller “risk assessment” as defined under the NAS paradigm and applied in programmatic and regional actions.

Sections 103, 108, and 109 of the Clean Air Act govern the establishment, review, and revision of the National Ambient Air Quality Standards (NAAQS) and direct the Agency to issue air quality criteria for identified ubiquitous pollutants that may reasonably be anticipated to endanger public health or welfare. HHRA MYP LTG 3 produces the mandated ambient ISAs which evaluate the latest relevant available scientific information addressing the nature and extent of health and welfare effects associated with exposure to ambient concentrations of the particular pollutant. ORD laboratory research is also conducted pursuant to the CAA under the Air MYP. The ISA’s incorporate and synthesize research of ORD and others into these assessments documents (e.g., NCER particulate matter (PM) research centers and ORD intramural PM research under Air MYP).

Risk assessment methods, models, and guidance development under the HHRA MYP are directed toward incorporating scientific advances into risk assessment practice. The LTG 2 outputs support the applied decision-making needs of the EPA programs and regions, either directly or through HHRA LTG1 (IRIS) and LTG3 (ISA) outputs. These program needs vary from estimating risk levels in exposed people and determining acceptable levels of environmental pollutants in media such as air and water, to supporting regulatory actions on specific substances and developing clean-up standards for restoring the environment. In making these decisions, risk

managers seek information on best estimates of risk, the uncertainty in these estimates, and whether their decisions will be sufficiently protective of potentially sensitive populations, such as children.

What are the associated research questions that need to be addressed?

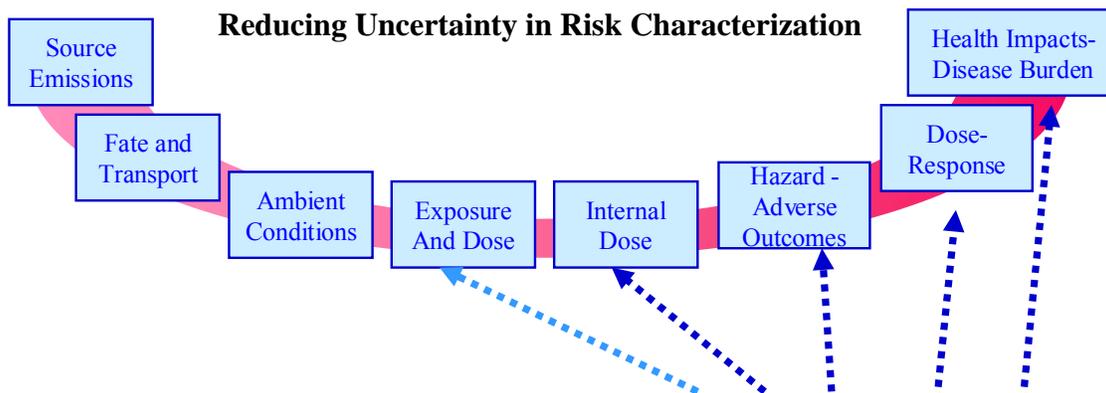
Illustrative questions include:

- How to use often limited information on one or more hypothesized modes of action in risk assessments?
- How to characterize risks to susceptible population with available data?
- What are the latest exposure factors, including distributional data and variation across lifestyles?
- How do we efficiently and appropriately use PBPK modeling in risk analysis?
- How can we improve dose-response quantification (e.g., BBDR modeling, Categorical Regression, meta analysis approaches)?
- When do we qualitatively characterize uncertainty versus to quantitatively characterize uncertainty in risk estimates and how do we do this in the most transparent fashion?
- What lessons can we learn from applying cumulative risk assessment principles to health assessments?

3. ORD's Current and Future Research Directions

What research is ORD currently doing ('07 enacted budget)?

Research under HHRA program is addressing the following major areas source to outcome continuum (see figure).



- Human Health Risk Assessment develops the methods, models, & guidance to reduce uncertainty in the ‘critical links’ across the exposure-to-effect paradigm and to improve risk characterization

(1) Approaches for Assessing Environmental Exposures: Exposure work is done in support of the needs of multiple risk assessors across EPA and States, with particular focus on information for which there are multiple clients such that a common centralized database or approach is of the greatest value.

(2) Internal dose and Physiologically-based pharmacokinetic (PBPK) modeling: More complex chemical assessments frequently include evaluation of PBPK models. This includes evaluation of how differences in metabolism affect risk estimation, either in considering when data is available

from only one route-of-exposure, to evaluate if PBPK explains differences across species, and for high-to-low-dose extrapolation.

(3) Hazard Characterization: Hazard characterization efforts include identifying likely human health effects to a chemical including consideration of susceptible populations (e.g., lifestage and genetic predisposition) and use of mode of action (MoA) in risk assessment. MOA efforts include applying available data to better inform decisions on the relevance of high dose effects to low level environmental exposures, within and between species, impact on susceptible populations (e.g., lifestage and genetic predisposition) and the quantitative impacts of these factors on dose-response functions used in risk assessment

(4) Dose-Response Analysis: Quantitatively relating exposure or dose to likely effect has received increased interest for nongenotoxic modes of action. There is a renewed need to consider appropriate dose-response models in the range of observed data and the underlying reasons for the default linear low-dose extrapolation for carcinogens and potential alternatives to that. The program has several projects in response to that need, including efforts specifically on low-dose extrapolation and the development of versions of existing dose-response models that can take into account potential additivity to background doses or background processes.

(5) Risk Characterization: Quantitative analysis of uncertainty, derivation of central estimates and confidence limits on estimates of risk is another need driven in part by those who wish to use risk assessment results in the context of formal decision analysis or in cost-benefit analysis. These efforts also inform the relationship between adverse outcomes and the impact of environmentally-induced burden of disease on human health.

What research should be done in future years, and what are the critical paths to getting there?

The HHRA MYP includes in FY'09 reports on actions undertaken to incorporate biological and mode-of-action considerations to refine risk assessment practice and to extend the analysis beyond the range of data. Mode of action information is critical to determining the relevance of animal data to humans, and to informing quantitative estimates of risk within the range of data and at environmental exposure levels. In fiscal years FY10 to 12 activities of this MYP are directed toward developing guidance, integrating findings and synthesizing the risk assessment advances accomplished under this HHRA program and from the scientific literature. In doing so, these goals consolidate the science, generate a common basis for Agency risk assessment practice, and provide a foundation for future planning activities.

Why is ORD the right place to do this research (our niche), and how will we collaborate with/complement the work of others?

ORD is the right place to do develop methods and create state-of-the-science health risk assessments because we can capitalize on lessons learned from assessments activities and feed that back through our research planning and implementation to improve the scientific basis for future assessments. The HHRA MYP plays a unique role in serving the needs of the EPA programs and regions through incorporating, integrating and coordinating the use of scientific information in support of regulatory decision-making. The IRIS, ISA and other assessments are directly responsive to program needs and are primary considerations in Agency actions to protect human health and the environment. A key advantage of HHRA program is that the experience in developing health assessments and synthesizing and integrating data for methods, models and guidance for the agency results in the identification of data gaps, data needs and priority research needs to reduce or better characterize existing science assessments. These include methods, models and refinement of existing tools. NCEA communicates these needs to partners within ORD, and to outside collaborators, and develops collaborations on priority areas.

The HHRA program encourages close relationships with these partner ORD, federal, state and international organizations, both in accessing sources of toxicological and epidemiological data and through collaborative risk assessment development activities. Access to data is facilitated through staff contacts within ORD and other federal agencies conducting primary environmental health research, particularly NHEERL and NERL, and the NIH-NIEHS National Toxicology Program and the CDC-National Center for Environmental Health. Assessment activities are coordinated through interagency working groups and collaborative relationships. Of particular note is the Memorandum of Understanding between EPA-IRIS and the Agency for Toxic Substances and Disease Registry (ATSDR). ATSDR prepares Toxicological Profiles for hazardous substances found at National Priorities List (NPL; “Superfund”) sites, including quantitative Minimal Risk Levels (MRLs) for non-cancer effects. The EPA-ATSDR MOU emphasizes coordination and sharing of information on substances under evaluation by both organizations. Close relationships are also maintained with international organizations dealing with environmental health risks, including the World Health Organization through its International Programme on Chemical Safety (IPCS), the International Agency for Research on Cancer (IARC), and the United Nations Environment Programme (UNEP).

4. Making a Difference

What are our planned research products?

The HHRA Program has numerous outputs under 3 long-term goals (LTGs). In 2008 LTG 1 is on schedule to deliver 16 Integrated Risk Information System (IRIS) assessments to interagency or external peer review, to complete 50 new or revised Provisional Peer Reviewed Toxicity Values (PPRTVs), and to post 6 final IRIS Health assessment documents.

In 2008, efforts under LTG 2 will result in a posting of a final Exposure Factors Handbook for Children to reduce uncertainty in exposure assessments, release an external review draft of improvements to BMD software enabling extrapolation across exposure durations and evaluation of peak responses as a function of exposure magnitude and/or duration, publish information regarding analysis of the sensitivity and uncertainty in 2-stage clonal growth models for formaldehyde with relevance to other biologically-based dose response models and post on website a report summarizing findings from workshop on uncertainty and variability in PBPK models including case example approaches for chemical-specific analyses (TCE applications).

In 2008, efforts under LTG 3 the first Integrated Science Assessments for Nitrogen Oxide and Sulfur Oxides will be finalized under the newly implemented process in support of NAAQS.

How will our clients—the programs, regions, and others—use our research?

Beyond EPA, HHRA products are widely recognized as the principal environmental health risk assessment benchmarks in the United States, exemplified by the IRIS outputs, ISAs, and guidance documents. Although non-regulatory and non-binding in nature, these health assessment products and the scientific analyses therein are referenced in many federal, state, local, and stakeholder environmental decisions.

How will the results of our research contribute to environmental outcomes that protect human health and safeguard the environment?

ORD's science assessments are widely regarded by regulators and stakeholders as providing a transparent and well documented resource on substances of central importance to environmental issues. IRIS values are now the primary toxicity values used in preliminary remediation evaluations (OSWER Directive 9285.7-53; 12/5/2003) and in many regulatory reviews conducted by EPA programs, such as the Office of Water and the Office of Air and Radiation. OSWER records of decision (RODs) for Superfund sites and EPA regulatory proposals that reference IRIS values are then subject to additional public comment and peer review under the relevant adjudicatory procedures and Administrative Procedures Act (APA). IRIS has also been in the forefront of applying scientific advances to substance-specific assessments, such as PBPK modeling and data-derived uncertainty factors for intraspecies and interspecies extrapolation (e.g., boron), and to advancing mode of action considerations in cancer hazard characterization (e.g., perchlorate).

ISAs have been prepared by NCEA or its predecessors since the creation of the EPA in early 1970s. ISAs and the resulting NAAQS have been pivotal in achieving the air quality standards experienced today in the United States and they have influenced regulatory actions worldwide. The AQCDs for Airborne Particulate Matter, Ozone, and Lead were finalized in 2004, 2006, and 2007, respectively before the new ISA process was implemented. The NO_x and SO_x ISAs are being developed utilizing new procedures and are scheduled for finalization in 2008. Through the preparation of ISAs, public health protection has been furthered by the ongoing, close, collaborative relationships between risk assessors, OAQPS regulators, and research scientists studying criteria air pollutants under other ORD research MYPs.

e) **SAFE PESTICIDES/SAFE PRODUCTS (MYP) (Elaine Francis)**

1. Program Context

The Safe Pesticides/Safe Products Research Program (SP2RP) is specifically designed to address the problem-driven science needs of the Office of Prevention, Pesticides and Toxic Substances (OPPTS). It provides OPPTS with the scientific information it needs to reduce or prevent unreasonable risks to humans, wildlife, and non-target plants from exposures to pesticides, toxic chemicals, and products of biotechnology. Some of OPPTS' science needs are being met by other research program (e.g., Human Health, Human Health Risk Assessment, Ecological). The SP2RP specifically addresses OPPTS' high priority research needs that are not addressed by any of ORD's other research programs. Historically, the SP2RP has been:

- providing OPPTS with test methods for use in developing testing guidelines by which chemical and agricultural industries conduct and submit data to assess potential human and ecological risks for >25 years;
- conducting research on underlying science to assist OPPTS in interpretation of data from industry-submitted studies; and
- responding to OPPTS' requests on specific shorter-term research needs by providing results on the effects, exposures, risk assessment, and/or risk management of chemicals or classes that are of immediate concern to the program office.

The current program builds on the decades of test method development for assessing the risks of chemicals, to develop genomic and computational methods for prioritization of regulatory data requirements, to facilitate the interpretation of submitted data in risk assessments, and conduct short-term research to address targeted needs for upcoming specific risk assessment/management decisions. It is developing the scientific underpinnings necessary to transform ecological risk assessments to a more realistic, probabilistic basis where effects can be judged by their impacts at the population level and plant community level. In 2002, a new initiative was begun to provide the underlying science OPPTS needs to evaluate products of biotechnology.

2. Strategic Directions, Science Challenges, and Research Needs

OPPTS is responsible for regulating certain chemicals for which there are little or no toxicological or exposure data (e.g., Pre-Manufacture Notification (PMN) and High Production Volume (HPV) chemicals, inert pesticide ingredients, antimicrobial pesticides). Therefore, there is a need for creating ways to accurately predict the toxicity and levels of exposure for these chemicals. Predicting the potency, activity, and exposure to these chemicals will enable OPPTS to make better informed decisions as to whether or not empirical studies are required to further refine a risk assessment for regulatory decisionmaking. Current approaches for testing chemicals require extensive resources. Therefore, priority setting approaches must be developed to determine the sequencing of chemicals or classes of chemicals to assess for a specified toxicity endpoint. Additionally, while extensive data sets are generated for many toxicity endpoints currently used in risk assessment, efficiency can be gained in using targeted testing to reduce critical uncertainty while minimizing resource utilization. The current inability to estimate endpoints sufficiently to set hypothesis-driven risk-based priorities is the result of a lack of understanding of pathways of toxicity and how they can be initiated by chemicals, as well as by a lack of methods to model the complex behavior of chemicals. By having an understanding of the initiating events of critical toxicity pathways OPPTS and ORD will be able to use credible *ex*

vivo techniques to estimate the toxic potential of chemicals and allow them to be ranked/prioritized for their potential to elicit adverse outcomes. With the development and application of new computational and molecular tools, it is anticipated that *in silico* and *in vitro* techniques for prioritization and screening of chemicals for toxic effects resulting from exposure to PMNs, HPV/inerts and antimicrobial chemicals is highly feasible over the next seven years. The determination of possible levels of exposure to these chemicals will also need to be included into any screening or prioritization program. Thus, of the issues facing OPPTS, the need to develop more efficient ways to screen and prioritize chemicals for testing to acquire sufficient, targeted, credible information for decision making is of high priority. To overcome these gaps, and to move toward a more sustainable risk assessment paradigm to support TSCA, FIFRA, and FQPA decisions, the SP2RP is providing OPPTS with predictive tools for hypothesis-driven prioritization of testing requirements and enhanced interpretation of exposure, hazard identification, and dose-response information. The research is complementary to and is coordinated with the Computational Toxicology (Comp Tox) Research Program.

OPPTS will always need ORD to have sufficient flexibility to address shorter-term targeted research needs. It is anticipated that as these needs are met, that they will be replaced with other emerging needs of priority at that future time. The SP2RP has built in sufficient flexibility to address these needs as they arise.

OPP is leading the way in expanding ecological risk assessments (ERAs) to provide probabilistic expressions of risk to aquatic and terrestrial wildlife populations and plant communities, including reducing uncertainties in all tiers of the risk assessment process as uncertainties that are extrapolated from limited data sets are better defined and put into context. For this purpose, methods are required to support population-level ERAs of increasing degrees of specificity, detail and realism; to determine the absolute /or relative (incremental) risk of chemical and non-chemical stressors; and at varying geographical regions/ or other areas of regulatory concern. The research conducted under the SP2RP is developing efficient methods, including models, for OPP to review, register, and regulate thousands of chemicals in a timely fashion. OPP's strategic direction toward probabilistic assessments is in response to recommendations from their Scientific Advisory Panel. ORD has developed the Wildlife Research Strategy which describes a tiered approach using a series of wildlife risk assessments. A similar tiered approach is used with plant risk assessments. In addition, because neither stressors nor wildlife populations or plant communities are distributed uniformly within the environment, the interplay between spatial and temporal heterogeneity in wildlife population and plant community structure and spatial and temporal patterns of stressors is a major factor controlling the severity of effects on wildlife populations and plant communities. Thus, a critical feature of this research is the development of probabilistic models that deal explicitly with the spatial distribution of wildlife populations, plant communities and stressors over time. The SP2RP is developing scientifically valid approaches to assess risks to wildlife populations and plant communities from multiple chemical and non-chemical stressors. This requires a means of mathematically integrating dose-response and habitat suitability relationships as well as computer platform for site-specific, spatially-explicit population modeling.

OPPTS needs the scientific information to assess and manage the potential human health and ecological risks of the various products of biotechnology. Many of the traditional approaches used to assess chemical pesticides are applicable to assessing risks from genetically engineered plants which produce their own pesticides, also known as plant-incorporated protectants (PIPs). PIPs are created when through the use of biotechnology, specific genetic material from a bacterium are transferred to a plant to create plants that produce pesticidal

proteins that the plant could not previously produce. PIPs may, however, pose uniquely different risks from traditional, chemical pesticides. Therefore, OPP requires additional scientific information and tools in order to adequately assess and manage potential risks. For example, there are issues regarding gene flow from PIPs to wild relatives and pollen movement spreading the new pesticides to non-altered crops. Cross-pollination of wild relatives can disrupt a local ecosystem by changing the makeup of local plants, crowding out related species and changing the local habitat. Other issues include the need for methods to monitor for pest resistance and the development of risk management tools to prevent or mitigate gene flow. In addition, while the level of protein produced by the newly engineered plant is very small, because proteins can be allergens, special emphasis on assessing potential allergenicity is needed of these products.

3. ORD's Current and Future Research Directions

Long Term Goal 1: OPPTS and/or other organizations use the results of ORD's research on methods, models, and data as the scientific foundation for: A) prioritization of testing requirements, B) enhanced interpretation of data to improve human health and ecological risk assessments, and C) decisionmaking regarding specific individual or classes of pesticides and toxic substances that are of high priority. SP2RP is:

- developing and applying the latest molecular and computational approaches to produce the next series of chemical prioritization tools and toxicity testing approaches; Some of this research is leveraged with the Comp Tox Research Program; Some research is conducted through the STAR extramural grants program;
- enhancing data interpretation by evaluating the diagnostic value of data obtained from current toxicity testing guidelines in order to develop improved targeted test methods for major classes of pesticides based on defined modes-of-action and identification and characterization of genomic and proteomic biomarkers; Some research is conducted through the Comp Tox STAR extramural grants program;
- characterizing toxicity profiles of perfluoroalkyl chemicals, examining the potential for selected perfluorinated telomers to degrade to perfluorooctanoic acid (PFOA) or its precursors; Some of this research is conducted in collaboration with chemical industry who are abiding by the Agency's Enforceable Consent Agreement;
- developing methods and models to forecast the fate of pesticides and byproducts from source waters through drinking water treatment systems and ultimately to the US population; This research is done in collaboration with the Office of Water and the water industries
- providing exposure methods for large-scale human studies; Some of this research was conducted with NIEHS and NCI; and
- addressing specifically identified research needs by studying chromated copper arsenate-treated wood (leveraged with activities at CPSC), asbestos, chiral pesticides, and lead-based kits.

Long Term Goal 2: OPPTS and/or other organizations use the results of ORD's research as the scientific foundation for probabilistic risk assessments to protect natural populations of birds, fish, other wildlife, and non-target plants. SP2RP is:

- creating the scientific foundation for conducting probabilistic risk assessments for fish and wildlife populations and plant communities by developing: methods for extrapolation among species and exposure scenarios of concern; models for characterizing environmental exposures and population biology in spatially-explicit habitats; models to assess relative risk of stressors; and tools to define geographical regions/ spatial scales for

risk assessment; A small part of this program is conducted in collaboration with a STAR awardee from the Comp Tox Research Program.

Long Term Goal 3: OPPTS and/or other organizations use the results of ORD's biotechnology research as the scientific foundation for decisionmaking related to products of biotechnology. SP2RP is:

- improving the evaluation of potential ecological effects of biotechnology products, specifically plant incorporated protectants (PIPs), on non-target species; the impact resulting from the escape of altered plants to the natural environment and the likelihood and effects of gene transfer; the development of pesticide resistance in the target insect species; the development of risk management approaches; and development of methods to assess for the potential allergenicity of genetically engineered plants. Some of the latter research is conducted through the Biotechnology STAR grants program.

4. Making a Difference

LTG 1 - The ultimate outcomes are the development of improved methods, models, and data for OPPTS' use in requiring testing, evaluating data, completing risk assessments, and determining risk management approaches. More specifically the outcomes are the development by ORD and implementation by OPPTS of more efficient and effective testing paradigms that will be better informed by predictive tools (chemical identification, improved targeting cost less, less time, and fewer animals); improved methods by which data from the more efficient and effective testing paradigms can be integrated into risk assessments; and that OPPTS uses the result of ORD's multidisciplinary research approaches, that it specifically requests, for near term decisionmaking on high priority individual or classes of pesticides and toxic substances. A few examples of specific products include:

- Development of assays to screen chemicals for their potential toxicity across a number of end points, e.g., developmental neurotoxicity, immunotoxicity, non-endocrine-mediated reproductive toxicity¹
- Development of multiple approaches (e.g., QSARs, metabolic pathways, ASTER) for prioritizing chemicals for testing¹
- Significant advancement in the development of computational approaches applied to 'omics data that will improve linkages in the source to outcome paradigm and quantitative risk assessments through cooperative agreements with the Environmental Bioinformatics Research Centers²
- Near completion of a multi-disciplinary research program on the toxicity, pK, and environmental pathways and fate of perfluorinated chemicals²
- Completion of treatment study results of at least six additional individual/classes of pesticides in drinking water³

LTG 2 – Results of this research will help the Agency meet the long term goal of developing scientifically valid approaches to extrapolate across species, biological endpoints and exposure scenarios of concern, and to assess spatially-explicit, population-level risks to wildlife populations and non-target plants and plant communities from pesticides, toxic chemicals and multiple stressors while advancing the development of probabilistic risk assessment. A few examples of specific products include:

- Significant advancement in the development of methods for extrapolating toxicological data across wildlife species, media, and individual-level response endpoints²
- Development of modeling approaches for characterizing spatial population level effects in aquatic life and wildlife for use in support of addressing the Endangered Species Act²

LTG 3 - OPPTS will use the results from this research program to update its requirements of registrants of products of biotechnology and to help evaluate data submitted to them. A few examples of specific products include:

- Development of multiple models (e.g., rodent, serum, databases) to assess potential allergenicity to genetically modified crops¹
- Provide guidelines and tools to mitigate gene-transfer and non-target effects and the development of resistance in targeted pest populations to aid the management of environmental risks associated with PIP crops²

¹ may become incorporated into EPA and/or international (e.g., OECD) testing guidelines/approaches

² of value to broader regulatory and scientific communities

³ of interest to OW also

2. Ecosystems, Water and Security

a) DRINKING WATER (MYP) (Audrey Levine)

1. Context of Drinking Water Research Program (DWRP)

The ORD DWRP 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". A primary focus of the Drinking Water Research Program (DWRP) is to provide research support for the statutory requirements of the Safe Drinking Water Act (SDWA) with an emphasis on controlling health risks associated with potential exposure to waterborne contaminants through public drinking water supplies.

Long Term Goals. The research strategy in the DWRP is organized under two Long-Term-Goals (LTGs):

Long Term Goal 1: Focus on Risk Characterization

Produce methodologies, data, and tools to characterize drinking water sources, treatment facilities, and distribution systems and elucidate health risks associated with exposure to waterborne contaminants. Research products will be used by the USEPA Office of Water, Regions, and other stakeholders in support of the development of health risk assessments and other needs pertaining to regulatory decisions under the Safe Drinking Water Act's statutory requirements.

Long Term Goal 2: Focus on Risk Management

Produce data, tools, models, and technologies to prevent, control, manage, and/or mitigate potential health risks associated with sources, treatment, distribution, and use of drinking water and to promote the sustainability of water resources and the reliable delivery of safe drinking water. Research products will be used by the Office of Water, Regions, and other stakeholders in support of rule implementation and future regulatory decisions under the Safe Drinking Water Act.

Program evolution over the past 3-5 years. The DWRP is moving towards an integrated framework for addressing drinking water issues in the context of the water cycle. The new organization of the program provides research support for SDWA decisions (rule development, implementation, potential rule revisions, 6-year review, CCL, UCMR) and simultaneous compliance issues and also accommodates emerging issues and new initiatives (e.g. accountability, infrastructure, global climate issues) and integration with other research programs (EPA and other research groups). Areas of increasing emphasis include:

- ***Source water protection and sustainability***(ground water and surface water systems)
- ***Water distribution/storage systems/infrastructure***: research needs associated with sustainable water infrastructure and research support for current activities in the Office of Water pertaining to distribution systems and potential revision of the Total Coliform Rule (TCR)
- ***Microbial risk associated with pathogen exposure***: improved tools for characterization and monitoring of pathogens and biofilms; methodologies for microbial risk assessment
- ***Health outcomes***: develop methodologies to quantify the impacts of SDWA rule implementation on public health outcomes

2. Strategic Directions, Science Challenges, and Research Needs over the next 5-10 years

The safety of drinking water supplies is intrinsically linked to the availability of sustainable and reliable sources of water. The quality and potential sources of waterborne contaminants in surface and ground water resources are influenced by a host of watershed-related factors including relationships between land-use (urban, suburban, rural, industrial) and water-use practices (municipal, agriculture, industry), energy-water interdependencies (water requirements for resource development and energy production, energy requirements to treat and transport water, and water quality impacts from energy production, distribution, and storage), and climatic patterns (precipitation intensity and frequency, temperature). Research is needed to develop strategies that can ensure the safety and sustainability of drinking water systems under increasing societal pressures on surface water and ground water resources. In addition, a better understanding of cumulative risks associated with exposure to waterborne contaminants through drinking water sources is needed. The major scientific challenges associated with drinking water research are the need for reliable tools that enable “real-time” assessment of health risks and evaluation of potential impacts of risk management approaches. DWRP research needs are summarized below by theme area.

Assessment tools. The development of analysis, monitoring, screening, and prioritization techniques for characterizing drinking water systems (sources, treatment, distribution) is a major focus of the DWRP. Key research applications are: 1) sample collection and concentration, 2) detection and enumeration methods for waterborne contaminants, and 3) screening methods to assess health effects and potency of waterborne contaminants. Emerging assessment tools include the use of proteomic, genomic and DNA microarray techniques for identification, detection, quantification and characterization of drinking water contaminants. In addition to developing assessment tools, it is important to facilitate transfer of these tools to practitioners in the drinking water community. Another active research focus is the application of biomarkers and indicators to provide more insight into associations between specific sources of exposure and observed or potential health effects and provide surrogate monitoring tools for evaluation of water quality in source waters, treatment and distribution systems. Research products from assessment tools are applied to answer research questions associated with source water protection, treatment and distribution systems, and water use-health outcomes. In addition, research products are used to support other ORD research programs (e.g. water quality, homeland security, human health, etc.).

Source water/Water Resources. The source water/water resources research theme is focused on characterizing (LTG1) vulnerability and sustainability of drinking water sources (surface and ground water) and demonstrating (LTG2) approaches to protect water resources and manage and mitigate potential and realized sources of contamination. From a regulatory perspective, source water protection research is at the intersection of requirements associated with SDWA and the Clean Water Act (CWA). To optimize research approaches and develop more effective Best Management Practices (BMPs), it is important to develop methods of protecting source water that integrate protection of public health (drinking water and recreational water) with aquatic habitat protection (CWA). A critical research need is to better understand how climatic factors may impact the quality and sustainability of drinking water sources. Potential consequences of climate change on drinking water sources include water quality changes (dissolved solids, organics, minerals, contaminants, microbiology), seasonal changes in water availability and storage requirements, and impacts of extreme weather events (flooding, droughts) on water quality. Key research questions relate to developing models to assess the impacts of water temperature changes on microbiology (opportunistic pathogens, species diversity, algae and cyanobacteria proliferation and toxin release) and water quality (gas and mineral solubility, reaction kinetics, etc.).

Another important research need is to develop approaches to quantify and manage potential source water quality changes due to implementation of new technologies (nanotechnology, membrane processes, etc.) and alternative water sources (indirect potable reuse). Results from research on source water/water resources will inform research planning on treatment, distribution systems, and water use/health outcomes.

The implementation of BMPs for **surface water protection** requires improved understanding and modeling capabilities to assess and manage impacts of land-use practices on water quality. Key issues that impact surface water quality include: stormwater and runoff management in urban settings and near roadways; water quality impacts associated with nutrients, sediments, and pesticide releases into watersheds; relationships between agricultural practices (irrigated agriculture, biofuel feedstocks, livestock production, etc.), water management approaches, and water quality; salt balances; surface water-ground water interconnections; drinking water source protection in coastal environments; and energy-water linkages. **Ground water protection** research is needed to better understand the cumulative water quality impacts and water resource implications associated with: ground water withdrawals and recharge practices and patterns, biogeochemical reactions associated with ground water recharge using stormwater and/or reclaimed water, aquifer storage and recovery systems, carbon sequestration, and irrigated agriculture.

Treatment/residuals. An important component of the DWRP is research that addresses the efficacy of treatment systems for control of waterborne contaminants. Treatment strategies for production of drinking water are directly linked to source water characteristics, SDWA requirements, and economic factors. As source water characteristics change and new technologies are adopted to meet SDWA requirements, it is important to understand potential impacts on water quality (disinfectability, corrosivity, salinity, microbiology, distribution system reactions, etc.), water and energy efficiency, residuals management (liquid and solid), and the stability of water through treatment, distribution, and storage systems. DWRP research focuses on sustainable technologies for public water supplies (including small systems), cost and energy efficiency, simultaneous compliance issues, and management of residuals. As membrane and other alternative treatment technologies (advanced oxidation, nanotechnologies, ion exchange, biological treatment) become more widely used, reject water (brine) management strategies are needed that protect watersheds and improve water recovery, particularly in inland communities and in cases where residuals contain hazardous contaminants (metals, radioactive elements, etc.). Another critical research need is field verification of treatment approaches that small communities can adopt to meet SDWA requirements including decentralized (point-of-entry or point-of-use) treatment to produce safe drinking water and cost-effective operational, monitoring, and data management tools. Treatment systems that are capable of providing potable water under emergency situations (hurricanes, earthquakes, floods, service disruptions, security breaches) with limited availability of electrical power are also an important research need (complementary research in the homeland security research program (HSRP)). Integrated models of treatment efficacy, co-contamination issues, and water quality changes associated with treatment are needed to evaluate CCL and simultaneous compliance issues.

Distribution/storage/infrastructure. The major research needs associated with water infrastructure (pipelines, tanks, pumping systems, etc.) and distribution/storage systems relate to improving our ability to: 1) characterize microbial, chemical, and physical interactions that occur through conveyance, storage, and delivery of public drinking water supplies; 2) control health risks associated with potential exposure to waterborne contaminants that are introduced, mobilized, or formed through water distribution and storage systems; and 3) forecast and respond to problems associated with aging and deteriorating potable water conveyance and treatment systems. Research questions relate to improved understanding of the role of biofilms in proliferation and control of pathogens, the role of secondary disinfectants on chemical and microbiological water quality, and developing water quality

information (mass-transport, disinfection kinetics and decay reactions, byproduct formation, biofilm-water interactions, etc.) that can be used to advance hydraulic modeling capabilities (e.g. EPANet) for managing distribution systems, optimizing design, and evaluating factors that influence potential health impacts associated with traditional and alternative distribution network designs and advances in dual distribution systems (potable and non-potable). Because water conveyance systems represent a major energy demand for water utilities, advances and optimization in energy management strategies has the potential to improve water system sustainability and yield economic benefits. A critical research need is the development of reliable tools for predicting, detecting, and rehabilitating water infrastructure components including practical and accurate methods for detecting, assessing and managing distribution system impacts on distributed water quality (contaminant intrusion, mobilization, and biofilms). Related research on distribution system security is conducted through the HSRP.

Water use/health outcomes. The overarching goal of SDWA is to protect public health by reducing drinking water exposures to potential waterborne contaminants. Exposure to waterborne contaminants is related to the quantity of water that is used, the potential exposure pathway (ingestion, inhalation, dermal), and host-specific factors (age, immune status, water and food consumption, exposure history, etc.). The water use/health outcome theme of the DWRP is focused on characterizing health effects and risks associated with exposure to potential waterborne contaminants and developing approaches to evaluate or predict public health outcomes associated with SDWA. The DWRP addresses exposure and potential health outcomes associated with drinking water systems, while complementary research in the Human Health Research Program (HHRP) focuses on quantifying the mode-of-action associated waterborne contaminants. Research needs include developing screening tools to identify and assess health risks associated with emerging contaminants (e.g. CCL), prioritize research needs, and quantify public health benefits associated with SDWA implementation. Major research questions are associated with developing tools to quantify and assess potential health impacts associated with cumulative exposure to multiple contaminants. There is a critical need to develop “real-world” data on drinking water exposure and health outcomes. Research is needed to help quantify public health benefits associated with implementation of SDWA. Cost-effective approaches for conducting epidemiological studies are needed to help fill this data gap.

3. ORD’s Current and Future Research Directions

An overview of the DWRP current and future research directions for each theme area is given in Table 1. Many of the current research activities are targeted at supporting regulatory needs and will continue in the future in conjunction with program office needs. There will be a general transition from focusing on individual contaminants to addressing multiple contaminants under LTG1 (characterization) and LTG2 (risk management) with increasing emphasis on source water protection, distribution systems, and microbial risk characterization. In addition, future research directions will incorporate water sustainability issues in the context of water availability, quality, treatment, distribution systems, and water use-health outcomes.

4. Making a Difference: What are the Benefits of the DWRP?

Research products from the DWRP include methodologies, models, tools, and data that can be directly used to help inform regulatory decisions and rule implementation.

- **Assessment tools:** Assessment tool development yields major benefits by improving our ability to understand drinking water characteristics, determine occurrence, and quantify potential health impacts associated with waterborne contaminants (CCL, SDWA, UCMR, etc.). Major advances

can result from adoption of methodologies by water utilities to identify, detect, monitor, and control waterborne contaminants.

- *Source water/water resources:* BMPs and models developed for source water protection can impact the safety and sustainability of water resources and reduce the costs of mitigating contamination through treatment. Improved understanding of factors that impact ground water quality and sustainability has direct value in providing decision support for implementation of technologies for aquifer sequestration of carbon and other constituents, alternative ground water pumping strategies, and ground water recharge or aquifer storage and recovery systems.
- *Treatment and Distribution systems:* Treatment efficacy and distribution system research can improve the safety of distributed water, help to inform SDWA decisions that reduce public health risks associated with exposure to waterborne contaminants, improve water sustainability and water-use efficiency, and reduce the costs of infrastructure rehabilitation and replacement.
- *Water use/Health outcomes:* Advances in understanding of exposure pathways associated with waterborne contaminants can yield public health benefits by improving our ability to reduce uncertainties in risk assessment models for chemical, microbial, and other emerging contaminants.

In addition to the research products produced through DWRP, ORD researchers play an active role in SDWA activities through on-going interactions with EPA's Office of Water and by working with regions, states, and utilities to facilitate implementation of rules and address simultaneous compliance issues. DWRP research products are disseminated to the scientific and regulatory community (peer-reviewed publications, reports, participation in meetings and workshops, seminars, etc.) and there are on-going efforts to leverage DWRP research by collaborating with other agencies (USGS, USDA, NSF, HS, etc.) and research groups (AwwaRF, WERF, WRF, GWRC, etc.). DWRP funds are used to support extramural research through the STAR program. Supplemental approaches for tracking the outcomes of DWRP research are needed that can capture the extent to which the DWRP impacts environmental and health outcomes that support the mission of the EPA and expand upon analysis of the extent to which research products are used by EPA program offices.

Table 1. Comparison of current and future research directions of the DWRP

DWRP Theme	Current research focus and SDWA regulatory drivers¹	Future research directions
Assessment tools	Pathogens, indicators, cyanobacteria, CCL contaminants, UCMR, 6 year review, DBPs, TCR-DS	Rapid detection of waterborne pathogens (bacteria, virus, protozoa), indicators, CCL chemicals and microorganisms, virulence, toxicity screening, distribution system monitoring tools
Source water/ Water resources	Surface water protection BMPs, pesticides, watershed models, underground injection control SWP, UIC, LT2, GWR	Watershed protection BMPs, underground injection control (recharge, aquifer storage and recovery, carbon sequestration), water quality modeling and prediction in context of global change
Treatment/ residuals	Advanced oxidation, UV, pathogen inactivation, membrane systems, adsorptive media, arsenic control, small systems CCL, DBPs, simultaneous compliance, LT2, 6 year review, GWR	Emerging contaminants, water stability, newly identified byproducts from chemical oxidation and reduction, radionuclides, simultaneous compliance, energy and sustainability
Distribution/ storage/ infrastructure	Corrosion control, disinfection byproducts TCR-DS, LCR, DBPs	Biofilms, accumulation and mobilization of contaminants from distribution systems, microbial risk assessment, simultaneous compliance, alternative indicators
Water use/health outcomes	Waterborne disease outbreaks, reproductive health impacts associated with disinfection byproducts, cancer and non-cancer health effects from arsenic CCL, DBPs, arsenic, LT2, 6 year review	Microbial risk characterization, screening tools for evaluating reproductive, cancer and non-cancer health effects from waterborne contaminants, cumulative exposure, relationships between SDWA implementation and public health

¹ SDWA: Safe Drinking Water Act; CCL: Contaminant Candidate List; UCMR: Unregulated Contaminant Monitoring Rule; 6 year review: Review of new information pertaining to SDWA regulated contaminants; DBPs: Disinfection byproduct Rule; TCR-DS: Total Coliform Rule (and distribution systems); SWP: Source Water Protection; UIC: Underground Injection Control; LT2: Surface water Treatment Rule; GWR: Ground water Rule; LCR: Lead and Copper Rule.

b) HOMELAND SECURITY RESEARCH (Framework) (Greg Sayles)

1. Program Context

Beginning in 2002, the EPA Homeland Security (HS) Research Program worked to close the most pressing, rapidly addressable HS research gaps facing the nation. This approach resulted in prompt enhancements to the nation's preparedness. Since then, the EPA's HS responsibilities have been further refined by law and Presidential Order to include:

1. The EPA is the Sector Specific Agency (SSA) for water. The EPA is responsible for protecting water systems and for detecting and recovering from terrorist attacks affecting water systems.
2. The EPA is responsible for decontaminating buildings and outdoor areas impacted by a terrorist attack.
3. The EPA is responsible for developing a nationwide laboratory network to support routine monitoring and response requirements.

The EPA HS Research Program is currently conducting a year-long process to align the program more closely with these EPA HS responsibilities. The program is refining the scope of its mission, the set of customers it directly supports, and the technical work it will pursue for the next 3 to 5 years. The results of this process will be summarized in the HS Research Program Multi-Year Plan (MYP) now under development. The process was initiated by refining the scope of the program from one that addresses a broad set of emergency response research needs to one that is aimed at primarily at terrorist attacks. The revised scope allows the program to devote its efforts to a limited set of primary customers: the Office of Water (OW) and the Office of Solid Waste and Emergency Response (OSWER).

Focusing mainly on these customers does not imply the program will work in a vacuum. On the contrary, 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 our Agency customers, we will conduct research that benefits multiple EPA programs and other Federal agencies as much as possible.

This refined programmatic focus is reflected in our newly drafted long term goals:

Long Term Goal 1: By 2012, the Office of Water, water utilities and other clients use Homeland Security Research Program products and expertise to improve protection from and the capability to respond to terrorist attacks on the nation's water and wastewater infrastructure.

Long Term Goal 2: By 2012, the Office of Solid Waste and Emergency Response and other clients use Homeland Security Research Program products and expertise to improve the capability to respond to terrorist attacks affecting buildings and the outdoor environment.

2. Strategic Directions, Science Challenges, and Research Needs

The overarching challenge for the program is to provide on-target, high-quality science products in time to help the nation prepare for and recover from the next terrorist attack. Some of the most difficult science challenges in achieving this goal are:

- The development of a microbial risk assessment methodology.
- The identification of standardized, validated, rapid and widely deployable methods for detecting and quantifying the presence of biological agents in water, air, and on surfaces.
- The development and demonstration of efficacious and cost-effective decontamination approaches for large outdoor areas and for water infrastructure for chemical, biological and radiological (CBR) agents.
- The development and demonstration of the effectiveness of disposal options for large volumes of CBR-contaminated materials
- The communication of risk and risk management options to the public during a crisis.

The program's current and future work is aimed at closing these and other science and engineering gaps so that the EPA can better carry out its HS mission. These gaps are summarized as research questions in **Table 1**. Research questions associated with the behavioral sciences are under development and so are not included in Table 1. In response to recommendations by the SAB and the NAS, the program is developing a scoping paper in FY07-08 on the EPA homeland security-related research needs in the behavioral sciences (e.g., risk communication and perception during crises). We plan to summarize relevant research needs, related research being conducted by other organizations, and an analysis of the niche that the HS Research Program can most appropriately fill in addressing these needs.

3. ORD's Current and Future Research Directions

In FY07, the HS Research Program conducted research that will result in improved preparedness of the nation for terrorist attacks on water infrastructure and on indoor and outdoor areas. Research and development activities were designed to improve:

- Prevention of attacks on water systems.
- Strategies and technologies to minimize the spread of and exposure to contamination following an attack.
- Risk-based advisory levels and cleanup goals to inform risk management decision-making.
- Analytical methods and detection technologies for CBR agents.
- Methods to decontaminate indoor and outdoor areas following an attack.
- Disposal options for the residues of decontamination.

Table 1. Homeland Security Research Program: Guiding Research Questions by Long Term Goal and Research Theme

Research Theme	Guiding Research Questions	
	LTG1 – Water	LTG2 – Indoor/Outdoor Areas
Prevention	How can terrorist attacks be or their impact on water infrastructure be minimized?	
Detection	<p>What are the most effective strategies to detect purposeful contamination of drinking water distribution and wastewater collection systems?</p> <p>What sampling, sample preparation and analytical methods should be used to (1) characterize the level and extent of CBR contamination in a distribution system following an act of terrorism, and (2) confirm successful decontamination of the distribution system and treatment of the associated contaminated water?</p> <p>How can scientifically-sound laboratory capacity be established in preparation for response to a CBR attack on our water infrastructure?</p> <p>What is the performance of commercially-ready detectors and what additional detection technologies need development?</p>	<p>What sampling, sample preparation and analytical methods should be used to (1) characterize the level and extent CBR contamination in buildings and outdoor areas following an act of terrorism, and (2) confirm successful decontamination of the indoor or outdoor areas?</p> <p>How can scientifically-sound laboratory capacity be established in preparation for response to a CBR attack on an indoor or outdoor area?</p> <p>What is the performance of commercially-ready detectors and what additional detection technologies need to be developed?</p>
Containment / mitigation	<p>What is the risk of exposure of humans to water contaminated with CBR agents?</p> <p>What is the fate and transport of CBR agents released into distribution and wastewater collections systems and how can the extent of contamination be minimized?</p>	<p>What is the fate and transport of CBR agents released into the environment?</p> <p>What is the risk of exposure of humans to CBR agents in buildings or outdoors?</p>
Decontamination	<p>What are the risk-based cleanup goals for water infrastructure and water contaminated with CBR agents?</p> <p>How can water infrastructure be effectively decontaminated following contamination with CBR agents?</p> <p>How can water contaminated with CBR agents be effectively treated?</p>	<p>What are the risk-based cleanup goals for CBR agent-contaminated indoor and outdoor areas?</p> <p>How can indoor and outdoor areas be effectively decontaminated following contamination with CBR agents?</p> <p>What is the performance of commercially-ready technologies for decontamination of CBR agents in indoor and outdoor settings?</p>
Disposal	What are effective options for disposal of the residuals associated with decontamination of water infrastructure?	How can the residuals associated with decontamination of indoor and outdoor areas be disposed of effectively?

The program has delivered many research products in FY07 – below is a short list of highlights:

- Revised the **Standard Analytical Methods Manual (SAM)**, which contains methods for laboratories to use in measuring specific contaminants possibly associated with a terrorist attack, evaluating the nature and extent of contamination, and assessing decontamination efficacy. SAM has been incorporated into response plans and was used in response to a suspected water tampering incident in Region 1 and 5.
- Developed over 80 oral and inhalation draft **Provisionary Advisory Levels (PALs)** for selected toxic industrial chemicals and warfare agents for acute, short-term, and chronic exposure conditions.
- **Building Retrofit Report and Cost-Benefit Software** provides building owners, managers, engineers, and architects with information about retrofit options that will protect against airborne hazards. The accompanying software provides economic analysis tools to support informed, cost-effective risk management decisions. The report and software are the result of research conducted by the EPA and the National Institute for Standards and Technology (NIST).
- EPANET is a computer model used by many water utilities to understand the movement of a single chemical transported through a distribution system of pipes and storage tanks. Recently, the NHSRC released a new extension to EPANET called **EPANET-MSX (Multi-Species eXtension)** that allows for the consideration of multiple interacting species in water and on pipe walls. EPANET- MSX provides the ability to model a wide range of chemical reactions of interest to water utilities, consultants, and researchers.
- Tested and evaluated homeland security-related tools and new technologies, including **Spray-applied Sporicidal technologies**. In response to stakeholder concerns about the reliability of technologies on the market, this report presents the results of EPA studies giving performance data for ten spray-applied sporicidal technologies that were evaluated for their effectiveness in decontamination of surfaces contaminated with *Bacillus anthracis* spores.
- **Conducted a third annual decontamination workshop** which was very successful in coordinating decontamination efforts across the government, eliminating duplicity and ensuring coverage of research gaps. The 2007 workshop was attended by representatives of the G8 nations.

Although the program's Multi-Year Plan is under development, highlights of some of the program's future emphases are described below:

- *Long-term Goal 1 – Water:* Modeling tools for distribution systems will be de-emphasized as this work matures, while research on developing and testing methods for decontamination of water infrastructure will increase. Developing recommendation on how to minimize the impact of attacks on water systems, especially due to explosions, will increase in emphasis. The testing of commercially-ready detection technologies will increase.

- *Long Term Goal 2 – Indoor and Outdoor Areas:* Research associated with decontamination of indoor areas is evolving to addressing wide-area, outdoor situations. Development of decontamination strategies for anthrax and other biological threats will transition towards chemical and radiological agents.
- *Cross-Program Areas:* Research will continue to develop risk-based advisory levels to inform response activities and cleanup goals to inform clearance decisions in addition to the development of necessary toxicity data for these activities. When the recommendations in the behavioral science scoping paper are implemented, the program expects to increase its efforts in risk communication science. The bulk of the work on development and validation of analytical methods will transition from chemical agents to microbial agents. Development of validated sampling and sample preparation methods will increase in emphasis.

4. Making a Difference

The HS Research Program plans its research products with our customers. The products are intended to address high priority science and engineering needs expressed by OW and OSWER so that these offices can be more effective in carrying out their HS responsibilities. Because the MYP is currently under development, identification of specific future products and their anticipated impact is difficult. However, **Table 2** lists general anticipated outcomes for each major research theme. The impact anticipated for each theme support the Agency’s mission to protect human health and the environment.

Table 2. Anticipated Impacts of HS Research Program Research by Research Theme

Research Theme	Anticipated Impact
Prevention	Reduce the risk to water utilities of being impacted by a terrorist attack.
Containment / Mitigation	Reduced and better defined extent of contamination thereby reducing human exposure and the area needing subsequent decontamination.
Detection	Exposure to contaminants will be reduced by faster recognition of an attack, better delineation of the extent and level of the contamination, better estimates of risk, and more reliable evaluation of decontamination effectiveness.
Decontamination	Reduced exposure to contaminants and faster, more confident return to use of water systems, buildings and outdoor areas.
Disposal	Reduced long-term exposure to contaminants and quicker return to use of water systems, buildings and outdoor areas

c) WATER QUALITY RESEARCH (MYP) (Chuck Noss)

1. Program Context

The Water Quality Research Program (WQRP) is designed to support the Clean Water Act (CWA), and is responsive to EPA's Office of Water and Regional Offices, which are the program's primary clients in developing research priorities. The Agency maintains a WQRP Multi-Year Plan (MYP) that outlines steps and provides a timeline for meeting these needs along with related annual performance goals and measures for evaluating progress. EPA's Board of Scientific Counselors (BOSC), a Federal advisory committee comprised of qualified, independent scientists and engineers, reviewed the WQRP in January 2006. The BOSC review found "...The program is responsive to EPA's Office of Water, which the program has correctly identified as its primary client, in developing their research priorities."

Revision of the 2003 MYP began in late 2006, beginning with restructuring of its long-term goal structure by consolidating its biosolids work into the remaining three LTGs as recommended by the BOSC. The program also increased its level of research in the area of watershed management. This activity was to support more outcome oriented efforts. That trend continues with a shift in focus to support sustainable systems, including water quality and quantity, watershed management processes, and infrastructure needs. The program conducts research on the development and application of water quality criteria; the implementation of effective and sustainable watershed management approaches; and the application of technological options to restore and protect water bodies using information on effective treatment and management alternatives.

2. Strategic Directions, Science Challenges, and Research Needs

The CWA, through use designations, provides the basis for current regulatory approaches. The WQRP research supports efforts to maintain quality to protect those designated uses. However, population growth and migration to coastal regions are leading to increased water demands and water shortages. These demands are also increasing in the agricultural sector to meet challenges for the development and production of biofuels as part of a larger energy policy. At the same time, changing weather patterns and the timing and quantity of precipitation may not continue to provide flows consistent with local and regional historical data, thereby affecting both water quality and quantity. The challenges for the next decade will be to generate new information and tools to support the development and use of water data for multiple uses including decision-making, and for regulatory purposes.

The water quality community has become very interested in developing sustainable systems for managing our nation's water resources. This includes topics such as maintaining our existing water infrastructure, developing and applying green technologies, and protecting water quality as we initiate plans to support the country's energy needs through increases in biofuel production.

Each of these topics brings specific water quality challenges. For example, various concepts of sustainable water systems, (including conservation, water reuse and zero effluent discharge) have been discussed for decades in arid regions of the country. But today, many regions are experiencing water shortages, and they need information and tools to promote sustainable practices.

Our communities are also facing huge expenditures to address problems associated with aging and decaying water and wastewater infrastructure. The issues are broad, but protecting public health and the aquatic environment is estimated to cost between \$300 billion to \$2 trillion in capital and O&M investments over the next 20 years. Research is needed to provide information and tools to help communities to make decisions that prioritize actions and implement plans to move them toward more sustainable activities.

Green technology has been identified as an important tool for addressing ways to decrease stormwater run-off and to enhance the urban environment. This concept is becoming increasingly important as our existing infrastructure is often not capable of dealing with the variable weather events of recent years. Information is needed to assist communities in implementing plans to reduce stormwater run-off, shaving peak flows to treatment facilities, and for protecting public health and aquatic resources.

Meeting energy requirements through biofuel production may broadly impact the environment, and therefore, many of the ORD research programs. Decisions regarding crop selection and agricultural practices can result in increased demands for water usage that in turn may alter water quality; and both may affect attainment of designated uses.

In each of these cases, Water Quality research has a role to play in developing the information and tools needed to help incorporate sustainability concepts into watershed management and decision-making processes. However, the research questions that need to be addressed remain focused on the program's three LTGs. They address the need to develop national criteria that protect designated uses; to provide information and tools to help communities make decisions that lead to sustainable water use practices; and to provide data and models to support the cost effective treatment of stormwater and wastewater including the beneficial use and/or disposal of residuals. The intent is to develop information and tools in an integrated fashion such that management choices made are consistent with other water use decisions being made within the watershed.

3. ORD's Current and Future Research Directions

The 2003 Water Quality MYP, which covers 2003 to 2008, set the primary direction for the program during this time period. The major thrust for the MYP was to aide in assessing the impacts of aquatic stressors in various waterbodies, initially by identifying the causes and sources of impairment; and then developing information and tools for restoring those waters and for protecting high quality and valued resources.

The WQRP program is now structured around the BOSC recommended three long-term goals (described below) to provide research products to be used by the Office of Water, EPA Regions, States, and Tribes as well as local wastewater utilities and regional watershed managers. The work focuses on those topics and products that will be of greatest use in decision-making to support sustainable watershed management.

Water Quality Integrity Research supports regulatory driven needs for revising aquatic life guidelines, recreational water criteria, the effects of emerging contaminants, nutrients, biocriteria and multiple stressor effects on stream biota, and on biological condition gradients for Tiered Aquatic Life Uses (TALU). Specific stressors include habitat alteration, nutrients, pathogens, and emerging contaminants. The Office of Water is the major client for research products developed under this priority and will use them in the development and application of water quality criteria.

Water quality integrity research linking the causes and sources of aquatic system impairment will enable EPA to improve scientific approaches that inform watershed management. Specifically, this research will provide the scientific foundation and information management scheme for an integrated process for assessing, listing, and reporting water quality conditions that meet or fail to meet statutory requirements, including a classification framework for surface waters, watersheds, and regions. As EPA directs and informs the efforts of the States to adopt nutrient criteria for individual waterbodies, research is required to identify nutrient responses based on geographic region, waterbody type, and designated use. Habitat research will continue toward linking stressor-response relationships to a biological condition gradient and TALU framework, while providing information on technical guidance for the development of nutrient water quality criteria for coastal wetlands and estuaries and Great Lakes. Also, the program will provide technical support from the Environmental Monitoring and Assessment Program (EMAP) to the Office of Water support for National Surveys.

Watershed Management Research supports Total Maximum Daily Load (TMDL) allocation processes with the development of information and integrated water quality and quantity modeling and monitoring tools, and including diagnostic tools for impairment, mitigation, and evaluating outcomes. This research supports diagnosis of impairment, mitigation, and achieving success, including support for 305b reporting, use attainability analyses identifying designated uses, and TMDL adaptive management.

To provide more efficient monitoring and diagnostic tools, EPA will continue to develop methods to apply landscape assessment data to improve watershed management and monitoring approaches. Models to determine the likelihood of impairment will be integrated with monitoring strategies in order to relate water quality to land use to better identify both impaired and restored waterbody segments.

To support water quality managers at the local and State level in their quest for cost-effective strategies to restore water bodies and to protect them in the future, research will continue on the development and implementation of watershed management strategies. Existing models of pollutant transport and fate will be expanded to allow the evaluation of alternative strategies for restoring and/or protecting local and state watersheds. Approaches will be developed for monitoring the reduction in the water column pollutants and improvements in aquatic systems. Effective monitoring approaches to demonstrate the effectiveness of protecting designated uses from future development or other impacts will also be studied. Also, a risk-based forecasting capability to aid water resource managers in making scientifically defensible nutrient management decisions will be developed for the Gulf of Mexico to reduce the hypoxia problem.

Other research addresses the role of headwater streams and wetlands as a factor in reducing pollutant loading effects on downstream quality and on information to evaluate the water quality trading programs (N-trading, N-farming). The water quality research that defines how wetlands perform is fundamental to the implementation of water quality trading programs. It will include a comparison of natural and constructed wetlands to determine how seasonal changes in hydrologic regime, stressor load, and upland land use affect the functioning of these systems and will inform the protection and restoration of wetlands. Economic assessments of the use of wetlands in water quality trading will also be conducted.

Research on the best management of manure is necessary to ensure that environmentally responsible practices are available and continue in support of EPA's Wastewater

Management program. Field studies of CAFOs will determine the magnitude of releases to ground waters and surface waters and evaluate control options with emphasis on nutrient and pathogen contaminants, along with emerging chemicals such as endocrine disruptors. This work will support the development of effective TMDLs and National Pollutant Discharge Elimination System (NPDES) permits.

Source Control and Management Research priorities will develop information and tools to characterize, control, and manage point and non-point sources of water quality impairment. Priorities address aging infrastructure, green infrastructure, wet weather flows, and residuals management. Research will be conducted to assess and improve the control of microbial releases from POTWs during periods of significant wet weather events. During these events wastewater flow may exceed POTW treatment capacity, resulting in diversion of wastewater around secondary treatment units followed by recombination with flows from the secondary treatment units or discharging it directly into waterways from the treatment plant. Studies will be conducted on the efficacy of disinfection treatment options under such conditions to determine how to optimize them. Current POTW practices for handling significant wet weather events, such as blending, will be assessed to identify best practices during such events. In out years, this work will lead to reports that POTW managers can use to more cost-effectively operate their systems in wet weather conditions while still protecting water quality.

Research on the performance of non-point source best management practices (BMPs) will be conducted in order to provide information to watershed managers and others for the more cost-effective reduction of pollutant loading to surface waters. Particular emphasis will be placed on green infrastructure and on the variation of BMP cost and performance with geographical and other major influencing variables.

Research will support the development of innovative solutions to manage the nation's aging wastewater infrastructure. It focuses on the science and engineering to improve and evaluate promising innovative technologies and techniques to increase the effectiveness and reduce the cost of operation, maintenance, and replacement of aging and failing wastewater conveyance systems. Research efforts will address uncertainties on demonstration of new and innovative condition assessment, rehabilitation, and designs of wastewater collection systems and comprehensive asset management. This research will support EPA in developing policy and revolving funds allocation decisions to address this multi-billion dollar problem faced by the Nation, and will support utilities and other stakeholders involved in meeting community watershed management goals and in the cost-effective assessment, rehabilitation and management of their systems.

ORD is performing this research to support the needs identified in the Agency's Strategic Plan. ORD and its collaborators are uniquely situated to provide support to the Program Offices and develop the data and tools when they are needed. The Water Quality Program-Targeted research builds basic scientific information and understanding and tool in support of water quality regulation and resource management.

4. Making a Difference

In conclusion, we envision a future where designated uses are met and maintained. It is a simple statement, and it spans many complex environmental problems that will not be solved during the next 5-8 year planning period. It is obvious that we have a long way to go to reach

these desired states, but our research will build on recent advances, and conduct the research that best moves us forward on a path aligned with the Agency's strategic objectives to:

- promulgate protective standards,
- identify contaminant contributions to impaired waters,
- use tools to restore and protect the nation's waters with due consideration to point and non-point sources of contamination, and
- maintain the nation's aging infrastructure.

In following the WQRP MYP, ORD research will support the development of criteria that underpin efforts to protect and maintain the quality and quantity of our water resources; develop predictive tools to help make management decisions to achieve results over various temporal and spatial scales; and promote sustainable and green infrastructure for restoring and growing our communities. Achieving those long-term goals is dependent upon more than just conducting quality research. Good communication is essential for client use of ORD research outputs. Therefore, the process of revising the WQ MYP began, and is concluding, with OW and Regional client input. Also, in late 2007, we are planning to conduct a joint executive level meeting between the ORD Laboratory and Center Directors and the OW Executive Research Committee, along with participation of the water program RCTs and other invited NPDs. The point of this meeting is to discuss corporate level science needs and priorities of the Agencies water programs, and to utilize the forthcoming Executive level conclusions and recommendations to make annual science and budget adjustments to the appropriate MYPs. In this way, any necessary MYP adjustments can be clearly articulated along with the impact of those changes on the research program.

d) ECOSYSTEM PROTECTION RESEARCH (MYP) (Rick Linthurst)

1. Program Context: Impetus and Evolution

The Ecological Research Program (ERP) is setting a new strategic direction to meet compelling needs for better understanding the implications of human impacts on ecosystems and the resources they provide. The processes and functions of ecosystems, the foundation of our health, livelihoods and well-being, are now at risk worldwide.

Scientific and policy reports over the last decade document the need to conserve irreplaceable services provided by ecosystems (e.g., NAS, 1997¹; MEA 2005²; BOSC, 2005³; EPA Stewardship Initiative, 2006⁴; EBASP, 2006⁵; SAB C-VPES 2007⁶; Restoring Nature's Capital, 2007⁷). The United Nations Millennium Ecosystem Assessment (MEA) is one of the most comprehensive reports to date, and documented declines in 15 of 24 ecosystem services worldwide.⁸ Of particular note, the MEA concluded that:

“Even today’s technology and knowledge can reduce considerably the human impact on ecosystems. They are unlikely to be deployed fully, however, until ecosystem services cease to be perceived as free and limitless, and their full value is taken into account.” (MEA 2005)

The nation’s health, security, economic potential, and much of its culture are directly and intimately tied to ecosystem characteristics and quality. Even so, policy and management decisions have failed to take these relationships into account. The ERP will work to change this.

The ERP has been recognized as being in a unique position within the federal government for its research to establish and communicate a greater understanding of the value of ecosystem services and their interdependent relationship to human activities and well-being (BOSC 2005, 2007⁹). ERP scientists conduct core, multi-media research in support of the Agency’s Healthy Communities and Ecosystems goal and past results directly support EPA program office needs, and are now used by EPA Regions, states, and Tribes (e.g., Office of Water is requesting that Environmental Monitoring and Assessment Program (EMAP) procedures be used in all 50 states).

¹ "NAS 1997" = Building a Foundation for Sound Environmental Decisions, Chapter 4: EPA's Position in the Broader Research Enterprise, National Academy of Sciences, 1997. available at <http://www.nap.edu/openbook/0309057957/html/49.html>

² <http://MAweb.org>

³ BOSC 2005 <http://www.epa.gov/osp/bosc/pdf/eco0508rpt.pdf>

⁴ www.epa.gov/epainnov/pdf/rpt2admin.pdf

⁵ US EPA. 2006. Ecological Benefits Assessment Strategic Plan. EPA-240-R-06-001. U.S. Environmental Protection Agency, Office of the Administrator, Washington, DC.

⁶ http://www.epa.gov/sab/07minutes/c-vpress_06-12-07_minutes.pdf

⁷ Restoring Nature's Capital: An Action Agenda to Sustain Ecosystem Services, 2007" available at http://pdf.wri.org/restoring_natures_capital.pdf

⁸ We define ecosystem services as **the products of ecological functions or processes that directly or indirectly contribute to human well-being, or have the potential to do so in the future**. This definition provides a broad interpretation of ecosystem services to characterize services that may or may not be quantifiable.

⁹ BOSC 2007 <http://www.epa.gov/osp/bosc/pdf/ecomc082307.rpt.pdf>

2. Strategic Directions, Science Challenges, and Research Needs

By 2009, the ERP will transition its focus to analyses of ecosystem services. We will conduct innovative, trans-disciplinary research that provides insights, information, and methods that enable decision-makers to assess the benefits of ecosystem services to human well-being. By doing so, we hope to secure the integrity and productivity of our ecological systems over time and at multiple scales. Our goal is to transform the way decision-makers understand and respond to environmental issues, making clear the ways in which their policy and management choices affect the type, quality, and magnitude of services we receive from ecosystems -- such as clean air, clean water, productive soils, and generation of food and fiber.

This new focus will be founded on ERP's extensive experience in environmental monitoring and assessment (EMAP), landscape ecology, modeling ecological stressor-response relationships, assessing vulnerability to natural and human stressors over regional scales (ReVA), and developing alternative future scenarios. It also reflects increased emphasis on ecological forecasting previously described in the ERP's 2003 Research Plan. This new focus parallels recent significant decreases in the ERP's budget and the resulting reduction in the amount of effort that can be placed on collection of regional and national scale field data.

Scientific Challenges: It is a significant scientific challenge to translate intuitive concepts about ecosystem services into operational methods for routinely incorporating quantitative information about these services into decision-making at all scales of governance. Doing so will require the development of credible, scientifically-based methods to:

- Inventory, measure and map, ecosystem services at multiple scales.
- Improve understanding of the effects of stressors on ecosystem services using stressor-response relationships and predictive models.
- Define compelling alternative management options and forecast future scenarios and outcomes.¹⁰
- Develop a decision support platform for decision-makers which enables them to explore outcomes of alternative decision options.
- Identify the "art of the possible" by making intelligent, informed use of knowledge about ecosystem dynamics, thresholds, and resilience; and cross-scale connections among social drivers and natural systems.

Drivers Prompting these Challenges: The ERP will be the first integrated US Federal program to address the difficult topic of maintaining, enhancing and restoring the services provided by the natural environment. The need is significant. In addition to national and international assessments noted above, policy drivers unique to EPA (Executive Order 12866), require an examination of the environmental costs and benefits of EPA's regulatory actions (<http://www.epa.gov/regulations/follow.htm>). Since its inception in 1993, implementation of this Order has been hindered by the inability of EPA to account for the value of ecosystem services and the cost of their loss. Having tools to account for ecosystem services will benefit all Agency Program offices responsible for implementing EO 12866. ERP research will also provide a foundation for implementing EPA's Ecological Benefits Assessment Strategic Plan (2006). To meet

¹⁰ Forecasting and scenario development yield plausible estimates of future outcomes, not precise predictions of short-term events. The latter is covered in the domain of calibrated modeling techniques.

needs for valuation and human health research, the ERP is forming partnerships with economists and social scientists within and outside the Agency to establish trans-disciplinary linkages among social and cultural values, economic and financial assessments, non-monetary valuation, and ecological outcomes. Our research will also support Administrator Johnson's charge to "advance environmental protection while maintaining our economic competitiveness." ERP will also provide methods to "conserve and restore ecosystem functions and services" as called for in EPA's Environmental Stewardship Initiative (2006). Our direction responds to needs identified in the Millennium Ecosystem Assessment (2005), the MEA Action Agenda (2007) and the BOSC 2005 and 2007 Program Review Recommendations.

Research Questions: The overarching research question for the Program is: *What are the effects of multiple stressors on ecosystem services, at multiple scales, over time?* To answer this question we need to develop quantitative, operational definitions for ecosystem services; know how these services are distributed throughout the landscape, and in what quantity and quality; project how they will respond to combinations of large and small scale stressors; and determine alternative management options that would optimize their sustainability.

3. Current Research Directions: Foundation for Future Research

In 2007, ERP is conducting research on monitoring, diagnostic and forecasting, and restoration.

Monitoring: The ERP developed the Environmental Monitoring and Assessment Program (EMAP) to establish statistically-valid, scientifically defensible monitoring frameworks to measure, assess, and report on the status and trends in ecosystem condition at regional and national scales. EMAP has successfully completed national assessments using this framework and has pioneered research to create landscape atlases that have been widely used in government and by NGOs. The ERP is transferring technical support for survey monitoring and assessment to EPA Program Offices; essential technical support for these activities will continue through the Water Quality Program. ERP will continue to analyze EMAP data and analyses as a starting point for identifying, measuring, mapping, and monitoring ecosystem services. The extensive EMAP data base will be invaluable in early testing of hypotheses focusing on landscape-related ecosystem services, such as provisioning and storage of fresh water, regulating nutrients and biogeochemical cycling, and maintaining diverse, resilient terrestrial and aquatic habitat. In collaboration with the Gund Institute at the University of Vermont and the National Geographic Society, the ERP is currently exploring the feasibility of joint production of a report and atlas describing the "State of the Nation's Ecosystem Services."

Diagnostics and forecasting: The ERP is nearing completion on a variety of new methods to diagnose impairments to ecosystems. These include the Causal Analysis / Diagnosis Decision Information System (CADDIS); on-line decision tool-kits to assess regional vulnerability to natural and human stressors in the Mid-Atlantic, Southeast, and Midwest; new multi-media models to estimate the time needed for decreased air mercury emissions to result in fish safe for human consumption; and a suite of studies that are developing ways to quantify and forecast thresholds, or tipping points, in aquatic ecosystems. The ERP will build on its experience in diagnostic and forecasting methods for developing models and spatial techniques to forecast the response of ecosystem

services to natural and human stressors at multiple scales and to quantify these responses in biophysical terms.

Restoration: The ERP has focused its research on restoration on aquatic systems. We are nearing completion of studies that document the effectiveness of riparian buffers on water quality; the effectiveness of small wetlands in restoring water quality in agricultural watersheds; prioritizing watersheds for restoration in the Mid-Atlantic highlands; examining the restoration potential for streams affected by mining; and restoring large floodplain rivers to obtain multiple ecosystem services, including innovative use of natural groundwater cooling to treat thermal discharges while simultaneously improving aquatic habitat, non-structural flood control, and recreational opportunities.

Future Research and Critical Path: The proposed research is designed to answer multiple questions about ecosystem services. We will 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.

Our 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 will meet high-priority EPA program office and region needs with direct relevance to EPA’s mission. We will address (a) *a national-scale pollutant – reactive nitrogen*, (b) *a priority ecosystem – wetlands*, and (c) *complex ecosystems —at community-specific locations* (Mid-west, Willamette, Tampa Bay and the Coastal Carolinas) representing a spectrum of physiographic and socioeconomic characteristics; local, regional, and national drivers of change to ecosystems; and the type and impact of decisions. In addition, cross cutting themes for *human health, landscape, inventory design, model development* and *valuation* will be investigated. Each research project and theme is currently being developed into a research and implementation plan that will include a critical path for work to be done.

Our Role and Partnerships: The ERP is pursuing a strategy of leadership and collaborative partnerships in order to implement its research program. The EPA mandate to “protect human health and safeguard the natural environment” places us in a unique position to lead efforts to characterize the critical link between ecosystem services and human well-being. However to meet our research objectives we must mobilize our own expertise and engage strong partners.

We have established partnerships with EPA Regions 4, 5, 7, 8, 10 and with EPA’s National Center for Environmental Economics (NCEE). We are benefiting from existing partnerships with the academic community via the extramural STAR grant program, representing about 15 universities through 2008 (currently there is no future funding for the ERP STAR program due to budget constraints). We are currently developing non-traditional partnerships with NGOs and other organizations. The ERP has established (or in process) collaborative agreements the Gund Institute for Ecological Economics, the Willamette Partnership, the Natural Capital Project, National Geographic, and NSF’s National Ecological Observatory Network (NEON). Finally, the ERP is co-chairing with USDA Forest Service, an Interagency Workgroup on Ecosystem Services under the auspices of OSTP’s Committee on Environment and Natural Resources (CENR) Subcommittee on Ecological Systems. Several individual collaborations are underway with NOAA related to coastal systems, and with USDA related to biofuels development.

We are also seeking ways to harness the capabilities of internet communications in order to achieve the widest possible review of our research program and to seek input and suggestions from others.

4. Making a Difference

The ERP will collaborate with partners to create a decision support platform housing models, maps, animations, and other data-rich displays that make possible the proactive examination of a range of management options for user issues at multiple explicit spatial and temporal scales. We intend to present a new generation of decision support tools, models and visual arrays to better engage and meet the needs of policy makers and managers, and enhance ecological, social and financial knowledge and resources needed to protect and restore ecosystems and their services. The ERP is meeting with federal partners, planners and others to investigate what is needed and by whom to build the architecture for this on-line product.

Research Products: The Ecological Research Program has created four major categories of research products: (1) *Measurements and dynamic maps of ecosystem services*: spatial representations of ecosystem services for communication, outreach, planning, assessment, and resource management; (2) *Predictive models relating to the response of stressors*: forming a foundation to forecast change and proactively assess how ecosystem functions and services are likely to respond to natural and human stressors; (3) *Management Options* using prospective tools, singly and in complex arrays, to develop alternative future scenarios; and (4) *Decision Support* to allow managers and decision-makers to explore how various policies may affect the likely distribution of ecosystem services, human health and well-being outcomes, now and in the future.

Applying Research Results in the Public and Private Sector: The ERP research program is designed to act as a catalyst for innovation in policies, rules, and governance by (1) *Setting policies and guidelines* that can achieve our mission through a variety of policy instruments that do not have the legal force of national rules; (2) *Quantifying benefits for national rule-making* in response to the Office of Management and Budget data requirements for benefit–cost assessments; (3) *Developing environmental metrics and indicators for ecosystem services* for use in periodic reports on the environment or for establishing environmental accounts within our national Gross Domestic Product accounts; and (4) *Catalyzing market innovations* that engage the private sector for environmental protection. ERP research can provide information useful for reducing transactions costs; estimates on the availability, reproducibility, permanence and/or longevity of ecosystem services over space and time; identify opportunities for maximizing multiple services per investment; recommend metrics for documenting environmental outcomes; and provide credible timelines required to achieve expected outcomes (i.e., there is often a lag between action and environmental response).

Environmental Outcomes: Measures of success for the ERP will best be found in enhanced environmental stewardship at local, regional, and national levels:

* Ecosystem services from natural and restored ecosystems are sustained for future generations.

* Ecosystem services are conserved or enhanced while maintaining use of ecosystem resources.

3. Economics and Sustainability

a) ECONOMICS AND DECISION SCIENCES (National Center for Environmental Economics) (Al McGartland)

1. Program context

- What is the impetus for the research program?

The Economics and Decision Science (EDS) research is designed to improve understanding of human and organizational environmental behavior and preferences, which is critical for improving EPA's decision-making, cost-benefit analyses, and implementation strategies. The EDS program assists EPA in estimating costs and benefits of proposed actions, identifies costs savings of non-regulatory approaches, and assists in optimizing the use of its enforcement compliance resources. Behavioral research is important to developing effective solutions to environmental problems because the causes and remedies are behavioral in nature. Better understanding of polluter motivations and environmental values can improve the human and ecosystem health, decrease pollution control costs, and improve the efficiency and effectiveness of environmental policies.

EDS research focuses on areas such as: (1) how people value their health and the environment; (2) corporate and consumer environmental behavior; and (3) market mechanisms and incentives.

- How have the program emphases evolved over the past 3-5 years?

The EDS program was organized around three general themes in 2000¹¹, each theme having a separate Request for Assistance (RFA), including: (1) Valuation for Environmental Policy; (2) Market Mechanisms and Incentives; and (3) Environmental Behavior and Decisionmaking.

In 2002, ORD and OPEI/NCEE initiated a joint effort to review EPA's economic research priorities, which culminated in the preparation of the *Environmental Economics Research Strategy* (EERS)¹². The strategy was developed to guide future environmental economics research at the EPA. The research team interviewed 75 people from 21 EPA offices to determine short and long-term research priorities. The strategy was peer

¹¹ ORD started issuing RFAs in the EDS area starting in 1996.

¹² *Environmental Economics Research Strategy*, EPA/600/R-04/195, ORD, NCER and OPEI, NCEE, December 2005 <http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/EEResearchStrategy.html>. Since publication of the EERS, several additional studies and documents have helped to inform considerations on the direction of the program, including work in the fields of ecological benefits (EPA's *Ecological Benefits Assessment Strategic Plan* <http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/EcologBenefitsPlan.html> (released in 2006), and information from the SAB – Committee on Valuing the Protection of Ecological Systems and Services.

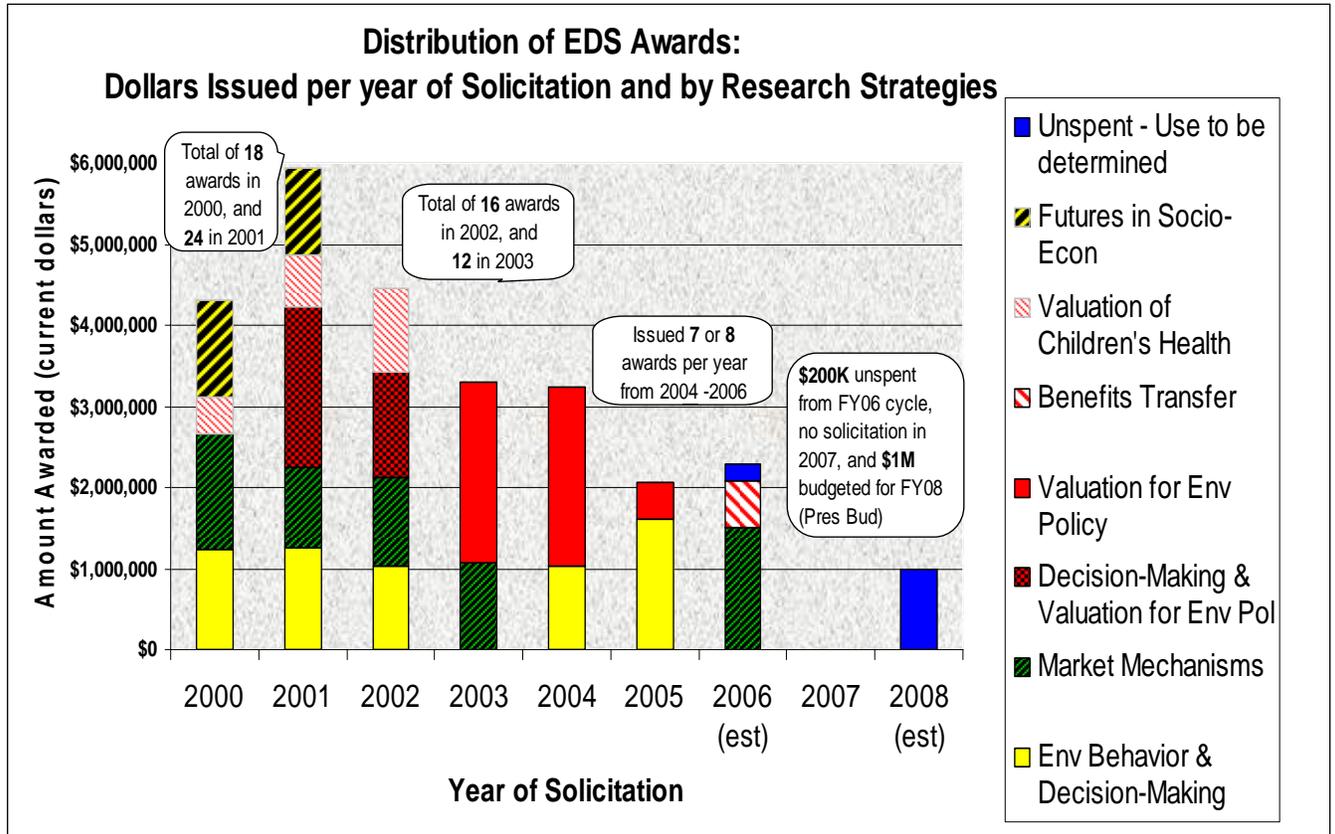
reviewed by the Science Advisory Board. Implementation of the EERS began with the 2003-2004 RFAs.

The focus of the *Valuation for Environmental Policy* RFA has shifted since 2003 based on the results of the EERS. Prior to 2003, it was an EPA-NSF partnership entitled *Decisionmaking and Valuation for Environmental Policy*, and covered a very broad area. From 2000 to 2002, the EDS program also issued separate RFA's on children's health valuation. In 2003, the *Valuation for Environmental Policy* RFA was created and focused more specifically on health and ecosystem benefits per the EERS, with children's health also incorporated. In 2004, a three-part RFA on ecological benefits was issued, focusing on benefits values, benefit transfer, and methodology. In 2005, the focus was on morbidity, with the same three parts. In 2006, the RFA focused more broadly on benefits transfer.

The *Market Mechanisms and Incentives* RFA was started in 2000. This RFA focuses on marketable permits, pollution taxes, and other incentive mechanisms. In 2003, the emphasis was on practical applications. This RFA was not issued in 2004 or 2005. In 2006, the RFA focused on experimental methods for designing new markets and case studies.

The *Environmental Behavior and Decisionmaking* RFA was first issued in 2000. Prior to 2005, it was called *Corporate Environmental Behavior*. This RFA examines behavior in response to government interventions. It was not issued in 2003. In 2004, the RFA examined compliance decisions and costs. In 2005, it was renamed and focused on information disclosure.

The following figure provides information on the distribution of funds issued as assistance agreements for different research objectives supported by the EDS program, covering solicitations issued for the period 2000 to 2006 (note: awards for 2006 Market Incentives solicitation not completed, so estimated based on information from solicitation).



- *What research is currently underway ('07 enacted budget)?*

There were no new EDS solicitations issued during FY2007, due to uncertainties about the financial status of the program, and also to help support efforts to complete work initiated in FY2006 for two solicitations issued in the following areas:

- Market Mechanisms and Incentives: Case Studies and Experimental Testbeds for New Environmental Trading Programs – still awaiting completion of award process, but expect to issue 4-6 awards with ~\$1.5M available.
- Methodological Advances in Benefit Transfer Methods - 3 new awards for ~\$600K.
- A small balance of unexpended funds (~\$200K from FY07) will be carried forward into the FY2008 and is proposed to be used for the next funding cycle.
- In addition to the new awards issued under the FY2006 solicitations, there continues to be ongoing research from prior EDS awards (additional 30+ EDS projects extending into FY2008)

2. EDS Strategic Directions, Science Challenges, and Research Needs (1 1/2 pages)

- *What are the scientific challenges and drivers for the research program in the next 5-10 years?*

Substantial progress has been made to help to advance and refine theories, models and data resources used to help characterize the relationships between the economic activity and environmental quality, including how research in the fields of economics and other

behavioral sciences can help to inform consideration of various environmental management policies. Nevertheless, many gaps remain in our understanding of these relationships, and questions continue to be directed at how to make effective use of research findings to help serve applied policy needs in a timely way.

There continues to be a substantial demand for economic analysis to support the regulatory development and program evaluation activities of the Agency, as well as to help to inform questions arising in legislative proposals (e.g., Greenhouse Gases (GHG) management and policy options). Some examples of these challenges and drivers include:

- Coordination between fields of risk assessment and social sciences to develop risk assessment measures that can be successfully linked to valuation methods and measures. Research programs supporting other disciplines have identified the importance of finding better ways to demonstrate their ability to help to articulate the benefits of improvements in environmental conditions. Potential for additional interdisciplinary work could help serve the analytic needs of economic and other decision science frameworks designed to communicate this information.
- Constraints remain on the amount of available new social science data needed to support original research. Despite the rapid advances in information and technology, challenges continue in constructing and administering sufficient numbers of high quality household, industrial and governmental surveys. Work in the area of economic benefits continues to explore the relative merits of using revealed and stated preference survey research methods. The evolution in environmental management from end-of-pipe controls, to process changes and integrating environmental management directly into product design and manufacturing, complicates efforts to design surveys to measure expenditures for pollution control and to generate cost estimates used for economic impact analyses. Also, as the amount of published literature expands, there may be greater opportunities to extract information from this data, including engaging in benefits transfer, and applying meta-analytic and other statistical tools.
- Advances in computational tools creating greater opportunities to develop analytic models capable of evaluating policies on both micro- and macro-economic scales (e.g., sector-based models integrated into regional or global models). More dynamic modeling might be feasible, rather than relying on simpler static models (e.g., employ more computable general equilibrium models to better track consequences throughout national or global markets).
- Greater emphasis is being placed on the importance and role for addressing uncertainties in the risk science and economic information used to construct regulatory analyses, including effectively incorporating low-probability, high-consequence outcomes into benefit-cost and economic impact evaluations. Even if the uncertainties are quantified, questions remain about choosing suitable means of communicating results of uncertainty analyses to policymakers.
- Market mechanisms have become more familiar as an environmental policy prescription for some air pollutants, and are being suggested as a possible way to address different environmental issues. The complexity and dynamic nature of environmental risks they seek to address (e.g., water pollution trading program) and

emergence of new markets (e.g., concurrent local, state, national and international policies and markets for GHG emissions) provides an opportunity to look at these tools in a new light.

- *What are the associated research questions that need to be addressed?*

Strategic research priorities were recently reassessed for the Environmental Economic Research Strategy (circa 2003-2004). The Research Strategy focuses on five strategic research objectives, where the agency has determined “concentrating research resources will make a difference.”

- Health Benefits Valuation
- Ecological Benefits Valuation
- Environmental Behavior and Decision-Making
- Market Mechanisms and Incentives
- Benefits of Environmental Information Disclosure.

Strategic objectives were developed based on responses to internal Agency survey and criteria:

- Be useful to EPA, states, or other clients;
- Fill a gap in the existing knowledge base;
- Be scientifically feasible and potentially of high quality;
- Be likely to provide useful answers within 5 to 10 years, and
- Be related to EPA’s mission in a policy-relevant context.

The following table taken from the Strategy identifies different research topics and their rankings on a number of dimensions used to gauge relative priorities. This information has assisted the program in organizing the RFAs and the order/frequency of solicitations issued on different research topics.

TABLE ES 1. GENERAL RESEARCH PRIORITIES

Research Topics	Rank Based on Long Term	Rank Based on Short Term	Rank Based on Number of Offices Requesting	Number of Offices Requesting Research
Valuation of Reduced Morbidity Benefits	1	3	2	6
Environmental Behavior and Decision-Making	2	2	2	5
Valuation of Ecological Benefits	3	5	2	5
Benefits of Environmental Information Disclosure	4	4	10	2
Valuation of Mortality Benefits	5	1	7	3
Market Mechanisms and Incentives, Other Than Trading	5	7	1	7
Green Accounting/International Trade/Finance	7	9	6	4
Market Mechanisms and Incentives, Trading	8	6	2	6
Discounting/Intergenerational Equity	9	8	7	3
Risk and Uncertainty: Integration With Valuation	9	10	7	3

3. EDS Future Research Directions (2 pages)

(1) *What research should be done in future years, and what are the critical paths to getting there?*

Consistent with the broad research questions identified in the EERS and identified by other sources of information¹³, there are a number of research directions that should be pursued in future years.

Mortality risk valuation continues to be a critical area. The SAB is in process of reviewing available literature produced that investigates the connection between fatal environmental risks and valuation of changes in these risks. Questions remain on the utility of data and models in the available literature on the valuation of changes in fatal risks. Some environmental policies explore reducing risks that contribute to short changes in life expectancy. It is possible that some distinctive characteristics of populations at risk (e.g., age, health status, income) may give rise to variability in economic values. Future research should address developing suitable risk metrics and valuation of these metrics.

In the area of *morbidity risk valuation*, willingness-to-pay estimates of specific nonfatal endpoints are limited, especially for chronic or long-term health effects. The large number of specific endpoints that could be valued dwarfs the limited resources available to conduct

¹³ Source of materials drawn from discussions with Agency economists, informed by the *Environmental Economics Research Strategy*, recent reviews and assessment of analytic practices at EPA (e.g., report *Estimating the Public Health Benefits of Proposed Air Pollution Regulations* (NAS, 2002); Institute of Medicine report on *Valuing Health for Regulatory Cost-Effectiveness Analysis* (IOM, 2006); SAB-EEAC forthcoming review of VSL and meta-analyses), and experiences developing and reviewing economic analyses produced for regulations and legislative proposals.

valuation research. Future research should examine how to think systematically about additional morbidity endpoints.

Another important area for further research deals with the *treatment of uncertainties* in risk and economic analyses. Uncertainty in economic analyses exists due to limited data and knowledge of economic and physical information. To increase the usefulness of economic analyses to decision makers, uncertainty needs to be rigorously addressed and properly presented and characterized in a clear and concise manner. Important areas of research include cost modeling and uncertainty, expert elicitation, and quantifying risk in economic terms. In addition, research should be conducted to address critical questions about how to deal with uncertainty in climate change.

Ecological benefits estimation is problematic because ecosystems provide a wide range of essential services, but people frequently do not understand the services provided, and many cannot be priced in markets. There is a continued need for measures for ecological services that would survive the rigor of the rule-making review process. Important research areas include defining generic ecosystem indicators and determining how to assign value for benefits transfer, determining what nutrient services are affected, and developing methods to better integrate ecological and economic models.

Few rigorous studies address *environmental justice* issues on a national scale. The continued emphasis on the Agency's implementation of the Executive Order on Environmental Justice, per recent GAO and EPA Inspector General studies, elevates the importance of understanding how to address environmental justice at the Agency. Future research should include national studies addressing measurement of environmental justice, cumulative effects, and how to address the issue in rulemakings and a variety of media.

Assessing the costs and benefits of U.S. policies to address *climate change* raises many new and unanswered questions. Research into the implications of technological advances for cost modeling is particularly important. In addition, research addressing modeling challenges related to how to bridge sector models with broader, economy-wide models and get the best information from both would be very informative.

Finally, in the area of *decision sciences*, there is a need to make progress in improving the understanding of decision-making with respect to compliance behavior and environmental performance, including motivations of firms to join voluntary pollution control initiatives.

(2) *Why is OPEI the right place to do this research, and how will we collaborate with/complement the work of others?*

The Office of Policy, Economics and Innovation contains the National Center for Environmental Economics (NCEE), and this organization will be in charge of managing the EDS program under the proposed move from ORD to OPEI. A primary role of NCEE is to ensure that the Administrator and other senior EPA leaders have sound economic analyses for decision-making. Since NCEE was created in OPEI in the mid-1990s, the institution has grown to contain the largest number of environmental economists within a single office in EPA (presently 24 PhD economists). In addition to NCEE's history of actively supporting the work of the ORD's EDS program, NCEE has a long-standing and productive economic research program of its own. This research is undertaken by both NCEE economists, and by outside researchers working collaboratively with NCEE staff with financial support from NCEE's extramural budget.

Not long after NCEE was founded, there were discussions in EPA on the merits of relocating the office from OPEI to ORD. EPA senior management sought the advice of EPA's Science Advisory Board-Environmental Economics Advisory Committee, and at that time they recommended NCEE remain in OPEI to enable NCEE's research economists to more readily participate closely with the regulatory and policy development processes. This relationship helps to make certain that the technical economic expertise of NCEE's research staff is available to support the development of EPA's economic analyses. NCEE economists help lead efforts to develop guidance on economic analyses, not unlike the role ORD plays in helping to guide development of risk science methods and practices in the EPA. NCEE also advises and review regulatory analyses prepared by other EPA offices, appraising the quality and soundness of their work. This level of access and involvement enables NCEE to identify critical gaps in quantifying the economic benefits and costs of environmental regulations and policies. Some of the benefits of these relationships can be found in several recent EPA documents co-authored by NCEE staff, which identifies critical research strategies and needs, including the above cited Environmental Economics Research Strategy and the Ecological Benefits Assessment Strategic Plan.

The relocation of the EDS program from ORD to OPEI will further EPA's efforts to support data collection and dissemination of research findings on the economic benefits, costs and impacts of environmental regulations. The EDS program will continue to follow a collaborative decision-making process with EPA's program and research offices to ensure research priorities are addressed, and the products of the research continue to be relevant, rigorous and yield high quality products. OPEI will work to ensure that the returns from resources invested in the EDS program are maximized. The direction and efforts of the EDS program will continue to be reviewed by the peer community outside of EPA.

4. Making a Difference (1 page)

- *What are our planned research products?*

Since its inception, the EDS program has produced dozens of published, peer-reviewed articles that have contributed to the field of environmental decision-making and have been used in crafting state and Federal environmental policies. In addition, NCEE economists and scientists engage in research to fill gaps in knowledge, resulting in numerous publications in peer-reviewed journals. Publications in peer reviewed journals by grantees and NCEE economists will continue in FY2008.

In addition, NCEE and NCER jointly sponsor the Environmental Policy and Economics Workshop Series. The purpose of this series is to hold in-depth workshops on timely topics that will further the use of economics as a tool for environmental decision making. Workshop presenters are primarily drawn from the pool of investigators whose research is funded through the EDS program. We generally hold one or two of these workshops per year. Workshops in FY2008 are planned for the Environmental Behavior and Decisionmaking as well as for Health Valuation.

We also plan to obtain information and engage other federal agencies (e.g., DOE, NOAA, USDA, NSF)¹⁴ who share common social science research needs. We hope to learn if there are opportunities for sharing ideas and entering into mutually beneficial research agendas. This approach is also being pursued with several of the existing STAR programs, including the ecological research strategy, where opportunities may exist to make progress in having the research designed so as to yield products suitable for use in economic and other policy analysis frameworks.

- *How will our clients—the programs, regions, and others—use our research?*

We will deliver results to agency decision-makers, program offices, regions, other federal agencies, as well as the research community. The research will be used in economic analyses and for designing policies, as well as to stimulate further research ideas. This will result in improved awareness of the latest scientific advances in economics and decision sciences. The research will result in a better-equipped economic and scientific workforce in the Agency, resulting in improved quality of economic work. In addition, our work will help keep the academic and non-academic research communities informed about EPA's priority economics issues. As a result, more relevant topics will be presented at conferences and published in journals. Research will be funded to fill gaps. Senior EPA leaders will have sound analyses for decision-making.

- *How will the results of our research contribute to environmental outcomes that protect human health and safeguard the environment?*

To be effective, the Agency must understand how people and firms make decisions about and affect the environment, and how the environment affects their quality of life. High-quality environmental economics research is the best way to improve this understanding.

The results of our research will lead to more efficient regulations and policies used to achieve environmental results. Society (individuals, public and private organizations) will be more aware of the social impacts of their behavior on the environment.

Our research will also improve the Agency's use of best scientific practices, resulting in higher quality economic science, and advancing the state of knowledge in the economics field. This will contribute to a better understanding of the underlying economic science.

Overall, this will result in a better use of societal resources, and contribute to cleaner air, water, land, and improved health.

¹⁴ Examples include: USDA's Program of Research on the Economics of Invasive Species Management (PREISM); recent Institute of Medicine report on Valuing Health for Regulatory Cost-Effectiveness Analysis; and products of the Transportation Research Board of the National Academies)

b) SCIENCE AND TECHNOLOGY FOR SUSTAINABILITY (MYP in development) (Gordan Evans)

1. Program Context

As increasing demands are being placed on the earth's resources, the ability of humanity to maintain or improve environmental quality becomes ever greater. The challenge is to prevent or mitigate the negative consequences that come with growth while simultaneously insuring continuous improvement in environmental quality, human health, and our overall standard of living. There is a need for environmental protection approaches that go beyond traditional end-of-pipe control strategies and embrace system-based, long-term solutions. This perspective lies at the heart of what we now refer to as "Sustainability" - 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.

In the Agency's early years, emphasis was placed on controlling or remediating environmental problems. With the passage of the Pollution Prevention Act of 1990, the Agency began to look for ways to incorporate pollution prevention activities into its regulatory framework, leading to the increased use of more holistic approaches. In recognition of this changing perspective, ORD created the "Pollution Prevention and New Technologies (P2NT) Multi-year Plan" in 2000. The overall goal of the P2NT program was 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. In 2004, recognizing the growing importance of sustainability, and pursuant to a long-standing vision that was first set forth in early days of the pollution prevention research program, ORD's senior management formally instructed the organization to begin planning a transition to a sustainability-based research program. This has resulted in the creation of the "Science and Technology for Sustainability (STS) Multi-year Plan".

2. Strategic Directions, Science Challenges and Research Needs

The strategic direction of the STS Research Program starts with the idea that sustainability must combine interrelated ideas drawn from economic, social and environmental realms. These three areas are often referred to as the "Three Pillars of Sustainability". The EPA, however, has a more narrowly focused mission – to protect human health and the environment. As such, the STS Research Program is focused on environmental dimension of sustainability while recognizing that sustainable environmental outcomes are best achieved in a systems-based context. This approach presents a fundamental change in research design. It moves EPA's traditional environmental protection paradigm beyond media-specific, "stovepipe" solutions towards multimedia and systems-wide solutions. To do this, the EPA, along with its partners, will need to develop integrating decision-support tools, sustainability metrics and indicators, and technologies that will ultimately allow decision makers to shift toward practices that promote and lead to sustainable outcomes.

So, how should EPA approach the question of environmental sustainability? From an extensive review of relevant literature and experience, 6 themes of environmental

sustainability research emerge. These so called “6 Themes of Environmental Sustainability” are more fully described in ORD’s “Sustainability Research Strategy”, but a list of key research question that speak to the specific objective of the STS Research Program are listed below: The first four themes of environmental sustainability concern the earth as a natural system, while the last two examine the role of human motivation and behavior.

1) Natural Resource Protection: How can we model the linkages between anthropogenic and natural resource systems in terms of material and energy flows? Can we develop scenarios and integrated models to assess impact on ecosystems and ecosystem services? How do we maximize the benefits received from renewable resources, while simultaneously taking into account the system-wide effects that their use has on the regenerative capacity of the entire system?

2) Non-renewable Resource Conservation: How can we make life cycle assessments more efficient, reliable, and comprehensive? Can technologies be developed that improve the efficiency of non-renewable resource consumption? What opportunities exist to replace non-renewables with renewable feedstocks and materials? How can we use material flow analysis to identify opportunities for reducing or eliminating the use of non-renewable resources?

3) Long-term Chemical and Biological Impacts: How can we improve the yield and specificity of chemical processes? Can we formulate products that reduce waste and that are environmentally benign? Can life cycle tools be used to compare the total environmental impacts of products generated from different processing routes or be used to evaluate new products and technologies including nanomaterials and green chemistries?

4) Human-built Systems and Land Use: What tools can decision makers use to assess the potential impacts of land use and building designs can have on community well being and environmental quality? What sustainability criteria should guide urban land development and revitalization efforts? What core set of principles can best guide the design, construction, and management of human systems (e.g., transportation, energy, water) in a manner that protects natural systems and their properties and functions?

5) Economics and Human Behavior: How can we integrate economic and ecological models to inform environmentally sustainable decisions? What is the relationship between environmental sustainability indicators and measures of economic value? Can economic instruments (e.g., trading schemes, auctions, and taxes) be devised which effectively incorporate society's concerns for sustainability in resource allocation decisions?

6) Information and Decision-making: What are appropriate sustainability goals for energy, water, air, land, materials, and ecosystems? What are the most appropriate trends, indicators, and metrics to measure society’s progress towards reaching sustainable outcomes? What data are needed to construct sustainability indicators and metrics; and how can the data be effectively and efficiently collected?

3. ORD's Current and Future Research Directions

While the STS Research Program officially begins with the start of the 2008 Fiscal Year, selected elements of the soon-to-be-ending P2NT Research Program will make the transition into the new program. To better understand current and future research directions, a brief overview of the overall goal structure of the STS Research Program will be presented, followed by a review of current P2NT research efforts transitioning into the STS Program, and ending with a overview of planned research as laid out within the STS Multi-Year Plan. It's important to note that the resources allocated to this area are modest. In FY07 Congress appropriated \$23.8 M to support the P2NT Research Program, however, the discretionary research budget (which includes extramural, expense and travel funds - but excludes items such as salaries, benefits and program overhead) was \$4.3 M. The assigned research staff consists of 36.5 people. An examination of historic resource trends suggests that the STS Research Program can expect similar allocations in future years.

The overall objective of the STS Research Program is to position the Agency to provide technical support to broader regional and national sustainability policies and initiatives. As such, the 3 Long Term Goals of the STS MYP are outcome-oriented and support the Agency's objective of applying scientific and engineering knowledge to effect long-term environmental improvements and protection of human health.

Long Term Goal 1: Decision-makers adopt ORD-identified and developed metrics to quantitatively assess environmental systems for sustainability. This is the foundation of the STS Research Program and builds on the research already conducted in support of the Agency's "Draft Report on the Environment". This goal seeks to establish a new set of scientifically-based sustainability indicators that are readily comprehensible at multiple scales, relevant to decision-making, and easily accessible to the public.

Long Term Goal 2: Decision-makers adopt ORD-developed decision support tools and methodologies to promote environmental stewardship and sustainable environmental management practices. These are tools designed to help Agency policy-makers, corporate officials, engineers, and local and regional planners to identify and implement sustainability options. In general, these methods, models and tools will assist businesses, communities, governments, and individuals to understand the potential implications of their decisions by relating human activities with the protection and consumption of resources.

Long Term Goal 3: Decision-makers adopt innovative technologies developed or verified by ORD to solve environmental problems, contributing to sustainable outcomes. The focus here is to provide practical technological solutions to those concerned with implementing environmental policies at the local and regional level or those impacted by environmental regulations.

The 7 P2NT research activities that will continue within the new STS Research Program are:

- 1) Sustainable Environmental Systems (LTG 1): An in-house, multi-disciplinary research team seeking ways to provide long-term solutions through new management strategies. Future work will focus on the development and application of

sustainability metrics to support local stakeholder in the management of a regional ecosystem.

2) Life Cycle Assessment Methods (LTG 2): An EPA research area since the early 1990's, the effort has been to improve and promote the use of LCA methods. Future work will focus on streamlining methods of analysis and exploring how to incorporate material flow methods.

3) Environmental Impact Assessment Modeling (LTG 2): These models allow users to evaluate the environmental impacts associated with an inventory of environmental outputs. The primary output has been the "Tool for Reduction of Chemical and Other Environmental Impacts" (TRACI). New work will incorporate sustainability issues such as land, water and energy use.

4) Green Chemistry (LTG 3): An in-house program which has focused on developing cleaner synthesis for chemicals. The research program actively seeks out collaborative partnerships with technology developers and industrial users.

5) Environmental Technology Verification Program (LTG 3): A program which provides the buyers of new technologies un-biased, scientific and quality controlled evaluations of new products.

6) Small Business Innovation Research (SBIR) Program (LTG 3): SBIR provides critical financial support to the best small businesses to help spawn successful commercial ventures that improve our environment while creating jobs and promoting economic growth.

7) P3 Student Sustainability Design Competition (LTG3): An annual collegiate design contest focused on promoting sustainable solutions to national and international environmental concerns.

In addition to the work described above, the new STS Research Program will begin work on two parallel research tracks in the development of sustainability metrics under LTG 1. The first track will start with a comprehensive review metrics currently in use to determine where gaps exist. While a number of fairly simple sustainability indicators currently exist, there is a concern that they are lacking in scientific rigor. If sustainability is to play any role in future environmental policy debates, the process of establishing benchmark values and measuring progress must be vastly improved. The second research track will test research results in real world situations. This will involve the applying indicators and metrics to problems in specific geographic regions, ecosystems and watersheds. It will also be done in collaboration with STS program partners and customers. It's expected that this work will result in a set of well-defined protocols, software tools and guidance for applying sustainability metrics to environmental problems. It will also help highlight the important role that data plays in the development of metrics.

There is an important feedback loop embedded here, and that is how metrics development work will inform both the assessment of current and future trends, and well as the work conducted in LTG 2 (Decision Support Tools) and LTG 3 (Technologies).

Finally, the STS Multi-year Plan provides thoughtful discussion on how this research plan links to other ORD Multi-year Plans, EPA Programs and Regions, other Federal Agencies, local and state governments, and industry.

4. Making a Difference

As was stated earlier, the overall objective of the STS Research Program is to position the Agency to provide technical support to broader regional and national sustainability policies and initiatives. By design it is an outcome-oriented research effort aimed at addressing the question of sustainability by applying scientific and engineering knowledge to effect long-term environmental improvements and protection of human health. The STS Multi-year Plan identifies a number of specific research products under each of the three Long Term Goals.

Under LTG 1 (Metrics): a) A suite of sustainability metrics suitable for inclusion in EPA's Annual Report on the Environment; b) Scientifically-based and validated sustainability metrics for use by industry which focuses on enhancing sustainability outcomes at the design and verification stages of production; and c) Scientifically-based and validated sustainability metrics which provide a means to evaluate innovative environmental technologies.

Under LTG 2 (Decision Support Tools): a) Streamlined LCA methods for use by EPA's Office of Pollution Prevention and Toxics; b) A decision support tool which integrates Life Cycle Assessment methods with Material Flow approaches to support the selection of sustainable materials and products for use by EPA's Office of Solid Waste and Emergency Response; c) An expanded suite of environmental impact assessment models that include sustainable land and water use; and d) A decision framework in support of sustainable management decisions at the local, regional and national level, built upon existing energy and environmental impact models.

Under LTG 3 (Technologies): a) Continue ongoing verifications of innovative environmental technologies and transfer that information to EPA Program Offices, Regional Offices, and other stakeholders; and b) Continue to award SBIR grants in technology areas that have been identified by EPA Regions and Program Offices.

Our clients will use the research products we develop. In creating the STS Research Program, it was clearly understood that the program must address the needs of the Agency's Regional and Program Offices. Toward that end, client offices were surveyed on their research priorities in the area of sustainability and their response guided the design of the program.

The value of the STS Research Program is that it provides the EPA with a suite of scientifically based models, methods, technologies, and strategies that are designed for the long-term protection of the environment. This approach recognizes that problems ultimately exist within systems, and that these systems vary in their scale, both in terms of space and time. The idea espoused here is simple; instead of trying to remediate or restore an ecosystem after damage is done, it is fundamentally better to seek ways to maintain the system's original environmental integrity. Actions must be examined for their system-wide impacts. Though the plan is modest in its scope, it is an important first step towards creating a new vision of environmental protection.

4. Air and Global Climate Change

a) GLOBAL CHANGE RESEARCH (MYP) (Joel Scheraga)

1. Program Context

ORD's Global Change Research Program is part of the interagency U.S. Climate Change Science Program (CCSP), which is mandated under 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. The program uses the results of its assessments to investigate adaptation options to improve society's ability to effectively respond to the risks and opportunities presented by global change.

The planning and implementation of ORD's program is integrated by the CCSP with other participating Federal departments and agencies. EPA coordinates with other CCSP agencies to develop and provide timely, useful, and scientifically sound information to decision makers. This includes support for the research and assessment activities called for in the 2003 CCSP *Strategic Plan*.

The Global Program's emphasis on assessing the impacts of global change and evaluating potential adaptation options has remained the core focus of the program during the past 3-5 years. This is consistent with its unique niche with the larger CCSP. However, with the evolution of the science of global change, the program's emphasis has evolved from assessing impacts towards a greater emphasis on evaluating adaptation options; and more recently, to the development of decision support tools to help resource managers consider global change in their decision making processes. (To support the program's evolution towards "decision support," the program is co-sponsoring with NOAA a new study of "Decision Support Science" by a panel organized under the NRC's Committee on Human Dimensions of Global Change. The objectives of the study are to (1) elaborate a framework for considering climate-related decision support objectives and activities; (2) assess the strengths and limitations of various strategies, activities and tools; and (3) recommend strategies that the sponsors might use for organizing decision support activities.)

The program has also been evolving in response to other stakeholder needs within the EPA Program and Regional Offices. Most recently, with the development of a new "Climate Change Strategy" by the EPA Office of Water (OW), the program will begin to assess the behavior of injected CO₂ in the subsurface and impacts to drinking water sources.

2. Strategic Directions, Science Challenges, and Research Needs

Based upon the recommendations of EPA's Board of Scientific Counselors (BOSC), the Global Program is now organized around three major areas of emphasis consistent with EPA's mission and the statutory requirements placed on the CCSP: (1) supporting the statutory mandates on the CCSP to produce periodic assessments of the potential impacts of climate change; (2) assessment of the impacts of global change on air quality; and (3) assessment of the impacts of global change on water quality/aquatic ecosystems.

Given its focus on supporting EPA's mission and the statutory requirements of its Program Offices, ORD's program fills a unique niche within the CCSP. ORD's program is unique among federal agencies because of: 1) its focus on the potential impacts of climate change on air quality, water quality, and aquatic ecosystems; 2) its focus on providing **decision support** to air and water quality managers; and 3) its unique set of capabilities based upon EPA's particular mission and statutory requirements. As the Global Program focuses on meeting the science needs of EPA's Program and Regional Offices, it relies on these unique capabilities and provides value derived from its comparative advantage relative to other programs.

Supporting Statutory Mandates on the CCSP: The Global Change Research Act of 1990 mandates that the U.S. Global Change Research Program (now the CCSP) produce an assessment of the potential impacts of global change at least every four years. The Office of Management and Budget (OMB) has directed that supporting the production of the periodic assessments mandated under the 1990 Act is the highest-priority activity for EPA's Global Program. (The directive to support the Congressionally-mandated assessment process is also consistent with the focus of ORD's Global Program on "impacts and adaptation.")

Air Quality: Few studies have investigated the effects of global change on air quality. The goal of the Global Program's air quality assessments is to inform EPA's Office of Air and Radiation (OAR) and air quality managers about the implications of global change for their ability to meet their statutory and regulatory requirements (*i.e.*, air quality standards). Another goal is to provide the approaches, methods, and models to quantitatively evaluate the potential effects of global change on air quality, and to identify technology advancements and adaptive responses and quantify their effect on air quality. EPA is the **only federal agency** focusing on the effects of climate change on air quality – rather than the effects of air quality on climate change.

Water Quality/Aquatic Ecosystems: EPA's mission is to protect human health and safeguard the natural environment. EPA provides environmental protection that contributes to making communities and ecosystems diverse, sustainable, and economically productive. Consistent with this goal, EPA's Global Change Research Program is assessing the impacts of global change on water quality and aquatic ecosystems in the United States.

Water quality is affected by changes in runoff following changes in precipitation and evapotranspiration and/or changes in land use. The program is investigating the possible impacts of global change (particularly climate and land-use change) on water quality using a watershed approach. A major focus is on studying the sensitivity to climate change of goals articulated in the Clean Water Act and the Safe Drinking Water Act, and the opportunities available within the provisions of these Acts to address the anticipated impacts.

The program also has been conducting research that evaluates the effects of global change on aquatic ecosystems (which may include lakes, rivers, and streams; wetlands; and estuaries and coastal ecosystems), invasive non-indigenous species, and ecosystem services. EPA's investigations of the effects of global change on aquatic ecosystems have used as input the research being done by other CCSP agencies on marine and terrestrial ecosystems.

Human Health: The assessment of human health impacts is done within the context of the Air Quality and the Water Quality/Aquatic Ecosystems focus areas. Health studies in ORD's Global Program go beyond basic epidemiological research to develop integrated health evaluation frameworks that consider the effects of multiple stresses, their interactions, and human adaptive responses. Along with assessments of the potential health consequences resulting from the impacts of global change on air quality and water quality/aquatic ecosystems, research activities are focused on the possible consequences of global change on weather-related morbidity and vector- and water-borne diseases.

3. ORD's Current and Future Research Directions

The strategic direction for the Global Change Research Program is to conduct innovative research and perform assessments that: 1) reduce uncertainties on the linkages between global change (with particular emphasis on climate variability and change) and air quality, water quality, and aquatic ecosystems; 2) enable EPA's Office of Air and Radiation to effectively account for global change while fulfilling its statutory requirements; 3) enable State and local air quality managers to consider global change in their decisions through improved characterization of the potential impacts of global change on air quality; and 4) enable EPA's Program Offices, Regional Offices, and the States to consider global change in their decisions through improved characterization of the potential impacts of global change on water quality and aquatic ecosystems.

Supporting Statutory Mandates on the CCSP: In its 2003 *Strategic Plan*, the CCSP made a commitment to produce 21 Synthesis & Assessment Products (SAPs). According to the National Research Council, "an essential component of any research program is the periodic synthesis of cumulative knowledge and the evaluation of the implications of that knowledge for scientific research and policy formulation." Production of the SAPs is intended to meet this fundamental need, and focus on the highest priority research questions being addressed by the CCSP to inform decision makers.

ORD's Global Program is leading the production of two SAPs: (1) SAP #4.4: "Preliminary review of adaptation options for climate sensitive ecosystems." (2) SAP #4.6: "Analyses of the effects of global change on human health and welfare and human systems." The SAPs being produced by ORD's Global Program are of particular importance because they are two of six SAPs required to meet the statutory requirements of Section 106 of the 1990 Global Change Research Act. Production of SAP #4.4 and #4.6 is being done through a Federal Advisory Committee Act (FACA) process, and both reports are on schedule to be completed in December 2007.

Air Quality: The Global Program will complete in 2007 an initial ("interim") assessment of the effects of *climate* change on air quality in the United States. The longer-term goal is to complete by 2012 an assessment of the effects of *global* change on air quality in the United States (including, for example, the effects of climate change, population growth, and economic development). The 2007 "interim assessment" and the 2012 "global assessment" are being conducted in partnership with EPA's Office of Air and Radiation (particularly the Office of Air Quality Planning and Standards), other CCSP agencies (particularly DOE), and academic partners supported through the Science to Achieve Results (STAR) program.

Water Quality/Aquatic Ecosystems: In FY 2007, the Global Program completed four major assessments related to climate change and water quality/aquatic ecosystems: **(1)** An assessment of effects of climate change on combined sewer overflow events in the Great Lakes and New England Regions. (Clients: Being used by Regions 1 & 5, and their State and City partners, in redesign of systems.) **(2)** An assessment of implications of climate change for pollutants and pathogens in surface waters. (Client: Office of Water) **(3)** An assessment of the effects of climate change and interacting stressors on the establishment and expansion of aquatic invasive species, and the implications for resource management. **(4)** A preliminary assessment of the consequences of global change for water quality related to biocriteria.

The Global Program also advanced its efforts to develop tools to inform the adaptive management decisions of water quality managers. The Global Program incorporated a Climate Assessment Tool into the new version of OW's BASINS System (v. 4). This new tool enables water resource managers to evaluate the implications of climate change for water resources, and to examine the effectiveness of alternative management practices under a changing climate. (Clients: OW 3000 registered users of BASINS; Regional, State and local agencies performing watershed and water-quality based studies to support regulatory [TMDL] compliance)

Looking towards the future: EPA's Office of Water recently completed a draft *National Water Program Strategy: Response to Climate Change* that is an initial effort to evaluate how best to meet the nation's clean water and safe drinking water goals in the context of a changing climate. ORD's Global Program played a major role in the developed of this new draft "Climate Strategy." And the Global Program's research and assessments in future years will be closely linked to the goals and "Key Actions" identified in the OW "Climate Strategy."

The most significant major study called for in the OW Strategy (and the Global Program's revised Multi-Year Plan) is a Water Quality Assessment of the sensitivity to climate change of the goals articulated by the Clean Water Act and Safe Drinking Water Act, and the opportunities available within the provisions of these laws to address the anticipated impacts of climate change. The assessment will also develop an atlas of vulnerabilities of water resources and aquatic ecosystems in the United States to climate change.

The Water Quality Assessment will be conducted in partnership with OW. However, ORD's Global Program recognizes that there is a lack of empirical data about the importance and prevalence of climate-related decisions related to water resources. To fill this information gap, the ORD Global Program is already developing a new "decision assessment" process to help prioritize future climate change/water research needs. This process will provide a focus for the Water Quality Assessment and a foundation for future research. It includes a "decision inventory" to identify different classes of climate-sensitive decisions related to water resources in different regions of the country, and an evaluation of the returns from providing better scientific information to inform those decisions.

Finally, ORD's Global Program will work with OW's National Water Program to complement research in the Drinking Water Multi-Year Plan on geologic sequestration. The OW Strategy explicitly calls for the Global Program "to assess and provide decision

support related to the behavior of injected CO₂ in the subsurface and impacts to drinking water resources.”

Partnerships with other CCSP agencies: Much of the research supported by the Global Program through the STAR Program is done through joint RFAs with other federal agencies. For example, the Global Program participated in an interagency partnership between 2000 and 2003 that funded research examining the effect of climate variability (over all temporal scales) on human health. The overarching goal of this effort was to build an integrated climate and health community. This partnership, which included representatives from NOAA, NSF, NASA, and the Electric Power Research Institute (EPRI), as well as staff from EPA’s Global Program, has been used as an example of the type of coordinated research the CCSP desires to promote. More recently, the Global Program issued a 2005 joint solicitation with DOE through the STAR program focused on nonlinear responses of ecosystems to global change. The Global Program will be issuing a joint RFA with the Centers for Disease Control and Prevention (CDC) in 2008 that is focused on the potential health impacts of climate change associated with changes in ecosystems.

4. Making a Difference

The work of EPA’s Global Change Research Program is rooted in provisions of the Clean Air Act (CAA), Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) – as well as the Global Change Research Act of 1990. Its focus on the implications of global change for air quality and water quality/aquatic ecosystems was reaffirmed in a 2005-2006 program review conducted by the EPA Board of Scientific Counselor’s Subcommittee on Global Change: *“The overall conclusion of the Subcommittee is that the Program on the whole has done the ‘right work’ and that it has done it ‘well.’ ... The Subcommittee concludes that the Program has provided substantial benefits to the nation and that it is on course to make significant further contributions to societal outcomes by informing and facilitating decisions by the public and private sector actors who must consider the prospects of global change.”*

b) CLEAN AIR RESEARCH (MYP) (Dan Costa)

1. Program Context

The Clean Air Research program supports the goal of Clean Air by providing the research needed to develop and implement the National Ambient Air Quality Standards (NAAQS) – primarily targeting PM and ozone as high risk pollutants. It also supports, although secondarily, the goals of managing hazardous air pollutants (HAPs). The research program has recently undergone a major restructuring to combine those research areas that had previously targeted air pollutants individually (e.g., PM, ozone, HAPs) into an integrated program that can serve the need for CAA mandated pollutant information while at the same time begin an evolution to a multipollutant program (MPP). The MPP is envisioned to build upon the “source to health outcome” paradigm. Fully implemented, the program would provide the science to support targeted control of emissions and subsequent atmospheric transformation products that most impact health – with the goal of more cost-effective regulation. The impetus to transition to an “air research” program emphasizing the broader mandate of the CAA for NAAQS and HAPs as well as multipollutant approaches reflects the recommendations of several EPA advisory boards (NRC, SAB, and BOSC), and is in-keeping with the reorganization of the Office of Air Quality Planning and Standards (OAQPS) which has adopted in part, a “sector-based” theme.

2. Strategic Directions, Science Challenges, and Research Needs

Facing an array of complex policy decisions that rely on the latest and most robust science, OAR is a major client of Clean Air Research. The challenges and needs of the Program Offices and users in the field (Regions, states and tribes) are many and multi-faceted, and therefore the Clean Air Research program cannot possibly address every research issue identified as a need. Instead, the Program’s research investment targets those needs (outlined below) identified as highest priority for regulatory and policy decisions.

a. PM and Ozone NAAQS - Setting and Implementation: The protection of public health (including susceptible populations) is best achieved through the development and attainment of appropriate, protective air quality regulations. Specific challenges to the review of the PM and ozone NAAQS include:

- Uncertainties surrounding the PM_{2.5} annual standard
- Uncertainties surrounding the PM₁₀ standard (*vis a vis* – coarse PM)
- Level and form of the ozone and PM standards
- Definition / characterization of populations that may be susceptible to air pollution effects
- Potential for an alternative to the mass-based PM standard through identification of hazardous components
- Role of other pollutants in causing adverse health effects

Specific issues related to NAAQS implementation include:

- Continuing non-attainment problems (post-sulfur controls)
- Uncertainties around predicting impact of control strategies on air quality
- Development of improved methods to effectively and rapidly measure pollutants

- Uncertainties around the input variables for refinement of air quality models
- Uncertainties around which sources contribute to ambient levels of PM
- Development of improved emission inventories

b. Mobile and Stationary Air Toxics: The 1990 CAA requires EPA to reduce emissions and exposures to 188 specified HAPs. Air toxics emissions arise from major stationary sources, smaller (area sources), on-road (mobile), and non-road sources (trains, construction equipment, barges, airplanes, etc.). The key challenge now facing the Agency is to determine if there are any remaining *residual risks* after MACT technologies have been installed. There is need for *refined emission inventories of HAP emissions* to support these residual risk determinations and to better estimate potential community exposures. Because air quality monitoring of the HAPS is more limited than with the NAAQS, the quality of the National Air Toxics Assessment (NATA) for the various HAPs is highly dependent on these inventories to model potential exposures. One of the most significant challenges is to understand those sources where pollutants are emitted over a wide geographic area and not from a single stack. These can range from landfills to refinery leaks. It will be critical to get a better handle on these emissions to address future risks

c. Near-Roadway / Traffic: Emerging information linking human proximity to roadways with a range of adverse health effects has led to growing public concern. This concern over potential health impacts has affected several transportation projects across the country as well as other decisions, such as “conformity” with NAAQS, local decisions regarding site selection for schools and freight terminals, and analyses of other projects required under the National Environmental Policy Act. These policy decisions are being made while the scientific certainty for the links to exposures, hazardous agents, and adverse health effects varies greatly, and mitigation techniques need to be identified and evaluated.

d. Moving Toward a Multi-Pollutant Program for Air Quality Management: Fundamental to a multipollutant approach to either policy or air pollution science is the recognition of the complex nature of atmospheric chemistry, deposition, and impacts with both health and ecosystem implications, including climate. There is need to develop new approaches to analyze multipollutant impacts, especially through multimedia pathways, with emphasis on indicators and benchmarks. OAQPS has recently undergone a reorganization to reflect a multipollutant and sector-based (source) perspective. Better tools to characterize the emission species from entire sectors will lead to cost-effective options to reduce the highest risks.

e. Assessing Health and Environmental Improvements Attributable to EPA Actions: Sulfur reduction and controls in combustion emissions have led to major environmental improvements with reduced acid rain and deposition, but the benefits of reductions in other pollutants have been more difficult to demonstrate in terms of health and/or ecological benefit. In spite of the tremendous complexities involved in attributing changes in health or ecological status to changes in air pollution alone, there is considerable interest in developing tools to measure these impacts--an issue also known as “accountability.” There is also interest in ensuring that use of specific technologies to reduce air emissions in response to a particular regulatory requirement does not result in unintended environmental emissions / releases of concern.

f. Indoor Air: The infiltration of outdoor air with its pollutants into the indoor environment is complicated by contaminants from indoor sources. The public looks to ORIA for advice on indoor air problems as well as overall guidance on the issue. ORIA in consultation with ORD generated a document entitled *Program Needs for Indoor Environments Research (PNIER)*. Some of the key needs to support future OAR guidance and policy related to indoor air focus on issues related to chemical and biological indoor contaminants. Intervention studies which examine the effectiveness of EPA's *IAQ Tools for Schools* guidance, and other mitigation measures that might be needed, to reduce indoor exposures in schools located near roadways.

g. Global Climate-Air Quality Interaction: The recent Supreme Court decision on CO₂ and climate has greatly expanded OAR's interest in quantifying climate impact on health, air quality, and other socioeconomic and environmental systems. The linkages between air quality and climate are of growing importance, but little is understood. OAR has increased interest and need for enhanced models to incorporate better chemical, transport, and meteorological parameters both regionally and globally. The interactions between climate change and air pollution loom as a major issue of the 21st century crossing all Offices and program areas.

3. ORD's Current and Future Research Directions

The Clean Air Research program's current focus falls into three main research areas (subdivided into themes) to move the program toward achieving its two long term goals.

- **LTG-1**: Reduce uncertainty in standard setting and air quality management decisions due to advances in air pollution science.

LTG-1 highlights two themes that provide direct support to OAR's mission: 1) development of the NAAQS and other air quality regulations and 2) implementation of the air quality regulations.

Theme 1: Support for the development of the NAAQS and other air quality regulations

The Clean Air Research program is undertaking a systematic evaluation of PM attributes (size and components) that will expand our understanding of how they are related to a range of health outcomes across a range of endpoints (e.g. pulmonary, cardiovascular, immunological, neurological, reproductive and developmental). Innovative epidemiological and toxicological approaches link PM components to effects in susceptible sub-populations while computational toxicology efforts support the development of rapid screening approaches to link results to health outcomes. Questions about PM and co-pollutant health effects continue to dominate the scientific agenda. Air Toxics health research will be undertaken for specific HAPs that are most prominent in the source dominated air sheds under study. To that end, the relative and interactive roles of specific pollutants in causing effects continue to be investigated to define causation and refine our understanding of biologic modes of action. Worthy of highlight is the ten-year, prospective epidemiological MESA-Air Study that will report the initial data (~2012) on the effects of exposure to fine particles and other air pollutants on cardiovascular disease and mortality. To the extent possible, the health research is interdisciplinary, not only across health disciplines but across the physical sciences including exposure science and air quality assessments. As such, maximum power is

gained to address potential interactions among pollutants as well as assessments of specific roles of other pollutants, including selected air toxics, in causing health effects.

Theme 2: Support for implementation of air pollution regulations – Program research provides new and updated data, as well as methods and models to characterize and estimate source emissions. Specific sources such as non-road vehicles, and more diffuse sources arising from airports, seaports, and natural / agriculture biogenic environments are to be emphasized. There is expanded research on carbonaceous particles that are expected to make up a more significant portion of ambient PM as recent regulatory programs reduce ambient sulfate. These improved source data will enrich air quality models that are being refined with more accurate meteorological algorithms to increased ability to forecast air quality changes, thereby improving SIP development and improving the ability to alert the public about episodes of adverse air quality. The concerns with HAPs at the community level have simultaneously forced refinements to smaller grid areas that open the possibility to tie to receptor-based models and allow more accurate identification of contributing source categories and better targeted control strategies.

- **LTG-2:** Reduce uncertainties in linking health and environmental effects to air pollution sources.)

Theme 3: Develop a multipollutant approach to research - The Program is evolving to a multipollutant program (MPP) predicated on integration of its core air pollution science efforts from source and atmospheric characterization to health assessment – this concept was likewise embedded as the major theme of the five year PM centers program. Comprehensive measurements of ambient, indoor, and personal PM concentrations will improve our understanding of how personal exposure to key PM components (and sources) is related to ambient measurements. This MPP is being built on the “source to health outcome” paradigm and is intended to adopt a prominent source (see below) for designated periods depending on source complexity while maintaining lesser efforts on other source categories to develop a frame for additional work as that source area database improves. The challenge is to design a research paradigm(s) to foster a logical and relevant transition from a single-pollutant research focus to a multi-pollutant approach, with the goal of controlling at the source to optimize health risk reductions. Initially, ORD must develop an integrated multiple pollutant research strategy that compliments the goals and needs of ORD clients The MPP will use the NARSTO report expected in 2008 as important insight for its basic design.

Theme 4: Identify specific source-to-health linkages, using “near roadway” as the prototype - As an initial focus for research on source-to-health linkages, ORD will address near road emissions, exposures, and related health risks from mobile sources and evaluate risk management options. Near road air pollution was selected as a central theme because it is a problem that: a) is of pressing Agency client interest / need; b) requires integrated, multidisciplinary field and laboratory sciences; and c) allows the assessment the impacts of mitigation (accountability - see Theme 5 below). A near-road pilot research effort has been initiated, with preliminary studies of near-road emissions, distance from road measurements, development of local-environment dispersion models, and assessments of low-cost mitigation strategies for the indoor-school environment. This research theme expands these efforts to determine the broader significance of near-road emissions from varied traffic, vehicles, and conditions, potentials for exposure and related health risks, and the development of tools for addressing the problem. This

research effort is being leveraged with federal partners to expand the scope and interpretative power of the research endeavor.

Theme 5: Assess health and environmental improvements due to past regulatory actions - Assessing the effectiveness or impact of regulatory decisions on exposure and health (often referred to as “accountability”) is challenging undertaking. ORD clients are particularly interested in any mechanism whereby measures of impact can be ascertained. The complexities of such evaluations are well-appreciated, especially when implementation periods are extended over time, when exposure and health may be affected by factors such as changes health care practices, changes in lifestyle (diet, smoking, obesity trends), or other regulatory or market forces. Several recent studies (intramural and from HEI) have suggested the feasibility of such assessments. As part of this research program, ORD in concert with OAQPS intends initially to develop a framework for accountability studies that will build on a platform of pilot or circumscribed studies which can be used with new innovative modeling approaches to expand over larger environments.

4. Making a Difference

The Clean Air Research program provides critical science to its clients to establish or refine the underpinnings for important regulatory decisions. The Program also provides the tools, models, and the technical support needed to implement these decisions in the field. Forty percent of the publications and reports comprising the database of the criteria and staff paper used for the 2006 PM rule-making were ORD products – both intramural and STAR / extramural. Likewise, products related to implementation of NAAQS have been communicated to states to develop SIPs and related actions to conduct local assessments and devise control strategies. These tools and models range from reliance on Federal Reference Methods (fine and now coarse) for monitoring purposes to CMAQ and related receptor models to assess the impacts of controls and forecast improvements through out-years. Initial compliance-noncompliance designations conducted by OAQPS are also CMAQ dependent. Each public release of CMAQ by ORD has both refinements and major adjustments of uncertainty to enhance their accuracy and precision. In 2007, ORD intramural and STAR products resulted in new atmospheric chemistry modules involving aromatic chemistry that has greatly improved assessments of motor vehicle contributions, and will be part of OTAQ rulemaking anticipated in 2008. Likewise, many of the improvements to SPECIATE which provides critical emission input data for many sources and component-species to the atmospheric models have emanated from ORD efforts, especially recent advances in poorly characterized, but important diffuse sources. These sources have required new technologies; among the sources that have or are undergoing characterization range from agricultural and forest burning and ammonia releases from varied feedlots to air / sea ports and complex highway networks. Similarly, HAP data and refined analytics for PM have aided OTAQ with its rule-making (e.g., off road diesel) and advanced source apportionment models used in the field and research.

The integration of the research with the programmatic mission is highly dependent on close communication between researchers and managers in the Clean Air Research program and client offices and field clients. The current MYP lays out a strategy that serves the current regulatory mandate of EPA and begins to move air pollution sciences that support regulatory decision-making to a more realistic multipollutant paradigm. This strategy has been developed with client involvement and has been integrated to the extent possible to ensure efficiencies or maximal utility of Program products. What has evolved

is a program vision to undertake the challenge to link pollutants sources to their ultimate health outcomes within a multipollutant construct. This construct will continue to evolve as the MYP is enacted. The Near-Road source-environment paradigm has been established as the prototype for initiating this endeavor. The envisioned goal is better-targeted and more efficient control and mitigation strategies – and resultant improved public and environmental health. The accountability framework will be the instrument upon which success can be judged.

5. Technology

a) LAND PRESERVATION RESEARCH (MYP) (Randy Wentzel)

1. Program Context

- **What is the impetus for the research program?**

The Land MYP describes ORD problem-driven research supporting the Office of Solid Waste and Emergency Response (OSWER) research needs. Superfund Amendments and Reauthorization Act (SARA) authorized and directed EPA to conduct and support hazardous substance research with respect to the detection, assessment, and evaluation of the effects on and risks to human health of hazardous substances and detection of hazardous substances in the environment. (SARA 9660b). The purpose of this research program is to provide improved scientific knowledge and develop and apply more cost-effective tools, models, and methods to support decisions on land restoration, materials management, and reuse/land revitalization.

- **How has the program emphases evolved over the past 3-5 years?**

A significant shift in the program to address customer needs in contaminated sediment issues occurred in 2002. More recently, shifts in the program to address vapor intrusion, asbestos effects, Brownfields, and nanotechnology fate and transport have been made. In the SAB review in 2004 and a BOSC review in 2005, emerging needs were stressed for areas such as nanotechnology, mining wastes, and resource conservation. Moving out of lower priority hazardous waste treatment and combustion research into Brownfields and material reuse areas is occurring. Numerous reports from expert panels (National Academy of Sciences, the NACEPT subcommittee on Superfund, Resources for the Futures, etc.) indicate ongoing research needs for protection and restoration of land.

2. Strategic Directions, Science Challenges, and Research Needs

- **What are the scientific challenges for the research+h program in the next 5-10 years?**

As an applied research program, addressing customer science and technology needs is our primary challenge. Successful transfer of research products to users to provide better science or reduce costs is a significant issue. In nanotechnology, working to establish Federal agency leadership for the fate and transport research program is a goal. In material reuse and Brownfields, focusing scientific activities to have a significant impact will be the goal.

- **What are the drivers prompting these challenges?**

The Superfund research program is designed, in collaboration with OSWER and Regions, to address the most important science issues that affect policy development and program implementation. Because of limited resources, it is essential that our efforts are focused on the types of sites and problems that have higher risks, higher uncertainty, and higher impact. The preservation-oriented research program is transitioning to be responsive to program peer-review recommendations and broader OSWER strategic directions by addressing emerging issues in materials management and support of land revitalization decision processes.

- **What are the associated research questions that need to be addressed?**

Contaminated Sediments

- How can we build consensus in application of fate and transport (F&T) models of contaminants and improve modeling use in site decisions?
- When dredging is used to remediate a sediment site, what are the fate and effects of contaminants?
- How effective are alternative technologies vs. sediment dredging?
- What are the critical tissue residues to use as screening levels for aquatic organisms exposed to persistent bioaccumulative toxins (PBTs)?

Ground Water

- What are alternatives to pump and treat methods?
- What characterization, sampling, and analytical methods will reduce the uncertainty in F&T models?
- What long-term performance tools are needed to evaluate the effectiveness of Monitored Natural Attenuation?
- Can Permeable Reactive Barriers (PRBs) be applied to treat inorganic GW contamination?
- How can modeling and sampling methods be improved to reduce uncertainty in analysis of vapor intrusion into homes?
- How can F&T models of fuel components (e.g. MTBE) be improved to reduce uncertainty?

Multimedia and Technical Support Program

- What cost-effective analytical and statistical methods are needed to support site characterization issues?
- What improvement will reduce uncertainty in modeling of oil spill fate and effects?
- What are the impacts of new or improved oil spill countermeasure approaches on fresh and saline water environments?
- What are process improvements can be applied to reduce the impact of mining sites on surface and ground waters?

Resource Conservation

- What are the risk reductions from waste minimization efforts?
- What models and tools can be developed and applied to support community decisions on Brownfields?
- What information on sustainable waste management practices can be integrated to support resource conservation?
- What are the metrics for sustainability in Revitalization/ Brownfields efforts, and their application in urban planning?

Nanomaterial Fate and Transport

- What are the major processes that govern the environmental fate of engineered nanomaterials, and how are these related to physical and chemical properties of those materials?

Disposal, Reuse, and Containment

- What is the mobility of metals in reuse of coal combustion products?

- What are the appropriate leaching methods to determine chemical mobility in material reuse scenarios?
- How can landfills be managed to conserve resources?
- What emerging waste materials issues require scoping?

3. ORD's Current and Future Research Directions

- **What research is ORD currently doing ('07 enacted budget)?**

Long Term Goal 1 Contaminated Sites

Sediments: This research integrates exposure, eco-effects, and remediation research to address client needs. Research themes include: development of a framework for modeling fate and transport of contaminants under different remedial alternatives, defining critical sediment and tissue residue threshold effects for aquatic biota, wildlife, and humans, development of alternative sediment remedies with the potential to be more cost-effective than conventional dredging or capping remedies, and improving the understanding of best management practices.

Ground Water: This research provides leadership to address fate and transport and remediation issues. Research themes include: improving characterization, sampling, and analytical methods to reduce the uncertainty in fate and transport models which will lead to improved exposure estimates supporting risk assessments; demonstrating, evaluating, and optimizing remediation technologies to support the development of in-situ and integrated source remediation approaches; and research on the long-term performance and efficiency of permeable reactive barriers (PRBs) for chlorinated organics and metals.

Multimedia: Research includes the development and application of electrochemical immunosensors, and coupled immunoassay/ mass spectrometry methods to for rapid, accurate, and precise quantification of contaminants in the field. Development of statistical methods to reduce data uncertainty in the measurement processes in site characterization. Mining research will produce lower-cost management of waste materials, limiting drainage and sediment discharges to reduce environmental impacts. Staff also provides technical support to sites.

Long Term Goal 2 Materials Management

Nanomaterial fate and transport: Initiate in-house research

Multimedia modeling: The 3MRA model is being used to develop comparative assessments of ecological and human populations risk reduction resulting from waste minimization priority chemicals (WMPCs) reduction. An outcome of this work will be an ability to quantify, on a national scale, the reduction in risk resulting from the reduction of selected WMPCs.

Brownfields and Land Revitalization: Through the development of tools and methods, we can facilitate revitalization of potentially contaminated sites while encouraging stakeholders to incorporate a balance of social, economic, and environmental interests into growth that will not negatively impact future generations. A decision support tool called SMARTe will inform stakeholders about the entire revitalization process. Application of ORD models and tools will assist in addressing chemical specific issues.

Landfill Research: Current research includes application of a multi-site study of alternative covers for landfills, which has resulted in selection of the new technology at both Superfund and RCRA sites.

Bioreactors will contribute to resource conservation by accelerated waste decomposition and accelerated methane production for energy recovery. ORD and OSW are working with the states in technology transfer.

Leach Testing for Material Reuse: Leach testing evaluates waste materials for compatibility with reuse in road beds, drywall and concrete, mine filling, etc. ORD is investigating a range of leaching tests that consider pH, redox state, liquid: solid ratio and other parameters recognized as factors in determining the release of hazardous constituents to validate their predictive capability. Coal combustion residues (CCRs) are being evaluated for beneficial reuse.

- **What research should be done in future years, and what are the critical paths to getting there?**

The Land Research Program Multi-year Plan was completed in July, 2007 (<http://www.epa.gov/osp/myr/htm#land>), and it lays out the planned program for 2007 - 2012. While much of the research described above will continue, areas of emphasis and shifts in the research are described below.

Superfund contaminated sediment research will emphasize alternative remediation technologies and monitoring. Ground water research will emphasize in-situ treatments, PRB applications, and biofuels. Multimedia research will initiate work in asbestos effects and emphasize mining mitigation technologies.

Multimedia, Multipathway, and Multi-receptor Risk Assessment (3MRA) modeling system will address quality assurance requirements: uncertainty analysis, sensitivity analysis, and parameter estimation and defensible confidence limits to support risk-based decision making.

Brownfields and Land Revitalization work will emphasize Sustainability Planning Criteria which will be developed and implemented for land use plans. Training and technical support to OSWER, regions, states, and local governments will continue for remediation of Brownfield sites.

For nanotechnology F&T research, the primary objectives will be: fate processes in air, water, soil, and biota; environmental modification of released materials; partitioning behavior; chemical interactions; environmental media interactions; and predictive environmental models.

Ongoing research on the operation of landfills as bioreactors will continue to be investigated as a promising practice to increase the lifespan and capacity of landfills. Research on the application of alternative landfill covers will continue because of the impact the research is having on protection of ecological receptors.

- **Why is ORD the right place to do this research (our niche), and how will we collaborate with/complement the work of others?**

ORD is in a unique position to link applied research to effective technical support at the site-specific level. This linkage is enhanced through eight ORD Technical Support Centers, which exist to address inquiries from site managers and regional risk assessors and engineers. ORD also has a liaison stationed in each region to facilitate the application of ORD science to address site-specific issues. ORD researchers partner with OSWER and Regional scientists and engineers to produce OSWER guidance documents, OSWER Directives, and fact sheets. They serve with regional staff on advisory groups and work with them to conduct technology demonstrations.

In 2006, we established an Interagency Collaboration on Environmental Remediation Research (ICERR) Workgroup to develop increased understanding of Federal environmental remediation research programs among the EPA, DOE, NIEHS, National Science Foundation (NSF), and DOD SERDP through the following: program manager-level research program reviews and identification of research areas among the agencies to enhance collaboration and encourage leveraging of research.

4. Making a Difference

- **What are our planned research products?**

- Long Term Goal 1 Contaminated Sites – partial list
- Provide state-of-the-art contaminated sediment transport modeling system for modeling remedial alternatives at contaminated sediment Superfund sites.
- Provide a fully field-validated hybrid modeling/ empirical approach for extrapolating BAFs & BSAFs and predicting the ecological effects of mixtures of PBTs with different rates of metabolism on a site-specific basis
- Report on AquaBlok cap after 3 years
- Evaluation of resuspended sediments and dredging residuals at Superfund sites

- Report on the vertical distribution of VOCs from ground water to soil or subslab interface

- Syntheses document on DNAPL remediation technologies

- Report on the use of decision support framework for MNA and inorganic contaminants

- Performance evaluation of organic-based PRB systems for treatment of arsenic and metals

- Characterizing and modeling water flow and solute transport in ground and surface water mixing zones

- Summary report on the use and assessment of PRBs at hazardous waste sites

- Summary report on the use and assessment of MNA at hazardous waste sites

- Report on evaluation of treatment options for alternative fuel oxygenates

- Capstone report on ex situ biological treatment of fuel oxygenates

- SCOUT statistical software package upgrade to contain new statistical procedures.

- Identification of PCB congeners in a complex matrix

- Journal article on dispersant effectiveness as a function of wave energy in batch and continuous- flow conditions

- Demonstrate the long-term performance of passive treatment of mine waste contaminants of surface water

- Long Term Goal 2 Material Management

- Synthesis report on evaluation of leaching procedures and limitations

- Evaluation of the performance of evapotranspiration covers

- Synthesis report on landfill bioreactor design, operation, and performance

- Workshop report on wastes from natural and anthropogenic disasters

- Report on relation of surface chemistry factors to transport and fate of nanomaterials in soils and sediments

- Nanomaterials: Report on the state-of-the-science for sampling and measurement in environmental media.

- Develop expanded capability within the multimedia modeling system to evaluate contaminant F&T

- Beneficial reuse of coal combustion products

Brownfields SMARTe 2009 edition published
 Journal article on vapor intrusion and engineering factors to determine approaches for remediation

- **How will our clients—the programs, regions, and others—use our research?** See table
- **How will the results of our research contribute to environmental outcomes that protect human health and safeguard the environment?**

Example Activities	Outputs	Client Uses (Regions and states)	Environmental Outcome
<p>Sediments</p> <p>1 Methods and models on extent of contam.</p> <p>2 Field evaluations of monitored natural remediation (MNR) and innovative caps</p>	<p>Sediments</p> <p>1 Advanced F&T models and tools</p> <p>2 Performance data on <i>in situ</i> methods.</p>	<p>Sediments</p> <p>1 Model resuspension and long-term remediation</p> <p>2 Use in guidance, adoption, and use in site-specific decisions</p>	<p>Sediments</p> <p>1 3 major site-specific applications</p> <p>2 In-situ treatment will reduce environ impacts</p>
<p>Ground Water</p> <p>3 PRBs to treat chlorinated organics;</p> <p>4 MNR applications for metals</p> <p>5 Fuel oxygenates transport/ treatment</p>	<p>Ground Water</p> <p>3 Capstone Report site demos, training</p> <p>4 Publication and site specific support</p> <p>5 Synthesis of fuel F&T models and treatment methods</p>	<p>Ground Water</p> <p>3 Used to replace pump & treat at over 100 sites;</p> <p>4 Used at major R1 site</p> <p>5 UST F&T of fuels used in guidance</p>	<p>Ground Water</p> <p>3 More effective, saves O&M costs, e.g. \$6M/ site</p> <p>4 Saved \$10M at site</p> <p>5 Used by states to regulate MTBE</p>
<p>Multimedia</p> <p>6 Technical Support Centers (TSCs)</p> <p>7 Alternative landfill caps</p> <p>8 Research on nanomaterial F&T</p>	<p>Multimedia</p> <p>6 Answer site-specific questions from regions</p> <p>7 Tech transfer to regions and states</p> <p>8 Reports F&T of nanomaterials in media, and key nanomaterial fate characteristics</p>	<p>Multimedia</p> <p>6 Regional staff use at specific sites</p> <p>7 Used at 8 sites in 2006</p> <p>8 Provides scientific leadership in this research area for Federal government.</p>	<p>Multimedia</p> <p>6 Better science or reduces time, or expense at sites</p> <p>7 Approx. \$30M cost savings in 2006</p> <p>8 Provide scientific direction on health and ecological issues</p>

b) NANOTECHNOLOGY RESEARCH (Draft Strategy) (Nora Savage)

1. Program Context

Research during the last two decades in science and engineering has resulted in the fabrication of atomically precise structures. Nanotechnology is generally defined as the ability to create and use materials, devices and systems with unique properties at the scale of approximately 1 to 100 nm. At this particle size, quantum mechanical effects often result in materials that exhibit unique optical, mechanical, magnetic, conductive, chemical and biological properties.

The challenge for environmental protection is to ensure 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 cleanup pollution is also needed.

The Agency currently has a leading role in the various efforts initiated to enhance scientific understanding in issues related to nanotechnology and the environment. EPA is uniquely positioned to play a pivotal role in this area in three main ways. First the Agency has the expertise to integrate human health and ecological data in assessments. Second, EPA's laboratories have unique capabilities to test engineered nanomaterials in aquatic and terrestrial ecosystems, and to measure and model the fate, transport, and transformation of materials in environmental media. Lastly, the Agency has experience and knowledge in the prevention and management of risks from environmental exposures, including the development of technologies to detect, measure, and remediate pollutants.

The Agency has developed an appropriate, complementary, and effective research portfolio by working with others including federal agencies, industry, academia, and non-government organizations to ensure research gaps are covered, critical issues are addressed, and information is communicated to all interested parties. Since 2001, the EPA has funded 35 grants for more than \$12 million on the environmental applications and 51 grants for more than \$17 million on the environmental implications of nanotechnology through its Science to Achieve Results or STAR grants program. Through our Small Business Innovation Research or SBIR program, we have awarded 32 contracts worth more than \$3 million to small businesses for nanotechnology research. In addition a small in-house program on environmentally benign nanotechnology has operated for several years.

In 2004 EPA's Science Policy Council (SPC) created an Agency-wide workgroup to examine nanotechnology from an environmental perspective. The Nanotechnology White Paper was issued in February, 2007.

2. Strategic Directions, Science Challenges, and Research Needs

The scientific challenge for environmental protection and nanotechnology is to ensure that, as the technology matures an increasing numbers of engineered nanomaterials are manufactured, used and recycled or disposed of, any unintended and

harmful effects resulting from human and ecosystem exposures are prevented or minimized.

In addition, regulatory decision making in EPA requires that risk managers have sufficient information on risk and the social and economic implications of various control options before making decisions. Regulatory decisions regarding nanomaterials must be made under existing statutes. Although these statutes do not specifically make mention of engineered nanomaterials, they can be used to determine research needs and identify data gaps. There is little official guidance available outside these statutes that can ensure nanotechnology products will not pose unacceptable risks.

To meet these challenges the Agency must conduct focused research that addressed risk assessment and management needs for nanomaterials in support of the various environmental statutes for which the EPA is responsible. However, there are significant challenges to addressing research needs for engineered nanomaterials and the environment. It will be a difficult and complex task to identify appropriate research needs due to the ever changing nature, amount and types of engineered materials. The type and extent of exposure to the material will vary with material, environmental conditions and surroundings, age of the material, reaction with other compounds, and transport through and between environmental media. It will also depend upon the life cycle stage at which the exposure is likely to occur. While embedded materials may pose little or no occupational or consumer exposure risk, such may not be the case when the material reaches the end of the product life and is recycled or disposed of. Each stage in their lifecycle, from extraction to manufacture, use and recycle/disposal, will present separate research challenges. Engineered nanomaterials also present a particular research challenge over their macro forms in that we have a very limited understanding of the resultant physicochemical properties. Research should be designed to determine the release potential of engineered nanomaterials into the environment and the physicochemical properties controlling the transport and transformation of nanomaterials in environmental media. Such research will come from many sources, including academia, industry, EPA, and other agencies and research organizations.

An overarching, guiding principle for all testing, both human health and ecological, is the determination of which nanomaterials are most commonly used and/or have potential to be released to, and interact with, the environment. These nanomaterials should be selected from each of the broader classes of nanomaterials (carbon-based, metal-based, dendrimers, or composites) to serve as representative particles for testing/evaluation purposes.

While some studies have been done to determine potential toxicity of certain nanoparticles to humans and other organisms (both in vivo and in vitro), less research has been performed on environmental fate and transport, transformation, and exposure potential. Research also is lacking on technologies and methods to detect and quantify nanomaterials in various environmental media. In addition, studies to date indicate that the toxicity of the nanomaterial will vary with size, surface charge, coating, state of agglomeration, etc. Data resulting from research in these areas can be used to inform and develop effects and exposure assessment methods and identify important points of release thereby enabling effective risk management. Specific results could include:

- Identifying, adapting, and, where necessary, developing methods and techniques to measure nanomaterials from sources and in various environmental media;
- Enhancing knowledge of the physical, chemical, and biological reactions nanomaterials undergo, along with resulting transformations, and of persistence

- in air, soil and water;
- Characterizing nanomaterials throughout their life cycles;
- Enabling the capability to predict significant exposure pathway scenarios; and
- Providing data to inform human health and ecological toxicity studies, as well as computational toxicological approaches, and aid in the development of the most relevant testing methods/protocols.

3. ORD's Current and Future Research Directions

NCER's STAR exploratory grants have funded nanotechnology research since 2001. As of the last grant funding cycle (FY 2006), EPA has awarded over \$22M—\$12.2M (35 projects) for environmental applications and \$17.8M (51 projects) to study potential health and ecological impacts. The FY 2007 RFA, lead by NIEHS, will result in the awarding of an additional \$0.5M to support health impacts research. NIEHS and NIOSH will award additional grants under this solicitation.

ORD's FY 2007 nanotechnology research efforts, STAR research will focus on evaluating potential ecological and health impacts in support of EPA's regulatory responsibilities and, to a lesser extent, measurement and treatment applications and "cleaner, greener" manufacture and use.

An ORD-wide Team is developing a Nanomaterial Research Strategy (NRS). The scope of this research document is strategic in that it discusses broad themes and general approaches. The purpose of this strategy is to guide the EPA's Office of Research and Development (ORD) program in nanomaterial research. The NRS identifies a research program which will be coordinated with research conducted by other Federal agencies, noting where the EPA will lead selected research areas and where, for other areas, it will rely on research products under the leadership of other Federal research partners.

The strategy builds on and is consistent with the foundation of scientific needs identified by two critical documents. In 2004 EPA's Science Policy Council (SPC) created an Agency-wide workgroup to examine nanotechnology from an environmental perspective. The Nanotechnology White Paper was issued in February, 2007. Also, in September 2006, the Nanotechnology Environmental and Health Implications (NEHI) work group of the Nanoscale Science, Engineering and Technology (NSET) subcommittee released a report, "Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials", outlining the research needed for the federal government to understand and adequately address the potential risks of nanomaterials. These documents were used as a starting point for identifying critical research needs of the Agency.

This research strategy covers fiscal years 2007-2012 and is problem-driven and focused on addressing the Agency's needs. These research topics were prioritized by determining what research themes were important to support agency risk assessment and management activities, evaluating where ORD expertise could be applied to address and lead the Federal government in research areas, and identifying how partnerships with Federal, academic, and industry researchers would enhance research activities and enable the Agency to play pivotal roles in areas where EPA is not taking the lead. Key scientific questions within each research theme that needed to be addressed were identified. These scientific questions then form the basis of the research strategy. This strategy is currently

undergoing review by the Science Policy Council and an external peer review is planned for November 2008. The four research themes and associated science questions are:

- Theme 1: Sources, Fate, Transport, and Exposure
 - Which nanomaterials have a high potential for release from a life-cycle perspective?
 - What technologies exist, can be modified, or must be developed to detect and quantify engineered materials in environmental media and biological samples?
 - What are the major processes that govern the environmental fate of engineered nanomaterials, and how are these related to physical and chemical properties of those materials?
 - What are the indicators of exposure that will result from releases of engineered nanomaterials?
- Theme 2: Human Health and Ecological Research to Inform Risk Assessment and Test Methods
 - What are the effects of engineered nanomaterials and their applications on human and ecological receptors and how can those effects be best quantified and predicted?
- Theme 3: Risk Assessment Methods and Case Studies
 - How do Agency risk assessment and regulatory approaches need to be amended to incorporate the special characteristics of engineered nanomaterials?
- Theme 4: Preventing and Mitigating Risks
 - What technologies or practices can be applied to minimize risks of engineered nanomaterials throughout their life cycle, and to use nanotechnology to minimize other risks?

Anticipated outcomes from this research program will be focused research products to address risk assessment and management needs for nanomaterials in support of the various environmental statutes for which the EPA is responsible. ORD is uniquely positioned within the Federal government to support the overall NNI objectives while also supporting EPA's strategic goals.

- ORD's research laboratories and centers have the expertise to integrate human health and ecological data to provide the Agency's program and regional offices with scientific information most appropriate for risk assessment and decision support;
- ORD has extensive facilities to test nanomaterials in aquatic and terrestrial ecosystems, as well as to measure and model the fate, transport, and transformation of nanomaterials in environmental media;
- ORD has unique and extensive historical laboratory expertise and capacity to identifying approaches to prevent and manage risks from environmental exposures to nanomaterials, including the development and verification of technologies to detect, measure, and remove nanomaterials from environmental media; and
- ORD has the capability to leverage results from EPA STAR grant research, as well as collaborating with grantees to address the many challenging research issues.

ORD will identify industries, processes, and products which have relatively high potential to release engineered nanomaterials into the environment. Existing literature

will be evaluated to better understand the industries of importance and identify where gaps in information preclude a full assessment of emission/release points of concern. A systematic assessment of the production, use, and ultimate fate of nanomaterials needs to be performed to understand the potential for emissions/releases into the environment. A modified tool using life cycle principles will be developed to better understand which industries pose the greatest potential to emit/release nanomaterials of concern and to inform decision-makers about the overall impact of engineered nanomaterials. This effort will also include a series of assessments for the highest priority industry categories. Comparative assessments will be produced to help inform decision-makers at what stage in the lifecycle of nanomaterials interventions could be used to avoid future environmental pollution.

One of the primary objectives of ORD's research program in support of the National Nanotechnology Initiative is to inform the exposure assessment of nanomaterials, specifically to provide data concerning the source and environmental concentration of these materials. OPPT has recently requested the assistance of ORD to review the E-FAST model, which supports the New Chemicals and Existing Chemicals Programs, for its applicability to nanomaterials.

4. Making a Difference

Research data on the fate, transport and transformation of engineered nanomaterials generated by this program will assist the Agency in both risk assessment and risk management for engineered nanomaterials. Risk assessment research can be used to inform the Agency, industry, and academia about potential proactive and "green" approaches for manufacturing nanomaterials such that releases into the environment can be avoided and/or minimized.

This nanotechnology research program will enable EPA to manage risk associated with nanomaterials, which is vital to achieving the Administrator's priority of Healthy Communities and Ecosystems. The proposed work will allow the Agency to more rapidly assess the impacts on human health and the environment of engineered nanomaterials. This in turn, will result in enhanced protection of our air, water and land resources and healthy communities. Anticipated outcomes from this research program will be knowledge and data that address risk assessment and management needs for nanomaterials in support of the various environmental statutes for which the EPA is responsible. Specific outcomes include:

- Advancing the time line for obtaining realistic data on whether (and in what forms) engineered nanomaterials are released into the environment, and understanding the fate and transport in various environmental media;
- Developing toxicity test protocols necessary to enable nanomaterial safety determinations;
- Developing in vitro test methods predictive of in vivo toxicity, quantitative structure-activity relationships, and other predictive models; and
- Developing technologies or practices that can be applied to minimize hazard and exposure of engineered nanomaterials throughout their life cycle and advancing pollution prevention techniques.

The areas where the EPA has Federal government leadership (fate, transport and exposure; risk assessment; and ecological effects) will be enhanced by this research

program as well as by collaborative activities with other stakeholders. These collaborative activities will complement EPA's research program. EPA is also working with other federal agencies to develop research portfolios that address environmental and human health needs. In addition, the Agency is collaborating with academia and industry to fill knowledge gaps in these areas. Finally, the Agency is working internationally and is part of the Organization of Economic Cooperation and Development's efforts on implications of manufactured nanomaterials.

Initial research activities will provide a foundation for understanding possible material alterations under various conditions and subsequent activities will explore effects, specifically toxicity of the altered materials. This approach will be informed and refined by case studies designed to elicit information on how EPA can address high-exposure-potential nanomaterials. These activities will yield knowledge that will enable the development of systematic and integrated approaches to assess, manage and communicate risks associated with engineered nanomaterials in the environment.

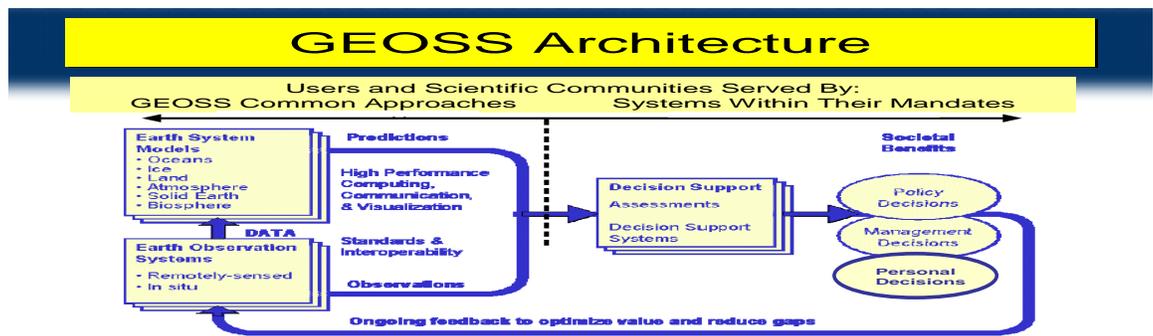
c) GLOBAL EARTH OBSERVATION SYSTEM OF SYSTEMS (GEOSS)/ADVANCED MONITORING INITIATIVE (AMI) (Initiative Description)
(Ed Washburn)

1. Program Context

The term “symbiotic” may be apt to describe the mutual attraction between EPA and GEOSS (Global Earth Observation System of Systems). By comparing the Goals and Objectives in the *2006-2011 EPA Strategic Plan: Charting Our Course* with the societal benefit areas identified in the *Strategic Plan for the U.S. Integrated Earth Observation System*, it is clear that GEOSS has the potential to make significant contributions to EPA’s mission, and likewise, EPA has the potential to make significant contributions to the vision of GEOSS. EPA seized this opportunity back in 2003, as the first Earth Observation Summit was being planned, and since science and technology enables the technical linkages of Earth observations for societal benefits, ORD led EPA’s early efforts in building Agency support for GEOSS, including the launch of AMI (Advanced Monitoring Initiative) in EPA’s FY 2006 budget. EPA continues as an active contributor and leader in both the interagency (US GEO) and international GEOSS effort.

The vision for GEOSS (Global Earth Observation System of Systems) is to realize a future wherein decisions and actions are informed by coordinated, comprehensive, and sustained Earth observations and information. GEOSS will “take the pulse of the planet” by integrating multiple Earth observation systems (networks, databases) and using computer modeling and decision support tools to help revolutionize our understanding of Earth’s complex processes. Over time, GEOSS will provide important scientific information for sound policy and decision making in every sector of society.

EPA started down the pathway towards GEOSS with: 1) its leadership in both the international Group on Earth Observations (GEO) and the US Group on Earth Observations (US GEO); 2) its Science Policy Council support; and 3) ORD’s 34 FY 2006 and 2007 Advanced Monitoring Initiative (AMI) “test bed” projects that inspired a short-term strategy (five strategic directions) with FY 2008 AMI funds to demonstrate some major tangible AMI results by September 2008.



4

Referring to the GEOSS Architecture diagram above - from a policy perspective - of all the players in GEOSS, it is the “EPA’s of the world” that play the most on the right-hand side of this diagram by providing the Earth observation information to the decision

support systems, and US EPA is leading the way.

2. Science Challenges and Research Needs

One major scientific challenge for AMI and GEOSS is being able to demonstrate immediate tangible benefit and value to society, while the underlying science and technology for computer, sensor, and information technologies rapidly changes. With increasing constraints on budgets and varying band width capacity, AMI is focusing on collaborative opportunities across the agency where clever nimble approaches can demonstrate cheaper, faster, delivery of better information for assessing environmental risks, making important environmental decisions, and measuring our performance based on outcomes.

In the first five years, the strategic directions for AMI are being guided from three levels: EPA's Science Policy Council (top-down perspective); the cross-agency committee called EPA GEO (middle-out perspective), and the first 34 AMI pilot projects (bottom-up perspective), which can be organized into three predominant thematic clusters (Air, Water, Integrated). In addition to the three thematic clusters, EPA GEO recognized the critical role of Information Technology (IT)-Information Management (IM) integration as an enabling function, and the need to address capacity building under all four directions.

In the five-to-ten-years time horizon, AMI will expand its focus to opportunities across all of ORD's Multi-Year Plans, and thereby serve to catalyze EPA's improved ability to use more Earth observations in more decision-making sectors. AMI opportunities among ORD's Multi-Year Plans, along with an enhanced presence of GEOSS within EPA, will motivate research questions specific to AMI. In general, the research questions from ORD's Multi-Year Plans will also serve to drive AMI, while AMI also addresses science and technology challenges unique to the case-by-case expansion and adaptation of research products into agency operations. As AMI grows and learns how to handle increasing complexity in modeling and predicting Earth processes, AMI's scientific challenges will become inherently more interdisciplinary in nature, e.g., semantics and taxonomies of data sharing.

For the immediate future, AMI challenges are:

- Maintain Leadership within GEO and US GEO advocating on behalf of the users of observational data and the environmental health decision makers
- Harmonize "Environmental Health Decision Making Opportunities," Sub-Objective's "Strategic Targets" and "Societal Benefit Areas" within EPA's, US GEO's, and GEO's Strategies
- Achieve "Interoperability" (system of systems) along the information continuum (sensors, data, models, decision support systems, outcome indicators) with sensor, information, computing, and communications technologies
- Build "Knowledgebase," through collaborative demonstrations or learning test beds, of improved environmental health decision making at EPA with the integrated systems of AMI, US GEO, and GEOSS

3. ORD's Current and Future Research Directions

The overriding theme of the current (FY07) AMI-GEOSS activities and the five strategic FY08 directions is to demonstrate some early tangible AMI results and the implications for AMI in improving decision making across the agency. AMI funds (FY06-07) now support 34 AMI pilot projects; for FY07 42 new AMI proposals were peer reviewed, of which 17 were funded (note – the number 17 was not pre-specified for FY07; it’s just a coincidence that the same number of proposals were funded in FY06 and FY07).

- Of the 17 FY06 AMI pilot projects, a dozen are focused on air quality, four are focused on coastal zone water quality, and one is focused on automating the time intensive process of converting analog aerial and satellite maps for digital GIS applications.
- The 17 FY07 AMI pilot projects break down into five focusing on air quality, eight focusing on water quality (fresh water and coastal), and four focusing on cross-media integration.
- As of September, 2007, OSP has three AAAS Fellows working on AMI-GEOSS; one renewing AAAS Fellow (oceanographer) and two new AAAS Fellows (immunology/parasitology, atmospheric chemistry).
- EPA’s AMI-GEOSS team supported ORD Assistant Administrator Dr. George Gray as he represented the United States at the GEO III Plenary Meeting in Bonn, Germany, November 27-29, 2006.
- U.S. interagency collaboration on air quality and information technology resulted in EPA leading the air quality demonstration (AIRNow International) expected at the Earth Observation Summit IV in Cape Town, South Africa, November 30, 2007; ORD Assistant Administrator Dr. George Gray is expected to attend.
- ORD-OEI collaboration resulted in improving information technology and performance reporting for AMI projects (e.g., Environmental Science Connector portal access for sharing data/information and ability to collaborate in "real time"), as well as enhancements to the Remote Sensing Information Gateway, and EPA's GEOSS web site www.epa.gov/geoss/ (EPA's GEOSS web site is listed first when one searches for “GEOSS” with Google)

Under each of the following four strategic directions for FY08 – a further breakdown follows: (note – capacity building – the fifth strategic direction - is embedded in each of the other four strategic directions; and not funded as a stand alone entity)

1) Air Quality Forecasting/Assessment and Decision-making for Human Health

- Develop best practices guide for GEOSS air quality applications
- Standardization - Invest in key tools and datasets to increase their usability and portability, e.g., AIRNow International piloted in Shanghai, China
- Develop and demonstrate operational “use cases” (model evaluation and intercomparison; air quality reanalysis for assessment and forecasting; and emissions inventories)
- Coordinate outreach and education efforts

2) Coastal/Source Water Quality and Decision-making for Human Health

- Shaping the way water monitoring information is collected
- Expanding DNA barcoding to periphyton

- Enhancing the way in which data are stored, shared, and used (publicly available GIS portal for Water Quality Exchange)
- Providing essential leadership in a fast-moving system of Earth observing systems (committee on data standards; facilitating water quality portal expansions; facilitate model development and training via the CREM; and outreach through professional papers and workshops)

3) Integrated (Air-Water-Land-Biota) Decision-making for Healthy Communities & Ecosystems

- Integration of multi-media Earth observations in the Great Lakes region (integrate data and software applications; develop a complete design book to document how multimedia Earth observation data, maps, models, other software applications, planning and environmental issues can be integrated; and build an on-line interface and guide to assist users in the understanding and use of the data and software applications)
- Capacity building for decision makers involved in land management in the Great lakes region (establish an advisory group to assist in the development and implementation of training and outreach activities; develop outreach products; and establish a communications/networking/ marketing process to increase awareness and use of the data and tools)

4) Information Technology (IT) Information Management (IM)

- Architecture and data management – address practical requirements for achieving interoperability and the “system of systems”
- System engineering and integration – develop tools to and products to link resources for interoperability (start connecting the AMI projects to enterprise IT)
- User needs, capacity building, and communities of practice – convene workshops and use other mechanisms to gather insights into user needs, means to build capacity, and opportunities to build communities of practice
- Knowledge management/knowledgebase – exploit IT advances that improve knowledge management and apply them to build our collective capacity to learn and make progress faster
- Governance – increase EPA GEO’s engagement beyond the Science Policy Council with other EPA governance entities that can help the AMI effort, such as mechanisms that govern the air program, EPA enterprise IT, and the EPA Innovation Action Council (development of communication and outreach materials and logistics support)

4. Making a Difference

As we get better at predicting Earth processes (extreme weather events, flooding, droughts, air quality, water quality, climate change, etc.) we tend to spend our public and private resources more wisely in a more focused and preventive manner, and tend to save lives, reduce health care costs, and generally improve society at large. For each of the individual 34 AMI pilot projects and collectively for all the 34 AMI projects and the five strategic directions, the research products are demonstrating improved decision making for societal benefit, especially protecting human health and safeguarding the

environment. This is accomplished by ORD collaborating with the expected users and decision makers (program offices, regions, states) in the AMI proposal process and pilot project implementation, and through EPA GEO oversight of AMI project progress.

In general, some expected achievements of the AMI program are:

- In terms of measurable outcomes, demonstrate Societal Benefit Area impacts that are responsive to observational data users and environmental health decision makers (2011+)
- Explicit GEOSS/AMI references embedded in next EPA Strategic Plan (2006)
- Crosswalk of the strategic linkages between EPA's, US GEO's, and GEO's Strategic Plans (2008)
- GEOSS/AMI multiyear strategy with strategic linkages to other ORD MYP Annual Performance Goals (APG)s (2009)
- EPA's Systems "Button Chart" becomes part of US contribution to GEOSS (2008)
- EPA achieves interoperability in at least one of US GEO's Near-Term or Mid-Term Opportunities (2010)
- AMI lessons learned captured and incorporated into a prototype knowledgebase (2008)
- Baseline and performance metrics documented to track the evolution of improving environmental health decision making and forecasting at EPA due to GEOSS/AMI (2009)
- At least one GEOSS/AMI case study (under one of EPA's Strategic Goals) prepared for independent review and evaluation (by 2011)

ATTACHMENT N

Comments of the EPA Science Advisory Board on the Draft Report: Valuing Mortality Risk Reduction

(October 2, 2007)

1. Dr. Cathy Kling:

Comments on the SAB Advisory on EPA's Issues in Valuing Mortality Risk Reduction

This report is clearly written and entirely responsive to the charge questions. I have just a few comments here.

1. Page 3, first sentence of second paragraph. Replace "if not" with "in lieu of" i.e., "How should studies be combined in lieu of using meta-regression?"
2. Page 3, 3rd paragraph. Did the committee discuss the degree to which criteria for identifying appropriate populations from which to select studies might be suggested? It seems likely that there will often be a mismatch between the population being affected by a particular regulation and many of the studies used to produce VSL estimates. If study does not use the identical population from which to sample, does that mean it can provide no information on the appropriate VSL? How close must the population be?
3. Page 4, line five and six. I suggest replacing the last sentence with something like: "Expert elicitation when adequate empirical estimates are available would require that the expert combine mentally the results of dozens of studies. Such a process lacks transparency."
4. Page 5, second paragraph, line 3. Does the panel really mean that more than one estimate from a study should NEVER be selected? How about saying something like "...only one estimate NORMALLY should be selected..." ?
5. On pages 4 and 5 the committee provides a set of information and questions that they indicate RP and SP studies should provide answers to in order to be included among the studies used in the meta-analysis. I assume that the committee means that not only should the answers be provided within the study, but that based on the answers some studies would be excluded from the meta-analysis. So, for example a criterion that might be developed is that an SP study should be excluded if it does not perform a scope test, or if it does, that the scope test fails. As written, the advisory sounds like they are suggesting that the criteria be based strictly on whether certain information is reported (having done a scope test) rather than on possible outcomes (scope was shown to exist or not).
6. Page 6, first paragraph in answer to charge question #5. This is quite subtle, but twice in this paragraph, the term "we may" is used when I think a better term might be "the analyst may." As written, some might infer the committee ascribes to the views following the "we may" language.

7. Page 8, bottom. There is a hard line return that separates the charge question mid line.
8. Page 9, third bullet. There is an unnecessary end parenthesis.
9. Page 9, last bullet. Rather than point specifically to the approach of Smith et al in combining RP and SP, it might be better to simply suggest that work that combines RP and SP be funded. Something like; "Fund studies that assess the advantages and disadvantages of combining RP and SP to estimate VSLs." You could stick "using structural approaches" in there as well if that was important to the committee.

2. Dr. Rebecca Parkin:

For this draft, I found:

- a) the original charge questions to the SAB Panel were adequately addressed in the draft report.
- b) the draft report is clear and logical, and
- c) the conclusions drawn were supported by appropriate information in the body of the draft report.

I do not have any substantive comments.

3. Dr. Rogene Henderson:

I briefly reviewed the letter and the report. The matter discussed is outside my field of expertise, so I can only make comments at a superficial level.

1. The report addresses the charge questions from the EPA.
2. The report appears to be clear and logical although the vocabulary used is foreign to me.
3. The conclusions and recommendations appeared to be supported by the body of the report.

4. Dr. Steve Heeringa:

I have reviewed the Valuing Mortality Risk Panel report. I am not particularly strong on the economic valuation concepts that are discussed in the paper but I was able to follow the presentation including the material in the appendix. I did not detect any substantive errors or inconsistencies and found that the report was responsive to the charge questions and appeared to reflect the best current state of knowledge and practice. I did have one minor editorial suggestion. The report uses many acronyms (WTP, RHS, ...) but there are occasions where the acronym is used before the full label, e.g. willingness to pay (WTP) is given and in a few cases there are acronyms with no prior explanation, e.g. RHS --> ("Right hand side"-an econometric term if there is one). The use of the acronyms should be reviewed to ensure that standard editorial guidelines are followed.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT
National Center for Environmental Assessment
Washington, DC 20460

October 27, 2006

NCEA Washington Office (8623D)

MEMORANDUM

SUBJECT: Request for SAB review of the Draft Ethylene Oxide (EtO) Carcinogenicity Assessment

David A Bussard

FROM: David A. Bussard, Director
National Center for Environmental Assessment-Washington (8623D)
Office of Research and Development

TO: Sue Shallal, Ph.D.
Designated Federal Officer
EPA Science Advisory Board Staff Office (1400F)

This is to request a review by the Science Advisory Board of the draft document entitled "Evaluation of the Carcinogenicity of Ethylene Oxide". This document is an assessment of the carcinogenicity of ethylene oxide (EtO). The assessment was prepared by the National Center for Environmental Assessment (NCEA), which is the health risk assessment program in the Office of Research and Development. The document has been made available for public comment on the Agency's NCEA web site at the following URL:

<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=157664>. The assessment broadly supports activities authorized in the 1990 Clean Air Act and is of particular interest to EPA's Office of Air and Radiation. However, the assessment should also be applicable to the needs of all program Offices and Regions in evaluating the carcinogenicity of EtO.

EPA last published an assessment of the potential carcinogenicity of EtO in 1985. The current assessment reviews the more recent database on the carcinogenicity of EtO. The scientific literature search for this assessment is generally current through June 2004, although a few later publications are included. This assessment focuses on lifetime cancer risk from inhalation exposure.

EtO is a gas at room temperature. It is manufactured from ethylene and used primarily as a chemical intermediate in the manufacture of ethylene glycol. It is also used as a sterilizing agent for medical equipment and as a fumigating agent for spices. The largest sources of human exposure are

in occupations involving contact with the gas in plants (facilities) and in hospitals that sterilize medical equipment. EtO can also be inhaled by residents living near production or sterilizing/fumigating facilities. This document describes the derivation of inhalation unit risk estimates for cancer mortality and incidence based on human epidemiological data.

Attached is a draft of a charge to the Science Advisory Board that identifies the questions and issues we want the Science Advisory Board to address in reviewing the document.

CHARGE QUESTIONS FOR EPA'S SCIENCE ADVISORY BOARD (SAB) REVIEW OF THE ETHYLENE OXIDE (EtO) CARCINOGENICITY ASSESSMENT

EPA's Office of Research and Development (ORD) has requested that the Science Advisory Board (SAB) review its document entitled "Evaluation of the Carcinogenicity of Ethylene Oxide". This document is EPA's draft of the evaluation of the carcinogenicity of ethylene oxide (EtO). The assessment was prepared by the National Center for Environmental Assessment which is the health risk assessment program in the Office of Research and Development. The assessment broadly supports activities authorized in the 1990 Clean Air Act and is of particular interest to EPA's Office of Air and Radiation. However, this review also should be applicable to the needs of all program Offices and Regions in evaluating the carcinogenicity of EtO.

EPA last published a health assessment of the potential carcinogenicity of EtO in 1985 (U.S. EPA, 1985). The current assessment reviews the more recent database on the carcinogenicity of EtO. The scientific literature search for this assessment is generally current through June 2004, although a few later publications are included. This assessment focuses on lifetime cancer risk from inhalation exposure.

EtO is a gas at room temperature. It is manufactured from ethylene and used primarily as a chemical intermediate in the manufacture of ethylene glycol. It is also used as a sterilizing agent for medical equipment and as a fumigating agent for spices. The largest sources of human exposure are in occupations involving contact with the gas in plants (facilities) and in hospitals that sterilize medical equipment. EtO can also be inhaled by residents living near production or sterilizing/fumigating facilities.

The DNA-damaging properties of EtO have been studied since the 1940s. EtO is known to be mutagenic in a large number of living organisms, ranging from bacteriophage to mammals, and it also induces chromosome damage. It is carcinogenic in mice and rats, inducing tumors of the lymphohematopoietic system, brain, lung, connective tissue, uterus, and mammary gland. In humans employed in EtO-manufacturing facilities and in sterilizing facilities, the greatest evidence of a cancer risk from exposure is for cancer of the lymphohematopoietic system. Increases in the risk of lymphohematopoietic cancer have been seen in several studies, manifested as an increase either in leukemia and/or in cancer of the lymphoid tissue. In one large epidemiologic study of sterilizer workers that had a well-defined exposure assessment for individuals, positive exposure-response trends for lymphohematopoietic cancer mortality in males and for breast cancer mortality in females were reported (Steenland et al., 2004). The positive exposure-response trend for female breast cancer was confirmed in an incidence study based on the same worker cohort (Steenland et al., 2003).

In accordance with EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 2005a), EtO was characterized as carcinogenic to humans based on the total weight of evidence.

This evidence, as assessed by EPA, included:

- a) strong, though less than completely conclusive, evidence of carcinogenicity from human studies
- b) sufficient evidence of carcinogenicity in laboratory animals
- c) EtO is a direct-acting alkylating agent with clear evidence of mutagenicity/genotoxicity, and there is sufficient evidence that DNA adduct formation and the resulting mutagenic/genotoxic effects are key events in the mode of action of EtO carcinogenicity
- d) evidence of chromosome damage in humans exposed to EtO, supporting the inference that the same mode of action for EtO carcinogenicity is operative in humans

This document describes the derivation of inhalation unit risk estimates for cancer mortality and incidence based on the human data. An EC₀₁ of 44 µg/m³ (0.024 ppm) was calculated using a life-table analysis and linear modeling of the categorical Cox regression analysis results for excess lymphohematopoietic cancer mortality in males reported in a high-quality occupational epidemiologic study (Steenland et al., 2004). Linear low-dose extrapolation from the LEC₀₁ yielded a lifetime extra cancer mortality unit risk estimate of 5.0×10^{-4} per µg/m³ (0.92 per ppm) of continuous EtO exposure. Applying the same linear regression coefficient and life-table analysis to background male lymphohematopoietic cancer *incidence* rates yielded an EC₀₁ of 24 µg/m³ (0.013 ppm) and a preferred lifetime extra cancer unit risk estimate of 9.0×10^{-4} per µg/m³ (1.6 per ppm). The preferred estimate is greater than the estimate of 5.0×10^{-4} per µg/m³ (0.91 per ppm; EC₀₁ = 44 µg/m³) calculated, using the same approach, from the results of a breast cancer incidence study of the same worker cohort (Steenland et al., 2003), and is recommended as the potency estimate for Agency use.

Because the weight of evidence supports a mutagenic mode of action for EtO carcinogenicity, and in the absence of chemical-specific data on early-life susceptibility, this assessment finds that increased early-life susceptibility should be assumed and the age-dependent adjustment factors (ADAFs) should be applied, in accordance with EPA's *Supplemental Guidance for Assessing Susceptibility From Early-Life Exposure to Carcinogens*, hereinafter referred to as "EPA's Supplemental Guidance" (U.S. EPA, 2005b). Applying the ADAFs to the unit risk estimate of 9.0×10^{-4} per µg/m³ yields an adjusted full lifetime unit risk estimate of 1.5×10^{-3} per µg/m³, and the commensurate lifetime chronic exposure level of EtO corresponding to an increased cancer risk of 10^{-6} is 0.0007µg/m³. [Note that for less-than-lifetime exposure scenarios (or for exposures that vary with age), the unadjusted (adult-based) potency estimate of 9.0×10^{-4} per µg/m³ should be used, in conjunction with the ADAFs as appropriate, in accordance with EPA's Supplemental Guidance.]

Unit risk estimates were also derived from the three chronic rodent bioassays for EtO reported in the literature. These estimates, ranging from 2.2×10^{-5} per µg/m³ to 4.6×10^{-5} per µg/m³, are about an order of magnitude lower than the estimates based on human data [unadjusted for early-life susceptibility]. The Agency takes the position that human data, if adequate data are available, provide a more appropriate basis than rodent data for estimating population risks (U.S. EPA, 2005a), primarily because uncertainties in extrapolating quantitative risks from rodents to humans are avoided. Although there is a fairly sizable difference between the rodent- and human-based estimates, the assessment infers that the similarity between the unit risk estimates based on

the male lymphohematopoietic cancer and the female breast cancer results increases confidence in the use of the unit risk estimate based on the male lymphohematopoietic cancer results.

The unit risk estimates were developed for environmental exposure levels and are not necessarily applicable to higher-level occupational exposures, which appear to be subject to a different exposure-response relationship. However, occupational exposure levels are of concern to EPA when EtO is used as a pesticide (e.g., fumigant for spices). Therefore, this document also presents extra risk estimates for cancer for a number of occupational exposure scenarios.

The SAB Ethylene Oxide Review Panel is being asked to comment on the scientific soundness of this carcinogenicity assessment. The specific charge questions to the Panel are as follows:

Issue 1: Carcinogenic Hazard (Section 3 and Appendix A of the Draft)

1. Do the available data and discussion in the draft document support the hazard conclusion that EtO is carcinogenic to humans based on the weight-of-evidence descriptors in EPA's 2005 *Guidelines for Carcinogen Risk Assessment*? In your response, please include consideration of the following:

1.a EPA concluded that the epidemiological evidence on EtO carcinogenicity was strong, but less than completely conclusive. Does the draft document provide sufficient description of the studies, balanced treatment of positive and negative results, and a rigorous and transparent analysis of the data used to assess the carcinogenic hazard of ethylene oxide (EtO) to humans? Please comment on the EPA's characterization of the body of epidemiological data reviewed. Considerations include: a) the consistency of the findings, including the significance of differences in results using different exposure metrics, b) the utility of the internal (based on exposure category) versus external (e.g., SMR and SIR) comparisons of cancer rates, c) the magnitude of the risks, and d) the strength of the epidemiological evidence.

1.b. Are there additional key published studies or publicly available scientific reports that are missing from the draft document and that might be useful for the discussion of the carcinogenic hazard of EtO?

1.c. Do the available data and discussion in the draft document support the mode of action conclusions?

1.d. Does the hazard characterization discussion for EtO provide a scientifically-balanced and sound description that synthesizes the human, laboratory animal, and supporting (e.g., *in vitro*) evidence for human carcinogenic hazard?

Issue 2: Risk Estimation (Section 4 and Appendices C and D)

2. Do the available data and discussion in the draft document support the approaches taken by EPA in its derivation of cancer risk estimates for EtO? In your response, please include consideration of the following:

2.a. EPA concluded that the epidemiological evidence alone was strong but less than completely conclusive (although EPA characterized the total evidence - from human, laboratory animal, and *in vitro* studies - as supporting a conclusion that EtO as "carcinogenic to humans"). Is the use of epidemiological data, in particular the Steenland et al. (2003, 2004) data set, the most appropriate for estimating the magnitude of the carcinogenic risk to humans from environmental EtO exposures? Are the scientific justifications for using this data set transparently described? Is the basis for selecting the Steenland et al. data over other available data (e.g., the Union Carbide data) for quantifying risk adequately described?

2.b. Assuming that Steenland et al. (2003, 2004) is the most appropriate data set, is the use of a linear regression model fit to Steenland et al.'s categorical results for all lymphohematopoietic cancer in males in only the lower exposure groups scientifically and statistically appropriate for estimating potential human risk at the lower end of the observable range? Is the use of the grouping of all lymphohematopoietic cancer for the purpose of estimating risk appropriate? Are there other appropriate analytical approaches that should be considered for estimating potential risk in the lower end of the observable range? Is EPA's choice of a preferred model adequately supported and justified? In particular, has EPA adequately explained its reasons for not using a quadratic model approach such as that of Kirman et al. (2004) based? What recommendations would you make regarding low-dose extrapolation below the observed range?

2.c. Is the incorporation of age-dependent adjustment factors in the lifetime cancer unit risk estimate, in accordance with EPA's Supplemental Guidance (U.S. 2005b), appropriate and transparently described?

2.d. Is the use of different models for estimation of potential carcinogenic risk to humans from the higher exposure levels more typical of occupational exposures (versus the lower exposure levels typical of environmental exposures) appropriate and transparently described in Section 4.5?

2.e. Are the methodologies used to estimate the carcinogenic risk based on rodent data appropriate and transparently described? Is the use of "ppm equivalence" adequate for interspecies scaling of EtO exposures from the rodent data to humans?

Issue 3: Uncertainty (Sections 3 and 4)

1. EPA's *Risk Characterization Handbook* requires that assessments address in a transparent manner a number of important factors. Please comment on how well this assessment clearly describes, characterizes and communicates the following:

- a. The assessment approach employed;
- b. The use of assumptions and their impact on the assessment;
- c. The use of extrapolations and their impact on the assessment;

- d. Plausible alternatives and the choices made among those alternatives;
- e. The impact of one choice versus another on the assessment;
- f. Significant data gaps and their implications for the assessment;
- g. The scientific conclusions identified separately from default assumptions and policy calls;
- h. The major risk conclusions and the assessor's confidence and uncertainties in them, and;
- i. The relative strength of each risk assessment component and its impact on the overall assessment.

ATTACHMENT Q

Comments of the EPA Science Advisory Board on the Draft Report: Ethylene Oxide

(October 2, 2007)

1. Dr. Rogene Henderson:

a. Does the draft report adequately address the original charge questions asked by EPA?

The charge questions were given in the form of three issues, with sub-charge questions under each issue. In the Executive Summary, the replies to charge questions on Issues 1 and 2 were given, but not for Issue 3. The responses to the charge question related to Issue 3 should be included in the Executive Summary.

It was not clear that there was a response to the charge question under Issue 3 in the text of the report. This appears to be a major omission or not clearly marked.

Otherwise the report did a good job of addressing the charge questions for Issues 1 and 2.

b. Is the report clear and logical?

There are some problems here.

1. For the clarity of the report, the Introduction should include a description of the organization of the report, including the topics discussed in the Appendices.
2. In the Introduction, the charge questions are listed and in parenthesis, by the name of each issue, section numbers and appendices are listed. No explanation is given for what these mean. Presumably the parenthetical information refers to where the issue is addressed. It is obvious what the Appendix numbers mean but I have no idea what the section numbers mean. For example, supposedly one might find the answers to charge questions regarding Issue #3 in Sections 3 and 4, but where are they? Under the answers to charge question 2b, there are paragraphs numbered 1 through 7. Are those sections????? This is confusing.
3. There was a major point of disagreement in the review panel which should be mentioned as a part of the Introduction. This could be done by including a description of the content of the appendices in the Introduction. For this compound, a major question is whether a linear or a nonlinear extrapolation to zero is appropriate for estimating risk at low doses. Ethylene is present normally in the human body and enzymes can oxidize it to ethylene oxide. Exogenous exposures are in addition to an endogenous baseline that is already there. How to handle this in risk assessments is a highly debated issue and the group did not agree on this question. The report does a good job of presenting the two views on page 32 and references the fact that the arguments on either side are given in more detail in Appendices A (Hattis) and C (Swenberg). The recommendation was for the Agency to consider both linear and nonlinear functional forms in the final risk assessment. I think this major point of disagreement deserves to be mentioned not only in the text, but clearly in the Introduction.

c. Are the conclusions and recommendations supported by information in the draft SAB report?

Yes I think the text of the document is clear as to the conclusions and recommendations and how they came to those results. This is particularly true for pages 32-42.

d. Are there technical errors or omissions in the report?

I was surprised to not see a reference to the recent IARC review (June, 2007) of ethylene oxide carcinogenicity. Perhaps it was too recent a report to be included.

2. Dr. Jana Milford

I have completed my review of the Ethylene Oxide report and find it very satisfactory. I liked the way this panel handled differences of opinion among the members, by identifying clearly the strength of opinion on each side and objectively laying out each perspective when they couldn't be reconciled.

3. Dr. Valerie Thomas

The report is very clearly written. It was a pleasure to read. I have no comments, and I think the report should be approved.

There are also several appendices attached to the report. These do not appear to be part of the panel report, and they don't appear to be minority reports or statements of disagreement from panel members. Although the material may indeed be useful to the EPA, I suggest that they not be included in the report, or that they be rewritten as material from the entire panel if that is what they are. I didn't review the appendices.

4. Dr. Rebecca Parkin:

Overall, I found:

- a) the original charge questions to the SAB Panel adequately addressed in the draft report;
- b) the draft report clear and logical; and
- c) the conclusions drawn and recommendations made supported effectively by information in the body of the draft report.

I have the following additional comments.

- a) In both the letter to the Administrator and the Executive Summary there is the statement that "epidemiological data ... were not in and of themselves sufficient to prove a causal association" While this is technically correct, it is crucial to recognize that epidemiological studies can never PROVE causation; they can only disprove a null hypothesis. It is inappropriate to criticize a methodology for what it is not intended or designed to do. Language in the body of the report is more appropriate and should be used in the letter and summary in place of any statement using "prove causation."
- b) EPA's Supplemental Guidance (EPA, 2005b) is cited numerous times, but I didn't find it in the references. Other sources cited but not found in the references include: EPA, 2005

a on p. 27, line 36; Steenland et al, 2004 on p. 28, line 31; Griefe et al, 1988 and Steenland et al, 1987 on p. 29, line 34; and Greenberg et al, 1990 and Teta et al 1993 and 1999, all on p. 31, lines 9-11. Maybe I just didn't find the right list of references; in my opinion, the numerous locations for references made searching for sources unnecessarily complicated.

- c) Which version of the Hill criteria is the committee referring to on p. 18, line 30? Several versions were published and present different lists of criteria. The committee needs to insert a specific reference here.
- d) Minor edit: "lose" on p. 33, line 9 should be "low."

5. Dr. Agnes Kane

The toxicity and carcinogenicity of ethylene oxide are complex issues. As pointed out by the members of the Review Panel, the EPA draft oversimplified some of these issues and omitted key published papers.

- a) Review of the epidemiological evidence: The EPA draft concentrated on one study; however, multiple studies have been reviewed previously by Shore et al., 1993 and LaMontagne and Kelsey, 1998. The women in the NIOSH cohort most likely had lower exposures that resulted in their lower risk of NHL (LaMontagne and Kelsey, 1998). Since the epidemiologic evidence for carcinogenicity of ethylene oxide is mixed, the EPA draft should include a more complete discussion of biological mechanisms and evidence from other animal and human studies using intermediate biomarkers as endpoints (for example, Schulte et al., 1992; Mayer et al., 1991; Schulte et al., 1995). These papers also compare these biomarkers in ethylene oxide – exposed workers as well as controls and may provide insight about exposure to endogenous ethylene oxide which is a metabolite of ethylene.
- b) Ethylene oxide is a highly-reactive, flammable, and explosive chemical. Accidental release resulting in transient, high-level exposures should be a serious concern for EPA. Accidental exposures have been documented in hospital workers (LaMontagne and Kelsey, 1998). In the past, ethylene oxide was intentionally vented to the urban environment in Providence by industries involved in sterilizing hospital supplies (RI Department of Health, personal communication). The EPA draft should mention the potential for accidental and environmental exposures.
- c) The EPA draft focuses on carcinogenicity as an endpoint. However, ethylene oxide has multiple toxic effects on mucous membranes, skin, and the nervous system. It also crosses the testis and placental blood barriers and can cause adverse reproductive effects in males and females in both animals and humans. Ethylene oxide can also cause allergic sensitization in animals and humans leading to skin rashes, eosinophilia, and asthma (reviewed in LaMontagne and Kelsey, 1998).
- d) The target cell involved in ethylene oxide – induced leukemias and lymphomas has not been identified. In primates, a subpopulation of peripheral blood lymphocytes were shown to have elevated frequency of sister chromatid exchanges that persisted up to six years after exposures (Kelsey et al., 1988). This observation raises questions about the repair of ethylene oxide – induced DNA alkylation and DNA strand breaks in some hematopoietic cell populations. In the absence of a substantial research base on ethylene oxide – induced DNA damage and repair in potential target cell populations, it is premature to speculate about the shape of the dose-response curve at low doses or the possibility of a threshold dose level.

6. Dr. Kristin Shrader-Frechette

9-23-07 Comments by Kristin Shrader-Frechette on EPA Ethylene Oxide Peer Review

This peer-review document is superb.

Especially good is the peer-review's emphasis on using the full NIOSH data set to estimate the cancer-slope coefficients (p. 35), and on reconsidering the scientific justification for a men-only model for assessing the risk of lymphohematopoietic cancer (p. 40).

Two particularly important sections of the peer-review report, which reinforce the correctness of the original EPA conclusions, are the pp. 36-37 discussion of the strengths of animal, over human epidemiological, data, and the Appendix A (pp. 46-65) discussion of the flaws in presupposing hormetic effects and risk thresholds for ethylene oxide. These two superb discussions clarify why the majority of the panel is right to support the descriptor of "Carcinogenic to Humans."

One minor way of improving the report would be to ensure grammatical agreement in number throughout the report. Two of the many places where there is disagreement are on p. 9 ("EPA...their...") and p. 14 ("EPA's Office...their..." and "ORD...they..."). To catch all the instances of this grammatical error, it would be possible to do search commands for "their" and "they" throughout the document.

7. Dr. Meryl Karol:

This is an excellent review that addresses the EPA request. The Panel was successful in addressing Charge 3 in the context of the Charges 1 and 2. The response to Charge 2b is organized and presented very clearly and effectively.

a) **Does the draft document address the charge questions?**

The Panel's decision to address the third charge in the context of Charges 1 and 2 is reasonable.

b) **Is report clear and logical?**

The *Cover Letter* is written very clearly and carefully. It identifies when Panel members expressed differing viewpoints, and the rationale for each viewpoint, with one exception (paragraph #7 of the letter). The Panel's recommendation for low dose extrapolation of cancer risk is unclear.

Summary, Charge 1a. The final sentence in response to this charge is unclear (ie, "Subsequent recommendations in our report MAY address the apparent inconsistency"). The recommendations either do, or do not, address the inconsistency.

Summary, Charge 2a. The Summary is unclear as to whether the Panel considers the NIOSH cohort to be the best data set for cancer incidence as well as for cancer mortality.

"Unit risk estimate" should be defined (by words and by formula) either in the

Summary or in the Introduction.

P. 28 lines 43-45, please clarify “cancer outcomes”. Is this more than cancer mortality?

c) **Are conclusions and recommendations supported**

It is stated that the literature search for the EPA assessment was current through June 2004. It is helpful that the SAB document includes more recent citations. Perhaps the Albertini and Sweeney reference, currently 2006, in press, can be updated.

d) **Technical errors/omissions**

None

8. Dr. Granger Morgan

The report is clear and well written and is responsive to the charge questions.

To my reading the discussion of the diversity of opinion on whether to label ethylene oxide "carcinogenic to humans" or "likely to be carcinogenic to humans" point up again the problem of using qualitative language that is not tied to any quantitative probabilities. But, at least for the moment we seem to be stuck with this approach and under the circumstances the committee has handled things well.

The argument to work directly with the NIOSH data makes good sense.

I found the Appendices by Dale Hattis and James Swenberg to be interesting and to make a valuable contribution. I would like the letter to include a sentence that mentions them.