Setting Research Priorities

The goals, objectives, and actions contained in this *Strategic Plan* will improve, but not fundamentally change, ORD's research planning process which has been steadily evolving since ORD's reorganization in 1995. ORD's priority-setting process for research has several significant characteristics, most notably the following:

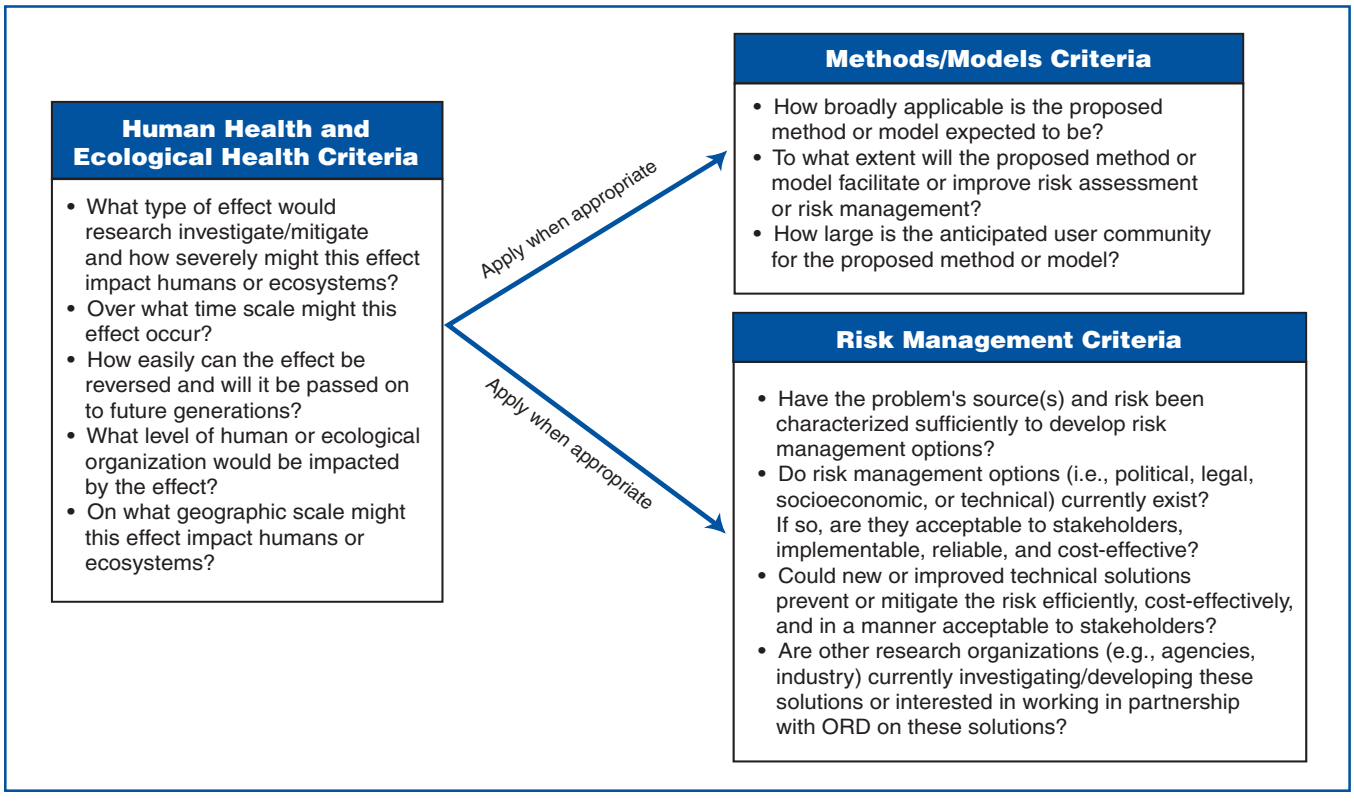
- We seek input from our customers throughout EPA as to the type of research and technical assistance of greatest importance to their programs, identifying in particular the research required to fulfill a legislative mandate, court order, or Agency GPRA commitment.

- We seek input from our staff as to the state-of-the-science and where the opportunities are for reducing uncertainty in our understanding of important environmental issues.

- For our preliminary ranking decisions, we examine research activities in terms of their scientific feasibility, resource constraints, compatibility with existing expertise, and our ability to make a contribution relative to other research institutions who may be doing work in the area.

In addition, we keep in mind a sense of human health, ecological health, and risk management criteria that we use to evaluate proposed research activities according to their potential to support effective risk reduction. The general criteria used in making these risk-based decisions are shown in Figure 2.

Figure 2: ORD's Criteria for Risk-Based Prioritization



The result of this comparative risk ranking is a broad portfolio of research spanning the full range of EPA's work. This process creates an appropriate balance between problem-driven and core research and aligns ORD's work in support of eight of EPA's 10 Strategic Goals. The research portfolio is then used to develop ORD's budget request and is reflected in the Annual Performance Plan, which EPA must submit under GPRA. In this way, all of ORD's work is aligned with, and linked to, specific annual performance goals that derive from EPA's Strategic Plan (see Table 1 on Page 28 for EPA's Strategic Goals).

Recently, ORD initiated a multi-year planning process as a way to link the Annual Performance Plan to the longer range objectives contained in the EPA Strategic Plan. Issue-specific plans are under development that will identify Annual Performance Goals and Measures for ORD's research program over a 5- to 10-year period. These plans will enable ORD both to better design its research program in support of EPA's Strategic Goals and to simplify the annual planning effort. Table 2 on Page 29 shows the linkage between ORD multi-year plans and EPA's Strategic Goals.

In addition to these planning efforts, ORD also develops strategies and plans for specific research areas. These plans are developed on an as-needed basis for large, complex research programs that require coordination and planning across the risk paradigm, several different media or organizations [e.g., Children's Research, Particulate Matter, Endocrine Disrupting Chemicals (EDCs)]. These strategies and plans identify the most important scientific questions to be addressed, what research is needed to answer these questions, and how ORD can uniquely contribute. In addition to input from within the Agency, these strategies and plans also receive independent, external peer review. All of ORD's research strategies and plans are available on the Internet at *http://www.epa.gov/ORD/WebPubs/final.*

The result of these inclusive, transparent planning efforts is a robust research program that identifies ORD's areas of research emphasis in support of EPA's mission to protect human health and the environment.

Many of our ***highest-priority*** research areas continue to be those identified in the *1997 Update to ORD's Strategic Plan*. While we have accomplished a great deal in these areas since then, more remains to be done to provide the best possible scientific basis for environmental decision-making. The following is a brief discussion of ORD's eight highest-priority research areas, described within the context of EPA's goals.

EPA Goal 1: Clean Air

Particulate Matter

In July 1997, EPA revised the National Ambient Air Quality Standard (NAAQS) for particulate matter (PM), recognizing that exposure to both fine and coarse fraction particles is associated with adverse health effects. The basis for these revisions was new epidemiological evidence of increased illness and death associated with exposure to PM. The health risks estimated from current PM exposures represent thousands to tens of thousands of premature deaths each year.

Significant scientific uncertainties remain, however, about the biological mechanisms that cause increased mortality or morbidity from PM exposures. Many studies are underway to identify and evaluate mechanistic hypotheses and to explore exposure-dose-response relationships. In addition, improving our estimates of potential PM risks requires research to better measure and characterize PM exposure (i.e., who is exposed and at what levels). Lastly, research to quantify and control PM sources is the central focus of risk management research efforts.

ORD's PM research program is devoted to the mission of providing an improved scientific basis for periodic review and revision as needed of the NAAQS (i.e., effects, exposure, and risk assessment) and

implementation and attainment of the NAAQS (i.e., risk management). Our program is focused on human health rather than ecological concerns, with complementary research on PM-associated ecological effects (e.g., acid deposition) addressed under ecosystem protection programs. Key research questions include the following:

- What characteristics of PM (e.g., size, composition) produce toxicity and by what mechanisms?
- What is the role of PM alone and in combination with gaseous copollutants in producing health effects?
- What subpopulations are most sensitive to PM health effects, and what are the levels of exposure for these groups?
- What are the sources of PM, and how can we best estimate the atmospheric transformation and fate of PM and precursors to support control strategy development?

EPA Goal 2: Clean and Safe Water

Safe Drinking Water

Disinfection of drinking water has been one of the greatest public health success stories of the twentieth century. Nevertheless, care must be taken to ensure our drinking water is safe. For example, the occurrence of waterborne disease outbreaks in the United States demonstrates that the safety of drinking water can still be compromised by waterborne pathogens (e.g., cryptosporidium) if treatment is inadequate. Concerns have also been raised about chemical contaminants in our drinking water supply. Surface water and groundwater sources may be contaminated with many different natural substances (e.g., arsenic) and synthetic substances (e.g., pesticides) that may pose a risk. Even the disinfection process itself can lead to the formation of a number of potentially toxic organic and inorganic chemical by-products. Some subpopulations, such as infants and children or those with weakened immune systems, are known to be particularly sensitive to the effects of many waterborne pathogens and chemicals.

The 1996 Amendments to the Safe Drinking Water Act require EPA to conduct research to provide a strong scientific foundation for standards that limit public exposure to specific drinking water contaminants. In response to this requirement, ORD has established an integrated, multidisciplinary research program to address the following key questions:

- What are the microbiological and chemical contaminants of greatest public health concern? What are the effects caused by exposure to these agents?
- What analytical methods are needed to adequately estimate the occurrence of contaminants in drinking water? What are the levels of contaminants to which people are actually exposed?
- How can the risks posed by pathogens, individual chemicals, and mixtures of contaminants be characterized?
- What are the most cost-effective treatment methods to minimize or remove contaminants from drinking water? How can the quality of treated water be maintained in the distribution system, and how can source water be adequately protected?

Clean Water

The health and sustainability of aquatic ecosystems and their ecological components are affected by chemical, biological, and physical stressors. These stressors can result both from point sources of pollution or by disturbances in the watersheds.

Table 1: EPA's Strategic Goals

Goal 1: Clean Air — The air in every American community will be safe and healthy to breathe. In particular, children, the elderly, and people with respiratory ailments will be protected from health risks of breathing polluted air. Reducing air pollution will also protect the environment, resulting in many benefits, such as restoring life in damaged ecosystems and reducing health risks to those whose subsistence depends directly on those ecosystems.

Goal 2: Clean and Safe Water — All Americans will have drinking water that is clean and safe to drink. Effective protection of America's rivers, lakes, wetlands, aquifers, and coastal and ocean waters will sustain fish, plants, and wildlife, as well as recreational, subsistence, and economic activities. Watersheds and their aquatic ecosystems will be restored and protected to improve public health, enhance water quality, reduce flooding, and provide habitat for wildlife.

Goal 3: Safe Food — The foods Americans eat will be free from unsafe pesticide residues. Particular attention will be given to protecting sub-populations that may be more susceptible to adverse effects of pesticides or have higher dietary exposures to pesticide residues. These include children and people whose diets include large amounts of noncommercial foods.

Goal 4: Preventing Pollution and Reducing Risk in Communities, Homes, Workplaces, and Ecosystems— Pollution prevention and risk management strategies aimed at eliminating, reducing, or minimizing emissions and contamination will result in cleaner and safer environments in which all Americans can reside, work, and enjoy life. EPA will safeguard ecosystems and promote the health of natural communities that are integral to the quality of life in this nation.

Goal 5: Better Waste Management, Restoration of Contaminated Waste Sites, and Emergency Response — America's wastes will be stored, treated, and disposed of in ways that prevent harm to people and to the natural environment. EPA will work to clean up previously polluted sites, restore them to uses appropriate for surrounding communities, and respond to and prevent waste-related or industrial accidents.

Goal 6: Reduction of Global and Cross-Border Environmental Risks — The United States will lead other nations in successful, multilateral efforts to reduce significant risks to human health and ecosystems from climate change, stratospheric ozone depletion, and other hazards of international concern.

Goal 7: Quality Environmental Information — The public and decision makers at all levels will have access to information about environmental conditions and human health to inform decision making and help assess the general environmental health of communities. The public will also have access to educational services and information services and tools that provide for the reliable and secure exchange of quality environmental information.

Goal 8: Sound Science, Improved Understanding of Environmental Risk, and Greater Innovation to Address Environmental Problems — EPA will develop and apply the best available science for addressing current and future environmental hazards as well as new approaches toward improving environmental protection.

Goal 9: A Credible Deterrent to Pollution and Greater Compliance with the Law — EPA will ensure full compliance with laws intended to protect human health and the environment.

Goal 10: Effective Management — EPA will maintain the highest-quality standards for environmental leadership and for effective internal management and fiscal responsibility by managing for results.

Table 2: ORD's Research is Aligned with EPA's Strategic Goals

EPA Goal 10 : Effective Management
EPA Goal 9 : A Credible Deterrent to Pollution and Greater Compliance with the Law
EPA Goal 8 : Sound Science, Improved Understanding, and Greater Innovation
EPA Goal 7 : Quality Environmental Information
EPA Goal 6 : Reduction in Global Risks
EPA Goal 5 : Waste Management and Restoration
EPA Goal 4 : Safe Communities
EPA Goal 3 : Safe Food
EPA Goal 2 : Clean and Safe Water
EPA Goal 1 : Clean Air

ORD Multi-Year Plan	1	2	3	4	5	6	7	8	9	10
Particulate Matter *	●			○			○	○		
Air Toxics	●		○	○	○	○	○	○		
Tropospheric Ozone	●			○		○	○	○		
Drinking Water *		●	○	○			○	○		
Water Quality *		●		○	○		○	○		
Safe Food			●	○			○	○		
Safe Communities	○			●			○	○		
RCRA Waste Management	○			○	●		○	○		
Contaminated Sites		○			●		○	○		
Global Change *						●	○	○		
Ecosystem Assessment and Restoration *	○	○		○	○	○	○	●		
Human Health Risk Assessment *	○	○	○	○	○	○	○	●		
Mercury	○	○	○		○	○	○	●		
Endocrine Disrupting Chemicals *	○	●	●	●	○		○	●		
Socioeconomics	○	○	○	○	○	○	○	●		
Pollution Prevention and New Technologies *	○	○	○	●	●	○	○	●		

* The topics addressed in these multi-year plans are ORD's highest research priorities
● Directly contributes to meeting this EPA Strategic Goal
○ Supports achievement of this EPA Strategic Goal

Protecting and enhancing the integrity of aquatic ecosystems and their biotic components require research on quantifying impacts and understanding cause-and-effect relationships.

ORD's research focuses on the development of watershed diagnostic methods and understanding the importance of critical habitats and the impacts of habitat alteration on aquatic communities. In addition, ORD's research provides the scientific foundation supporting the development of water quality criteria and total maximum daily loads (TMDLs), including the development and refinement of models, understanding chemical stressors such as nutrients and toxic chemicals in both water and sediments, and the impact of sedimentation on aquatic ecosystems. Research on the impacts of wet weather flows offers a technology focus for the mitigation of the unique impacts of these stresses.

There are five critical ecological research questions for water quality. These are:

- How can numerical nutrient criteria be formulated to protect natural waters from the harmful impacts of excessive loadings of nitrogen and phosphorus?
- Can population dynamic models be refined to estimate the cumulative risks of critical habitat disturbance and contaminated sediments on the integrity of fish, shellfish, and other communities?
- Can diagnostic indicators and models be assembled into a decision-support system to accurately prescribe mitigation and restoration options for TMDLs?
- How can chemical criteria be incorporated into site-specific risk assessments for the protection of aquatic life, wildlife, and birds from toxic chemicals?
- Can methods for controlling pathogens, sediments, and toxic chemicals arising from point and non-point sources be integrated into a comprehensive watershed management approach?

EPA Goal 6: Reduction of Global and Cross-Border Environmental Risks

Global Change

The earth's environment is constantly changing due to the complex interplay of natural processes and human activities. Changes in climate, climate variability, land use, and ultraviolet B band radiation are all occurring on a global scale. The potential consequences of these changes are wide ranging and could adversely affect human health, ecosystems, and socioeconomic sectors, all of which are vital to sustainable development. Recognizing that policy makers and resource managers are making decisions today that have important long-term ramifications for our global environment, the Global Change Research Program seeks to inform decision-making processes by providing comprehensive assessments of potential long-term consequences of global change.

EPA is one of the member agencies of the U.S. Global Change Research Program (USGCRP), which is focused on understanding the Earth system as a whole and the dynamics of environmental change and connecting that knowledge to societal needs. Within the USGCRP, EPA's principal role is to assess the potential consequences of global change on human health, ecosystems, and socioeconomic systems in the United States. This entails: improving the scientific basis for evaluating effects of global change in the context of other environmental stressors and human activities; conducting assessments of the risks and opportunities presented by global change; and assessing adaptation options to improve society's ability to effectively respond to change.

ORD's Global Change Research Program is focusing on those areas where EPA has the most to offer—assessments of the consequences of global change on air quality, water quality, human health, and ecosystem health. Therefore, researchers are addressing the following scientific questions:

- What are the potential consequences of global change on vector- and water-borne weather-related morbidity and health effects related to air pollution, especially tropospheric ozone and PM?

- What are the potential effects of global change on aquatic ecosystems, invasive nonindigenous species, and ecosystem services?

- How may global change affect air quality, especially tropospheric ozone and PM? How will global change affect cities' ability to meet Clean Air standards?

- What are the potential impacts of global change on pollutants and microbial pathogens in aquatic resources?

Goal 8: Sound Science, Improved Understanding of Environmental Risk, and Greater Innovation to Address Environmental Problems

It should be noted that most of the core research conducted under this Goal also provides direct support to the objectives of other EPA Strategic Goals. For example, the work done under Human Health Risk Assessment to address cumulative risk will directly support requirements of the Food Quality Protection Act covered under EPA Goal 3: Safe Food.

Research to Improve Ecological Risk Assessment and Management

Natural ecosystems are under constant stress from a variety of factors: pollutants through air, water, and soil; alteration or fragmentation resulting from urban sprawl and resource extraction; nonindigenous species; and global change, to name a few. These "stressors" act synergistically and/or antagonistically, both with each other and with natural processes, at scales that range from local to global. Many of the mechanisms by which stressors act on and alter ecosystems are poorly understood or quantified, as are their immediate and long-term impacts, creating uncertainties in environmental decision-making, such as whether to protect, exploit, conserve, or restore natural resources and processes.

The goal of ORD's ecological research program is to provide scientific leadership and knowledge for assessing, improving, and restoring the integrity of ecosystems. The program addresses the following fundamental research questions:

- What are the most efficient and effective indicators, monitoring systems, and designs for measuring the exposures of ecosystems to multiple stressors and the resulting responses of ecosystems at local, regional, and national scales?

- How can we better identify and understand the processes that lead from stressors to effects? Can we develop models to predict the results of alternative actions on the future exposures and responses of ecosystems at the most relevant scales?

- What are the best assessment methods, indices, and guidelines for quantifying risks to ecosystems from multiple stressors at multiple scales?

- What are the most efficient and effective prevention, management, adaptation, and remediation technologies to manage, restore, or rehabilitate ecosystems to achieve local, regional, and national goals?

Research to Improve Human Health Risk Assessment and Management

Human health risk assessment is the process EPA uses to identify and characterize human health impacts associated with environmental exposures. There are many uncertainties associated with the risk assessment process due to limitations in available data on pollutant sources and exposures, and to limitations in our current understanding of the physical, chemical, and biological processes that relate human exposure, dose, and response.

The overarching goal of ORD's human health risk assessment research is to improve our scientific knowledge base and to develop risk assessment methodologies to enable the Agency to more accurately assess and characterize hazards and risks to the general population and vulnerable subgroups, such as children and communities that practice subsistence lifestyles, from exposures to single pollutants from multiple sources and multiple pathways (i.e., aggregate risks) and cumulative risks from exposures to multiple stressors by increasing the use of measured data and mechanistic information.

To meet this long-range Goal, ORD's health risk assessment research program is contributing to answering the following questions:

- How can we improve our mechanistically based understanding of toxicities and susceptibilities for the general population and subpopulations such as children, the elderly, and persons with pre-existing diseases?
- What are the relevant biomarkers of exposure, dose, effect, and susceptibility and their relationships?
- What is the biological basis for adverse health effects in children, especially asthma?
- What are the interactive effects from exposures to chemical mixtures with common or different modes of action?
- How can we develop improved models and methodologies to better estimate human exposures, assess aggregate exposures to single stressors, and assess cumulative risks from exposures to multiple stressors?
- How can we develop more consistent and harmonized risk assessment approaches and methods for all human health endpoints, with special attention to different durations and patterns of exposure and life stages?
- How can we conduct research to evaluate the consequences of environmental risk management decisions on public health?

Endocrine Disrupting Chemicals

In recent years, there has been growing scientific concern and public awareness regarding the potential of some chemicals in the environment to cause adverse health effects in human and wildlife populations by interacting with the endocrine system. Collectively these substances are known as endocrine disrupting chemicals (EDCs). It has been hypothesized that exposure to EDCs might result in a variety of adverse effects, including cancers that may be mediated by endocrine mechanisms, developmental or reproductive disorders, neurological impairment, immune dysfunction, and thyroid damage.

There are numerous examples of adverse effects of EDCs on wildlife such as birth defects in fish-eating birds exposed to polychlorinated biphenyls (PCBs) in Lake Michigan, mortality of young Lake Ontario trout as a result of exposure to dioxin-like chemicals, abnormal reproductive development in Lake Apopka alligators following contamination by a pesticide. In humans, the

impact of prenatal exposure to diethylstilbestrol (DES) on the reproductive tract of both male and female offspring is well documented. In addition, studies have demonstrated that PCBs cause neurodevelopmental impairment in exposed children.

Despite these reported effects, there is little known about their causes and what effects may result in the human and wildlife populations from exposures to ambient environmental concentrations of EDCs. However, it is known that the endocrine system plays an important role in normal growth, development, and reproduction and that small perturbations in endocrine status, during critical periods, could have profound and long-reaching impacts. Based on the potential scope of the EDC problem, the possibility of serious effects on the health of human and wildlife populations, the persistence of some EDCs in the environment, and the widespread global concern about their fate and transport over national boundaries, this area is a high-priority for ORD research.

Key areas of uncertainty and research questions include the following:

- How, and to what degree, are human and wildlife populations exposed to EDCs? What effects are occurring in exposed human and wildlife populations?

- Do current testing guidelines adequately evaluate potential endocrine-mediated effects?

- What are the dose-response characteristics at environmentally relevant concentrations?

- What are the major sources and environmental fates of EDCs?

- How can unreasonable risks be managed? Are new technologies needed?

Pollution Prevention and New Technologies

Pollution prevention, or anticipating and avoiding human health and environmental problems before they occur, offers a proactive alternative to the legal mandates and command and control regulations traditionally used to protect the environment. The goal of pollution prevention research is to provide more flexible, lower cost, and less polluting alternatives to address the pollution challenges facing the United States and the world in the twenty-first century.

Development of new pollution prevention tools and technologies, verification of new environmental technologies, and research that advances the fundamental understanding of the economic and behavioral sciences as they relate to the environment are important components of ORD's pollution prevention and new technologies research program. This research program relies on substantial stakeholder input and participation as a means of identifying those human health and environmental problems most conducive to innovative, alternative approaches to environmental protection. Because of the broad applicability of this research program and its potential for realizing significant economic and environmental benefits, pollution prevention and new technology for environmental protection are extremely important risk management components of ORD's research agenda.

Research in this area focuses on four important questions:

- What pollution prevention technologies and approaches can be employed in various economic sectors, particularly on industrial and consumer products, to advance "green" processes and clean technologies?

- What tools and methodologies can be applied in various economic sectors to utilize the most cost-effective pollution prevention technologies and approaches to protect ecosystems?

- How best can the performance of private sector products, technologies, and approaches that address human health and environmental problems be verified using a high-quality and efficient program to target important performance and operational characteristics?

- What are the socioeconomic and behavioral aspects of decision-making that foster the adoption of pollution prevention by the public and private sector at all levels (e.g., local, state, regional) to manage human health and environmental risks?