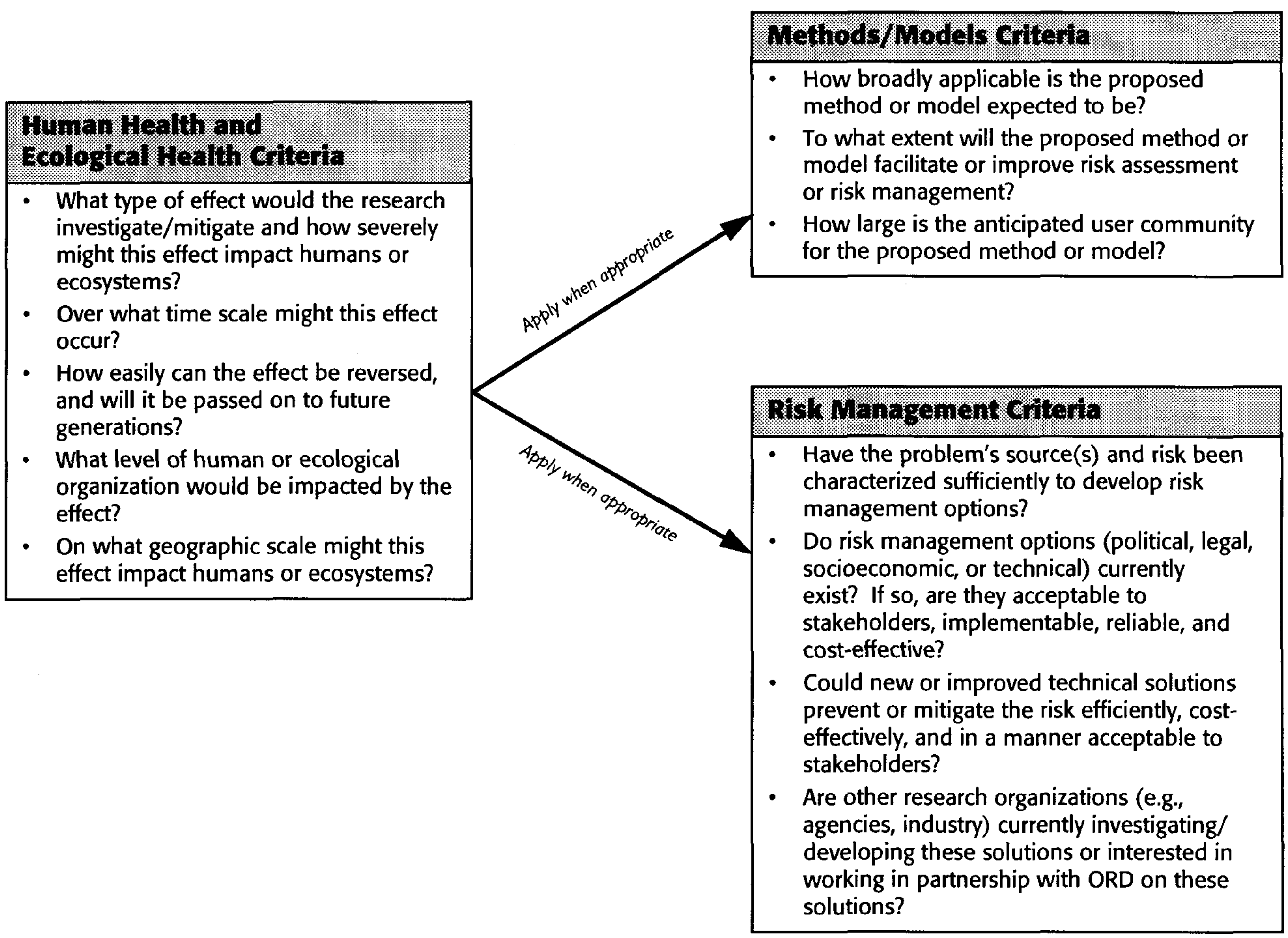
- We then further narrow this pool of topics by retaining only those areas where ORD can make a significant contribution to environmental science. Factors we consider at this stage include: Is the work feasible from a scientific and resource perspective? Does ORD have access to the appropriate expertise? What contributions are other research organizations making to this area of research?

- ***For these remaining topics where ORD can make a significant contribution, as well as all nondiscretionary topics,*** we then define specific research and development projects by considering each topic in totality. For each topic, we determine what the research needs are within each component of the risk paradigm: effects (hazard identification and dose-response assessment), exposure assessment, risk characterization, and risk management. At this stage, we give priority to research that will make the greatest contribution to reducing the uncertainty associated with risk characterization, or will improve the efficacy of or reduce the cost of risk management.

This approach to strategic planning clearly indicates the following areas where ORD will reduce or eliminate resources:

- Exposure or effects research in areas of low risk or where the risk is well characterized.
- Risk reduction research in areas of low risk or where cost-effective risk reduction approaches already exist.
- Routine measurements and monitoring where R&D has been completed or that does not support R&D efforts.

Figure 5. ORD Criteria for Evaluating and Ranking Potential Research Topics



Criteria for Setting ORD Research Priorities

A key component of ORD's planning process is the criteria we use to set priorities among research topics. We currently employ three sets of criteria: human and ecological health research criteria, risk management research criteria, and methods/models development criteria (Figure 5). These criteria, described below, are not set in concrete, nor are they universally applicable to all research areas. Additional or alternative criteria may be used in some cases as appropriate.

We are continuing to refine these criteria. In particular, the criteria have been undergoing extensive discussion and review during fiscal year 1997 with the twin goals of creating a system that will more directly link ORD's work to the important issues facing the Agency and that will more closely integrate human health and ecological research. We anticipate future modifications to these criteria that will both improve our ability to evaluate the effectiveness of ORD research and help our scientists understand how their research will be used to answer the Agency's most important risk-based questions.

Human and Ecological Health Research Criteria

ORD's human and ecological health criteria are based on five broad categories: the severity, time scale, and permanence of the response; the level or organization where the response is expected to occur; and the geographic extent of the response. Table 3 lists criteria ORD has developed in each of these five categories. These factors help us determine the importance of a human or ecological health problem in terms of its magnitude of risk and extent of scientific uncertainty, and thus point to the areas most needing research (Figure 6a). (Conversely, areas of low risk or well-understood risk typically need the least new research.)

Table 3. ORD's Human and Ecological Health Research Criteria

	Ecological Health	Human Health
Severity of Response/ Function of Stressor	• Mortality • Morbidity • Degree of physical disruption	• Mortality • Morbidity
Time Scale of Response	• Immediate effects • Effects that will occur in the future	• Acute effects • Subchronic effects • Chronic effects or effects with a long latency period
Permanence of Response	• Irreversible effects • Effects that can be reversed only by human intervention • Temporary effects that reverse naturally over a long time • Temporary effects that reverse naturally over a short time	• Transgenerational effects • Nontransgenerational effects
Level of Organization	• Effects on an entire ecosystem/community • Effects on a single species • Effects on a population within a single species • Effects on individual animals or organisms	• Effects on the general population • Effects on a subpopulation • Effects on individuals
Extent of Response	• Global effects • Ecoregional effects[1] • Effects on several localities • Localized effects	• Global effects • International effects • National effects • Effects on several localities • Localized effects

[1] An ecoregion is a geographic area that has similar topography, climate, and biota across the entire area.

Risk Management Research Criteria

Risk management criteria are applied to those research topics that concern risk management. These criteria, listed in Figure 5, are designed to give priority to research that will produce the most effective and useful risk management options. The criteria consider whether sufficient risk characterization information is available to set meaningful objectives for the risk management research; the availability, acceptability to stakeholders, reliability, and cost-effectiveness of existing options; the potential benefits of the proposed research; and whether other research organizations are already conducting or interested in this type of research. Applying these factors directs us toward research investments in areas where risk problems are adequately characterized and where risk management options do not exist, are poorly characterized, are out-dated or inefficient, are too costly, or might be significantly improved (Figure 6b). (Conversely, areas where risk problems are as yet poorly characterized or where management options are already optimized typically need the least new research.)

Methods/Models Development Criteria

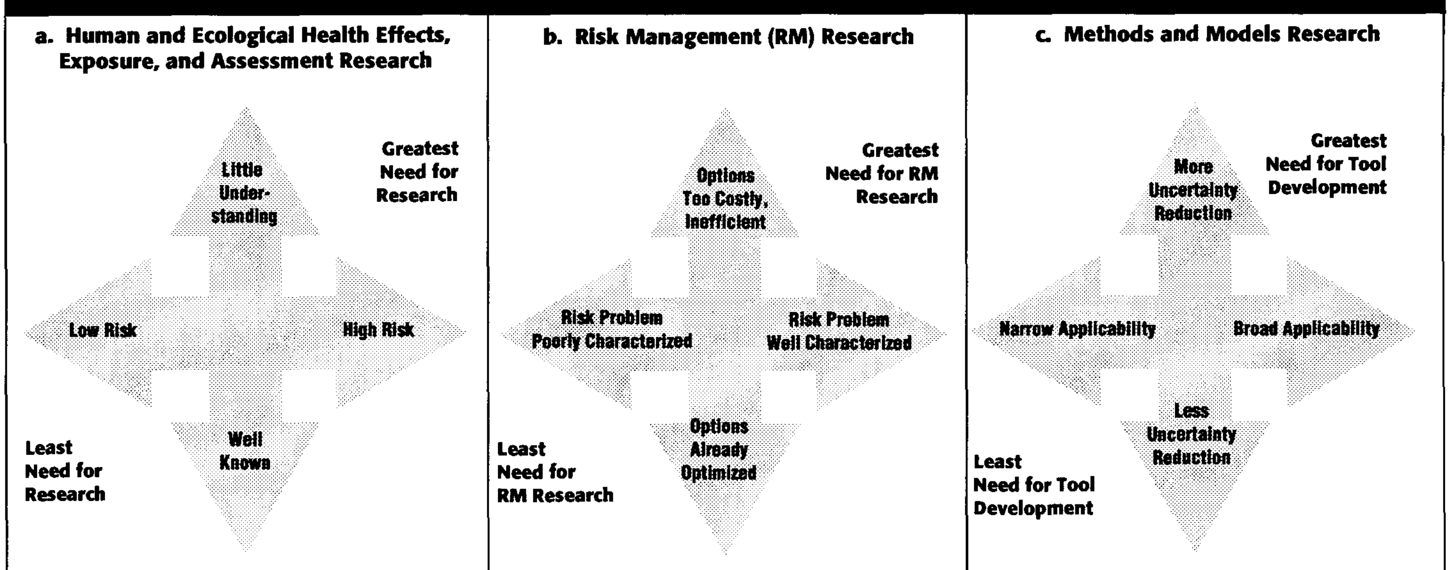
The methods/models development criteria are applied to research concerning the development or application of methods or models for gathering, analyzing, or applying risk-related data. These criteria give priority to research that will likely produce the most useful results. The criteria consider how broadly the method or model would be used, the size of the anticipated user community, and the degree to which the method or model would improve risk assessment or risk management. As a result, ORD can then direct research attention to those areas where tools would be most broadly applicable and where uncertainty in risk assessment or risk management would be most reduced (Figure 6c). (Conversely, tools with narrow applicability or low potential for reducing uncertainty reduced will typically receive the least support.)

Strengths of ORD's Research Planning Process

Our planning approach has many strengths:

- It encompasses both scientific and stakeholder priorities.
- It ensures that ORD will continue to fully support EPA in fulfilling its mandates.
- It focuses our resources where we can make our most significant contributions.
- It reinforces our sense of direction and accomplishment as we see our objectives met and goals realized.
- It establishes a structure linking us to Agency-wide strategic planning and the GPRA.
- It enables us to generate practical, credible information and tools for risk-based decision-making.

Figure 6. Setting Research Priorities



Adapted from Paul Slovic, *Risk Perception*

Chapter 3

Translating ORD's Strategy Into a Research Program

The steps involved in translating ORD's Strategic Plan into a research program are illustrated in Figure 7. Once we have identified our high-priority research topics, we develop and implement a research program based on these topics. This involves:

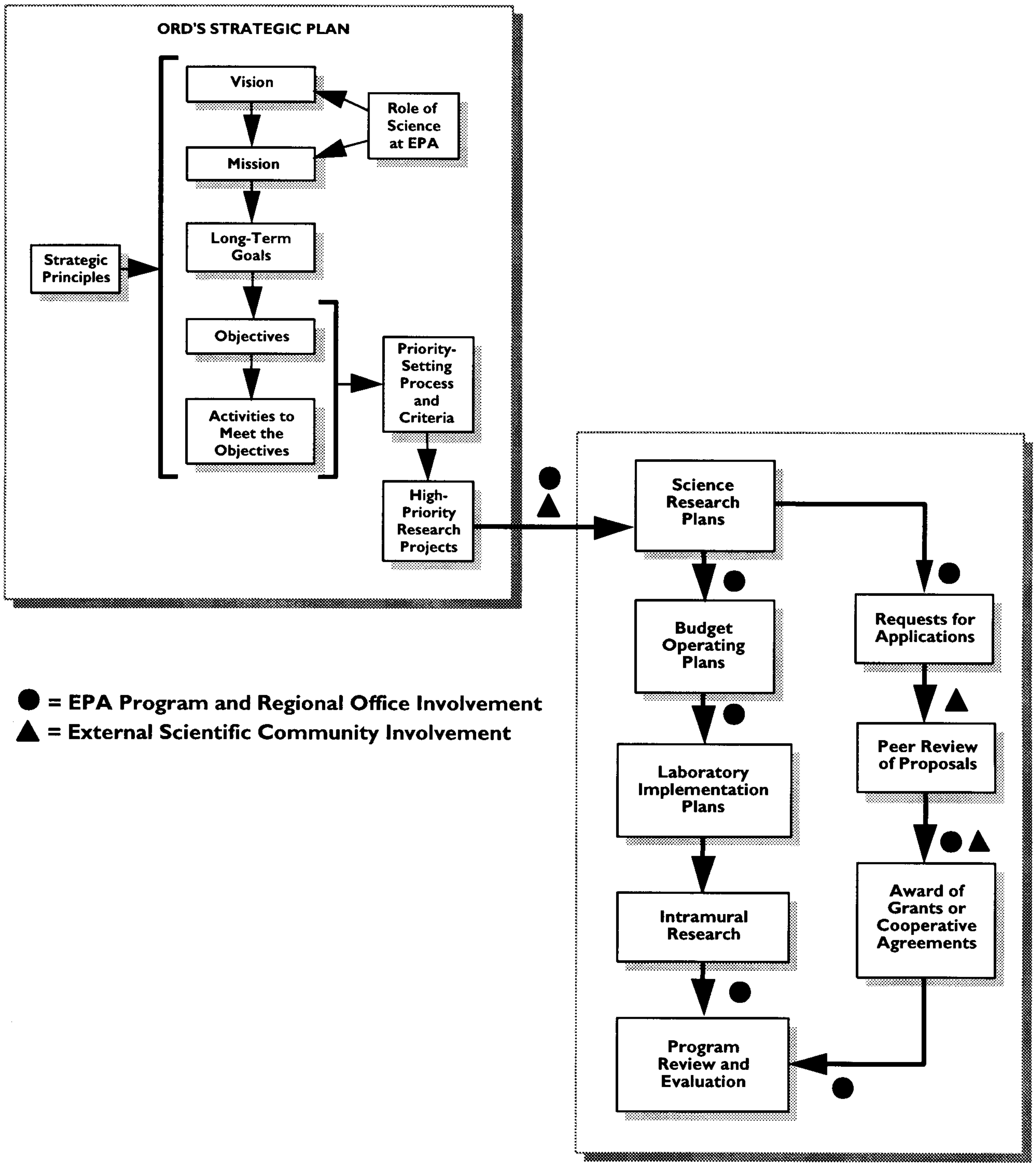
- Developing science research strategies and plans.
- Deciding whether the work will be conducted in-house or extramurally. (ORD's research program is comprised of intramural and extramural research.)
  - For intramural research, developing budget operating plans and laboratory implementation plans.
  - For extramural research, selecting and implementing the appropriate mechanisms to access the external scientific community.
- Integrating information management into research planning.

Developing Science Research Strategies and Plans

Once ORD has identified its high-priority research topics using the process described in pages 11 to 13, teams composed of ORD scientists and engineers as well as representatives of EPA's Program and Regional Offices develop science research strategies and plans for each topic. These plans:

- Lay out the major research components and directions we will pursue over the next few years.
- Describe how these components fit into the risk assessment/risk management paradigm.
- Describe how the data and information to be generated by the research will be used and managed.
- Delineate the major outputs to be produced over the next several years.

Figure 7. Translating ORD's Strategic Plan Into a Research Program



Research plans are important tools for measuring accountability because they make clear to our clients and stakeholders the rationale for and intended products of our research. And, by explicitly specifying up-front how we will manage our scientific data and information products, we ensure that the results of ORD research will be effectively communicated to our clients and stakeholders. Research plans also enable ORD to clearly track its progress toward achieving its goals, as required by the 1993 Government Performance and Results Act.

We consult ORD's main research clients—the EPA Program and Regional Offices—to ensure that the final research plans clearly include the research products they will need to fulfill their responsibilities. In addition, all our research plans are subjected to rigorous external peer review.

Deciding Who Will Do the Work

This is the point of ORD's planning process where we decide whether the work would best be accomplished internally at ORD or externally through one of several mechanisms: grants to universities or nonprofit centers; cooperative agreements with another government agency or with universities; or by contract. Many factors influence this decision, including:

- Which organization has the most appropriate expertise.
- What type of work is called for (risk assessment and regulatory support work are generally retained in-house, whereas research, including assessment methods research work, may be done externally).
- How urgently the research products are needed (since some mechanisms are faster than others).
- If there would be value in involving multiple institutions.
- The extent to which we can specify what is needed (contracts). The extent to which we must rely on the creativity and insight of the researcher (grants).
- What is our available in-house capacity.
- What are the opportunities for leverage.

Internal Research

Development of Budget Operating Plans

For internal research, ORD integrates the science research plans with budgetary decisions in order to allocate resources to the selected research topics by laboratory program and research component. This helps ensure that our priority-setting decisions (guided by science) also reflect budgetary realities.

Development of Laboratory Implementation Plans

Based on the science research plans and budgetary decisions, ORD's Laboratories and Centers develop detailed plans for implementing each area of research to be undertaken internally. These laboratory implementation plans provide a blueprint for Laboratory and Center work and form the basis for managerial oversight and guidance.

Extramural Research

Extramural research is conducted via grants, cooperative agreements, or contracts. Rigorous external peer review is a key mechanism we use to evaluate both the proposals for and results of external research.

One of ORD's primary mechanisms for involving external scientists is the Science to Achieve Results (STAR) program. STAR targets the best scientists from universities and nonprofit centers because they are an integral and important part of the environmental research community. STAR consists of focused Requests for Applications (RFAs), investigator-initiated exploratory research grants, graduate fellowships, and several "critical mass" environmental research centers.

The bulk of the STAR program supports RFAs that focus on specific research needs to support the mission of the Agency. Working with EPA's Program and Regional Offices, we write these RFAs to be consistent with ORD's Strategic Plan and science research plans, and complementary to ORD's in-house work. The RFAs are announced annually to scientists at U.S. academic and nonprofit institutions. Proposals from the external scientific community are peer-reviewed and projects are then selected for funding, in consultation with EPA's Program Offices and Regions, through grants or cooperative agreements. ORD leverages the STAR program resources by jointly funding research with other federal agencies. Appendix D shows how the fiscal year 1997 RFA topic areas relate to ORD's high-priority research topics.

Integrating Information Management Planning Into the Process

To further enhance the quality and value of our work, we have been developing a plan for managing data and information in ORD. The plan is based on coordinating and enhancing existing ORD and EPA systems and resources. It is built on four fundamental tenets of successful information management:

- Planning and incorporating policies for information management.
- Making potential users aware that information exists.
- Making the information accessible to users.
- Making the information usable.

The plan sets forth an approach to managing all levels and types of ORD information—from the scientific data and information that result from ORD's in-house or extramural research (e.g., raw data collected at field sites, health or ecological risk assessments, aggregated data sets) to the administrative information needed to manage ORD research (e.g., resource data, grant award information, and laboratory implementation plans).

ORD's information management plan will provide a consistent, ORD-wide approach to efficiently planning for, collecting, documenting, manipulating, exchanging, archiving, and distributing science data and information. It will address the full spectrum of ORD's information management needs, including data management; policies and standards; management, staffing, and budget issues; and electronic information technologies.

Information management planning for specific research projects will commence as soon as ORD has identified its specific project needs. For each research project, ORD management and budget decisions will be made considering the entire project, from data collection through long-term archiving of data sets. Information management planning will, to differing degrees, encompass all ORD research projects—including in-house research as well as the extramural research that ORD funds with contracts, cooperative agreements, and grants.

Measures of Success

In general, the success of a research organization can be measured in several ways: by the number of articles published in prestigious scientific journals, by the number of times that articles written by the organization's scientists are cited in other journal articles, and so on. However, for a mission-oriented organization like ORD, measures of the extent that we help and support EPA in meeting its goals are equally crucial. In measuring the success of this Strategic Plan, the quality of ORD's work, and the usefulness of our research products, we will use the following measures of success.

Significance: Is ORD Working on the Right Issues?

This is a measure that the EPA Program Offices and Regions and the broad scientific community can help us judge. For our research, development, and support efforts to be useful, we must work on the most important environmental issues and target areas for research that will significantly improve risk assessment and/or risk management in the Agency and elsewhere. Peer review by scientists in the external scientific community will assist us in judging significance.

Relevance: Is ORD Providing Data That the Agency Can Use?

This question can best be answered by the rest of the Agency and is best judged by the degree to which ORD's contributions support EPA decisions. ORD will strive to ensure that its work is useful to the Agency and has a positive impact on advancing EPA's mission. ORD's new information management plan seeks to ensure that we make our stakeholders aware of and able to access ORD's science data and information products.

Credibility: Is ORD Doing Research of the Highest Quality?

ORD's credibility can best be judged by the external scientific community through such mechanisms as peer review of ORD products, reviews of programs at the ORD Laboratories, peer-reviewed journal articles, scientific citations, and external recognition of both ORD and its people. Further, we will be judged by the external scientific community on the extent to which we advance the state of environmental science.

Timeliness: Is ORD Meeting EPA's Expert Consultation and Assessment Needs in a Timely Manner, Providing Research Products According to Schedule, and Addressing Long-Term Issues With Adequate Forethought and Preparation?

The first part of this question can best be answered by EPA's Program Offices and Regions as they determine whether ORD consultations and assessments are being provided in time to be optimally useful for Agency decisions. The middle part of this question can be answered by ORD managers and EPA's Program Offices and Regions through annual program reviews and other activities. The final aspect of timeliness is more subjective and therefore more difficult to assess. ORD has accepted the challenge of anticipating important environmental issues that are just emerging and may not become critical problems until well into the next century. The U.S. public is the ultimate judge of how successful ORD has been in this effort. ORD will strive to regularly gather the public's view on this issue.

Mechanisms for Evaluation and Accountability

ORD has several mechanisms for evaluating its performance, communicating progress and results, and measuring success. These include:

- *Annual research program reviews,* jointly organized by ORD's Research Coordination Teams and EPA's Program and Regional Offices, that present to EPA senior managers the entire EPA research portfolio in a given area. These joint reviews focus on the status and accomplishments of the ORD research program to ensure that ORD's research continues to meet ORD and client objectives. They also present the ongoing research being conducted by the Program Offices and Regions so that the total research agenda can be viewed. The objectives of these reviews are to evaluate progress in completing planned research projects, to track and evaluate research results, and to generally obtain feedback on ORD's work and any adjustments that may be needed to help us better meet our clients' needs. These reviews complement, rather than supplant, external peer reviews.
- *ORD review of its science research plans.* ORD examines its research plans periodically and adjusts them if warranted by our research results, by changes in EPA or national priorities, or by emerging issues and concerns.
- *External peer reviews of ORD science research plans and products* and overall progress in meeting our goals and objectives. These reviews are conducted at key intervals in our research planning and implementation process.
- *External peer reviews of research proposals* received from extramural research scientists in response to the Requests for Applications.
- *External peer reviews of ORD Laboratories and of ORD's use of peer review* through our Board of Scientific Councilors under the Federal Advisory Committee Act.
- *Annual science workshops* designed to make the progress and results of all ORD research (including the external grants program) accessible to EPA's Program Offices and Regions.
- *A data tracking system,* part of ORD's Management Information System, which tracks resources and progress.
- *Yearly evaluations* under the Government Performance and Results Act.

Through these mechanisms, ORD will strive to develop and conduct the most responsive, scientifically justifiable research program possible within the constraints of our available resources.

Closing Out Completed Work

Through the continuing involvement of the Research Coordination Teams and the annual program reviews mentioned above, ORD will assess ongoing research to evaluate:

- Whether the research is on track for meeting its goals and schedule.
- When the research should be concluded.

Prudent management of evolving priorities and declining resources requires that we clearly define our research and conclude it within an appropriate time frame, so we can begin work on new priorities without delay.

Technical Support

One of ORD's most important functions is to provide technical support to EPA Program Offices and Regions and states. ORD is committed to a strong and sustained technical support program.

In 1996, the EPA Program Offices, ORD, and the EPA Regions initiated the first comprehensive assessment of all technical support activities within EPA, with particular emphasis on ORD's roles and responsibilities for technical support. The purpose of this evaluation was to ensure that ORD:

- Provides the types and quantities of technical support most needed by the Program and Regional Offices, states, and others.

- Focuses its technical support efforts in areas where ORD has unique capability or where the support is not readily available outside EPA.
- Fosters greater involvement of the EPA Program Offices and Regions in guiding ORD's technical support activities.
- Promptly develops exit or entrance strategies for activities that are being phased out or newly introduced.

As an outgrowth of this initial effort, ORD comprehensively assessed its technical support function. We defined the term *technical support*, developed criteria for setting support priorities, inventoried the current distribution of our technical support resources, and developed a process for making technical support decisions.

As defined by our assessment, ORD *technical support* comprises activities ORD conducts in response to specific requests by the Program Offices, Regions, or states to address well-defined needs that are not covered by ORD's research program. For example, ORD's current technical support activities include maintaining the Integrated Risk Information System for the Agency and consulting with the Office of Water on sediment quality criteria guidelines.

The criteria ORD will now use to set its technical support priorities are the extent to which:

- The proposed technical support will provide fundamental support for regulatory programs.
- ORD has unique scientific and or technical capabilities to address the problem.
- Environmental quality and human health will directly benefit from the activity, relative to the resource requirements of the technical support.
- ORD can help solve the problem.

ORD technical support decisions for fiscal year 1998 were made during fiscal years 1996 and 1997 using a process that involved the Research Coordination Teams, the Research Coordination Council, the Environmental Monitoring Management Council, and others. This allowed participants to resolve long-standing issues and develop a common reference point for making future decisions. In the future, decisions about the type and quantity of ORD technical support will be made as part of ORD's overall research planning process.

ORD Customer Focus

ORD is committed to providing excellent service to all external and internal customers. To this end, we will support our employees in applying the Agency's customer service standards, and our senior executives will provide leadership in advocating high quality customer service.

Human Resources and Infrastructure

The success of ORD's Strategic Plan depends on an adequately funded and well-managed infrastructure, including ORD's work force, systems, and equipment. ORD's recognition of the importance of our infrastructure is reflected in our strategic principles (Table 1), which highlight the critical role of infrastructure in achieving and maintaining an outstanding research and development program in environmental science.

Because we recognize that scientific excellence must be built on a strong foundation, we are committed to constant improvement of our organization and infrastructure. As we implement this Strategic Plan, we will continue to devote leadership and resources to developing and fostering our work force, modeling effective management, and creating a supportive work environment.

ORD's Work Force

By far the most important component of ORD's infrastructure is our work force of scientists, engineers, managers, other environmental professionals, and support staff. ORD can achieve its vision of providing the scientific foundation to support EPA's mission only if we can attract, nurture, and support a productive work force. ORD's strategic principles (Table 1) emphasize the importance of nurturing and supporting the development of outstanding scientists, engineers, and other environmental professionals at EPA.

The cutting-edge nature of research and development at ORD places great demands on our scientists and engineers to continually upgrade their skills and knowledge in response to and anticipation of new scientific developments. ORD maintains its commitment to building and maintaining solid linkages to the external scientific community, with an emphasis on scientist-to-scientist interactions (e.g., through ORD-sponsored scientific workshops). In addition, we will provide opportunities for ORD scientists and engineers to increase their contribution, as respected members of the scientific community and leaders in the environmental sciences, to the general scientific literature and community (e.g., through publication of scientific articles in peer-reviewed journals and participation in national and international scientific conferences).

Further, our work force support must include an effective human resources program that encourages an increasingly diverse cadre of employees to continuously learn new skills and a career development program that promotes career development in directions congruent with ORD's mission. In addition, we must anticipate work force needs and recruit new, culturally diverse employees with the appropriate skills and experience to support ORD's mission.

ORD's organizational structure (see Appendix B) relies on a relatively small headquarters staff and places program management responsibilities in the hands of ORD's field Laboratories and Centers. This flattened organizational structure requires a team-based, matrix-management approach in place of the traditional, more hierarchical approach to management.

ORD's Organizational Improvement Activities

ORD held its *First Annual Workshop on Managing Change* in Williamsburg, Virginia, on December 2-5, 1996. This meeting marked the beginning a long-term process for managing change within ORD. The overarching purpose of the workshop was to improve the delivery of high-quality science in EPA by:

- Understanding the new directions in ORD.
- Building the ORD team and improving communications.
- Sharing ideas and listening to all participants' views.
- Developing action plans and identifying change agents to achieve specific organizational improvements.
- Strengthening strategic management of ORD's research program.

The workshop was the first of its kind for ORD in terms of its scope, design, and breadth of participation. Participants included a cross-section of staff from ORD Laboratories, Centers, and Offices. ORD's Strategic Plan provided the overall framework for the deliberations.

Participants identified 564 issues and then consolidated and prioritized them to specify five focal areas for improvement:

- Reduce red tape—Empower staff by reducing unnecessary paperwork.
- Communications—Develop and implement a comprehensive communications plan to improve two-way communication and make electronic communications more effective within ORD.
- Career advancement and development—Provide career enhancement opportunities for all employees.
- Resources and infrastructure—Define "infrastructure" and provide adequate resources to support science.
- Integrate science with EPA's mission—Take action to put science first at EPA and to better integrate science with EPA's mission.

Follow-on activities to address these five improvement opportunities include: "local" initiatives to keep commitments made at the workshop; Laboratory/Center/Office groups to identify additional specific actions; the development and administration of the second ORD Organizational Climate Survey to assess progress in implementing improvement in the five areas of concentration; and establishing an ORD-wide Improvement Network that enhances the communications among and between the various ORD Laboratories, Centers, and Offices.

Common problems identified through the Network will be addressed utilizing the Executive, Management, Science, and Human Resource Councils. The Network will also assist in the annual organizational survey and the next annual workshop.

In addition to supporting the innovative actions taken within each ORD Laboratory, Center, and Office, the Network showcases new ideas as models for replication, thereby keeping alive the "spirit" of Williamsburg. Key to this "spirit" is the participation of all levels of employees, an ORD atmosphere of openness, and a commitment to action by a management team that listens.

Systems and Equipment

To promote successful implementation of this Strategic Plan by our work force, ORD is committed to providing safe, environmentally sound, well-maintained, state-of-the art laboratories, equipment, and supplies. Further, by implementing our information management plan described on pages 19 and 20, we will provide ORD staff with data management, technical, and fiscal information systems to support the conduct of research, as well as the management, planning, budgeting, and accountability functions.

As we implement our Strategic Plan, we will monitor work force needs and strive to provide other programs, mechanisms, and support as necessary to ensure that our work force has the tools, work environment, and equipment it needs to achieve ORD's vision and goals.

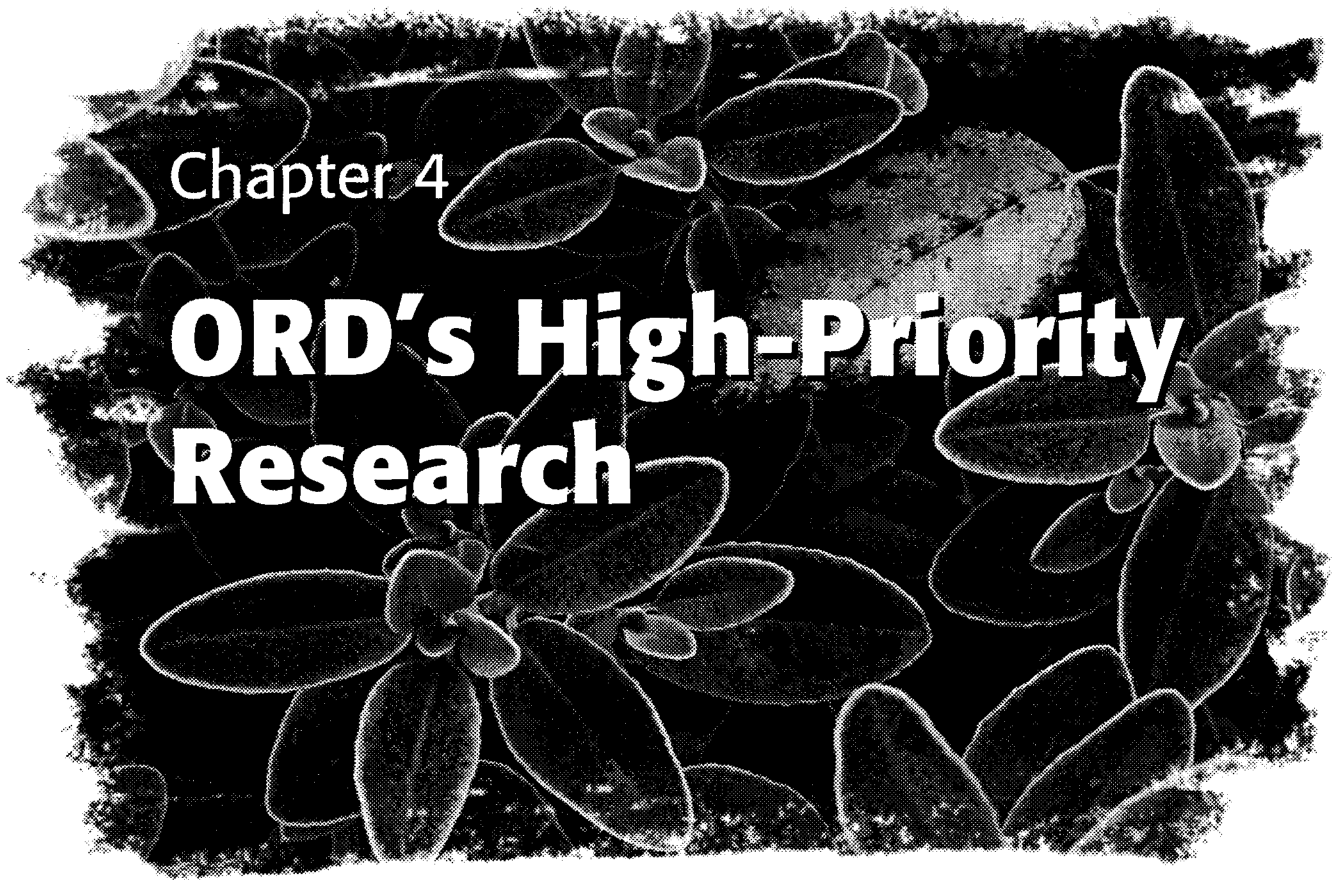
Challenges for the Future

ORD is continuing to study peer reviewer and internal staff recommendations for use in future updates of our Strategic Plan. Comments we are considering include the following:

- Reviewers recommended that ORD periodically reexamine the basis for its Strategic Plan to accommodate ongoing changes in risk assessment concepts generally, and in the risk assessment/risk management framework in particular. Such reexamination is a central feature of the process envisioned by this plan, and ORD is committed to the concept that its risk-based priority-setting system will evolve with evolving risk assessment and risk management concepts.
- Reviewers also commented that the risk assessment paradigm has limited applicability for some EPA programs, thus limiting the utility of a plan based on the paradigm. ORD recognizes the validity of this comment in particular cases. As we implement this Strategic Plan, we will be working in close collaboration with EPA's Program and Regional Offices to ensure that our research agenda is tailored to their particular programs and priorities. Based on this experience, we will consider modifications to the plan over time to accommodate these special circumstances, as necessary.

In addition, ORD is currently involved in several activities that will impact future updates of this plan:

- We will continue our work to refine the evaluation criteria for determining research priorities.
- In cooperation with the EPA Program Offices, we will continue to merge ORD's goals and objectives into EPA's strategic planning process and GPRA activities.
- Finally, and most importantly, we will examine emerging environmental issues and new scientific information to determine whether we need to adjust our major scientific directions, goals, or objectives in light of new knowledge and developments.



Chapter 4 ORD's High-Priority Research

The goals and objectives listed in Appendix A of this plan define an ambitious research program for ORD. Within this program, however, the extent of research we can actually perform will be limited by the available resources. Therefore, in consultation with EPA's Program Offices, ORD uses the priority-setting process to select from its overall program those topics that are of highest priority for research. Priorities to be emphasized for the next few years are (in no particular order):

- Safe drinking water (with a near-term focus on microbial pathogens, disinfection by-products, and arsenic)
- High-priority air pollutants (with a near-term focus on particulate matter)
- Emerging environmental issues (with a near-term focus on endocrine disruptors)
- Research to improve ecosystem risk assessment
- Research to improve health risk assessment
- Pollution prevention and new technologies for environmental protection

These areas will receive more intense research attention (and resources). Intramural efforts will be supplemented with the talents of extramural scientists through external grants, cooperative agreements, interagency agreements, and contracts.

Proposed research for the six high-priority areas is summarized in Table 4. Tables 5 through 10 provide a breakout, by risk assessment/risk management area, of the strategic issues and proposed research tasks, products, and applications in each of the six topic areas. Tables 4 through 10 can be found at the end of this chapter on pages 31 through 54.

Other areas of high importance that will continue to be a major part of ORD's research program include:

- Tropospheric ozone
- Global change
- Environmental monitoring
- Contaminated sites—ground water, soils, and sediments
- Exposures to pesticides and toxic substances

- Ecosystem water quality
- Air toxics

ORD's research agenda also includes additional topics necessary to help the Agency fulfill its nondiscretionary mandates.

Other topics were considered during the planning process, but they did not meet the criteria to be included in ORD's research program. In general, these include exposure or effects research in areas of low risk, risk reduction research in areas of low risk, and routine measurements and monitoring where R&D has been completed. In general, ORD will not pursue major research programs in areas where other research organizations are capable of making a more significant impact.

ORD's entire research program will be captured in more detail in the science research plans being developed by the Research Coordination Teams. These research plans will be finalized after a rigorous peer review. Interested readers should consult these documents.

ORD also uses the principles and priorities of this Strategic Plan as a basis for developing its annual budget requests to fund our research agenda. Our fiscal year 1997 and 1998 requests were based on this plan, as will be our fiscal year 1999 budget proposals.

Evolution of ORD Priority Areas Over Time

The six high-priority areas intentionally are a mixture of:

- ***Research targeted at specific pollution problems*** (i.e., safe drinking water, high-priority air pollutants, and emerging issues).
- ***Broad-based research in methods and approaches*** to advance the fields of risk assessment and risk management (i.e., research to improve ecosystem and health risk assessment, and pollution prevention and new technologies for environmental protection).

We will evaluate progress on all ***research targeted at specific pollution problems*** periodically to ensure that our research program continues to focus on the most significant problems. As work on problem-specific topics progresses and moves toward closure, we will redirect our research and resources to emerging high-priority areas. For example, as we successfully completed work in one of our former priority areas (the health risks of ozone), we shifted resources to particulate matter, one of our current high-priority topics. In the future, the particulate matter research likely will give way to other topics of emerging priority.

We will also evaluate progress on our ***broad-based methods, measurement, and models development research*** annually. These cross-media areas, which reflect ORD's fundamental risk assessment and risk management research programs, will remain high-priority topics. However, the individual projects within these areas will change to reflect research progress and emerging concerns. As the individual projects change, we will revisit and revise research plans for these areas.

Selection of the Six High-Priority Research Topics

The following summaries illustrate how application of the selection criteria described in Chapter 2 gave rise to the six high-priority research topics.

Safe Drinking Water (Microbial Pathogens, Disinfection By-Products, and Arsenic)

The 1996 Safe Drinking Water Act Amendments reemphasized the importance of EPA research on disinfectants, disinfection by-products, and pathogens in drinking water. The Amendments also stressed the need for research on arsenic, sulfates, and radon; risk assessment in sensitive subpopulations (e.g., children); mixtures; and estimating the risk-reduction benefits of drinking water regulations. ORD's near-term focus in this research will be to address uncertainties in drinking water disinfection and arsenic.

Disinfection of drinking water has been one of the greatest public health success stories of the twentieth century. Nevertheless, some public health concerns still remain. For example, many hundreds of thousands of people have become ill and some have died during recent outbreaks of exposure to the protozoan *Cryptosporidium* in drinking water. Recent studies demonstrate that there is a low threshold of infectivity for *Cryptosporidium* and that people with compromised immune systems—such as the elderly, HIV-positive individuals, and persons receiving chemotherapy—may be at greater risk. In addition, other microorganisms exist in drinking water that may also pose serious risks of infection.

We still lack methods to measure many known pathogens in water and are uncertain about their infectivity doses and risks. There is also a high degree of uncertainty about whether disinfection by-products—the chemical by-products that result when disinfectants react with organic matter in drinking water—pose a significant human health threat. Because of the ***high uncertainty***, the ***widespread human exposure*** to drinking water, the ***severity of the known effects*** from certain microbes, and the ***potentially high costs of further regulation*** of drinking water, this issue is the highest priority to EPA's Office of Water and ORD's water research agenda.

The current U.S. standard for arsenic in drinking water is based on policy recommendations developed in 1942 that predate modern cancer and other health-related data. Even today, regulation of arsenic in drinking water is controversial because of the health risk uncertainties and the costs of removing arsenic from drinking water. However, legislation now requires EPA to issue a revised standard for arsenic by 2001. Reports of hundreds of thousands of people being poisoned by arsenic in their drinking water in other countries (Taiwan, China, India, Bangladesh, and Chile)—as well as the fact that people in the U.S. on public and private water supplies are exposed to arsenic, particularly in the Southwest—have also heightened the need to address these health uncertainties. Accordingly, this issue is also of high priority to EPA's Office of Water and ORD's water research agenda.

High-Priority Air Pollutants (Particulate Matter)

Recent publications in the scientific literature indicate that exposure to particulate matter (PM) poses a ***high potential human health risk***. These studies suggest exposures to PM alone, and in combination with other priority pollutants such as ozone, may shorten the human life span of susceptible subpopulations (e.g., the elderly) and cause illness in these and other susceptible groups such as children. There is, however, a ***high degree of uncertainty*** about the size and composition of the particles that may be responsible for these effects, the biological mechanisms of action, and the nature of the concentration-response relationship across a wide range of concentrations and conditions. In addition, ***control costs are potentially very high***. For all these reasons, this area is of very high priority to EPA's Office of Air and Radiation and of high priority to ORD's research agenda.

Emerging Environmental Issues (Endocrine Disruptors)

Through the 1990s, concern has grown that humans and wildlife have suffered adverse health effects from exposure to environmental chemicals that interact with the endocrine system. Collectively these substances are known as endocrine-disrupting chemicals (EDCs). The endocrine system as the central mediator of toxicity may explain effects ranging from increased incidence of some birth defects in humans and wildlife, to diminished semen quality in adult males, to increases in certain cancers (breast, prostate, testes). For example, we have clear evidence of a cause-and-effect relationship in the nearly complete mortality of Lake Ontario lake trout in the sac-fry stage, presumably from exposure to dioxin-like EDCs.

Despite these reports, we still know relatively little about the causes of many of the adverse health outcomes in humans of endocrine disruption. However, we do know that endocrine factors regulate the normal functions of all organ systems. Even small disturbances in endocrine function, especially during certain stages of the life cycle, can lead to profound and lasting effects. Developing offspring are likely to be the most sensitive to EDC exposure.

ORD is already committed to explicitly considering health risks to children when assessing environmental risks. EDC issues only heighten our concern that this special population be provided adequate levels of protection from environmental exposures.

Based on the ***potential scope*** of the EDC problem, the ***possibility of serious effects*** on the health of populations, and the ***persistence of some endocrine-disrupting chemicals*** in the environment, this area has been designated as a high priority for ORD research. Consistent with ORD's long-term goals and objectives, particularly pollution prevention, ORD leads international efforts to define the scope of the EDC problem, identify the areas of scientific uncertainty, and develop recommendations for research. Working via an Endocrine Disruptor Work Group under the Committee on the Environment and Natural Resources of the National Science and Technology Council, we have helped develop a government-wide framework to coordinate research that specifically targets improving the risk assessment process for EDCs. Primary endocrine-disruptor questions include:

- What are the effects of EDCs in exposed human and wildlife populations?
- What are the chemical classes of interest and their potencies?
- What are the dose-response characteristics in the low-dose region?
- Do ORD's testing guidelines adequately evaluate potential endocrine-mediated effects?
- What extrapolation tools are needed?
- What are the effects of exposure to multiple EDCs and will a Toxicity Equivalence Factor approach be applicable?
- How and to what degree are human and wildlife populations exposed to EDCs?
- What are the major sources and environmental fates of EDCs?
- What is needed to assess risks to humans and ecological systems?
- How can unreasonable risks be managed?

Answering these questions will require a coordinated effort by the international research community.

At present, EDC research focuses heavily on developing methods for characterizing the hazards and risks of EDCs, quantifying exposure levels, determining the fate and transport of EDCs in the environment, and developing extrapolation tools. If future research concludes that humans and/or ecosystems are at significant risk due to EDC exposure, research on how best to lower the risks will be needed. At present, EDC sources are poorly characterized and we know little about how effectively current controls reduce EDC emissions. For some EDCs, current controls may be inadequate or too costly; for others, new approaches may be needed that minimize generation and use of EDCs. As the EDC research program matures, we anticipate increasing attention on risk management activities.

Research to Improve Ecosystem Risk Assessment

Ecosystems provide valuable renewable resources and services such as food, water storage and flood control, wood for construction, biodegradation and removal of contaminants from air and water, pest and disease control, and moderation of climatic extremes. If these benefits are impaired by man-made environmental stresses, they must be replaced at great expense by civil works, man-made chemicals, and increased use of nonrenewable energy supplies. In addition, healthy ecosystems contribute to our quality of life through recreational opportunities and scenic beauty.

We have made considerable progress in reducing the most egregious forms of ecological harm from pollution, such as areas of devastation around industrial plants and burning rivers devoid of fish. However, much remains to be understood if we are to avoid future disasters, such as vector-borne epidemic disease, global climate change, forest decline, widespread epidemics of toxic microorganisms in estuaries, reproductive failure of wildlife, and destruction of critical habitat. In particular, we need to better understand the vulnerability and sustainability of our ecological resources within the context of multiple stresses affecting multiple endpoints at multiple scales. And, we need to develop the scientific understanding and tools to better measure, model, and maintain or restore the integrity and sustainability of ecosystems at local, regional, and national scales now and in the future. Specific research needs include:

- Monitoring research to identify and characterize those ecosystems most sensitive to anthropogenic stresses.
- Processes and modeling research to predict future stressor exposures and ecological effects at multiple scales.
- Risk assessment research to define the relative risk posed by multiple stressors on the vulnerability and sustainability of ecosystems.
- Risk management and risk reduction research to provide efficient options to manage and reduce the risk of ecosystem degradation.
- Research to maintain or restore the integrity and sustainability of ecosystems.

This research is essential to significantly reduce the uncertainty surrounding the difficult decisions we must make to protect our ecological resources at local, regional, and national levels. Because of the ***broad applicability of this research*** (particularly its potential to help local communities avoid costly environmental management failures by better understanding the exposures to, effects on, and restoration of our nation's ecological resources) and the ***significant potential for enhancing ecological risk assessment and risk management,*** ORD has selected research to improve ecosystem risk assessment as a high-priority topic for its research agenda.

Research To Improve Health Risk Assessment

Health risk assessment is the process EPA uses to identify and characterize environmental health problems. The results of health risk assessment are crucial to decisions on health protection measures. ORD's research to improve health risk assessment addresses major deficiencies and uncertainties in health risk assessment (including both problem- or agent-specific risk assessment, as well as cross-cutting or generic risk assessment). For example, ORD's research to improve health risk assessment includes:

- Developing state-of-the-art testing approaches for noncancer and cancer endpoints.
- Conducting mechanistic and toxicokinetic research to improve the exposure and dose-response steps in the risk assessment process.
- Identifying biomarkers that can be used to measure exposure or effects.
- Determining how individuals vary in their response to toxic insults, so that EPA can better identify sensitive subpopulations, such as children and the infirm.

Research to improve health risk assessment provides the essential foundation for reliable and scientifically strong risk assessments based on new science and state-of-the-art methods. In addition, this research area supports the development of:

- Computer-based tools to assist risk assessors at the federal, state, and local levels.
- Information management databases that EPA uses to effectively communicate risk information to stakeholders.

Ultimately, the results of this research will enhance risk assessments to support national environmental goals, such as safe drinking water, safe indoor environments, clean air, and safe food. Because of the ***broad applicability*** of improved methods for health risk assessment to ***many user communities,*** research to improve health risk assessment is a high priority for ORD's research agenda.

Pollution Prevention and New Technologies for Environmental Protection

Pollution prevention, or anticipating and stopping problems before they occur, is a powerful risk management tool because it is far more cost-effective and protective of the environment than solving environmental problems after they have been created. Pollution prevention, supported by objective scientific and technical data, actually reduces or eliminates the need for legal actions and regulatory standards, which can be costly and difficult to implement. It also offers an opportunity for meaningful stakeholder input and participation as part of the risk management research and development process.

Pollution prevention will be the first strategy considered for all EPA programs and EPA will lead the nation in efforts to reduce and eliminate pollution at its source. Because of the ***broad applicability*** of pollution prevention strategies and the ***potentially large economic and environmental benefits*** of this approach to risk management, pollution prevention is a high priority for ORD's research agenda. This research builds on ORD's commitment to support and respond to the needs of EPA's Program and Regional Offices for prevention options and information on how best to implement them.

ORD's intramural and extramural research programs support cutting-edge research and development of new tools, techniques, and processes for preventing pollution. This includes analysis tools, such as Life Cycle Assessment, and fundamental precompetitive research on cleaner processes through competitive extramural research solicitations, such as Technology for a Sustainable Environment (a joint program with the National Science Foundation). In addition, the Small Business Innovation Research Program accesses the expertise of private innovators for pollution prevention and other environmental technologies.

The accelerating development of new environmental technologies (e.g., remote sensing, information systems, and computer technologies) has created growing opportunities for managing environmental threats to public health and natural resources. To capitalize on these opportunities, EPA and several other agencies (e.g., the National Aeronautics and Space Administration [NASA], U.S. Department of Energy [DOE], U.S. Geological Survey, and National Oceanic and

Atmospheric Administration) are working cooperatively to identify, evaluate, and develop new advanced technology solutions.

Specifically, ORD has initiated a program—the Advanced Measurement Initiative (AMI)—to guide the identification, research, and application of advanced monitoring tools and enabling technologies in support of EPA's mission. Examples of the kinds of technologies to be evaluated include:

- Thermal infrared sensing of water and watersheds
- Light Detection and Ranging (LIDAR) measurements of air pollutants
- Very high-resolution, visible and infrared wavelength imaging of polluted land areas

AMI's initial emphasis has been applications for remotely sensed information, with NASA and DOE as primary partners. We will progress to investigating other (e.g., in situ) monitoring approaches and will expand to include other agencies and nonfederal developers.

In addition to AMI, the application of high-performance computing to environmental science can improve our ability to access and use data, environmental models, and graphical/analytical tools for informed, risk-based decision-making. Further, the demonstration of new technologies through activities such as the Environmental Technology Verification Program will accelerate development by independently and objectively verifying and reporting technology performance under real-world conditions.

Because of the ***broad applicability*** of these new or improved technical solutions to environmental problems, their ***significant potential for enhancing risk assessment and risk management,*** the ***potentially large economic and environmental benefits*** of these approaches, and the ***opportunities to leverage EPA's resources,*** pollution prevention and new technologies are of high priority for ORD's research agenda.

Table 4.	Summary of EPA/ORD Research Program for Six High-Priority Research Topics			
Research Topics	**Strategic Focus**	**Tasks**	**Products**	**Uses**
Safe Drinking Water—Disinfection	What is the comparative risk between waterborne microbial disease and the disinfection by-products (DBPs) formed during drinking water disinfection? How can both be simultaneously controlled?	Develop methods for measuring pathogen/DBP exposure from drinking water, determine effects and dose-response for them, develop/apply a microbial risk assessment framework, improve DBP risk assessments, and evaluate alternative treatment processes for DBP/microbial control.	Data on effects, dose-response, exposure, comparative risk, and treatment for pathogens/DBPs.	To support DBP/microbial risk assessment/risk reduction rulemaking and compliance monitoring.
Safe Drinking Water—Arsenic	What are the health risks of arsenic at low doses found in U.S. drinking water? What cost-effective technologies will be available for removing arsenic from drinking water?	Develop methods for measuring arsenic species in drinking water and diet, develop improved dose-response and risk assessments for arsenic species, and evaluate cost-effective treatment processes.	Analytical methods for arsenic species, data on effects, dose-response and treatment processes, and improved risk assessment/characterization of arsenic in drinking water.	To improve the risk assessment/characterization of arsenic in drinking water and ultimately for rulemaking and compliance monitoring.
Particulate Matter	What morbidity/mortality is associated with low ambient levels of particulate matter (PM) alone, and in combination with other high-priority air pollutants, and what cost-effective methods are available to reduce PM and copollutants' emissions to an acceptable level?	Conduct clinical/epidemiology/toxicology studies of effects of PM and copollutants, reanalyze past epidemiology studies and develop improved methods; conduct dosimetric and mechanistic studies; characterize the size/species of PM; conduct human exposure studies; and develop, evaluate, and demonstrate methods to identify and characterize emissions of PM and precursors and technologies to reduce these emissions.	Morbidity/mortality, dose-response, and mechanistic data; dosimetric model; methods for measuring PM mass/species; improved human exposure estimates; data on emissions composition; improved risk estimates; and data on cost-effectiveness of PM control strategies.	To improve criteria documents and risk assessments in support of PM National Ambient Air Quality Standards review; to provide information for evaluating alternative PM control strategies.

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Table 4. Summary of EPA/ORD Research Program for Six High-Priority Research Topics (Continued)

Research Topics	Strategic Focus	Tasks	Products	Uses
Endocrine Disruptors	Understanding the potential scope of the endocrine disruption in humans and wildlife, including: defining the range of health effects, critical life stages, sensitive species, and exposures relevant to alterations in endocrine function; developing risk management options to reduce or prevent additional adverse effects in populations.	Develop screening methods for endocrine disruptors; construct predictive dose-response and ecological risk models with emphasis on low-dose effects and effects of combined exposure to endocrine disruptors on the reproductive, neuroendocrine, and immunological systems; provide predictive fate, transport, and exposure models; link exposure models to effect models and characterize effects of ambient exposure to demonstrated endocrine disruptors.	Field data and monitoring tools and delineated effects and predictive models that clarify the health and ecological impact of specific endocrine disruptors and related exposure levels for improved risk assessment and risk management activities.	To develop risk management options for reducing exposures; to ensure that present testing guidelines are adequate for detecting hazards and risks posed by endocrine disruptors, and to assist in implementing the FQPA[a] and SDWA[b] of 1996.
Research to Improve Ecosystem Risk Assessment	How can we determine ecosystem risk and capacity to tolerate stress? What are the chemical and nonchemical exposures to the most sensitive systems? Which ecosystems are vulnerable? Where? How can we reduce risk in a cost-effective manner?	Study ecosystem vulnerability and stressor-response relationships; identify eco-effect measures; characterize habitat distribution and chemical exposures; develop/apply eco-risk assessment methods; and study eco-risk reduction.	Ecosystem criteria, models to predict ecosystem effects/risks, national land-cover map, baseline data for documenting future changes, ecosystem exposure profiles, and information on risk reduction approaches for ecosystems.	To inform stakeholders about ecosystem protection, ecosystem assessment, environmental planning, and ecosystem risk reduction/restoration.

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Table 4. Summary of EPA/ORD Research Program for Six High-Priority Research Topics (Continued)

Research Topics	Strategic Focus	Tasks	Products	Uses
Research to Improve Health Risk Assessment	How can we better define/predict hazards, improve dose-response extrapolation, characterize variation in human susceptibility, and estimate risks from varying exposure scenarios?	Develop or improve methods for screening hazard data, collecting toxicity data, and interpreting hazard data; develop models to estimate target tissue dose and responses to those doses following exposures of varying pattern, frequency, and magnitude; identify and characterize factors conferring enhanced susceptibility to pollutant exposures.	Hazard screening/testing protocols and models for predicting chemical disposition and biological response.	To rank/screen chemicals, develop test guidelines, and provide guidance and methods for more confident risk assessment.
	What is the population distribution of total exposure? What are the source-exposure-dose relationships?	Determine how exposure is influenced by age, lifestyle, behavior, and socioeconomic factors. Develop total human exposure models, which include source/pathway contributions to total exposure.	Improved exposure measurement and assessment methods, models, and data.	To support exposure assessment during risk-based decision-making.
Pollution Prevention and New Technologies for Environmental Protection	How can pollution prevention be integrated into environmental decision-making?	Study engineering/performance costs for pollution prevention; develop technologies; identify audiences needing technical assistance; develop life-cycle analysis/audit tools; and assist in disseminating technologies to the commercial sector.	Pollution prevention cost accounting protocols, cost data, technology transfer products, life-cycle analysis tools, audit procedures, pollution prevention technologies, and performance data.	To evaluate and implement pollution prevention approaches.

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