# 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.

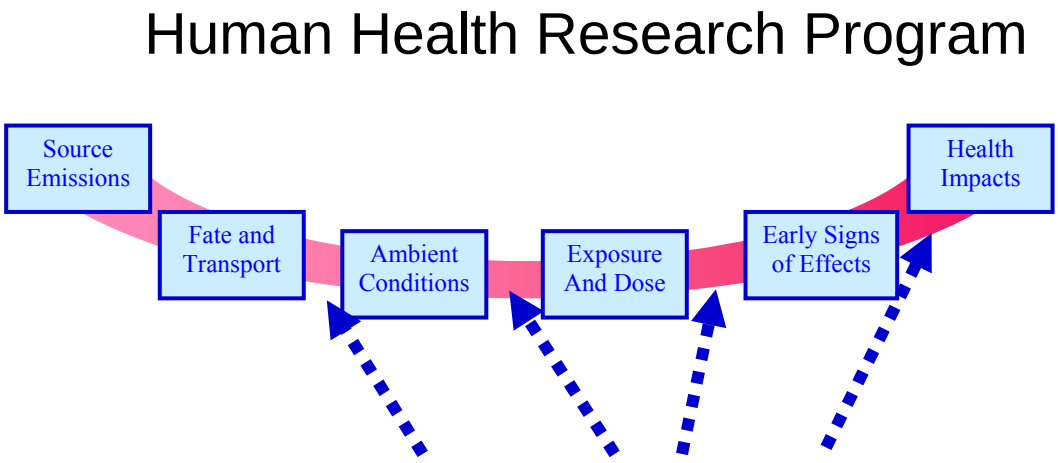
B. Over the last several years, there has been increased interest in assessing the effectiveness the Agency's regulatory and non-regulatory decisions. In that regard, several knowledge gaps, uncertainties, limitations, and scientific challenges were identified in the 2003 and Draft 2007 Reports on the 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 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.

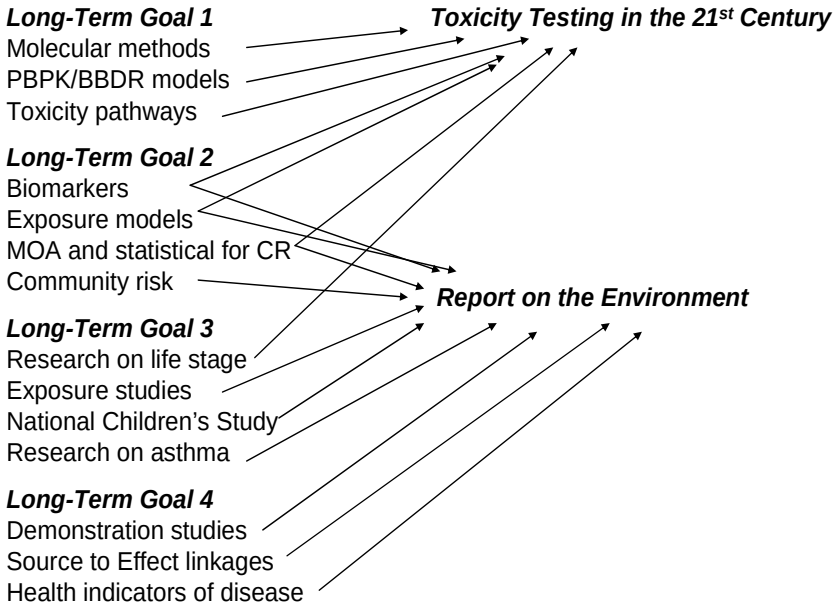
**LTG 4 Risk assessors/risk managers use ORD's methods, models and data to evaluate the public health impact of environmental decisions.** The HHRP supports demonstration projects to assess the impact of drinking water regulations related to microbial pathogens and the cumulative impact of air pollution 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 on-going 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 is 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$^{TM}$, 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$^{TM}$, 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$^{TM}$ Phase I experiments, ToxRefDB (defined below under the ToxCast$^{TM}$ 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 FY07following 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 identifiably 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$^{TM}$ 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: Evaluatation 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$^{TM}$ program, and launch of Phase II (signature extension and validation). ToxCastTM 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 being 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 lesions[3]
- 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/reproduction[2]-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 endpoints[4]
- 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 screening[4]

- Enhanced in utero lactational protocols that would include addressing gaps in the areas of exposures to mixtures and dose response in low dose region[4]

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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?*

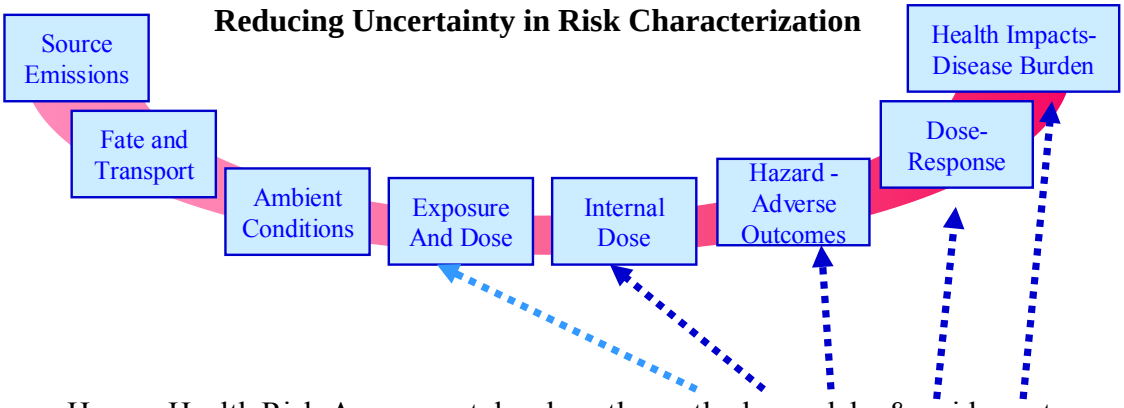
Illustrative questions include:

- 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 lifestages?
- 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 is 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 (LTG)s.
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 NOx and SOx 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 perfluoroctanoic 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 toxicity[1]
- Development of multiple approaches (e.g., QSARs, metabolic pathways, ASTER) for prioritizing chemicals for testing[1]
- 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 Centers[2]
- Near completion of a multi-disciplinary research program on the toxicity, pK, and environmental pathways and fate of perfluorinated chemicals[2]
- Completion of treatment study results of at least six additional individual/classes of pesticides in drinking water[3]

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 endpoints[2]
- Development of modeling approaches for characterizing spatial population level effects in aquatic life and wildlife for use in support of addressing the Endangered Species Act[2]

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 crops[1]
- 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 crops[2]

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[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 drivers[1] | 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<br>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<br>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<br>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<br>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** | What are the most effective strategies to detect purposeful contamination of drinking water distribution and wastewater collection systems?<br><br>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?<br><br>How can scientifically-sound laboratory capacity be established in preparation for response to a CBR attack on our water infrastructure?<br><br>What is the performance of commercially-ready detectors and what additional detection technologies need development? | 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?<br><br>How can scientifically-sound laboratory capacity be established in preparation for response to a CBR attack on an indoor or outdoor area?<br><br>What is the performance of commercially-ready detectors and what additional detection technologies need to be developed? |
| **Containment / mitigation** | What is the risk of exposure of humans to water contaminated with CBR agents?<br><br>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? | What is the fate and transport of CBR agents released into the environment?<br><br>What is the risk of exposure of humans to CBR agents in buildings or outdoors? |
| **Decontamination** | What are the risk-based cleanup goals for water infrastructure and water contaminated with CBR agents?<br><br>How can water infrastructure be effectively decontaminated following contamination with CBR agents?<br><br>How can water contaminated with CBR agents be effectively treated? | What are the risk-based cleanup goals for CBR agent-contaminated indoor and outdoor areas?<br><br>How can indoor and outdoor areas be effectively decontaminated following contamination with CBR agents?<br><br>What is the performance of commercially-ready technologies for decontamination of CBR agents in indoor and outdoor settings? |
| **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 responsivee 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, 1997[1]; MEA 2005[2]; BOSC, 2005[3]; EPA Stewardship Initiative, 2006[4]; EBASP, 2006[5]; SAB C-VPESS 2007[6]; Restoring Nature's Capital, 2007[7]). 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, 2007[9]). 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).

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[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-vpess_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 0f 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 2000[11], 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.

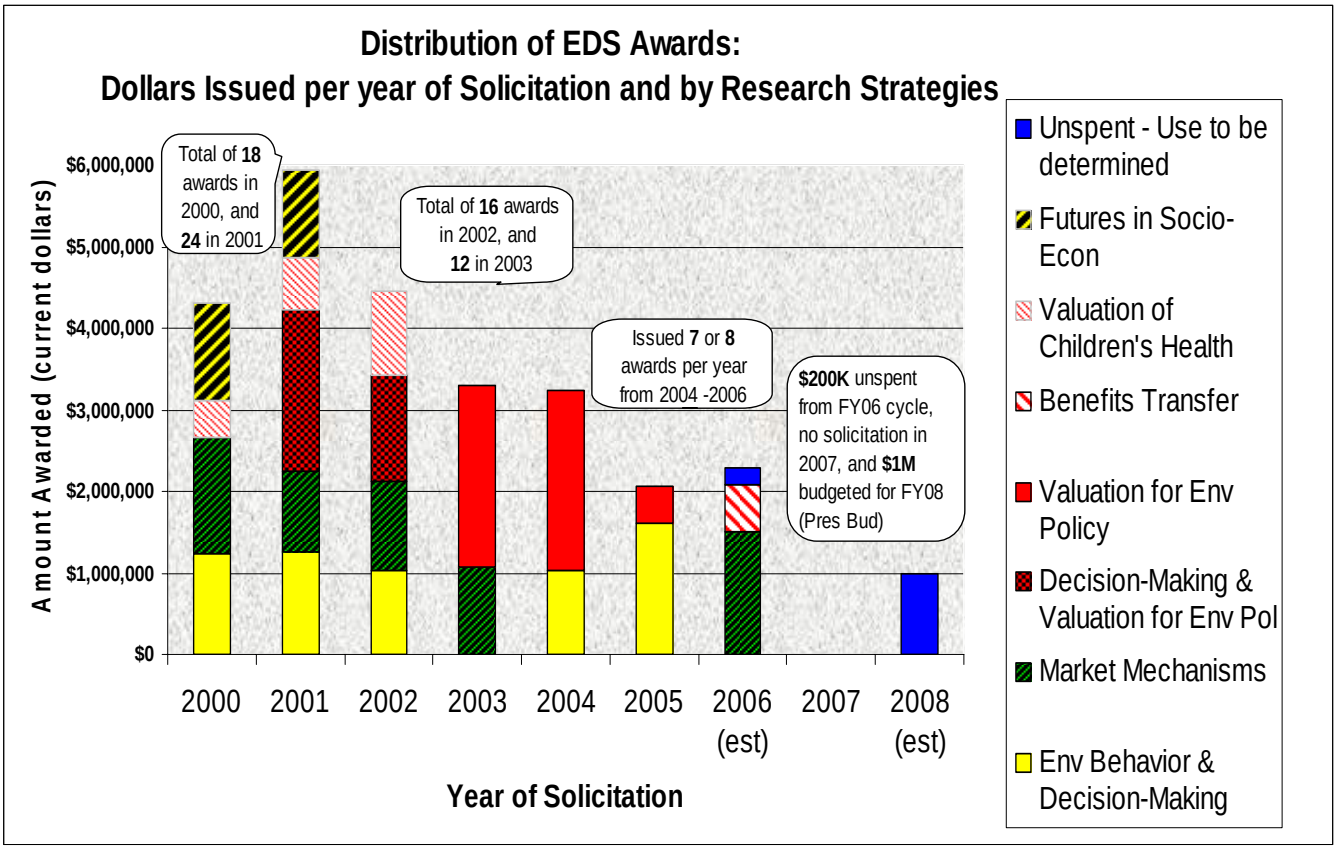
reviewed by the Science Advisory Board. Implementation of the EERS began with the 2003-2004 RFAs.

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 Decisionm*aking 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 ES1. 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 information[13], 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 evironmentally 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 comprehendible 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 be 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 $CO_2$ 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 $CO_2$ 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 $PM_{10}$ 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 $CO_2$ 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 mobiles 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, multidisciplined 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 Wentsel)

### 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/myp.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
  Synthèses 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 |
|---|---|---|---|
| **Sediments** | **Sediments** | **Sediments** | **Sediments** |
| 1 Methods and models on extent of contam. | 1 Advanced F&T models and tools | 1 Model resuspension and long-term remediation | 1 3 major site-specific applications |
| 2 Field evaluations of monitored natural remediation (MNR) and innovative caps | 2 Performance data on *in situ* methods. | 2 Use in guidance, adoption, and use in site-specific decisions | 2 In-situ treatment will reduce environ impacts |
| **Ground Water** | **Ground Water** | **Ground Water** | **Ground Water** |
| 3 PRBs to treat chlorinated organics; | 3 Capstone Report site demos, training | 3 Used to replace pump & treat at over 100 sites; | 3 More effective, saves O&M costs, e.g. $6M/ site |
| 4 MNR applications for metals | 4 Publication and site specific support | 4 Used at major R1 site | 4 Saved $10M at site |
| 5 Fuel oxygenates transport/ treatment | 5 Synthesis of fuel F&T models and treatment methods | 5 UST F&T of fuels used in guidance | 5 Used by states to regulate MTBE |
| **Multimedia** | **Multimedia** | **Multimedia** | **Multimedia** |
| 6 Technical Support Centers (TSCs) | 6 Answer site-specific questions from regions | 6 Regional staff use at specific sites | 6 Better science or reduces time, or expense at sites |
| 7 Alternative landfill caps | 7 Tech transfer to regions and states | 7 Used at 8 sites in 2006 | 7 Approx. $30M cost savings in 2006 |
| 8 Research on nanomaterial F&T | 8 Reports F&T of nanomaterials in media, and key nanomaterial fate characteristics | 8 Provides scientific leadership in this research area for Federal government. | 8 Provide scientific direction on health and ecological issues |

## 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.

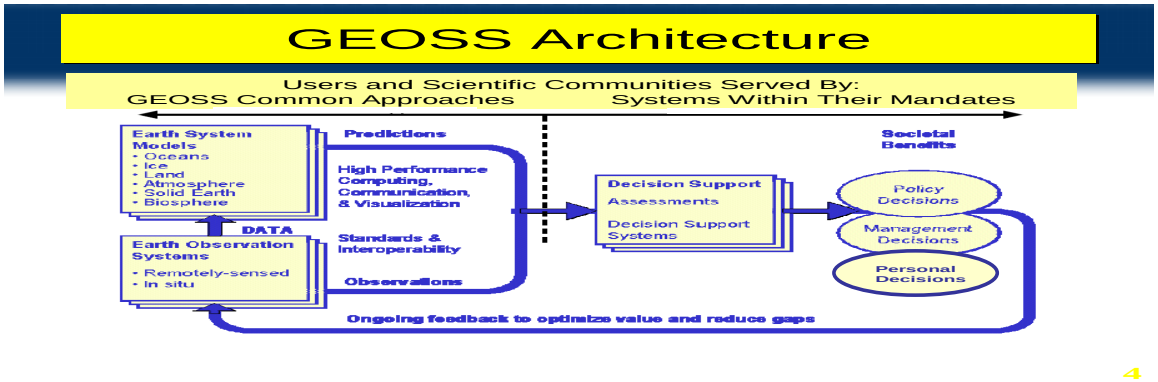
**c) GLOBAL EARTH OBSERVATION SYSTEM OF SYSTEMS (GEOSS)/ADVANCED MONITORING INITIATIVE (AMI)** (Initiative Description) (Ed Washburn)

**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.




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)