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EPA

Protecting the Environment: A Research Strategy for the 1990s

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FOREWORD

Mounting evidence suggests that we are facing a new generation of environmental problems – problems that threaten not just isolated areas, but global ecological resources; not just the health of certain individuals, but our ability to sustain life on this planet. Coping with these problems will require a fundamental change in our approach to environmental protection. We must develop the capabilities to anticipate and prevent pollution, rather than simply controlling and cleaning it up after it has been generated.

The tools with which we protect our environment – policy, education, regulation, and technology – are grounded in the knowledge and understanding provided by environmental research. As the federal agency charged with protecting our environment, the U.S. Environmental Protection Agency (EPA) has conducted environmental research since its inception in 1970. However, this research has generally been designed to fulfill EPA's immediate regulatory needs. It is inadequate for addressing the critical, long-term, system-wide environmental problems we now face.

There are many basic questions that we cannot answer now and will never be able to answer without fundamental changes in our national environmental research agenda:

- What is happening to our ecosystems?
- How quickly are the changes occurring?
- Are we causing irreversible damage?
- What are the impacts of these ecological changes on human health?

This document describes an innovative new research program proposed by EPA to provide the knowledge essential for addressing the environmental issues of the future. The proposed program would integrate EPA's current basic research and expand it into critical new areas. It would enable EPA to attract and retain leading environmental scientists and policy makers. And it would generate the information we need to develop effective solutions to our mounting environmental problems.

Erich Bretthauer
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Office of Research and Development

EXECUTIVE SUMMARY

INTRODUCTION

About 30 years ago, we became conscious as a nation that our local environments were deteriorating: rivers, lakes, and estuaries were dirty, our city air was unhealthy to breathe, and the water unsafe to drink. The environmental legislation enacted during the following years reflected our perception of pollution as a relatively discrete local problem: It charged EPA with controlling the pollution generated by individual sources.

This "end-of-the-pipe" approach has successfully enhanced the quality of many local environments. However, despite these improvements, we now face another level of environmental deterioration far more ominous for our future than any end-of-the-pipe problem: Continuing, persistent, and cumulative pollution, from sources large and small, controlled and uncontrolled, is gradually eroding the fabric of our ecosystems that form the basis for life on this planet:

- In the eastern U.S. and many other areas of the world, some evergreen forests have died and certain lakes no longer support fish.
- Stratospheric ozone, an essential part of the atmosphere that sustains our life, is gradually becoming depleted.
- Our estuaries are becoming increasingly polluted, with increased occurrence of fish kills and "toxic tides."
- We are adding "greenhouse gases" to our atmosphere, increasing the chances that we may cause major climatic changes and the resulting ecological and public health effects.
- An increasing number of marine mammals, including porpoises and whales, are diseased or dying.

Addressing this new generation of environmental and public health problems will require a major shift in our overall approach to environmental protection, and in our strategy for generating the knowledge necessary to create and implement environmental protection programs. The EPA, as the federal agency responsible for protecting our environment, must take the lead in responding to this new challenge. Yet, it cannot develop solutions without understanding what is happening to our environment and why.

In a recent report (*Future Risk: Research Strategies for the 1990s*, September 1988), the Science Advisory Board (SAB) called research "the most fundamental of the tools that promote environmental quality." It recommended that EPA "reshape its strategy for addressing environmental problems in the next decade and beyond" and "plan, implement, and sustain a long-term research program" to support this new strategy.

In response, senior scientists and engineers in the Office of Research and Develoment recently reevaluated the Agency's environmental and health research programs. They looked at the basic research EPA is currently conducting and asked what changes would be needed to ensure that we will have the fundamental scientific information needed to formulate solutions to future environmental problems.

Based on their recommendations, we are proposing a major new "core" research program, described in this document, to generate knowledge essential to *all* areas of environmental decision-making, not just the immediate and individual regulatory needs of EPA's program offices. This core research program will require not only strengthening and expansion of existing efforts, but substantial new initiatives in critical areas we have neglected far too long. Also, it will require a commitment to sustaining long-term research projects that may take years to complete, and to maintaining a steady core of expertise and resources that will provide the continuity essential for effective basic research. Major priorities of the program are, in order of priority:

- Research and development of a nationwide integrated Environmental Monitoring and Assessment Program (EMAP) to monitor the baseline condition of and trends in our ecosystems.

- Long-term research to develop new tools and strategies for pollution prevention, including mechanisms to involve industry, state and local governments, communities, and individuals.

- Development of a national data base on the extent and nature of human exposure to pollution in the U.S.

- Substantially increased support for the growth and maintenance of an academic environmental research community.

- Increased effort to understand the relationship between health and multiple exposures to low levels of many different pollutants.

We estimate that approximately 25% of our current $400 million research effort addresses fundamental issues applicable to core research. We are proposing to integrate this research and expand it to create a new program devoted to core research. This is consistent with the SAB's recommendation in its September 1988 report that EPA's total R&D efforts double over the next five years.

Many other agencies and institutions are currently conducting environmental and health research. In implementing the proposed program, we will coordinate and cooperate with these groups to seek the maximum yield from the collective federal investment in these research areas.

The proposed core research program consists of four parts:

- Ecological risk assessment.

- Health risk assessment.

- Risk reduction.

- Exploratory grants and research centers.

The two risk assessment components are designed to help EPA evaluate the risks that environmental contamination poses to our ecosystems and our health. This knowledge will guide the Agency in designing strategies to anticipate and reduce these risks using the technologies and ideas generated by the risk reduction research. And, an expanded investigator-initiated grants program is proposed to ensure the continued strength of this nation's academic environmental research efforts.

The key elements of the proposed program are presented in this executive summary. The subsequent chapters provide additional detail, and a separate chapter on exposure assessment shows how exposure related research in each of the core areas interrelates. Charts at the end of each section show the budgetary resources required to implement the proposals.

The program, in conjunction with the research activities of other agencies, will help us to:

- Redirect our efforts towards preventing rather than cleaning up pollution.

- Understand how pollution is degrading our environment and affecting our health.

- Monitor the status of our ecosystems and our exposure to pollutants.

- Anticipate problems by predicting the health and environmental effects of a changing chemical climate.

- Evaluate the effectiveness of our environmental protection programs.

In the words of the Science Advisory Board, "Our success at protecting public health and environmental quality in the modern world will be measured by the extent to which we understand and manage those human activities that can affect the environment both for better and for worse. . . .The longer we remain ignorant of environmental problems and their possible solutions, the greater the risk of adverse consequences to human health and the environment."

The proposed program will provide the knowledge and understanding we will need to wisely manage our rich and vital environmental legacy in the coming decades. It will provide decision-makers in the U.S. and abroad with the tools and information to make the difficult choices that will be necessary in the years ahead. We fully recognize that these proposals represent a significant national investment in this time of fiscal austerity. However, we believe strongly that without the advances this program will make possible, we are forced to gamble with our future: We would most likely implement solutions that would ultimately be more expensive and less effective than possible, and we would risk causing widespread irreversible damage to the environment that sustains our life.

CORE AREA 1: ECOLOGICAL RISK ASSESSMENT

What is the Problem?

Ecological risk assessment is the scientific process of evaluating the risk that pollution poses to our environment. This process, and the supporting research program, have traditionally been narrow in scope: They have focused on evaluating the effects of individual pollutants and discharges on a limited number of species to provide the data needed for regulation. Consequently, we lack the base of information and resources needed to assess the impact of system-level stresses we are now facing, such as global climate change, destruction of our wetlands and forests, eutrophication of coastal waters, and acid precipitation. We simply don't know:

- What is happening to our ecosystems.
- How quickly the changes are occurring.
- Whether we have passed a threshold of irreversible damage.
- How we can effectively protect our ecosystems.

The ecological research program, summarized below, will develop the information and methodologies that the Agency needs to answer these critical questions. Should this research not be done, we will not know with any acceptable degree of confidence the magnitude or location of ecosystem changes; how to diagnose the causes of major ecological disruptions; how to prevent harm from occurring; or whether our risk reduction solutions are adequate to protect ecosystems and the necessary diversity of life on this planet.

What is EPA's Role?

Many Federal agencies conduct ecological research that is critical to EPA decision-making. However, none of these agencies has the mandate to protect the environment as a whole. Rather, they manage specific ecological resources, such as forests, parklands, and wetlands. EPA is the only Federal agency with the mandate to take a holistic view of environmental problems. Therefore, it is appropriate for EPA to take the lead role in developing our nation's core environmental research program, in cooperation with other agencies and institutions that are also conducting environmental research.

What are We Proposing?

The core ecological research program is designed to provide the scientific basis for protecting ecological resource systems from environmental pollution. It represents a major new initiative in ecological risk assessment: the assessment of risk not just to individual species, but to all levels of biological organization. Key aspects of the program include:

- An intensive initial effort to define the types of ecosystems at risk and to develop measures to indicate the condition of these systems.
- Creation of a nationwide program to monitor the status of and trends in our ecosystems.
- Periodic reporting on the condition of environment and how it is changing.
- Long-term research to improve our understanding of how pollutants affect the structure and function of ecological resource systems.

The program will help EPA answer questions in four critical areas:

- Which ecological resources are at risk?
- What is the condition of the environment and how is it changing?
- To what levels of pollutants are our ecosystems exposed?
- How do pollutant exposures affect ecological resource systems?

Key Elements of the Core Program

1. Which Ecological Resources Are at Risk?

To preserve our ecosystems, we must understand what these ecosystems are, where they are, and how they are being affected by pollution. As a first step in the proposed core ecological research program, EPA will conduct a multifaceted research program to:

- Survey and classify the major ecosystems according to their characteristics and how they respond to pollution.
- Define the extent and population of these ecosystems.
- Identify endpoints, such as hunting success, tissue burdens, and nutrient cycling rates, that indicate the condition of the various ecosystems.
- Develop and apply sensitive methods to rapidly screen and"fingerprint" multiple pollutants in soil, water, air, and biota.
- Select representative systems for further study in other components of the core research effort.

This research will provide the basis for developing a nationwide program, described below, to monitor the status of our ecosystems. It will help us determine where to monitor, what to monitor, and how to interpret the results.

2. What Is the Condition of the Environment and How Is it Changing?

Our current monitoring efforts are limited. Typically, they tell us whether a particular effluent is in compliance with current regulations, but provide little useful information about the ecosystem as a whole. Consequently, we don't know how our ecological resources are being affected by pollution and whether we are adequately protecting them.

To remedy this situation, EPA will establish a nationwide, integrated Environmental Monitoring and Assessment Program (EMAP) to monitor the condition of our ecosystems, including forests, lakes, streams, and estuaries. EMAP will fill one of the major gaps in current ecological risk assessments: It will monitor the status and trends in representative ecological resource systems that are at risk from multiple environmental stresses. The data will indicate whether any serious changes are occurring in these systems and whether multiple or single pollutants are causing the changes.

Central to EMAP will be annual reports on the status of and trends in the environment. Every two to three years, EMAP will publish integrated assessments that interpret relationships between exposure and ecosystem condition, and that assess environmental quality in general.

The program will answer several critical questions:

- What are the baseline characteristics that define a healthy ecosystem and that can be used as a standard against which to measure change?
- How are our ecosystems changing?
- Which pollutants are contributing to ecosystem deterioration?
- How accurately can models for ecosystem exposure and effect predict reality?

EMAP will be developed over several years. During the first year, a conceptual framework for the program will be developed. This monitoring framework and the selected indicators of conditions will be tested and refined in several pilot studies. Then EPA will begin to phase in fully operational monitoring networks on an ecosystem-by-ecosystem basis.

Implementing EMAP will require creating the data base capability to effectively manage, analyze, and regularly report the data, and developing the scientific and technological basis to support the monitoring. EPA will make maximum use of existing data and will coordinate with other agencies now doing ecological resource monitoring.

EMAP will alert us to potential large-scale ecological changes, so that we can take action to prevent them from developing into disasters. The program will also supply a rich data base with which to evaluate the effectiveness of our environmental policies and regulations in safeguarding our environment.

3. To What Levels of Pollutants Are Our Ecosystems Exposed?

Resource limitations make it impractical to monitor all ecosystems. Therefore, to answer this question, we must be able to model how pollutants are transported through the environment from their source to the ecosystem. Models make it possible to assess exposure without frequent and extensive direct measurement of pollutant levels, and they help us to predict and reconstruct exposure.

The models EPA currently uses are inadequate for assessing ecosystem exposure. In particular they are seriously limited in their ability to assess the fate and transport of pollutants through ecosystems.

The proposed program will conduct research in several areas to develop and validate models for evaluating exposure at the ecosystem level.

- *Fate, Transport and Uptake of Pollutants*. Our lack of knowledge about how pollutants and pollutant complexes are transformed by biological, chemical, and physical processes as they travel through the environment severely limits our ability to develop accurate exposure models. Research will be conducted to fill this gap and to investigate factors that influence how pollutants are taken in at the point of exposure (e.g., bioaccumulation, predation, biomagnification).
- *Biomarkers*. Biomarkers are characteristics (e.g., biochemical, biophysical, or physiological changes) within an exposed system that indicate the degree of exposure to a specific pollutant or stress. They make it possible to determine exposure retrospectively and to validate models. Biomarker research has only recently been made possible by advances in biological and chemical sciences. The proposed research program will capitalize on these advances to identify biomarkers that could be used as sensitive and accurate indicators of exposure. (See also the discussion of biomarkers under Core Area 2: Human Health Risk Assessment.)
- *Field Evaluation*. Once the exposure models have been developed and potential biomarkers identified, they will be validated in the field by comparing their predictions with real-world exposures.

4. How Do Pollutant Exposures Affect Our Ecosystems?

At present, we have little idea how ecosystems as a whole are affected by environmental stresses such as pollution. There are many reasons for this critical knowledge gap:

- Much of our current dose-effect data comes from small-scale experiments that do not capture the complexity and sensitivity of ecosystem interactions and therefore tell us little about potential system-wide effects.
- The results of field studies usually can't be extrapolated to other systems.
- We don't understand basic environmental processes that affect a pollutant's fate and activity within an ecosystem.

Developing models to predict how pollutants and other stresses affect entire ecosystems, rather than simply isolated components, will require major advances in our state of knowledge. The core program will study responses at all levels of biological organization, from the biochemical level to system-wide responses, to develop models that can predict effects at these levels. This element of the core program will have several components:

- *Using Chemical Structure to Predict Activity.* Quantitative Structure-Activity Relationships (QSAR) is a technique that uses computational chemistry to predict a chemical's environmental activity (bioaccumulation potential, toxicity) based on its structure. Under the proposed program, EPA will develop QSAR capabilities by identifying key structural properties that make chemicals hazardous. (See also the discussion under Core Area 2: Health Risk Assessment for a different application of this technique.)
- *Extrapolating Laboratory Data to Ecosystem Effects.* Most of EPA's ecological risk assessments to date have been based on results of toxicity tests in individual plant and animal species that are not useful for predicting system-wide effects. This research component would investigate new laboratory tests that could be used to indicate ecosystem effects.
- *Evaluating the Effects of Pollution on Populations,Communities, and Ecosystems.* Natural populations can be devastated by long-term, indirect, and cumulative impacts of pollutant exposure that cannot be predicted based on observations in a laboratory. The core research program will develop, refine, and validate models for assessing the effects of exposure at the population, community, and ecosystem levels. This will require identifying populations and communities most likely to be affected, identifying endpoints to measure response, and understanding the environmental parameters and community characteristics that influence response.
- *Comparing the Effects in Different Species.* This area of research will help scientists use data on effects in one species, population, or community to predict effects in another species, population, or community. The work will focus on gathering the exposure and response data necessary to develop models for predicting effects in various species and at different organizational levels.

These topics are discussed in more detail in Chapter 1: Ecological Risk Assessment. Figures which indicate current and projected resources for core research activities follow this Executive Summary.

CORE AREA 2: HUMAN HEALTH RISK ASSESSMENT

What is the Problem?

Environmental pollution – the by-product of our technologically advanced society – is taking a toll on our health. The National Institute of Medicine recently estimated that a significant part of the $400 billion spent annually in the U.S. on health care is attributable to environmental pollution. Yet we still understand very little about how and to what extent environmental contaminants are affecting our health.

Environmental health research at EPA has historically focused on assessing the health risks of single chemicals. Based on this research, we have successfully reduced exposure to several important pollutants, including lead and other criteria pollutants, that clearly pose a risk to human health. But this is only part of the problem. In reality, we are exposed to a wide variety of contaminants in our air, water, soil, and food.

EPA's current approach to health research is insufficient to understand and mitigate these complex real-world exposures: Because of the pressing needs of the program offices to fulfill EPA's immediate regulatory responsibilities, basic scientific issues that require a commitment to long-term research have been neglected in favor of short-term studies. Consequently, our ability to protect public health has been compromised. For example:

- We don't know the real levels of many environmental pollutants to which we are being exposed.

- Most of our health effects information is based on short-term exposures of laboratory animals to high levels of single pollutants. We are still unsure how this relates to the low-level, varied exposures that we typically experience in our daily lives.

- We are not sure how accurately effects in animals predict effects in humans, even though most health risk assessments are based on animal data.

- We don't have the necessary information to understand how mixtures of chemicals are affecting our health.

- We don't understand the basic biologic mechanisms by which pollutants cause their effects.

- We have focused on cancer-causing chemicals, and paid relatively little attention to environmental causes of other health problems such as heart disease, lung disease, behavioral effects, and reproductive and development effects that are of major concern to the public.

What is EPA's Role?

Many Federal agencies conduct or support environmental health research, including the National Institute of Environmental Health Sciences, the National Cancer Institute, the Agency for Toxic Substances and Disease Registry, and the Centers for Disease Control. EPA has the primary responsibility among these agencies for understanding the effects of low concentrations of pollutants to which people are typically exposed, and for mitigating these exposures to protect public health. In this capacity, EPA occupies a unique niche at the interface of basic and applied science. EPA's understanding of real-world needs can help fashion a productive basic research program. Similarly, through its involvement in basic research, EPA can apply developments at the cutting edge of science to make our environment a healthy place to live.

What are We Proposing?

The proposed program will develop tools and knowledge to enable us to understand how environmental exposures are affecting our health and what we can do about them. It will provide sound data, improved methods, and validated models that will help us to assess the status of public health, identify potential problems, develop risk reduction programs, and evaluate the efficacy of these programs.

A significant portion of EPA's current environmental health research program is directed towards core activities. The proposed program would strengthen these existing efforts and add critical new areas. In particular, the program would considerably increase the funding in the assessment of human exposure. It would:

- Determine, on a national basis, the exposure of humans to pollutants.

- Increase our understanding of the mechanisms of environmentally induced noncancer health effects.

- Assess the hazards of new environmental agents, such as bioengineered organisms, UV radiation from stratospheric ozone depletion, alternative fuels for motor vehicles, and mineral fibers used to replace asbestos.

- Investigate the human health effects of exposure to multiple chemicals.

- Develop biomarkers to estimate exposure and effects of exposure.

- Incorporate into the risk assessment process a consideration of not just whether a chemical causes an effect, but how severe that effect is.

- Base risk assessment on the dose delivered to the vulnerable tissues in the body, rather than on the amount of pollutant we are exposed to before it enters the body.

As discussed below, the program will help us answer some basic scientific questions essential to enhancing our ability to protect public health:

- How can we detect environmental agents that pose hazards to human health?

- To what extent are human populations exposed to pollutants?

- What happens to pollutants once they enter the body?

- What health effects do environmental exposures produce?

Key Elements of the Core Program

1. How Can We Detect Environmental Agents that Pose Hazards to Human Health?

Determining which contaminants threaten human health and what effects they cause is the fundamental basis for risk assessment. This area of research – hazard identification – has historically been a focus at EPA because of its applicability to regulatory needs. The core program will focus on developing methods for detecting and characterizing environmental agents:

- *Developing Methods to Screen and Characterize the Effects of Pollutants.* This is a dynamic research area that must continually incorporate advances in biomedical sciences. EPA will continue to develop methods that will allow us to rapidly screen large numbers of chemicals and chemical mixtures to identify those that are most hazardous. EPA will significantly expand its efforts to develop and refine methods for detecting noncancer effects, including damage to the nervous system, immune system, liver, heart, and reproductive system.

- *Using Chemical Structure to Predict Activity.* The study of structure-activity relationships (SAR) allows scientists to predict the effects (activity) of chemicals based on their molecular structure, and to understand how pollutants cause their effects. Currently, our ability to use this tool is limited to particular chemical groups. If sufficiently refined, SAR could provide a powerful alternative to testing. The proposed program would expand SAR research to include a broader spectrum of environmental contaminants and biological endpoints.

2. To What Extent Are Human Populations Exposed to Pollutants?

Past research efforts have largely neglected this question. Consequently, we know little about how our population as a whole is exposed to pollutants. How many pollutants are we exposed to? Which ones? At what levels? How widespread is exposure? What conditions increase or decrease exposure? The research described below represents an innovative program to help us answer these critical questions. It will provide a much-needed scientific basis for guiding hazard identification and health effects research, and for suggesting new ways of managing exposure to minimize the overall public health threat. This research area will be substantially expanded in the proposed program, with the long-term goal of establishing a national human exposure data base that can be used to answer questions about exposure and to develop and validate models.

- *Model Development.* When direct measurement is not feasible or practical, we must use models to estimate human exposure. Models are useful for reconstructing past exposures, estimating current exposures, and predicting future exposures. Human exposure models require information about how the chemical is released and transported in the environment, and about human behavior and activity patterns that influence exposure. Research will be conducted in several areas to develop and validate models:

  - *Fate Studies.* Studies will be conducted to understand how pollutants move through the environment from the point of release to the point of human exposure.

  - *Media Monitoring.* Real-world monitoring of pollutants in environmental media (air, soil, water) has been greatly neglected over the past decade and has become a critical gap in model development. This area will be considerably strengthened in the new program.

  - *Population Activity Patterns.* Knowledge of human activities related to chemical exposure is another major gap in our ability to predict real-world exposures. The proposed program would initiate research in this critical area.

- *Model Validation.* Models must be validated during their development by comparing their predictions with real-world exposures. The core research proposes that the Agency create an integrated, centralized exposure model validation program.

- *Direct Measurement/Personal Monitors.* Human exposure can be measured directly, while it is taking place, using devices called personal monitors. Coupled with chemical "fingerprints" of various emissions, these measurements can substantially improve our ability to determine what sources are causing exposure in the real world. Current instrumentation can measure only several dozen chemicals. The proposed program would develop instrumentation to measure many other chemicals, and would develop a large data base of direct measurements for use in answering questions about priorities for corrective action and in developing and validating exposure models.

- *Biomarkers.* Biomarkers are specific biochemical, genetic, or other physiological changes within an organism caused by a pollutant. They provide sensitive, specific methods for measuring exposure and characterizing effects. However, because the development of biomarkers is at the cutting edge of science, few biomarkers are currently used routinely for estimating exposure. Scientific advances in the next several years are likely to provide new and increasingly sensitive biomarkers. Under the proposed program, EPA would substantially increase its research in this area to identify useful biomarkers and determine the relationships between biomarker levels and absorbed doses. The goal of this research would be to develop inexpensive, hopefully noninvasive tests to measure exposure and absorption of various chemicals.

3. What Happens to Pollutants Once They Enter the Body?

A major area of uncertainty in risk assessment today is what happens to a pollutant once it enters the body. Where does the pollutant go in the body? How much stays in the body and how much is excreted? How much of the chemical is broken down to metabolites? Where do the metabolites end up, and are they more or less toxic than the original compound? Because we usually cannot answer these questions, we tend to regulate chemicals based on the concentration to which we are exposed, not on the dose that actually reaches tissues vulnerable to damage (the "delivered" dose). This introduces a level of uncertainty into risk assessments.

Currently, very little research is being done in this area. The proposed program will conduct studies to help us understand how environmental chemicals are transported and transformed within the body, and will use this knowledge to develop pharmacokinetic models that will allow us to estimate the delivered dose under varying exposure conditions, and to estimate historical and current exposure.

4. What Health Effects Do Environmental Exposures Produce?

Our ability to answer this fundamental question is limited because of many gaps in our scientific knowledge: How do pollutants cause effects? How do mechanisms of disease and repair influence the health outcome of environmental exposures? If a substance affects experimental animals, will it also affect humans? If a substance causes an effect at high experimental doses, will it also cause effects at low environmental exposures? To address these gaps, EPA proposes to develop biologically based dose-response models, and biomarkers, as described below.

- Biologically Based Dose-Response Models. These models are used to predict human health risks under realistic exposure conditions. EPA will develop biologically based dose-response models based on data from a wide variety of sources and studies:

  - Pharmacokinetic models, described above, to elucidate the fate of environmental agents in the body.

  - Pharmacodynamic models, which provide information about the response of the body to these agents.

  - Inter- and intraspecies comparisons to determine how animal data can be used to predict the effects of human exposures.

  - Epidemiological research to enhance our knowledge about effects in humans that result from real-world exposures.

  - Mechanistic studies to elucidate the basic cellular and biochemical processes by which chemicals cause their effects.

  - Studies to determine the effects of exposure to chemical mixtures.

  These data would be gathered for a wide variety of effects, including cancer, as well as developmental, pulmonary, reproductive, neurotoxic, immunotoxic, and genetic effects. In time, the models would be developed to predict the effects associated with complex mixtures, as well as individual pollutants. The ultimate product of this effort will be more scientifically defensible risk assessments for both cancer and noncancer endpoints.

- Biomarkers. EPA will also conduct research, as described under the exposure section above, to develop biomarkers for characterizing effects. Research will focus initially on markers for genetic effects and then expand to markers for other effects, including immunologic, neurologic, and reproductive effects.

These topics are discussed in more detail in Chapter 2: Human Health Risk Assessment. Figures which indicate current and projected resources for core research activities follow this Executive Summary.

CORE AREA 3: RISK REDUCTION

What is the Problem?

Risk reduction converts assessment into action. It includes any policies, technologies, or activities we implement to protect ourselves and our ecosystems from hazardous environmental contaminants. EPA and industry have traditionally focused on only one approach to risk reduction: controlling end-of-the-pipe pollution. However, this approach has a major disadvantage: It tends to transfer pollutants from one medium to another – for example, when the sludge from air pollution control is disposed of on land. This reduces, but usually does not eliminate, risk. Also, there is much we still don't know about the performance, reliability, and cost of many of the control technologies that we are now using to reduce risk.

Pollution prevention offers a powerful risk reduction alternative that is usually less costly and more effective than end-of-the-pipe control. However, as a nation we have largely neglected this alternative in the past. Consequently, much research is needed to develop and evaluate new technologies and process modifications, to create strategies for pollution prevention, and to help us develop the most effective means for educating and motivating people and institutions to cooperate in reducing the risks to our health and our environment.

What is EPA's Role?

A major responsibility for risk reduction research lies with industry. Therefore, a key element of EPA's proposed risk reduction program is to stimulate and work cooperatively with the private sector. EPA also has a mission to support state and local risk reduction efforts that go beyond EPA's regulatory responsibilities, and to promote research in the academic community. Finally, EPA must provide leadership in fostering the communication and cooperation between government, industry, academia, and the public that will be essential for effective development and implementation of comprehensive risk reduction solutions.

What are We Proposing?

The core research program will significantly expand EPA's capability to develop and promote risk reduction activities at all levels and in all environmental media. The program will help us to understand where pollutants are coming from, so that we can know how to focus our risk reduction activities. The program will provide much-needed research into how we can promote the changes needed in industrial processes and products to prevent pollution. Core research will also help us understand how we can educate and motivate individuals and institutions to make the changes needed to reduce risk. Finally, the program will help us to develop more efficient and effective technologies for controlling the pollutants that we do generate. Risk reduction research will be significantly enhanced in many new areas that have received limited attention to date: municipal and medical solid waste, global climate change, stratospheric ozone depletion, nonpoint source control, indoor air pollution, and emissions from alternative fuels. The proposed core research program will help us answer questions in five critical areas:

- What are the sources of pollutants?
- How can we prevent pollution?
- How can we control the pollutants that we do generate?
- How can we involve people and institutions in preventing and controlling pollution?
- How can we anticipate and reduce emerging risks?

Key Elements of the Core Program

1. What Are the Sources of Pollutants?

The information generated by the risk assessment portions of the core program, described earlier, will help us identify pollutants that pose threats to human health or our ecosystems. To reduce the risks associated with these pollutants, we must know where they are coming from.

At present, we understand very little, on a regional and national scale, about the overall scope of pollution and waste generation in the United States. How much pollution and waste do we produce? What kinds? In what quantities? To what extent is industry successfully reducing pollution? The basic information gap hinders our ability to mitigate pollution, particularly the widespread and persistent pollution that comes from a variety of sources. It also makes it difficult for us to anticipate the pollution problems of the future and to evaluate our success in reducing pollution.

EPA will conduct research to understand the nature and rates of releases from point and local emission sources such as industrial furnaces, incinerators, and discharge pipes. The core program will also study the chemical, biological, and physical mechanisms that govern how various dispersed sources, such as agricultural runoff, methane gas from marshes, and natural vegetation, release gases and particulates. Also, EPA will expand its efforts to identify and characterize sources of indoor air pollution, such as heating devices, construction materials, and household chemicals. Specifically the research will help us understand:

- What pollutants are released from particular sources.
- How pollutants change as they are released.
- How various environmental and climatic conditions affect the rate and type of emissions, and the resulting contaminant levels.
- To what extent treatment technologies, designed to help us control pollutants, actually reduce pollution rather than transfer contaminants into other environmental media.

2. How Can We Prevent Pollution?

Pollution prevention has many advantages over end-of-the-pipe control:

- It often costs less, since there is less waste to manage, and because recovered and recycled materials have value.
- It reduces the need for regulation and the potential for liability.
- It is effective not only for larger, distinct sources of pollution, but also smaller, widespread sources, such as agricultural pesticide runoff, small business and commercial operations, and residential wastes, where control technologies are difficult to apply.

Preventing pollution requires three activities: We must generate the technological knowledge and tools for prevention. We must educate individuals and institutions about these resources. And we must motivate them to use these resources. The core program will broaden EPA's research to identify and evaluate pollution prevention technologies. It will significantly enhance EPA's activities to communicate its findings to industry, states, and communities, and it will provide funds for basic research to help us understand how we can motivate people and institutions to change. The technology development aspects of the proposed pollution prevention research are described below. The research to increase the national involvement in preventing pollution is described below under *4: How can we involve people and institutions in reducing and controlling pollution?*

There are three basic technological approaches to preventing pollution: modifying industrial processes, recycling, and changing product design and use. EPA will conduct research in all three areas. A major area of focus will be technologies likely to be neglected by the industrial sector because they apply to businesses, such as dry cleaners, that are too small or too dispersed to conduct their own research. The three core research areas are:

- *Modifying Industrial Processes to Reduce Wastes.* Examples of industrial process changes that reduce the generation of pollution include changing raw material feedstocks, redesigning the process for higher efficiencies and yields, and preventing leaks and spills. The key objectives of EPA's core research program in this area are to:
  - Develop standardized methods for assessing waste reduction opportunities in various industries.
  - Conduct model waste reduction assessments in key industries.
  - Identify, demonstrate and evaluate in both new and existing industrial processes innovative methods for reducing pollution generation, such as modifying the processes, upgrading their maintenance, using different raw materials, preventing spills, and concentrating waste streams.
  - Conduct pilot-scale research to establish model pollution prevention processing facilities.
  - Identify and stimulate cross-industry applications of innovative production and processing technologies that reduce wastes.
- *Increased Recycling.* Recovery, reuse, and recycling are important ways in which industries, communities, and governments can

reduce pollutants and waste. Under the core program, EPA will:

- Identify, demonstrate, and evaluate strategies to increase the use of recycled materials in products.
- Identify and evaluate new and innovative uses for materials that would otherwise be discarded as wastes.
- Evaluate the cost and performance of various technologies to recycle, reuse, and recover wastes.
- Develop guidelines for model recycling programs.

- *Changing Product Design and Use.* Pollutants can be reduced by eliminating toxic and hazardous substances in products; increasing product lifetime; and improving the durability and repairability of products. EPA's core research will:
  - Analyze product lifetimes to identify opportunities for reducing wastes associated with individual products.
  - Develop criteria for evaluating specific products to predict their pollution loads.
  - Evaluate the performance of products that generate less wastes.

3. How Can We Control the Pollutants that We Do Generate?

Pollution prevention activities will help us minimize pollution, but there are many facets of contemporary life, e.g. manufacture and use of material goods and production of energy, which will continue to generate some pollutants. For this reason, technologies that enable us to effectively control pollutants will continue to be an essential component of risk reduction in the years to come.

EPA currently conducts research to develop and test a variety of control technologies. This research will be expanded under the core program to explore the fundamental mechanisms that govern pollution control technologies, to refine innovative technologies that show great promise for control and cleanup, and to evaluate new technologies based on recent scientific and technological developments. Areas of research under the core program will include:

- *Understanding Combustion Processes.* Many different wastes are now treated by combustion, but there is much that we still don't understand about the process: What are the products of incomplete combustion and how can we minimize them? What happens to metals during incineration? How do the characteristics of the waste and the operating conditions of the incinerator affect the type of gases and ash created by the process? The core research program will study the fundamental principles of combustion and thermal destruction to develop more efficient processes that minimize adverse emissions. The use of catalytic devices to destroy or prevent the generation of unwanted by-products will be investigated. The program will also investigate the kinds of emissions that home heating devices such as woodstoves and kerosene heaters produce, so that we can develop effective controls for these emissions.

- *Using Microorganisms to Treat Wastes.* Biological processes, which use microorganisms to degrade and detoxify wastes, have successfully been used to treat sewage and organic industrial wastes for many years. Now, genetic engineering offers the potential for creating organisms that could increase the effectiveness of proven technologies and revolutionize cleanup activities at spill and hazardous waste sites. This research area is expected to yield substantial benefits, but we still have much to learn. Research will focus on helping us understand how we can:
  - Effectively release and disperse microorganisms in the media to be treated.
  - Promote the survival of microorganisms in the field.

- Monitor the effectiveness of these processes in treating wastes.

- *Physical Separation.* This includes a broad variety of processes to separate contaminants from drinking water, wastewater, sludges, solid wastes, and gaseous emissions. These processes help to decrease the toxicity of the matrix, and concentrate toxic pollutants. Under the core research program, EPA will study the mechanisms that influence the effectiveness of the various physical separation processes in order to improve the efficiencies and cost-effectiveness of existing technologies and to develop new technologies.

- *Using Chemical Processes to Treat Wastes.* Chemical processes are used to separate, immobilize, and destroy a variety of contaminants. Under the core program, EPA will conduct research to:

  - Enhance our understanding of how chemical processes degrade a variety of contaminants in soil.

  - Study the environmental impacts of the chemical treatment processes themselves.

  - Investigate the chemical mechanisms that influence the effectiveness of water treatment processes.

  - Investigate the chemical mechanisms that can be used to stabilize and immobilize contaminants in soils and wastes.

- *Containing Wastes.* Containment technologies use some form of barrier (e.g., tanks, drums, sealants, protective clothing) to separate harmful materials from the environment. The program will investigate the physical and chemical mechanisms associated with a broad range of containment materials, and will develop methods for monitoring the performance of containment technologies. Research will focus on one of the most critical containment questions we face today: How effective are the caps, liners, and immobilization/stabilization technologies we are using to protect the environment from landfilled waste? The program will study how chemicals, microbes, sunlight, subsidence, and other factors influence effectiveness, which will help us to retard and predict failure. The program will also investigate mechanisms that influence the entry and accumulation of indoor air pollutants, so that we can develop cost-effective barriers to reduce this pollution. Finally, containment research will investigate the basic mechanisms leading to the failure of underground storage tanks.

4. How Can We Involve People and Institutions in Preventing and Controlling Pollution?

Risk reduction requires the participation of all segments of our society: industry, government, institutions, communities, and individuals. Under the core program, EPA will provide leadership in developing effective methods for educating and motivating these various groups to implement risk reduction strategies and technologies. Core research will include technology and information transfer techniques, as well as research to understand what factors motivate people and institutions to change their behavior.

- *Educating Our Nation.* EPA currently uses many approaches (publications, workshops, training, expert systems, etc.) to deliver scientific and engineering information to a broad array of environmental users. Under the core program, EPA will work together with private industry, trade and professional associations, state and local governments, and academia to develop mechanisms for disseminating information on risk reduction, and evaluating the effectiveness of these activities. Which audiences do we need to reach? How can we reach them most effectively? What kind of follow up is needed? EPA's contributions to this national educational program would include a pollution prevention clearinghouse, and training and technical assistance through seminars, conferences, computer-animated graphics, video tapes, computer-assisted instruction, and expert systems.

- *Changing Behavior*. Implementing risk reduction technologies and strategies will require major changes in individual and institutional behavior. A major focus of the core research program will be to study the factors that influence and motivate change. The core research program will study several basic questions:

  - How do people perceive risk and how can we best communicate risk? Key topics will include: methods for placing diverse risks in perspective, how social and cultural factors influence risk communication, and how to present uncertainty.

  - What factors influence an industry's willingness to develop and utilize new technologies? Core researchers will examine the relative effectiveness of various incentives and disincentives that influence adoption and commercialization of new technologies. Based on this research, EPA will develop expert systems to assist the technology developers to identify the actions required for commercialization. These systems should help reduce the time it takes to get new environmental technologies into the marketplace.

5. How Can We Anticipate and Reduce Emerging Risks?

Trends in many different areas can indicate societal changes that may cause future environmental problems. As part of the core program, EPA will develop a system for monitoring technological trends (e.g., new manufacturing processes and products) for their ability to affect the characteristics and amount of production emissions. EPA will develop methods for monitoring and analyzing demographic, economic, infrastructure (e.g., transportation), foreign trade, and other data to aid in anticipating future environmental problems. This information will be used to set priorities for risk reduction research so that strategies can be implemented as early as possible.

To date, EPA has identified several emerging issues for study under the core program:

- *Municipal Solid Waste*. We are rapidly running out of landfill space to dispose of our refuse. Research will be conducted to investigate resource recovery options, and to enhance our knowledge about the cost, performance, and public acceptability of various options for solid waste disposal, including incineration.

- *Global Climate and Stratospheric Ozone Depletion*. Core research will identify affordable technological and nontechnological options for reducing emissions of carbon dioxide, chlorofluorocarbons, and other air pollutants that contribute to ozone depletion and global warming.

- *Indoor Air*. Recently we have started to realize that air within our homes and buildings may sometimes pose a human health risk. The problem appears to be increasing as buildings are sealed off to conserve energy. EPA currently has a modest program to identify the emissions from construction materials. This program will be expanded to identify emissions from combustion appliances and household chemicals. Using this information, a pollution prevention and control program will be initiated to provide mitigating guidance to the public.

- *Medical and Infectious Wastes*. Careless disposal of medical wastes has become a major concern in recent months. The core program will evaluate the efficacy of various transportation, handling and disposal options.

- *Nonpoint Source Contaminants*. A significant portion of the pollution that is threatening our ecosystems comes from innumerable, widely dispersed nonpoint sources such as pesticide runoff. The EPA will work cooperatively with the U.S. Department of Agriculture, academia, and the private sector to identify, evaluate, and disseminate successful prevention technology options to users.

- *Water Supply*. As our population grows, we will need new water sources, especially in arid areas and areas of groundwater contamination. The core program will identify cost-effective water treatment options so that we can reuse water, reclaim contaminated groundwater, and create alternative water supplies (e.g., desalinization). The program will also evaluate approaches for reducing water use.

- *Alternative Fuels.* One way to reduce the risks posed by air pollution would be to use alternative fuels for heat and transportation. Core research will be conducted to characterize the emissions of potential alternative fuels, so that we can evaluate the health and environmental implications of making a switch.

- *Environmental Infrastructure.* Our nation faces a major problem with the aging and decay of its infrastructure, including water delivery systems, sewers, and wastewater treatment plants. Core research will identify opportunities for incorporating pollution prevention practices as the infrastructure is replaced.

These topics are discussed in more detail in Chapter 3: Risk Reduction. Figures showing current and projected resources for this core area follow the Executive Summary.

EXPLORATORY GRANTS AND ACADEMIC RESEARCH CENTERS

What is the Problem?

A recent study conducted by EPA indicates that while many different departments and agencies fund environmental research, no one agency considers its mission to be general support of the nation's environmental research community. In fact, in fiscal year 1986 only about one percent of the funds directed towards nonhealth environmental research supported investigator-initiated grants. The situation in environmental health research was not much better. There is near universal agreement that a large applied research program cannot be sustained without significantly more support for fundamental knowledge upon which the applied program is based. This statement is based on a wealth of experience with large Federal applied research programs as diverse as defense, space, medicine, etc.

The lack of grant support not only lets the data base dry-up, it also results in the drying up of the research personnel base. Researchers cannot risk committing themselves (i.e., their careers) or their graduate students to environmental research unless there is a reliable source of funding available. At present, there is none. This raises the specter of shortages of technically competent environmental researchers and managers in the future.

What is EPA's Role?

The investigator-initiated grants and academic research centers we propose will not be limited to the specific priorities and requirements of other departments and agencies operating in the environmental arena. Only EPA has the necessary synoptic view of the interface between basic and applied environmental science that led the SAB to conclude in its recent report, *Future Risks: Research Strategies for the 1990s*, that "... EPA must do more to increase the amount and improve the quality of the scientific and engineering talent dedicated to environmental research."

EPA's former Administrator, Lee Thomas, echoed the sentiments of the SAB in his January, 1989 planning guidance to the Office of Research and Development. He noted that "... the Agency's research program is at a turning point in its evolution," and further, that "...With the recognition of the critical state of the earth's environment, and of our inability to understand the many changes that are occurring, has come the realization that EPA must be a scientific research agency as well as a regulatory and enforcement agency." He concluded that "EPA must provide the principal support for the country's environmental research community," and based his conclusion on two facts: (1) no one else is doing it and (2) only EPA has the necessary breadth of needs to support it.

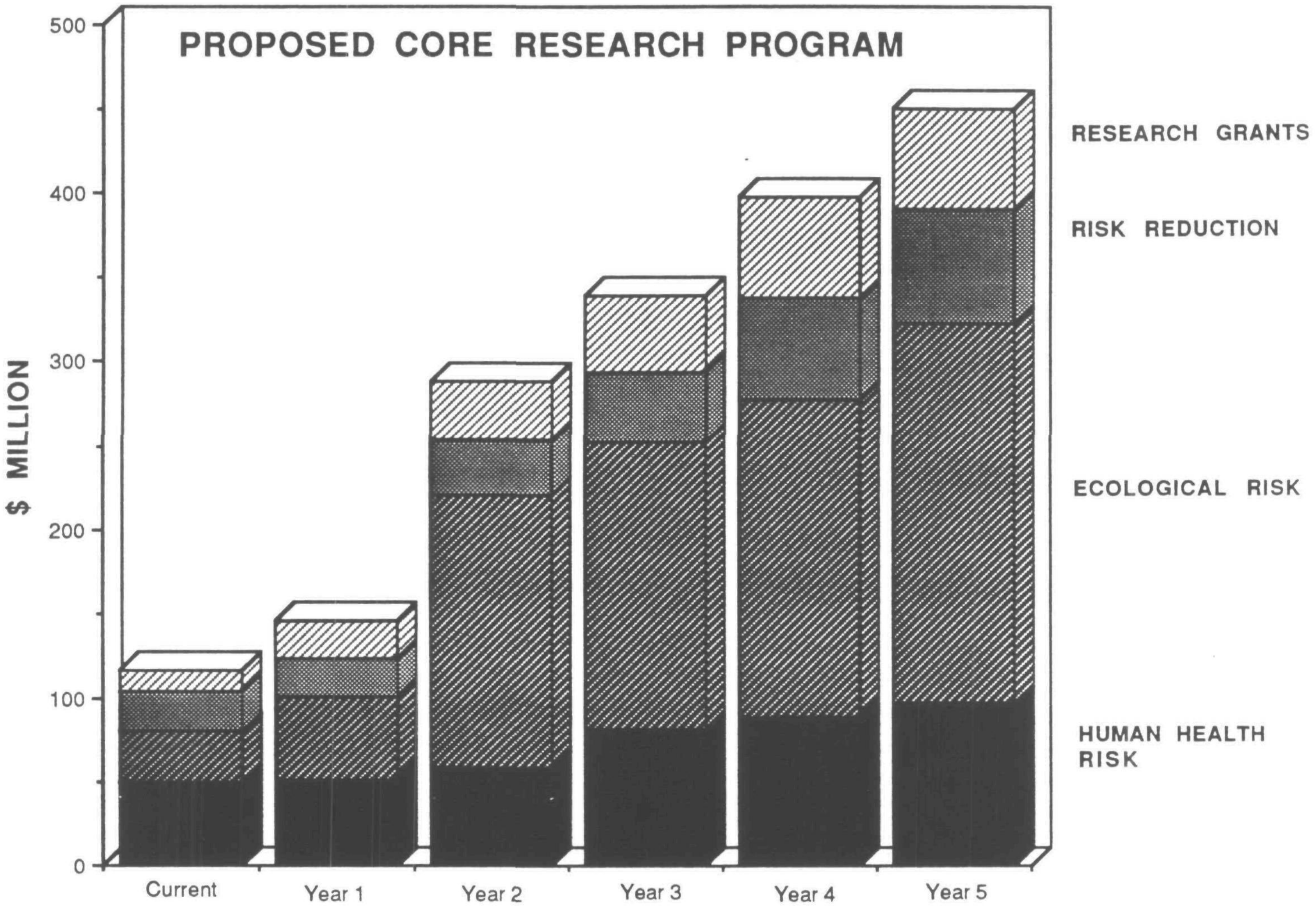
What are We Proposing?

U.S. experience since World War II clearly demonstrates that success in mounting large applied research programs depends on stable, reliable support for individual researchers, largely in academia. Environmental research grants:

- Stimulate progress in fundamental knowledge upon which the larger, applied program feeds.
- Provide graduate and post-doctoral training for the young scientists and engineers who will become future environmental researchers and managers.
- Increase the probability of detecting environmental problems earlier and the methods to avoid or ameliorate them, thereby significantly decreasing the cost of coping with such problems.

We are proposing to create a significantly larger, more stable source of funding for investigator-initiated grants and to expand our support of academic centers in those research areas which require a definite commitment of time and money not achievable through individual grants. In other words, we are proposing that EPA become a reliable partner with the academic environmental research community. EPA will derive direct benefits from the research performed by grantees while reaping the indirect benefits of a substantially larger, more vigorous, and more highly skilled community of environmental research scientists and engineers. From their ranks will come not only the knowledge we will require to confront emerging environmental challenges, but also the environmental policy makers and research managers of the future.

These topics are discussed in more detail on page 61. Current and projected resources for investigator-initiated grants and research centers, as well as those for each of the core research activities described in this Executive Summary, follow.



Implementation Priorities

The Environmental Monitoring and Assessment Program (EMAP) and the pollution prevention component of risk reduction have the highest priority for implementation. By the second year of the core research program, EMAP will be fully funded, so that research on characterization can be completed and the full monitoring network established as soon as possible. By its very nature, a National Monitoring Network such as we propose here depends on comprehensive planning and funding to succeed. Pollution prevention research will also be fully funded by the third year.

The next priority will be to increase the emphasis on human exposure in year three by establishing a program on human exposure monitoring and assessment. This program will grow steadily in the ensuing two years.

The investigator-initiated grants program also has a high priority for implementation. This program will begin the first year and grow steadily until year five, when it will attain full growth.

Additional areas of core research growth are proposed over the next five years. These include pollution control, ecological effects, and the identification of future environmental issues.

ECOLOGICAL RISK ASSESSMENT

INTRODUCTION

EPA is responsible for protecting the environment from the adverse effects of pollutants and damaging activities such as the disposal of dredge material, which destroys wetlands and species habitats. Ecological risk assessment is the term that describes the scientific component of the process the Agency uses to formulate policy and regulations for controlling pollutant releases or activities in order to prevent unreasonable damage to ecological resources.

In general, EPA needs to conduct an ecological risk assessment to make three types of decisions. The first is a prospective one involving requests for approval of releases of chemicals to the environment or for effluent or emission limitations for categories of sources. The second involves remedial action to deal with problems that have been discovered, e.g., DDT in the food chain, mercury in river and lake sediments, acidification of surface waters, and PCB and dioxin contamination. The third is that of integrated environmental management. In order to plan and strategically manage its programs, the Agency needs to know how effective the aggregate of its past actions has been in protecting ecological resources. The Agency also needs to be able to anticipate and set priorities among probable future threats to ecological resources in order to conduct research and mount programs to deal with them.

The ecological risk assessment approach that has been developed and used by the Agency has relied almost exclusively on a combination of: 1) single-species ecotoxicity tests best suited for single chemical or single stressor issues; and 2) media-specific exposure models that exclude or treat simplistically biological mediation, transformation, and transport. The existing approach has allowed the Agency to make reasonable decisions about individual chemicals, particular types of releases, and remedial actions. However, as we face the emerging problems of the future, the shortcomings of this approach are becoming all too evident.

The two most important shortcomings associated with the current approach are its inability to predict or evaluate, after the fact, the ecological effects of cumulative pollutant loadings; and its inability to deal with the stresses that affect system level structure and function.

Currently, the EPA research program on ecological effects has been tailored to deal with the single pollutant or single discharge type of decision. There has been no near-term or long-term core research program focused on the system-level decisions that the Agency now faces in trying to assess its aggregate effectiveness in ecological protection and trying to deal with system-level stresses like global change, wetland destruction, eutrophication, and acidification. The purpose of the proposed program is to develop the information and methodologies that will allow the Agency to conduct ecological risk assessments that address these broader issues.

The core program consists of research in four areas. The first is research needed to characterize and classify ecological resource systems so that specific research priorities can be established and representative systems can be selected for monitoring and research. The second is design and operation of an environmental monitoring and assessment program that will determine status and trends in the exposure and condition of ecological systems and periodically assess environmental quality. The third is research to improve the Agency's ability to predict ecological exposure by developing models and measurement techniques that incorporate the chemical and biological processes that determine actual exposure to sensitive receptors. The final component consists of the development of models of response that integrate effects at different levels of biological organization, e.g., biochemical, cellular, physiological, population, etc. in order to predict and assess the status and condition of ecological resource systems.

RESEARCH ISSUES

Together, the components of the core research program are designed to provide answers to four critical policy-related questions that will become most important as the Agency evolves toward a systems view of ecological resource and protection.

What are the Ecological Resource Systems at Risk?

This program will identify representative ecological resource systems for purposes of designing and setting priorities for both monitoring and research. It will also select and evaluate appropriate measures for monitoring the exposure and health of these systems; develop and apply biological and chemical sampling and measurement techniques; survey and classify ecological resource systems; select representative systems; and develop the scientific basis for selection of end-points that are appropriate structural and functional measures of the condition of the relevant ecological resource systems.

What is the Condition of the Environment and How it is Changing?

The Environmental Monitoring and Assessment Program (EMAP) is an integrated chemical and biological monitoring program for representative ecological resource systems. The data will be analyzed and interpreted periodically to determine changes in chemical exposure trends and in the structure and function of representative ecological resource systems. The sampling frame of the program will allow the results to be extrapolated to ecological resources generally.

EMAP should guarantee that large scale ecological disasters do not result from uncertainties in our ecological risk assessment decisions. The onset of major indirect and cumulative effects as well as unforeseen systemic changes should be detected and diagnosed in time to adopt appropriate remedies. The program should also supply a rich data base which can be used to evaluate the performance of regional ecological risk assessment models and the effectiveness of policies and regulations designed to reduce ecological exposure and to promote ecological protection or recovery.

To What Level of Pollutants are Ecological Resource Systems Exposed?

The primary focus of the research will be the development of predictive models and indicators of exposure. A critical component of ecological risk assessment is the actual exposure of sensitive resources resulting from the release of pollutants into the environment. The physical, chemical and biological reactions of a pollutant determine its environmental pathways to sensitive receptors. The systems view of ecological risk requires major advances in our knowledge of these critical mediating environmental processes and the development of predictive models and indicators that capture these advances, particularly for terrestrial and marine environments.

What are the Effects of Pollutant Exposures on Ecological Resource Systems?

Finally, the core includes a major expansion of ecological effects research. The purpose of this expansion, along with the proposed new research in characterization, status, trends, and exposure is to respond to a fundamental shortcoming in our ability to determine or predict the system-wide ecological effects of major environment stresses. The goal of the effects program is to combine theory with laboratory and field experimentation to improve methods for predicting the effects of single and multiple environmental stresses on higher levels of ecological organization.

CORE RESEARCH PROGRAM

A more detailed description of the proposed program follows.

Ecological Classification and Environmental Characterization

	Year/$ M				
Current	1	2	3	4	5
2.0	8.0	30.0	30.0	40.0	47.0

As it is unreasonable to study all ecosystems or every biological and chemical component of all ecosystems, it is essential that the systems chosen for study are representative of the population or areal extent of the resource of interest and that studies within representative ecosystems are focused on chemical and biological properties indicative of their condition. Therefore, the objectives of the ecological classification and environmental characterization core research area are to:

1. Classify major freshwater, estuarine, and terrestrial ecosystems based on similar physico-chemical, biological and/or response attributes.
2. Define quantitatively the areal extent and population of these major ecosystems.
3. Identify indicators of system condition and ecological endpoints of primary concern for monitoring and effects research.
4. Refine classifications of major ecosystems based on improved understanding of their physico-chemical, biological, and/or response attributes.

From these studies, a necessary foundation will be established for developing sampling frameworks for ecosystem status and trends monitoring, selecting ecosystems most sensitive to change from cumulative effects of pollution, extrapolating research and monitoring findings of representative sites to the resource population, and quantifying the extent and location of resources at risk.

Ecosystem Classification

	Year/$ M				
Current	1	2	3	4	5
0	5.0	10.0	10.0	15.0	15.0

Although many classification schemes have been proposed over the years for both aquatic and terrestrial ecosystems, few studies have been conducted to assess the effectiveness of these schemes in reducing sampling variance in monitoring programs or their applicability to reducing uncertainty in large-scale extrapolations of exposure and effects model predictions. This program will refine ecosystem characterization biologically and chemically; develop new hierarchical classification schemes for estuarine, lake, stream and forest systems; and test existing schemes for their applicability to the design of monitoring systems for determining ecosystem condition and pollutant exposure, and to the selection of representative systems for effects studies and model prediction extrapolation. This classification effort will be the critical element needed to improve monitoring systems design and reduce uncertainty in large-scale risk assessments. Over time and with findings from ecosystem response studies, hierarchical, multi-scale classification schemes can be established that will serve as the basis for quantifying existing and potential risk to ecological resources.

Ecological Condition Indicators

	Year/$ M				
Current	1	2	3	4	5
0	0	5.0	5.0	10.0	22.0

Ecological condition indicators are characteristics that define the health of an ecosystem. These may range from hunting success, tissue burdens or biomarkers, to complex indices of species abundance or diversity or measures of nutrient cycling rates. The definition of indicators of condition is essential for developing cost-effective ecosystem condition monitoring networks and for focusing effects research. The Agency will compile currently used indicators, test the sensitivity and selectivity of these indicators, and identify new indicators. These indicators, in combination with exposure and effects data, will aid in identifying potential ecosystem problems, in determining the effectiveness of current control programs at the ecosystem level, and in developing the periodic reports on the condition of the environment proposed in the Ecological Monitoring and Assessment Program.

Chemical Characterization

	Year/$ M				
Current	1	2	3	4	5
2.0	3.0	15.0	15.0	15.0	10.0

With the rapidly escalating number of chemicals entering the environment, it is essential that we know what pollutants are present in ecosystems and where they reside. The chemical characterization effort will focus primarily on the development of methods for rapid screening of multiple pollutants in soil, water, air, and biota and on increasing the sensitivity and selectivity of these methods. Broad-spectrum, chemical techniques have been used effectively to "fingerprint" surface water chemistry and are now being investigated as tools to characterize pathogens and bioengineered organisms in water.

Extensions of these capabilities will lead to improved characterization of both selected ecosystems and the ambient environment. Incorporation of broad spectrum analyses into a status and trends monitoring program should produce a cost-effective means of better understanding the complexity of pollutant exposures in ecosystems.

Environmental Monitoring and Assessment

	Year/$ M				
Current	1	2	3	4	5
5.0	15.0	78.0	83.0	85.0	90.0

Current approaches to monitoring ecosystem degradation are typically compliance oriented, site specific, and undertaken without knowledge of the representativeness of the results. Consequently, we are currently unable to assess with confidence changes in the environment such that we can judge whether ecological resources are being protected from pollutant damage.

The goal of the Environmental Monitoring and Assessment Program (EMAP) is to establish a national scale, integrated, pollutant exposure and ecological condition monitoring network. The unit of most interest will be the ecosystem; for example, forests, lakes, streams, estuaries, and fresh water wetlands; and the program will be developed around the mosaic of these systems over the landscape. The objectives of the network include:

- Establishing baseline conditions for detecting changes in pollutant concentrations/exposures and ecosystem condition at regional scales.
- Quantifying trends in pollutants and ecosystem condition.
- Developing causal hypotheses and identifying emerging problems from relationships between pollutant changes and concomitant ecosystem changes.
- Verifying predictive ecosystem exposure and effects models.
- Reporting regularly on the condition of the environment.

EMAP will achieve its objectives by developing rigorous statistical sampling designs and protocols, by building on existing networks, by facilitating interagency cooperation, and by maximizing the use of existing data for developing a sound program.

Coupled with the research in the ecological classification and environmental characterization program, initial efforts will be devoted to designing the conceptual framework for the Program and then to pilot studies and associated research. The phased implementation of fully operational networks on an ecosystem-by-ecosystem basis will begin thereafter.

The primary research elements within EMAP are:

1. Monitoring Systems Design
2. Methods Development
3. Operational Monitoring
4. Data Base Management
5. Integrated Assessment/ Environmental Statistics

Monitoring Systems Design

	Year/$ M				
Current	1	2	3	4	5
0	4.0	15.0	15.0	10.0	10.0

Critical to the core program is the analysis of data from existing monitoring programs and special purpose surveys to develop innovative designs that can be used to quantify ecosystem status and trends, with known confidence, while maximizing the use of existing monitoring systems. A high priority will be the development of model-based systems that can be used to extrapolate trends from existing monitoring sites to a specific regional population of interest. Cost-effective regional surveys that index more complicated patterns of status also need to be developed and pilot tested. Integrated sampling frames that allow patterns and trends to be compared across ecosystems and media also are prerequisites to implementing a national monitoring network and these will be investigated in this research element.

Methods Development

	Year/$ M				
Current	1	2	3	4	5
1.0	1.0	10.0	10.0	10.0	7.0

A field monitoring program requires that research techniques used for ecological condition indicator definition and chemical characterization be adapted to continuous and remote sampling methodologies, often with minimally trained operators. Reducing costs and increasing both reliability and information gathered are essential to this core element. Research activities include examination of specimen banking techniques, advanced field monitoring methods (e.g., x-ray fluorescence spectrometry, dosimeters for animals and plants, and fiber optics), broad-spectrum pollutant monitoring instrumentation for field use, and interpretation of remote imagery and reconnaissance-level remote sensing (e.g., UV DIAL).

Operational Monitoring

	Year/$ M				
Current	1	2	3	4	5
4.0	4.0	43.0	48.0	50.0	55.0

The core program includes development and implementation of an operational network for determining the status of and trends in the condition of freshwater, estuarine, and terrestrial ecosystems and associated air, soil, and water media as well as the status of and trends in pollutant exposures/ concentrations at the ecosystem level.

Data Base Management

Current	Year/$ M 1	2	3	4	5
0	2.0	5.0	5.0	7.0	8.0

Combinations of existing data bases and network monitoring data will be required. The measurements and their respective uncertainties provide the basic units for estimation and hypothesis testing. The use of different measurement methods and instruments along with different calibration procedures, sampling techniques, and the presence or absence of quality control practices must be considered in determining the overall uncertainty. When building data sets from different sources, it becomes necessary to have a mechanism for tracing the data to their origins and for integrating the quality control information within the data base into a comprehensive quality assessment product. It will require several years to develop and evaluate sound and workable approaches for defining the uncertainties in integrated data bases.

One of the first targets of the data base management (DBM) core research task will be to produce an updated directory of environmental and resource data bases and monitoring networks. This directory and the associated data bases will be critical to the design of the operational status and trends network. The second task will be the development of a DBM system to support the network. The key to a successful program will be moving quality-assured data into, through, and out of the system rapidly, in a form and format convenient to data users. The core program will focus not only on managing data, but also on developing and applying innovative techniques to increase responsiveness and reduce costs. Automation will be used to the maximum in the production of annual statistical reports. Geographic information systems (GIS) technology will dominate the DBM system.

Integrated Assessments/Environmental Statistics

Current	Year/$ M 1	2	3	4	5
0	4.0	5.0	5.0	8.0	10.0

Operation of EMAP will fill one of the major gaps in current ecological risk assessments. The results will provide system-level measures of status and trends in the condition of representative ecological resource systems that are at risk from environmental stresses. The data will indicate whether any serious changes are occurring in the condition of the ecological systems and whether multiple pollutant or single pollutant stresses appear to be causing the changes.

Central to EMAP will be annual reporting of findings that are relevant to the Agency's hazard identification and risk characterization effort. The focus of the reports will be on indices of condition and exposure. On a two-to-three year interval, integrated assessments will be produced that interpret relationships between exposure and condition and that assess environmental quality in general. In addition, these reports will contribute to the verification of exposure and ecosystem effects models as well as assessments of the effectiveness of current control programs in protecting ecological resources.

Considerable effort will be devoted to exploring the data for developing hypotheses and identifying emerging problems, statistical techniques for data interpretation on both temporal and spatial scales, empirical models, and for maintaining cost effectiveness of the information gathered through assessment of its value.

Ecological Exposure*

	Year/$ M				
Current	1	2	3	4	5
5.0	7.0	16.8	17.0	20.0	28.0

The EMAP program will provide a number of measurements of direct or indirect exposure to ecological resources. In some instances, the direct measurement approach of EMAP will suffer because of the absence of acceptable measurement techniques. That problem is being addressed by the methods development portion of the EMAP program. In most cases, however, the direct measurement approach to exposure will alone prove inadequate for ecological risk assessment for two reasons. First, the decision maker usually needs to know where the exposures come from if alternatives to reduce exposures are to be considered or if possible future changes in exposure are to be understood. Thus, some level of source characterization is necessary to relate ambient levels to their sources or sites of release. Source characterization is predominately an engineering function which would include research to understand the scientific and engineering principles and mechanisms that characterize the pollutants (type, amounts and rate of release) from sources. However, there are circumstances (e.g., releases from hazardous waste sites; release of chemicals from contaminated sediments) that do not lend themselves to an engineering approach to characterization. To this extent, the ecological exposure program will include fundamental research to identify and characterize pollutant sources that are unique for ecological systems. Predictive exposure models that quantify the physical and chemical behavior of pollutants are needed to solve these problems of source attribution and prediction.

The second reason that reliance on direct measurements can be inadequate is that they are often too few and too infrequent to provide estimates of exposure to biological systems that are accurate from the point of view of indirect and cumulative exposures. Biomarker techniques offer the possibility that measurements can be developed that, in combination with models, will provide much improved estimates of indirect and cumulative exposures to ecological resources.

The current research program has not been able to address adequately the need to improve predictive exposure modeling or exposure biomarkers. The development of exposure models has focused primarily on the need to be able to predict pollutant concentrations in ambient water, air, and soils. These models have been tailored primarily to predict exposures to people. The models have not incorporated the kind of biological processes and pathway knowledge that is necessary to predict exposures to sensitive receptors in ecological resource systems.

Though now promising, research in the past to develop biomarkers of exposure has been virtually nonexistent. Only recently has the state of chemical and biological science advanced to make research in this area practicable. And only recently has there been a recognition that advances in this area could be most valuable toward advancing the science of ecological risk assessment.

The expanded core program includes the five types of research that will be necessary to improve our ability to predict future and to reconstruct past direct, indirect, and cumulative ecological exposures. These five interrelated research areas are: (1) source characterization; (2) transformation and transport process research; (3) mathematical model development; (4) biomarker development for ecological exposure; and (5) field evaluation of process descriptions, of models, and of biomarker measures. The major research emphasis in the expanded core program in these areas is as follows:

Source Characterization

	Year/$ M				
Current	1	2	3	4	5
2.0	2.0	4.8	5.0	5.0	6.0

Point or area sources discharge many known and unknown pollutants into the air, water and soil. Information on the chemical and physical nature of these discharges serves to identify sources of

* See also Appendix A Exposure Assessment – A Cross-Cutting Issue

pollutants in ambient media on the basis of their elemental "fingerprints."

Mobile and stationary source characterization are most familiar. In mobile sources, new engine designs and alternative fuels may change the mix of organics, NOx, and other pollutants. Changes in catalytic converters may result in altered emissions of toxic metals. Stationary source emissions change with fuel mixtures, pollution control devices, raw materials, process streams, and burner and reactor configurations. The research here involves primarily continued application of existing technology to new sources and development of new techniques to expand the suite of measurable pollutants.

Source apportionment techniques have been developed which can identify far-field sources of polluted air masses on the basis of trace element proportions derived from the sources of fuel they burn. Research must be extended to increase the statistical precision with which signals can be measured, and to evaluate the technique for non-air pollutant sources. There are a large number of sources that need to be characterized which do not lend themselves to the traditional monitoring and engineering approaches of measuring and tracing back. This is especially true of non-point sources in which the source strength is not easily measured or characterized, e.g., pesticides in groundwater, agricultural run-off and urban storm water run-off.

Transformation and Transport Processes

	Year/$ M				
Current	1	2	3	4	5
2.0	3.0	5.0	5.0	5.0	6.0

The expanded core program will examine basic fate processes to determine exposures to sensitive receptors for the relevant ecological resource systems. For example, biodegradation is influenced by the salt content of water and the tidal cycle; thus, how near coastal systems biodegrade pollutants will be a part of this core area. Understanding partitioning in aquatic (fresh and saline) sediments will be another element of the core program. Understanding the chemical processes at environmental interfaces and in specific compartments is necessary to predict ecological exposures because the receptors live at these interfaces. The program will also include study of the fate of pollutant complexes, since systems are never exposed to just one pollutant at a time. The processes that determine exposure to near coastal resource systems from non-point source pollution, including deposition and air chemistry, to wildlife populations from chemical and biological pesticides, and to freshwater aquatic systems from non-point sources of metals and organics from atmospheric emissions and surface water runoff will be emphasized.

Ecological Exposure Models

	Year/$ M				
Current	1	2	3	4	5
1.0	1.0	2.0	2.0	2.0	4.0

If the ecological effects of xenobiotics are to be realistically assessed from observed or predicted environmental concentrations, appropriate ecological exposure models that characterize and predict the bioaccumulation/bioconcentration and bioavailability of chemicals must also be developed and validated.

The first expansion will focus on estuarine eutrophication models and on upgrading general water quality models to better simulate limiting nutrients, red/green tide blooms and interactions with toxics. Research will also focus on the definition of various terrestrial ecosystem types (e.g., croplands, grasslands, forests, rangelands) in order to develop food chain models, species completion models, predator-prey/behavior patterns and uptake/distribution models needed to complement existing terrestrial exposure models.

The second expansion will include uptake/bioaccumulation, predator-prey, food chain, and behavior-avoidance, in the improvement of aquatic exposure assessment models.

Currently, models are being developed for several media, including surface and subsurface water, terrestrial ecosystems, and large lakes.

Ecological Exposure Biomarkers

	Year/$ M				
Current	1	2	3	4	5
0	1.0	5.0	5.0	5.0	7.0

Very little research is being conducted in this area now. However, it is possible to relate exposure to a specific pollutant or stress by analyzing subcellular and cellular responses within certain ecological receptors (organisms). Some of the early work with stress proteins and metal contamination in fish indicates that this area has merit as core research. This form of ecological epidemiology can be used to determine exposure retrospectively and to validate the work in pathways and ecological modeling. The first three years will be devoted to testing hypotheses using key species occupying critical compartments of the ecosystem. The selection of species and compartments will be influenced by the work on ecological indicators and the early results of the status and trends program.

Field Evaluation

	Year/$ M				
Current	1	2	3	4	5
0	0	0	0	3.0	5.0

If a predictive exposure model is to be used effectively, it must be evaluated. This core area will validate the ecological exposure models and exposure biomarkers developed for the various ecosystems being studied. The first model that will be validated is the prototype row-crop model that has been developed to predict avian exposures from chemical pesticide applications. As other models and biomarkers are developed they will be evaluated in the field.

Ecological Effects

	Year/$ M				
Current	1	2	3	4	5
19.0	19.0	38.0	40.0	43.0	60.0

The central theme of the integrated ecological risk assessment research program is to provide EPA with the combination of data, knowledge and methods to enable assessment of the risks of pollutant exposure to ecological resources. The fundamental assumption in the design of this core research program is that ecological risk assessment must consider the potential long-term, indirect and cumulative system-wide impacts associated with Agency policy and regulatory options.

In the past, assessment of ecosystem response has been based on three approaches, each of which has suffered from serious deficiencies: 1) extrapolation from small-scale experimental results such as bioassays or microcosms that do not capture the full range of ecosystem interactions and have been known to misrepresent ecosystem sensitivity, 2) results from specific field studies or impact assessments which have rarely been sufficient to extrapolate to other systems, and 3) attempts to construct ecosystem dynamic models which have suffered from the lack of observations needed to understand and quantify basic system processes.

The cost-effective prediction of potential system-wide ecological effects from pollutants and other stresses will require advancement in our state of knowledge about responses at several levels of biological organization from biochemical up to system level indicators. The core program is designed to investigate structural and functional relations at these different levels with early priority being accorded to new coastal systems, to population and community studies, and to field evaluation of all predictive effects models.

The core program assumes that there is a spectrum of needs to predict effects at different levels of biological organization. At one end of the spectrum is the need for first-order prediction of effects. In some instances, an appropriate screening level ecological risk assessment can be carried out simply based on knowledge of the molecular structure of a chemical or the results of a single species bioassay. At the other end of the spectrum, there are cases where a complete ecosystem-effects model prediction would be desirable. The research program tries to satisfy this need for a range in predictive ability.

The components of the program, along with the principal approaches and priorities, are as follows:

Ecosystem Effects

	Year/$ M				
Current	1	2	3	4	5
3.0	3.0	16.0	17.0	20.0	27.0

Ecosystems are so complex and variable that we are unlikely to understand and describe them completely in the near future. The most feasible approach is to define measurable indicators of ecosystem condition and response to stress, determine the range of natural variation of these indicators, and measure and model the response of these indicators to anthropogenic stress at the ecosystem level.

During the first two years, priority will be given to field data collection and modeling for near coastal ecosystems and freshwater wetlands and to indicator development and retrospective studies for all major ecosystem classes. Additional major ecosystems will be added for field data collection and modeling in the third through the fifth years in the following order: forested ecosystems, fresh surface waters, and agroecosystems. EPA currently has little or no research at this complex level, except in acid deposition.

Field Validation

	Year/$ M				
Current	1	2	3	4	5
3.0	3.0	3.0	3.0	3.0	3.0

Although major advances can be expected in direct measurement of the effects of stress on higher levels of ecological organization such as communities and ecosystems, these are not likely to be sufficient for EPA's ecological assessment needs. Therefore, there is a need to determine the validity of the assumptions upon which the use of data from lower levels of biological organization to predict higher level effects is based.

The emphasis during the first three years of the program will be on validation of existing bioassay tests and models. Plans will also be developed under the effects research program. Evaluation of the complex models will begin in year four.

Quantitative Structure-Activity Relationships (QSAR)

	Year/$ M				
Current	1	2	3	4	5
1.0	1.0	3.0	3.0	3.0	5.0

The potential environmental effects of limited numbers of hazardous chemicals can be tested and evaluated. The QSAR approach develops carefully selected reference data and relates the activity of each chemical to the structure using computational chemistry techniques. QSAR provides estimates of bioaccumulation potential, acute and chronic toxicity, and many chemical properties important in forecasting fate and effects.

The development of predictive QSAR technology follows a logical progression of increasing sophistication in computational methods and reference endpoints. EPA needs four primary reference data sets: acute toxicity, metabolism/biodegradation, bioaccumulation, and macromolecule reactivity (DNA adducts). Two databases are nearing completion. The reference data set for metabolism/biodegradation will be one of the first areas for core research. Another major expansion of QSAR will be the development of a systematic reactivity profile of chemicals toward DNA and other proteins. This reference set and the associated reactivity models will require five years to complete.

Current activities involve developing quantitative structure-activity computational methods for anticipating the environmental behavior of chemicals from chemical structure. Key structural properties which make chemicals hazardous are being identified to provide the basis for initial risk assessments before test data are available. The products of structure-activity research permit EPA to focus resources on the greatest chemical hazards and identify potential risks before environmental damage occurs.

Single Species Effects

Current	Year/$ M 1	2	3	4	5
2.0	2.0	2.0	3.0	3.0	4.0

Acute and chronic laboratory toxicity tests that measure effects of pollutants on animals and plants have provided the primary basis for ecological risk decisions made by EPA. Single species-single pollutant tests will continue to be important in making decisions about restricting chemical use, in setting ambient environmental criteria and in establishing permit limitations. This continued use is based largely on advantages of short time requirements, low resource intensity and a large scientific knowledge base that has accumulated during the last 20 years.

To ensure reliable extrapolation of single species laboratory data to ecosystem effects for chemicals and chemical mixtures, the feedback components between effects endpoints in the laboratory and those in mesocosm or field studies need to be coherent. The core program will be expanded to prepare the scientific basis for species extrapolation models, and to test, in the laboratory, hypotheses that biomarkers at cellular levels can be used for extrapolating among species and to higher levels of organization. In year three, the program will be expanded to develop species extrapolation models and to begin controlled experiments to determine the utility of biomarkers under field conditions. Results obtained here are critical to understanding effects and to extrapolating across species, route to route, and low dose to high dose. Current activities are oriented toward supporting water quality criteria, and providing the basic data for structure/activity research correlations.

Comparative Toxicology

Current	Year/$ M 1	2	3	4	5
1.0	1.0	1.0	1.0	1.0	3.0

How precisely can we predict the response of one species, population or community to a given stress based on toxicological data from another species, population, community, or stress?

To achieve a more ecologically based approach to risk assessment, comparative toxicology must define species at risk and stressors of concern under representative marine, freshwater, and terrestrial ecosystems. Existing comparative toxicological data on individual species only allow rough estimates of acceptable levels of environmental stress. We use these data to predict environmental impacts through construction of models and empirical dose-response relationships. Currently, our approaches to hazard assessment range from simple and informal attempts to more elegant arrays of relationships and mathematical expressions construed to represent an ecosystem. These complex approaches to cause and effect assessments are neither reliable nor sophisticated enough to provide comprehensive, quantitative inputs for ecological risk assessment. Few approaches have been validated (field verified) or had their uncertainties quantified.

In the first three years, data and related information will be collected and critically reviewed. Existing databases will be statistically analyzed to define species at risk, stressors of concern, and mechanisms and relationships that need to be studied.

Research will be conducted to develop a database on dose and significance of residues in biota for short- and long-term effects, improve techniques for determining exposure/dose, determine environmental factors affecting exposure/dose-response relationships, identify species required for ecological representation to determine species at risk, evaluate current and new effects endpoints, and define ecologically significant endpoints (structure and function) for community level risk assessments.

Beginning in year four, we will develop empirical models for species/life state at risk and stressors of concern, cause-effect relationships (species to community level), schemata for diagnosing cause-effects, and endpoints necessary for evaluating status.

Finally, toxicokinetic models will be developed to compare exposure, dose, and effect from one organism or situation to another, and mechanistic toxicological models will be developed to extrapolate among biological organization and classes of stressors.

The current efforts in comparative toxicology focus on predicting effects in other species and at different organizational levels. These studies are fundamental to define the relationships among various endpoints at population or community levels.

Population Effects and Models

	Year/$ M				
Current	1	2	3	4	5
2.0	2.0	4.0	4.0	4.0	6.0

Even when single-species methods suggest that impacts of environmental stressors should be minimal, natural populations can be devastated by indirect impacts unobservable in a laboratory setting. Indeed, many of the ecological impacts of Agency concern result from events at the population level of organization and have not been directly observed in physical laboratory models. Examples include the long-term bioaccumulation of pollutants (e.g., DDT and PCB) via food chains, increased maternal susceptibility and maternal/fetal transmission or seasonal physiological stress, and transmission of toxic contaminants in the human food chain.

The initial increase in resources will be devoted to the assessment of existing population models for aquatic and terrestrial species and the expansion of these models based upon results provided by the ecological effects research program.

The increased resources in years two and beyond will be devoted to the development of new field data for both aquatic and terrestrial species/populations so as to quantify natural variation, identify the key demographic parameters and their response to pollutant stress, and to evaluate and improve the models discovered/ postulated in the initial phases of this core expansion.

Current activities are limited to developing and testing empirical models that: a) predict the effects of stress on physiological fitness as it relates to demographic parameters, b) estimate the variability of populations in space and time, and c) relate genotypic variability to demographic response to stress. Current activities address mainly acid deposition effects.

Community Effects

	Year/$ M				
Current	1	2	3	4	5
7.0	7.0	9.0	9.0	9.0	12.0

How do major terrestrial, freshwater, and marine communities respond to stressors of regional/national importance? How precisely can we predict the responses of select communities using exposure-response data from a single species or another community exposed to a similar or different stress?

The status or response of a community cannot be predicted by a simple addition of the status or response of its individual components. The Agency now regulates environmental pollutants largely on the basis of a single species/single pollutant risk assessment paradigm which ignores complex physical, chemical, and biological interactions that may magnify, mitigate, or have no effect on an adverse response. Community response studies are essential if our eventual environmental goal is to protect complex ecosystems through credible ecological risk assessments.

In the first three years, the program will critically examine existing data to define: a) most reasonable structural and functional community endpoints, b) important communities most likely to be affected (exposed and sensitive) by major classes of stressors. Controlled community (microcosm and mesocosm) studies will be conducted to: a) confirm the value of endpoints for major communities and stressors, b) define interactions among community responses, variable stressor scenarios (single and multiple stressors), and environmental parameters, c) provide a basis for relating community structure and function to experimental toxicity data.

Beginning in the fourth year and continuing, community level stress-response models will be developed to predict community structure/process responses given stress statistics, community description, and environmental variables, and identify causal links between effects at or below the whole-organism level and those at or above the population level.

Community level assessment integrates a multitude of lower level concerns and impacts. It offers a different perspective to the interactions of the resources and addresses endpoints which sometimes are meaningless at other levels. The key is to develop the tools to perform risk assessments at this level and above and to assess the impact after the insult. Current activities are limited mainly to acid deposition.

IMPLEMENTATION STRATEGY

The long-term core strategy is designed to provide the data, knowledge, and methodologies necessary if the Agency is to progress from toxicology to ecology as the basis for making decisions to protect the environment. At least three major developments in the area of environmental protection dictate the move to decision-making based on ecological risk assessment. The first is the realization that the aggregate effect of apparently rational decisions about single chemicals, releases, or stresses may place a total multi-pollutant stress on ecological systems that is damaging. The Germans use the term *neuartige schaden* to describe this new form of multi-pollutant stress and its effects on forests. The second development that is driving the Agency toward a systems view is the realization that indirect and cumulative effects from pollutants are a serious threat to ecological resources and can only be anticipated by having the requisite understanding of pollutant/systems interactions. Finally, some of the most important stresses that have to be dealt with now are so pervasive that their full impact can only be understood at the systems level, e.g., regional acidification, eutrophication of coastal waters, elimination of wetlands, and global climate change.

Progress in ecological risk assessment for pollution stresses will require a substantial research effort over the next ten years, in a broad range of monitoring, research and modeling activities for the different ecological systems. This strategy proposes to begin building the research program over a five-year period.

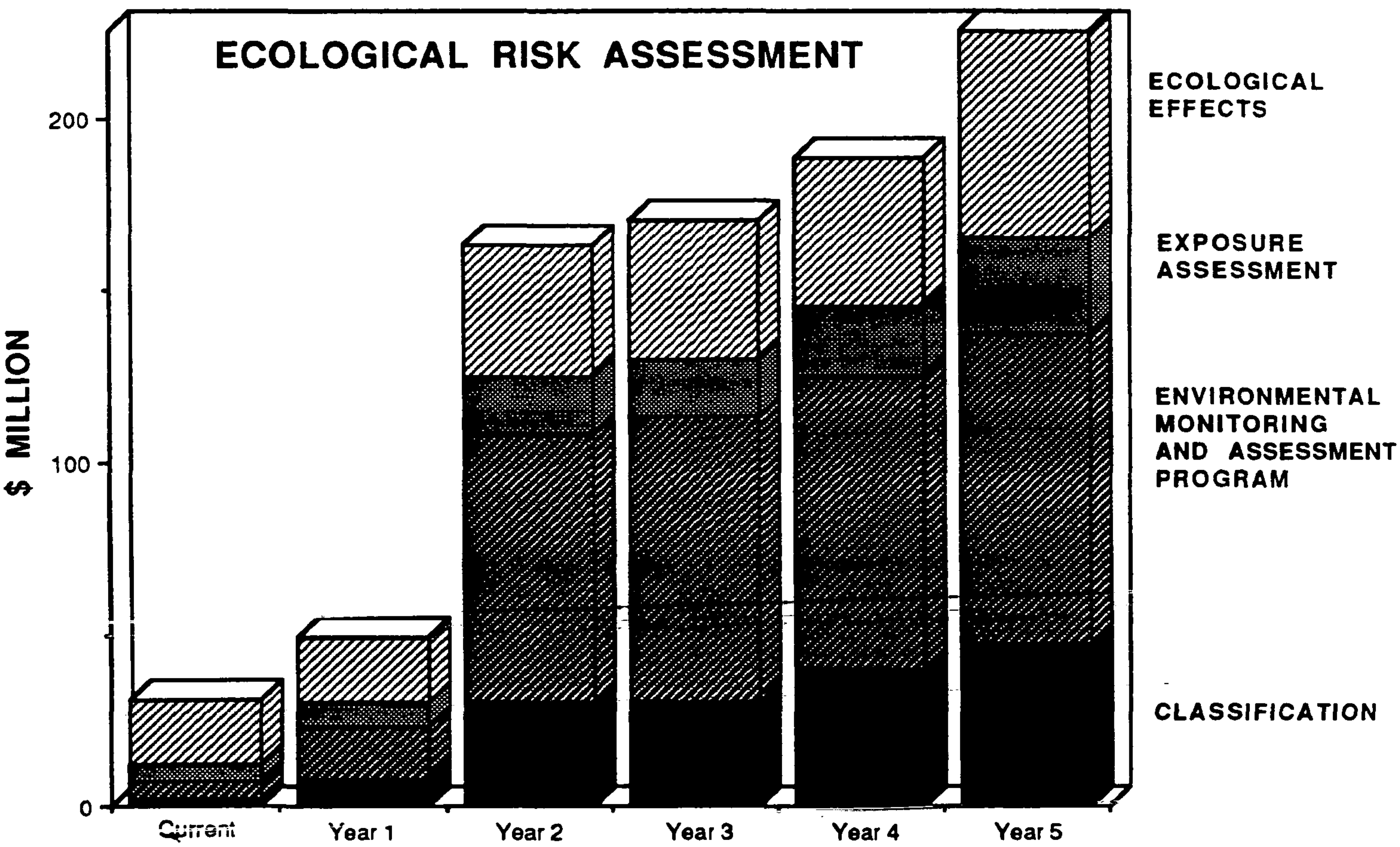
The strategy presents a deliberate view of how the research program should be phased in order to be most effective. The strategy assumes that the initial phase of the program will consist of an intensive effort to define the types of ecological systems at risk and to develop measures that can serve as indicators of the condition of those systems with respect to exposures to stresses and state of health. The program will complete a comprehensive review of available information on classifications, inventories and current status of ecological resource systems and their exposure to pollutants. Studies and workshops will be commissioned to identify, evaluate, and develop measures that might serve as indicators of condition or stress to these systems in monitoring and research studies. Designs will be developed utilizing existing data systems for initiating the status and trends monitoring program.

The monitoring systems will provide baseline information that will permit the Agency to evaluate the effectiveness of its prior actions. Working cooperatively with the National Oceanic and Atmospheric Administration, the first full-scale monitoring effort will be implemented for near coastal and marine systems. To achieve our goal of a holistic view of the nation's ecological resources, we will work cooperatively within the Federal establishment to phase in monitoring programs for the other ecological resource systems as scientific feasibility and economic considerations dictate.

The early characterization and classification efforts will also provide the basis for later expansion of the exposure and ecological effects portions of the core program. The emphasis of the research will be on the prediction of effects on systems. The program will strive for integration of studies at biochemical, physiological, organismic and systems levels to provide the knowledge of system/pollutant interactions necessary to predict ecological exposures and risks.

The program will establish intensive experimental and control field sites for each of the ecological resource systems at risk. These sites will include comprehensive baseline monitoring as well as extensive controlled experiments to test cause and effect relations and to evaluate exposure and effects models. The first priority in the exposure and effects area will be on near coastal and estuarine systems. Implementation of the wetlands and surface water system programs will follow.

The following chart depicts the estimated budget in Ecological Assessment for current and ensuing years.



HUMAN HEALTH RISK ASSESSMENT

INTRODUCTION

The Environmental Protection Agency (EPA) increasingly relies on quantitative assessment of health risks to make decisions about protection of public health. The utility of the risk-based approach for decision making is dependent upon the availability of an adequate data base that is appropriate for the questions being asked. Insufficient and inappropriate data can lead to large uncertainties that, in turn, allow wide latitude for interpretation. Where the underlying scientific uncertainties are great, the data may support diametrically opposed interpretations, each with dramatically different ramifications for related regulatory decisions. The goal of the core research program in human health risk assessment is to provide sound data, improved methods and validated models that will lead to better decisions.

The elements of the risk assessment process, as well as the interrelationships between research, risk assessment, and risk management are shown in Figure 1. Research provides the scientific data bases that underlie the three steps in risk assessment; namely, hazard identification, dose-response assessment, and exposure assessment. Once a hazard has been identified, risk characterization can be thought of as the combined results of exposure assessment and dose-response assessment with the weight of the evidence. Depending on the pollutant and the situation in question, lack of understanding about exposure or dose-response can result in uncertainties associated with the final risk number that span several orders of magnitude.

The major scientific issues that produce uncertainties in the risk assessment process are: (1) lack of appropriate and adequate data; (2) limitations on our ability to extrapolate from artificial experimental conditions to actual real-world situations; and (3) lack of understanding of the basic biological mechanisms that explain the relationship between exposure, dose at the target site, and effects. As we have come to realize, the major contributors to uncertain health risk assessments are deficiencies in our knowledge about the underlying physical (e.g., atmospheric and aquatic dispersion characteristics, human activity patterns), chemical (e.g., chemical reactions and transformations), and biological (e.g., metabolism, disease and repair processes) mechanisms that affect the validity of extrapolation assumptions.

The purpose of this document is to provide a brief overview of the core research program in human health risk assessment and to present the rationale for growth over the next several years in key research areas.

RESEARCH ISSUES

Traditionally, the Agency's risk assessment efforts have focused on the carcinogenicity of long-term, low-level exposures to single environmental agents. It is now recognized, however, that there is a real need to expand our focus to include noncancer health effects, and the complex exposure conditions that exist for both single and multiple chemicals. This will necessitate a coherent and coordinated research program that improves substantially our understanding of the relationships among exposure,

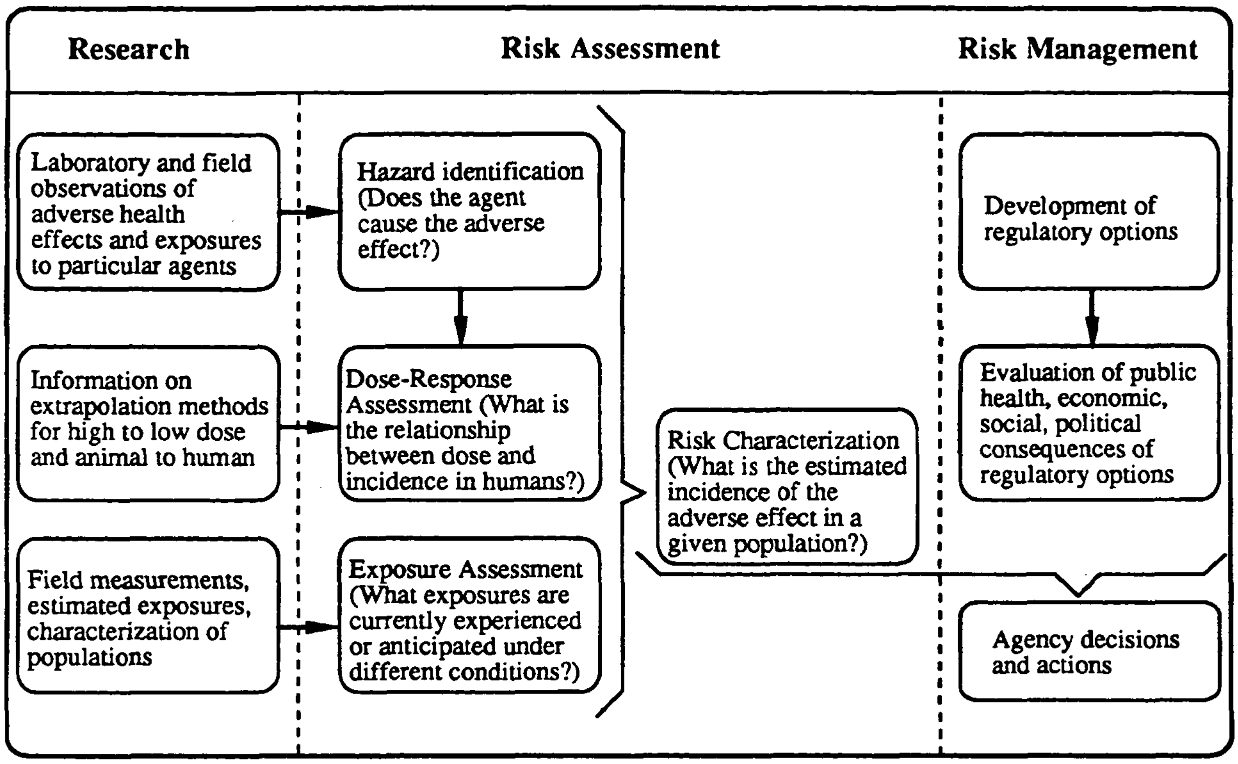


Figure 1.Elements of Risk Assessment and Risk Management (From: National Academy of Sciences [NAS], 1983.)

dose, and associated health consequences. The EPA research program must emphasize the direct application of basic scientific knowledge to the short-term and long-term problems facing the Agency.

Development of a stronger scientific basis for health risk assessment is a prerequisite for improved decision-making about protection of public health. Among the critical issues that must be addressed in order to reduce the uncertainties in risk assessment are the following:

- Identification of Potential Environmental Health Hazards
  - We must have the capability to determine, in a timely manner, whether there is a causal relationship between an environmental factor and an adverse health outcome.
  - Examples of recent technologies, activities, and issues for which hazard identification is needed include biotechnology, ultraviolet radiation resulting from stratospheric ozone depletion, commercialization of superconductors, alternative fuels for motor vehicles, and mineral fibers used to replace asbestos.
- Improved Extrapolation Methods
  - Health risk assessment often relies on extrapolation from animals to humans and from high to low exposures.
  - Because of our lack of understanding about basic underlying biological mechanisms there are large uncertainties associated with this extrapolation process.
  - We must undertake research that will enhance our understanding of physiologic and

biochemical mechanisms, including disease and repair processes.

- Our aim should be to develop methods that take account of the relationship between exposure and dose (i.e., physiologically based pharmacokinetic models) and between dose and effect (i.e., biologically based dose-response models) that reduce uncertainties in health risk assessment.

- Evaluation of Human Populations

- It is essential to obtain exposure, dose, and effects data in human populations in order to assess the status of the public health, to identify potential problems, and to evaluate the efficacy of risk reduction measures.

- Human data are required to evaluate and validate the extent to which effects in animals are analogous or homologous to those observed in people.

- The acquisition and utilization of human data to estimate exposures and to document effects is an important component of improving health risk assessments.

- It also is important to identify, study, and safeguard population subgroups which may be at elevated risk because of either increased susceptibility or high exposures.

- The ability to use biological markers of exposure, effects, and susceptibility in human populations is rapidly becoming a reality.

- EPA must be prepared to take advantage of these advances in the state-of-the-science to improve decisions about protection of public health.

- Integrated Exposure Assessment

- People are exposed to a wide spectrum of chemicals during their routine daily activities.

- Environmental contaminants may enter the body through inhalation, ingestion, and/or dermal absorption.

- Exposures may be episodic (e.g., chemical spill), intermittent, short-term (e.g., rush hour traffic), chronic, long-term (e.g., contaminated drinking water), or some combination thereof.

- Better information about actual human exposures, including magnitude, duration, frequency, and route, will improve health risk assessments substantially.

- Health Risk Assessment for Non-cancer Endpoints

- It is now clear that there are often a variety of health outcomes that may arise from an environmental insult.

- In addition to carcinogenicity, effects may include any or all of the following--pulmonary, cardiovascular, reproductive, developmental, neurologic, immunologic, and hepatic.

- Noncancer health risk assessment depends on our ability to determine which health outcomes are important, for which environmental contaminants, and in what kinds of situations.

- It is important to move beyond the current "safe dose" approaches to noncancer effects (e.g., reference doses, maximum concentration limits) and to develop an appropriate methodology for quantitative risk assessment.

- This will be a challenging endeavor in which criteria for defining the adversity and severity of effects must be established and the possibility that different effects can be induced in multiple organ systems must be taken into account.

- Hazard and Risk Assessment of Complex Mixtures

- Human exposures to environmental contaminants typically occur not to single agents, but rather to a complex mixture or "soup" of agents.

- Examples include emissions from hazardous and municipal waste incinerators, urban air pollution that is produced by a combination of primary emissions from mobile and stationary sources and secondary products formed in atmospheric reactions, drinking water contaminants that include wastewater effluents and disinfection by-products, pesticide residues and degradation products on foods and in ground water, and indoor air pollution in residential and commercial buildings.

- The Agency must develop a methodology for hazard identification and risk assessment of complex mixtures that will be protective of public health.

- In the meantime, developing testing strategies to establish which components of a mixture are most hazardous and to compare the health risks of various mixtures is an appropriate focus for the research program.

- In the long-term, however, it must be determined whether it is reasonable to assume that the health risks of a particular pollutant mixture are equivalent to the sum of the individual risks associated with specific mixture components (i.e., the assumption of additivity of risks).

All of the research issues mentioned above are long-term questions that cut across environmental media and regulatory offices. They are the basic scientific questions that EPA must address if we are to make substantial progress in assessing the human health risks of environmental exposures.

RESEARCH APPROACHES

In order to carry out a research program that will markedly improve health risk assessment, it is necessary to utilize the full range of research approaches. Thus, the strategy for addressing the important questions in a systematic manner will include a combination of four major approaches.

- Animal Studies - the application of *in vitro* and *in vivo* research techniques to laboratory animals in order to better understand exposure-dose-effect relationships

- Human Studies - clinical studies, epidemiologic investigations, and *in vitro* techniques applied to human tissue, aimed at understanding exposure-dose-effect relationships in humans

- Structure-Activity Relationships - research to examine the relationship between molecular structure and biological activity

- Mathematical Models - the use of appropriate mathematical and statistical techniques to develop and validate predictive models

Key Questions to be Addressed

- What are the important environmental pathways by which contaminants are transported through the air, water, and soil?

- What chemical, physical, or biological transformations do contaminants undergo as they move through the environment?

- What is the magnitude, duration, frequency, and route of exposure for human populations under real-world conditions?

- What are the characteristics of people, places, and pollution that may be incorporated into mathematical exposure models and how can such models be validated to assure that they estimate exposure with acceptable accuracy?

- How much of a contaminant to which an individual is exposed actually enters the body, how is it transported, metabolized, stored or eliminated and what is the dose to the target tissue?

- What is the nature of the relationship between exposure, dose, and health effects for important environmental contaminants?

- What are the mechanisms of disease and repair that influence the health outcome of environmental exposures?

- Which biological processes and interactions do we have to represent numerically in order to develop mathematical dose-response models of acceptable accuracy?

Resource limitations obviously prevent a comprehensive treatment of all these issues. The goal is to identify the highest priority areas within and between issues so that resources can be focused on the most critical questions.

CORE RESEARCH PROGRAM

The outline of the core research program is given in Table 1. The relationship between components of the outline and the sequence of events leading from pollutant emissions to human health effects is shown schematically in Figure 2. Definitions of important terms are as follows:

Table 1. Human Health Risk Assessment Core Research Program

Hazard Identification
Screening and Characterization
Structure-Activity Relationship
Dose-Response Assessment
Dose Measurement/Extrapolation Methods (Effects)
Biologically Based Dose-Reponse Models
Human Exposure Assessment
Source Characterization
Predictive Methods
Direct Measurement
Dose Estimation/Extrapolation Methods (Exposure)

Hazard Identification: Research to determine if the agent causes an adverse effect.

- Screening and Characterization: the development, refinement and validation of methods for determining toxic effects on key target systems.

- Structure-Activity Relationships: investigations of the quantitative relationships between molecular structure and biological activity.

Dose-Response Assessment: Research to determine the relationship between dose and incidence in humans.

- Dose Measurement/Extrapolation Methods (Effects): development of data bases and models to estimate the dose that actually reaches the target tissue and determine the relationship between that dose and associated health effects.

- Biologically Based Dose-Response Models: development of models that incorporate biological formation and mechanistic hypotheses into quantitative dose-response extrapolation.

Human Exposure Assessment: Research to determine the exposures experienced or anticipated in the real world by individuals or populations.

- Source characterization: determination of pollutant concentrations in vehicles that impact individuals or populations.

- Environmental Fate: collection of data and development of models that characterize pollutant emissions, their movement through the environment, and their disposition and concentration in air, water, soil or other media.

- Predictive Methods: integration of data on environmental or microenvironmental pollutant concentrations and information about human activities and characteristics to estimate exposures.

- Direct Measurement Methods: direct measurements of pollutant concentrations that individuals are exposed to using portable, personal monitors.

- Dose Estimation/Extrapolation Methods (Exposure): this approach uses measurements of delivered dose within the organism to estimate exposure including the reconstruction of historic exposures.

The following text provides a brief justification for expansion of effort within key topical areas. The presentation is organized according to the outline in Table 1.

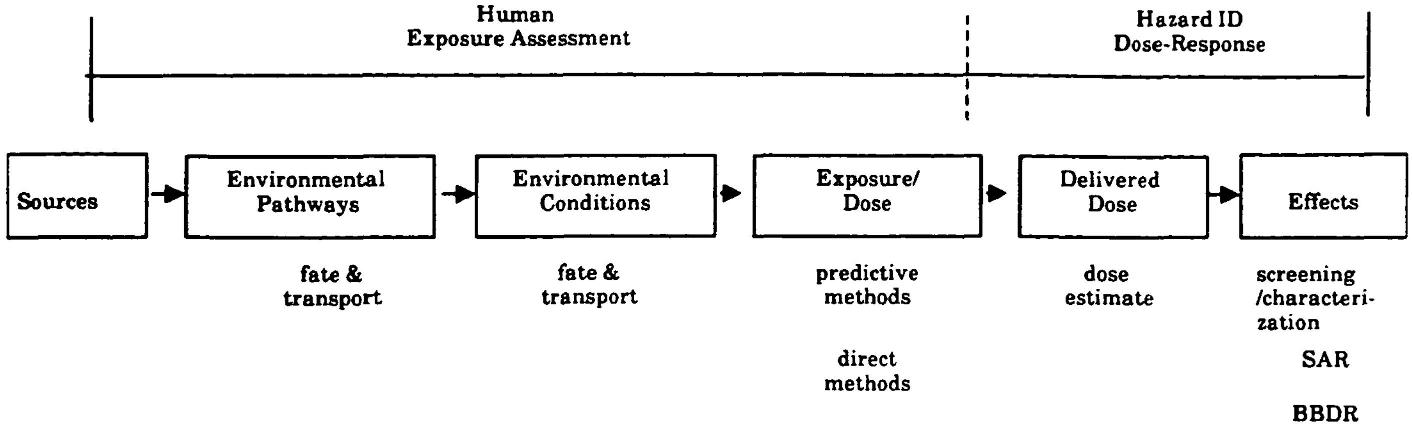


Figure 2. Human Health Risk Assessment Core Research Program

Hazard Identification

	Year/($M)				
Current	1	2	3	4	5
5.4	5.4	5.4	5.8	6.0	6.2

This area of the core research program will develop the test methodologies and analytical models used in the hazard identification step of the risk assessment process. Hazard identification has been defined as "the process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (cancer, birth defect etc.)" (NAS, 1983). All EPA programs require improved and expanded hazard identification methods for the following reasons: (1) to identify potential health hazards requiring further investigation (screening-problem identification), (2) verification (validation) that the suspect effect is indeed caused by the exposure (characterization) and (3) identification of testing strategies and methods for use in the development of testing and risk assessment guidelines.

Screening and Characterization

	Year/($M)				
Current	1	2	3	4	5
4.4	4.4	4.4	4.6	4.8	5.0

Test methods research develops and validates methods for identifying and characterizing the effects of environmental pollutants on biological systems. This research effort is a dynamic one that builds on new and unanticipated advances in biomedical science to develop more diagnostic and/or efficient methods for identifying and characterizing the full range of toxic effects associated with chemical exposure. The modest, but stable increase in this area will ensure the continued development and validation of state-of-the-science test methods. The increase will support expansion of test methods research in target organ toxicity and support work to refine test methods in neurotoxicology, reproductive toxicology, hepatotoxicity, immunotoxicology, and pulmonary toxicology to improve their predictive capabilities for identifying potential health hazards from exposure to environmental agents.

Structure-Activity Relationship

	Year/($M)				
Current	1	2	3	4	5
1.0	1.0	1.0	1.2	1.2	1.2

A major goal of structure-activity relationship research is the development of rational models for molecular toxicity. These models facilitate the prediction of the potential biological effects of individual chemicals from their relationship to other members of the same chemical class. The limited increase in this area will enhance our current program and allow for consideration of a broader spectrum of environmental contaminants and biological endpoints. These data are important to the regulatory and scientific issues associated with health risk assessment. In other activities the methods that form the basis for these models are being developed. This additional research will provide a basis for understanding the underlying mechanisms of action for the toxicity of the classes of chemicals selected and provide a test of the utility of these methods. Models of this type will provide an additional rational basis for selecting agents which require more in-depth analysis of their potential hazard.

Dose-Response Assessment

	Year/($M)				
Current	**1**	**2**	**3**	**4**	**5**
24.2	**24.3**	**24.8**	**25.8**	**28.0**	**30.3**

Dose-response assessment is the quantitative characterization of the relationship between a given exposure to an agent and the ultimate health outcome. Two major uncertainties affect the Agency's ability to accurately conduct dose-response assessments: (1) limited understanding of the relationship between ambient exposure and the dose at the site of action; and (2) limited understanding of the biological mechanisms responsible for the observed effects. These issues will be addressed through a coordinated research program to improve methods for dose estimation and the development of biologically based, dose-response models (BBDR). Activities to improve the estimation of dose will concentrate on the development and validation of biomarkers of exposure/effect and pharmacokinetics research. The latter focus will link with both the Human Exposure Assessment core activities as well as with BBDR modeling efforts.

Dose Measurement/Extrapolation Methods (Effects)

	Year/($M)				
Current	1	2	3	4	5
6.4	6.5	7.0	7.5	8.0	9.3

With greater emphasis being placed on quantitative aspects of risk assessments, the ability to estimate the toxic dose becomes critically important. Development of data bases and models to estimate dose is an integral component of the core research program, for the results of these activities will directly impact on the development of biologically based, dose-response models (BBDR), as well as serve to validate assumptions used in the development of exposure models. Dose estimation efforts in the health area will generate data and models on direct measures of delivered dose (i.e., parent or metabolite) or dose surrogates (i.e., biomarkers). This information will be linked with the knowledge/hypotheses regarding the physiological processes that influence attainment and maintenance of dose at the target and the ultimate expression of effect.

(a) Pharmacokinetics

A major emphasis in this area will be identifying and accounting for intra- and inter-species differences in pharmacokinetic/pharmacodynamic processes. Initial work will be a continuation of efforts to develop simplified, prototypic PK models (i.e., accounting for limited species and exposure variables) primarily in the areas of pulmonary, developmental toxicology, and cancer. Subsequent growth would extend these efforts to other target systems (e.g., neurotoxicology). Another evolutionary component of this program would relate to the development of PK-effects models for complex exposures (i.e., more than a single agent and/or exposure variable). Early efforts will develop consensus strategies for defining complex exposure interactions including putative, mechanistic interactions. Subsequent work will test, validate, and recalibrate these initial complex exposure models. The magnitude of effort in the PK area requires relatively significant expansion of the skill mix and resources available over the next several years. Thus, the majority of relative growth is anticipated in this core area.

(b) Biomarkers

Scientific advances in the next several years are likely to provide new biomarkers that are more sensitive and specific methods for measuring exposures, determining susceptibility to disease, and characterizing the health related outcomes. When applied in parallel studies of humans and experimental systems, they will also provide new approaches to understanding the similarities and differences between humans and experimental systems widely used in risk assessment on both an empirical and a mechanistic level. In response to these opportunities, we will establish a broad based program in biomarkers, focusing initially on markers for genetic effects. The increased resources in following years would enhance this program by expanding the efforts to include other effects such as immunologic, neurologic, reproductive, and other outcomes.

Biologically Based Dose-Response Models

	Year/($M)				
Current	1	2	3	4	5
17.8	17.8	17.8	18.3	20.0	21.0

The overall goal of this core program is to evolve models for the prediction of human health risks under realistic exposure conditions. A major part of this process entails moving from the current limited approach for quantitative risk assessment (i.e., RfD or reference dose and uncertainty factors) to more thorough and scientifically sound dose-response analyses. This goal is achieved by developing models that incorporate biological information and mechanistic hypotheses into quantitative dose-response extrapolation. Four basic components comprise this research area: (1) elucidation of basic mechanisms and processes; (2) inter- and intra-species comparisons (including the development of homologous models); (3) delineation of predictive end point relationships within and across target systems (processes); and (4) enhancement of the human data base (i.e., an increase in epidemiological capabilities). Initial "core years" will reflect a continuation of current efforts in these areas and require limited resources. It is anticipated that these current base efforts will define and crystallize the most profitable avenues to pursue in developing BBDR models.

In order to describe growth in this core area, one must examine the state of development and research priorities for the various target systems (processes) as related to the four component issues described above. Thus, most of the disciplines (e.g., cancer, neurotoxicology, etc.) will have some activity in each of these four areas. However, the sequence of questions to be addressed may differ markedly. Because of historic attention, areas such as cancer, developmental toxicology, and pulmonary toxicology have more substantial data bases and are beginning to integrate and test mechanistic hypotheses into BBDR modeling. It is anticipated that funding in these areas would remain essentially stable over the next several years. Other areas such as reproductive toxicology and neurotoxicology are accruing data bases that within the next few years will provide clarification on basic issues of species homology and end point interrelationships to provide testable dose-response models. A gradual increase in scientific and biostatistical expertise will be needed to advance these areas. Other areas are in the early stages of formulating a comprehensive strategy for assessing health risks (i.e., immunology and heritable genetic risk). It is anticipated that growth in resources and expertise will be increased relatively more in these less advanced areas.

An integrated human health assessment program must develop a framework for linking progress in its core components (i.e., exposure and effects) from its inception. Such a network will be established early on. Moreover, long-term research planning will reflect a growing emphasis of resources directed at the integration of exposure, pharmacokinetics, and BBDR modeling. Similarly, progress will also entail moving from simplified exposure-effect paradigms to the quantification of risks associated with complex exposures.

The ultimate product of these efforts will be more scientifically defensible risk assessments for both cancer and noncancer endpoints, especially in pulmonary toxicology, neurotoxicology, immunotoxicology and reproduction and developmental toxicology.

Human Exposure Assessment*

	Year/($M)				
Current	1	2	3	4	5
20.0	22.1	27.8	49.8	55.2	60.9

Exposure assessment is the qualitative or quantitative determination/estimation of the magnitude, frequency, duration, and route of exposure. The practice of exposure assessment attempts to quantify the contact (exposure) of chemical agents and humans through air, soil, water and food pathways, and the subsequent absorption into the body (dose) so that this information can be used in dose-response relationships to predict risk. The goal of the exposure assessment program is to provide accurate exposure information for Agency risk managers and decision-makers to use in risk assessment and risk management.

This core research program proposal outlines a program that will result in an integrated approach to exposure assessment, using three different approaches to exposure assessment: predictive, direct measurement, and dose estimation/extrapolation methods. The predictive approach characterizes the chemical environment and human activity patterns, then estimates exposure by linking these data. The direct measurement approach uses personal monitoring devices at the point of contact with humans to monitor the intensity of contact while it occurs. The dose estimation/extrapolation approach uses measurements of delivered dose within the body to estimate exposure.

These three approaches, when integrated for exposure determination, can be enormously effective in helping answer some of the most difficult questions confronting the Agency both today and in the future. Specific long-term objectives of the core program include: (1) developing methodologies for exposure measurement and modeling, (2) characterizing representative microenvironments on a national scale, (3) defining regional and nationwide activity patterns, (4) measuring exposure and body burden directly in field studies, (5) determining the major sources of exposure including food, dermal, and beverages - and their contribution to risk, (6) developing and validating exposure models and exposure-dose relationships, (7) providing a comprehensive national data base on exposure for use of the Agency and the environmental community, (8) monitoring nationwide trends and regional differences in human exposure and activity patterns, and (9) assessing the effectiveness of regulations by observing these trends in total exposure.

The following sections describe the growth envisioned in these four areas. In addition to developing exposure assessment methods and gathering data, the core program proposes a major effort in the area of validation and uncertainty assessment, to help assure that the best data, models, and relationships are used in developing exposure information.

Predictive Exposure Assessment Methods

	Year/($M)				
Current	1	2	3	4	5
17.5	18.5	21.4	34.8	37.8	39.8

Predictive exposure assessments estimate the location and amounts of chemicals or pollutants

*See also Appendix A, Exposure Assessment - A Cross-Cutting Issue.

present (the "chemical" side) and combine them with estimates of the location, numbers, and activities of individuals or populations exposed (the "population" side). This combination can be done through use of scenarios or other devices to arrive at quantitative estimates of exposure. Characterizing the "chemical" side of the exposure involves assessing fate processes and monitored concentrations, including concentrations in so-called "microenvironments" (see below). Characterizing the "population" side of exposure involves activity pattern research. Human exposure models are usually used to combine the chemical and population estimates. These topics are discussed further below, along with validation.

(a) Source Characterization

Source characterization, as it relates to human health, is the determination of pollutant concentrations in vehicles that impact or potentially impact individuals or populations. This information provides the basis on which predictive exposure models and monitoring strategies are developed. Source characterization can also aid the hazard identification process by providing information concerning the extent of potential exposures. Research in source characterization involves chemical analysis in various media and both its current and future emphases are indoor and ambient air, vehicle emissions, drinking water, and food.

(b) Fate Processes/Models

Fate processes research and its practical application, fate model development, have been the mainstays of predictive exposure assessment for many years. Models are used to link releases from sources with the resulting concentrations in environmental media. In many cases, this research is applicable to both human and environmental exposures, and there is a section covering environmental fate for ecological exposures under "Ecological Risk." The fate work covered here is limited to air and ground water where human populations are the specific exposure concern. This work will continue research into important fate processes in these areas and the application of that research in models.

(c) Media Monitoring for Use In Human Exposure Assessment

This area contains analytical methods development and monitoring. Currently, the program is limited to monitoring in support of the hazardous air pollutant program. The development of real-world data for all the media is an area which has been neglected over the last decade and has become a critical gap in predictive exposure assessment. It is proposed that this area be considerably strengthened to allow much more data to be included in predictive exposure assessments.

(d) Human Exposure Assessment Models

Predictive models for humans take several forms; two of the major types are scenario models (which combine the "chemical" and "population" sides of exposure through the use of scenarios) and microenvironmental models (which characterize the contact as a series of exposure events of individuals who pass through places where the chemical concentration is relatively homogeneous [microenvironments]). Currently, both scenario models and microenvironmental models can be described mathematically but suffer from a need for realistic input data. The needed data are to be acquired in part as described below.

Microenvironmental Studies. This proposed research will develop data for use in the "chemical" part of microenvironmental models. Currently, there is very little work in this area and it needs to be substantially expanded if the Agency is to have a predictive tool which can readily identify the relative media importance of chemicals.

Population Activity Patterns. Research into activity patterns is the most critical gap in both microenvironmental and scenario models. Currently there is very little research in this area; it is generally recognized by exposure assessors to be the data gap which most seriously affects the assessors' ability to predict "real-world" exposures. It is proposed that studies of human activities related to exposure to chemicals be designed and carried out to begin filling this data gap.

(e) Model Validation/Uncertainty Analysis.

Model validation and uncertainty analysis are perhaps the two most widely heard requests of risk managers when addressing exposure assessments. This is a critical gap which must be dealt with effectively and quickly if the exposure assessment program is to reach its goal of providing realistic exposure information to risk managers. Currently, there are a few projects to validate various fate models, but no centralized validation program. It is a high priority of the exposure assessment program to quickly establish such a centralized focus on getting validation data on the models we use. Validation is viewed as a process rather than a single step, and models used will be in various stages of this process for any specific use. The model validation program can define terms and set up the program in the short term, work through the backlog of most-used models (both reviewing previous validation efforts and doing further field work if necessary) in the mid-term, and eventually provide a working system, complete with model-specific information, to inform assessors about how much validation work has gone on for any given model. The three independent methods of determining exposure (predictive, direct measurement, and dose estimation/reconstructive methods) provide the Agency with a unique opportunity to compare results as part of an overall integrated validation program.

Direct Measurement of Exposure

	Year/($M)				
Current	1	2	3	4	5
1.7	2.2	4.0	12.0	14.0	16.0

Direct measurement of exposure involves taking measurements of the intensity of contact between a person and a chemical while the exposure is taking place. In addition to providing a major link to the real world by producing actual data, it provides the best way of answering questions such as "which medium or exposure pathway contributes the most to exposure?" Coupled with source characterization "fingerprints," this multimedia research could lead to a major improvement in our ability to determine what sources are causing exposures in the real world. Direct measurement research includes both development of the instrumentation necessary to measure exposure directly and also development of a data base on direct measurement which can be used to answer questions about media priorities for corrective action.

(a) Instrumentation

Currently, instrumentation exists to measure several dozen chemicals by direct measurement techniques, but there is specific research on only one other monitoring device. The number of chemicals that are important to EPA decisions requires that instrumentation be developed for many other chemicals.

(b) Data Collection/Analysis/Management

Currently, there are data for a few dozen chemicals taken for populations in a handful of cities. In order to realize the potential for using these data to make more informed decisions, a much larger data base must be developed. In addition to helping answer questions about exposure directly from the data base, the data base would be used to develop a predictive tool which can answer questions about exposure of various segments of the population.

Dose Estimation/Extrapolation Methods (Exposure)

	Year/($M)				
Current	1	2	3	4	5
0.8	1.4	2.4	3.0	3.4	5.1

Recently, it has become increasingly desirable to base quantitative risk assessment on the "delivered" dose rather than on estimates of applied dose or ambient concentrations. Delivered dose may be a measure of the parent compound, metabolite, or a biological marker that may serve as a surrogate for the parent or metabolite. The data on body burden or biomarker values can be used directly for exposure assessment and can provide several important tools to the risk manager including (1) proof that exposure to the chemical has resulted in absorption,

(2) the ability to reconstruct exposure levels even if there is no longer an opportunity to measure these levels externally, and (3) by employing pharmacokinetic models, the capability to extrapolate dose-risk across varying exposure conditions (e.g., different routes, durations, dose rates, etc.). Research efforts in the areas of pharmacokinetics and biomarkers become the critical components of this core area, which could result in new tools to allow the Agency a much more effective way to deal with situations where a local population may have been exposed to toxic chemicals.

(a) Pharmacokinetics

Establishing pharmacokinetic models and developing the data needed to use these models are the keys to deriving estimates of delivered dose under varying exposure conditions as well as developing reconstructive exposure assessments. Currently, there is very little research being done; a few PK models have been developed, but data necessary for inputs (e.g., partition factors, local blood flow data, etc.) and route extrapolations are limited. This research would continue model development, begin developing the necessary data to run the models, and integrate these tools into the exposure assessment process.

(b) Biomarkers

Although biomarkers have the potential of being a direct test for exposure (obviating the need for worst-case scenarios and bringing exposure assessment closer to the real world), there are few biomarkers currently that can be used routinely for this purpose. Although current research levels are small, pronounced growth is anticipated in research to identify potential biomarkers of exposure and to determine the relationships between the biomarker levels and absorbed doses.The goal of this area of research is to find an inexpensive and hopefully non-invasive test which can be used in specific cases to determine if exposure and absorption have occurred, and to what extent, for various chemicals.

IMPLEMENTATION STRATEGY

Human health risk assessments, either explicit or implicit, are an integral part of regulatory decisions in all major program offices within EPA, including: Air and Radiation; Drinking Water and Water Quality; Toxics and Pesticides; Hazardous Wastes; and Superfund. Although there are a number of regulatory-specific and site-specific questions associated with each individual program, certain scientific issues are germane to all programs, such as questions about environmental concentrations, exposure and dose levels, and dose-response relationships. All risk assessors, regardless of program, are faced with the uncertainties surrounding extrapolation from test species under laboratory conditions to humans going about their normal day-to-day activities. The goal of the core research program in health risk assessment is to improve the scientific basis for critical extrapolation assumptions by carrying out key research on hazard identification, dose-response assessment, and human exposure assessment.

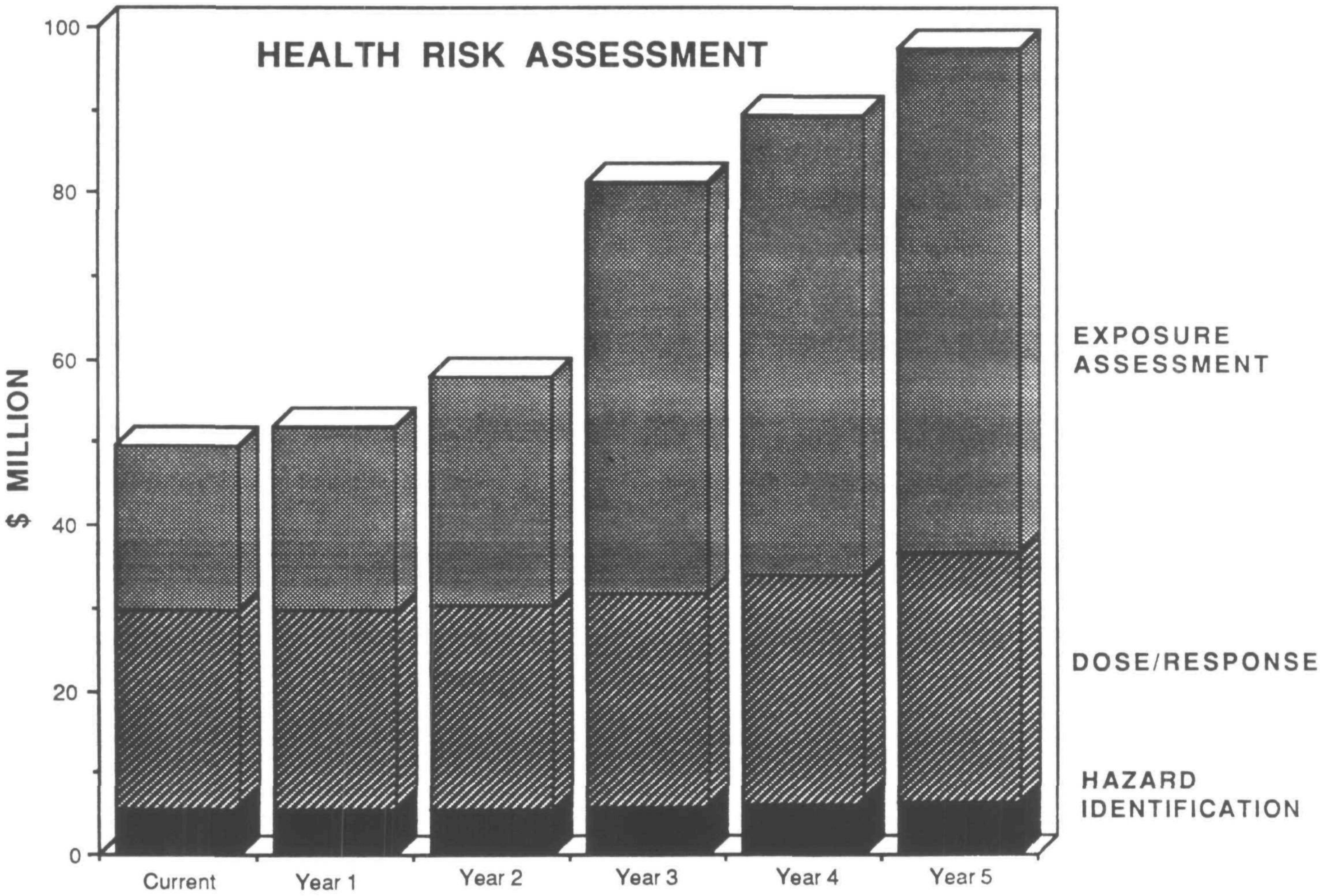
Almost $50 million is devoted to core health research in the current budget, of which $5.4 million is hazard identification, $24.2 million is dose-response assessment, and $20.0 million is human exposure assessment. Although these resources support a substantial amount of relevant research, there are still significant unanswered research needs. The preceding discussion has attempted to provide a justification for growth in specific core research areas to meet the critical needs.

Hazard Identification. We anticipate a relatively small increase in this area over the next five years. Some resources in the base program will become available for redirection as we complete validation and refinement of certain tests. The added resources will be used to support expansion of research on test methods for target organ toxicity and to refine existing methods in neurotoxicology, reproductive toxicology, immunotoxicology, pulmonary toxicology and heritable genetic risk.

Dose-Response Assessment. We are planning a relatively modest increase for this issue since a substantial portion of our program is already devoted to this area. Efforts in dose measurement/extrapolation will increase most rapidly because these data will be used extensively in subsequent development of suitable dose-response models. Growth in biologically based dose-response models will occur at a gradual but sustained rate and will emphasize incorporation of relevant pharmacokinetic information.

Human Exposure Assessment. Research efforts in this area will increase dramatically under our plan. Because we have been slow to recognize the importance of human exposure assessment, our current activities are considered to be inadequate. Therefore, we anticipate a very large increase in resources that will be devoted primarily to data collection and model validation for predictive methods, for direct measurement methods, and for dose estimation/extrapolation.

The following chart depicts the estimated budget for Human Health Assessment for the current year and five ensuing years in the future.



RISK REDUCTION

INTRODUCTION

As indicated in earlier discussions, the Environmental Protection Agency has adopted a risk management-based approach for cleaning up past environmental problems, managing current sources of pollution, and minimizing the generation of pollutants in the future. This approach utilizes ecological risk assessment, human health risk assessment and risk reduction. The two risk assessment components determine the magnitude of the risk. If the risk is unacceptable, risk reduction offers options for reducing risk to acceptable limits.

There are three ways to approach risk reduction:

1. *Pollution Prevention.* The most effective way to reduce risk is not to produce wastes and contaminants in the first place. This involves minimizing waste at the sources through industrial process modifications or changes in product design. Reclaiming usable materials from byproduct streams and recycling spent materials also eliminates release to the environment.
2. *Treatment.* Treatment technologies are employed to destroy, detoxify or immobilize those wastes and contaminants that cannot be eliminated or recycled.
3. *Minimization of Exposure.* Once the generation of wastes has been reduced and undesirable constituents treated to the optimum extent, the remaining risk must be addressed by avoiding or minimizing exposure (e.g., improved building ventilation, secure land disposal, etc.).

To design regulatory and other Agency programs that are effective, implementable, and which produce the minimum negative impact on society, Agency decision makers must have credible information on the cost effectiveness and efficiency of appropriate risk reduction alternatives. The function of the Office of Research and Development is to: provide that information on an array of risk reduction alternatives; propose improvements to available alternatives or provide new alternatives where current ones are inadequate; anticipate environmental and human health issues and solve them before they reach crisis proportions; transfer technical information to those who make risk reduction decisions; and coordinate and stimulate research and development on risk reduction alternatives with academia, industry, and other governmental agencies.

However, because the current risk reduction research, development, and demonstration program has emphasized short-term, program-related issues, the following shortcomings have been in evidence:

1. EPA has focused both its regulatory and research and development programs on end-of-the-pipe control technologies. As a result, the private sector has also largely focused on these technologies. Yet, to varying degrees, these technologies often shift risk from one medium to another.

2. Inadequate attention has been given to risk reduction through pollution prevention. Several industrial firms have demonstrated that

pollution prevention is more cost effective and environmentally sound than pollution control.

3. Reliable information on the cost-effectiveness and efficiency of specific technological solutions is not being developed in a timely fashion. Often, programs must be developed and decisions made in the absence of sufficient information on the technological risk reduction alternatives. In some cases, technology development lags behind the need for it.

4. There needs to be improvement in methods of transferring technical and other information to potential users in a way that will influence their decision making.

EPA proposes to address these issues in the risk reduction research and development program by focusing an expanded research program in these core areas.

CORE RESEARCH PROGRAM

The proposed core risk reduction research program is designed to generate basic information that will engender answers to such questions as:

1. What are the pollutants of concern? What are their sources and how are they released? How do we measure the release of the pollutants?

2. How can we prevent the generation of pollutants? Can we design processes that do not produce pollutants? Can we recycle or reuse potential pollutants instead of releasing them to the environment?

3. How can we treat, dispose of, or contain pollutants that exist in the environment to minimize harmful exposure?

4. How can we ensure that adequate, cost-effective technology is available and that it is implemented to reduce risk?

Risk reduction core capability in an EPA context involves fundamental scientific and engineering principles in the following areas:

1. Pollution Prevention

2. Pollution Control

3. Emerging and Neglected Issues

4. Information and Communication

The following discussion of the four risk reduction topics summarizes the programatic utility of the work, current core efforts, future types of core research, and anticipated funding requirements. A table introduces each topic with an estimate of resources applied to the core research area currently and for five years in the future.

Pollution Prevention

	Year/$ M				
Current	1	2	3	4	5
2.4	2.4	10.0	20.0	20.0	20.0

In 1976, EPA issued its waste management hierarchy, which stated that pollution prevention (also referred to as waste minimization) is the preferred approach to managing residues. While the concept was first applied to hazardous waste, it applies equally well to other residuals, effluents, and emissions. As compared to end-of-pipe treatment and disposal or dispersal, pollution prevention has several benefits:

1. It is generally less costly than end-of-the-pipe controls; there is less waste to manage and dispose of resulting in smaller, often simpler, and less costly pollution control facilities.

2. Recovery of byproducts or reduced losses of raw materials may result in actual savings.

3. Regulatory requirements may be avoided.

4. Third-party liability problems associated with accidents or releases may be reduced.

5. Residual risk to human health and the environment is almost invariably reduced or eliminated.

6. It avoids shifting waste among media.

7. It applies equally well to smaller and area-wide sources of pollution where control technologies may be costly or difficult to implement.

Based on the success of a few larger manufacturing companies and the obvious advantages of this approach, EPA has been urged in several reports to make pollution prevention a central part of its mission. To this end, the Agency has recently created a new office, the Office of Pollution Prevention as a focal point for a coordinated Agency-wide effort.

The Office of Research and Development has had a small program for several years that has focused exclusively on hazardous waste minimization. Recently the program has been expanded to other residuals, effluents, and emissions.

The following is a description of this multimedia/multi-year research program, which encompasses four areas – technology evaluation, technology transfer, and data management and trends analysis.

Technology Evaluation

Many environmental problems are caused by processes that are inefficiently designed and products that are ineffectively manufactured or improperly discarded. Standardized methods are needed for evaluating pollution-generating characteristics of various industrial processes and the compounds that are used in these processes. Research is needed to evaluate redesigning products or changing the use pattern and life cycle of products to reduce waste.

Industry specific methods for conducting waste minimization assessments (audits) are needed. Promising pollution prevention strategies for various industrial processes need to be identified. These strategies include process modernization, upgraded maintenance, feedstock substitutions, spill and avoidable release prevention, recycling and reuse options and waste stream concentrations.

To date very little attention has been given to the pollution prevention opportunities that can result from modifying products. Changes in product content, form, durability, and repairability can have significant impacts on wastes and pollutants. Products and processes that promise to reduce total pollution loads (e.g., using less polluting feedstocks to produce existing products, capture and recycling of waste stream substances or producing an alternative less harmful product) need to be demonstrated and evaluated objectively.

Pollution prevention can be achieved through three generic technological approaches:

Modification of Industrial Processes to Reduce Wastes. Change of raw material feedstocks, redesign of the process for higher efficiencies and yields, and prevention of leaks and spills are examples of industrial process changes that reduce the generation of pollution. Key objectives of the research program in this area are:

1. To develop standardized methods for conducting assessments of waste reduction opportunities in various industries.

2. To actually conduct model waste reduction assessments in key industries.

3. To identify, demonstrate and evaluate, in both new and existing industrial processes, innovative methods for reducing pollution generation such as process modification, upgraded maintenance, feedstock substitution, spill prevention and waste stream concentration.

4. To carry out pilot scale research to facilitate the establishment of model pollution prevention processing facilities.

5. To identify and stimulate cross-industry applications of innovative production and processing technologies that reduce wastes.

Increased Recycling. Recovery, reuse, and recycling are important options for reducing pollutants and wastes by industries, communities and governments. The objectives of the recycling research program are:

1. To identify, demonstrate and evaluate strategies to increase the use of recycled materials in products.

2. To identify and evaluate new and innovative uses for materials that would otherwise be discarded as wastes.

3. To evaluate the cost and performance of various technologies to recycle, reuse and recover waste.

4. To develop guidelines for model recycling programs.

Changes in the Design and Use Patterns of Products. Elimination of toxic or hazardous substances in products, increased product lifetime or improvements in the durability or repairability of products are ways of reducing product wastes. Objectives for research in this area include:

1. To carry out product lifetime analyses to identify opportunities for reducing the generation of pollutants associated with individual products.

2. To develop criteria for evaluating specific products to predict their pollution loads.

3. To evaluate the performance of products that generate less wastes.

Technology Transfer

Technology transfer and technical assistance are essential components of a research program in pollution prevention. The success of a national plan to encourage the development and adoption of new, more environmentally acceptable production processes and products depends on the quality and effectiveness of the technology transfer and technical assistance programs utilized to effect these changes. To realize pollution prevention goals, consumer and producer behaviors, attitudes, and possibly lifestyles may require changes. As Federal, state, and local agencies and private industries develop and implement pollution prevention programs, data are generated, experience is gained, and technologies are improved. This information is of limited value until it is assembled and distributed in a format designed for the specific needs of the intended users. This is where technology transfer, technical assistance, and other outreach efforts come into play.

These efforts provide information transfer services, training and guidance on pollution prevention techniques and programs, as well as foster their acceptance and growth. There are many mechanisms, products and services that can be utilized. These include developing a pollution prevention information clearinghouse which could include telephone hotlines, electronic information exchange networks, and hardcopy information. Technical assistance and training techniques could include seminars, conferences, computer animated graphics, video tapes, computer-assisted instruction and expert systems.

EPA would work closely with state and local officials to identify and evaluate the efficacy of pollution prevention activities, disseminate pollution prevention information, and develop/implement pollution prevention measurement systems. In addition, EPA will investigate pollution prevention efforts in other countries.

Data Management and Trends Analysis

There is a need for better information on the amounts of wastes and pollutants being generated. There is a lack of information on the amount of waste that results from current industrial production and processing procedures. Thus, it is difficult to determine how well we are doing, how we should set our priorities and what the success has been. Further, the potential for more reductions, and in what industrial sectors reductions are most likely, is not known. Hence, we have no trends analysis and we can not measure our progress.

EPA should establish a data collection system that measures progress in waste reduction. In addition, waste reduction data should be multi-media in scope, because a multi-media view is required to assess the nature and scope of waste reduction possibilities, set priorities, and help determine the Federal actions that will best serve the general public. This requires that the government be able to determine how much waste of all kinds is being released into all environmental media. Existing environmental data bases such as toxic air release surveys and wastewater effluent permits could be evaluated and incorporated into this baseline data process.

The data management research program we propose will address such issues as industry waste generation and reduction data, types of waste reduction completed, waste reduction measurement systems, practical sources for data collection, and methods for compiling and manipulating data. A complementary trend analysis program can track the effectiveness of existing programs as well as identify the priorities for potential waste reduction activities. The combination data management and trends analysis programs would enable industry to account for their waste generation and reduction data, allow the data to be used on a multi-media/multi-industry basis and provide a means for the government to verify results.

Pollution Control

	Year/$ M				
Current	1	2	3	4	5
14.5	14.5	14.5	14.5	21.0	24.3

Historically, nearly all of EPA's pollution control research program has focused on near-term technical needs of the regulatory development program. As a result, there has been a lack of emphasis on understanding the fundamental mechanisms of pollution control.

The core research program in the pollution control area will build the capability to explore fundamental principles that govern pollution control processes. For the most part, these resources will be focused on addressing selected opportunities to improve the state-of-the-art. To assist in defining the problems and opportunities that can be most fruitfully addressed, EPA will convene national experts in each topical area to develop national research priorities to guide core research activities. The following discussions identify areas in which we plan to focus attention.

Thermal Destruction and Combustion

Understanding the scientific principles of combustion is important because incineration (thermal destruction) has become the most common waste treatment technique. Furthermore, combustion of fossil fuels is most often used to generate heat and power. Understanding the fundamental principles of combustion and thermal destruction can result in the development of technologies which do not produce adverse byproducts (air emissions and ashes), thereby providing risk reduction alternatives with significantly lower, more acceptable levels of risk.

Thermal Destruction. Fundamental work in this area will improve our ability to predict and minimize products of incomplete combustion (PICs), understand and control the fate of metals, and understand and predict the fundamental relationships between waste characteristics, physical characteristics, and operation conditions of unit processes, and the resulting residues. This information will help industries improve their capability to design cost-effective incinerators and predict emissions produced with different wastes, fuel composition, and operating parameters. This will lead to improved waste incinerators that have an acceptable risk.

Fuel Combustion. Current research is aimed at understanding the mechanisms of N_2O formation in the flame zone and developing design parameters for low NO_x heavy oil burner nozzles. Expansion of this program will result in a comprehensive understanding of how to increase fuel (coal, oil, gas, wood) combustion efficiency while decreasing the production of gaseous pollutants (SO_2, NO_x, N_2O, HCl) and particulates. Research will also be conducted on new or improved techniques such as catalytic devices to minimize formation or enhance destruction of unwanted byproducts. This knowledge will lead to improved fuel combustion devices which reduce the amount of air emissions and thereby reduce unacceptable adverse environmental (e.g., acid deposition) and human health risks.

In addition to work associated with utility and industrial fuel combustion, effort will be focused on heating by woodstoves and kerosene heaters. The nature and extent of indoor pollutant emissions and their control via design modifications will be investigated.

Physical Separation

Under the broad topical heading of physical separation, there are a multitude of processes used mainly in water and wastewater treatment and in air pollution control. Many of these processes have been used for a long time, e.g., sand filtration, electrostatic precipitation, and fabric filters. Others, such as ultrafiltration are newer. Although improvements in the cost effectiveness of these processes should be possible, opportunities involving emerging environmental issues warrant early attention. These include source separation and central facility classification of municipal solid wastes, and evaluation of basic approaches to indoor air cleaners. Specific research efforts will address separation of metals and organic constituents from drinking water; separation of contaminants from wastewater and sludges; separation of solid wastes to facilitate recycling or treatment; and separation of particulates from gas streams.

Biological Processes

There is both a long successful history and a bright future for the use of biological processes in the environmental field. Sewage and industrial organic wastes have long been treated by biological means (e.g., activated sludge). The use of genetically engineered organisms and new reactor designs promises improved cost effectiveness of these processes. In-situ treatment of contaminated soils and ground water using acclimated natural and genetically engineered microorganisms promises to revolutionize spill and Superfund cleanup activities. Another potential application is in the treatment of trace organics in municipal water supplies. Biological degradation processes offer tremendous potential for improvements in effectiveness and substantial cost savings when treating relatively low concentrations of organic contaminants in wastewater, groundwater, and water supplies. There is still a lot to learn and a focused effort should yield substantial benefits. The initial focus of this work will be on:

- Identifying microorganisms with significant potential for biodegrading wastes and pollutants,
- Evaluating how to deliver and disperse the microorganisms effectively,
- Determining how to maintain their viability in the field,
- Determining how to monitor and track remediation progress.

In addition, the production and use of biological agents in the economy, particularly genetically engineered organisms, poses technical and regulatory control challenges for the Agency. EPA is responsible for registering and approving these agents. There is a need for an R&D program investigating release and dispersal of these organisms. The core research program will look at technical issues involving the production and use of commercial genetically engineered microorganisms.

Chemical Processes

Chemical processes are used in a variety of environmental applications including separation of contaminants from water (e.g., via precipitation), destruction of biological agents (e.g., in drinking water disinfection), and immobilization of contaminants (e.g., metal fixation in soils). While improvements can be made to many of these processes through better understanding of the fundamental principles governing them, the largest untapped potential appears to be in chemical destruction of organic constituents in hazardous waste, and *in-situ* immobilization of metals and destruction of organic contaminants in soil and ground water. Optimization of these processes to achieve their potential will involve improving surface reactor designs and finding ways to enhance distribution of chemicals in the subsurface environment (e.g., by electrokinetics). Initially, the core program will focus resources on these areas. In addition, research will focus on improved understanding of chemical destruction of organic contaminants in soil and debris, chemical destruction of biological agents in drinking water and wastewater, chemical separation of contaminants in drinking water and wastewater, and chemical stabilization and immobilization of contaminants in soils and wastes.

Containment

Containment is a broad topic involving separation of harmful materials using some form of barrier. It includes such diverse activities as containing contaminated materials in tanks, drums, and landfills, minimizing dispersion of airborne material (e.g., minimizing asbestos dispersal by using encapsulants), minimizing migration of contaminants into buildings (e.g., by using sealants to stop radon entry), and use of protective clothing to protect workers from contaminated environments.

One neglected area warranting further attention is separation of waste contaminants in landfills from the environment using liners and caps. The RCRA reauthorization legislation of 1984 mandated use of complex liner and cap systems and these systems have begun to be installed over the past few years.Protection of human health and the environment depends on the long-term effectiveness of these systems, yet there is little information on their longevity. The core research program will initially focus on fundamental study of the key factors that determine the performance of liner and cover systems such as chemical compatibility, microbiological and UV resistance, and subsidence. The program will also address problems such as seam stress cracking and develop ways of monitoring cap performance.

Another important area for early years is research directed at understanding the physical and chemical integrity of solidified and stabilized wastes. We must be able to measure, both short-term and long-term, whether the wastes are truly contained by such processes and therefore unable to be released into the environment.

Other areas of potential research involve furthering our understanding of the physical and chemical mechanisms associated with devices for containing pollutants from soil, for example, geosynthetic membranes, slurry walls, and clay liners; preventing exposure in contaminated areas through improved protective clothing; developing effective technologies for reducing indoor contaminant levels; furthering our understanding and effectiveness in containing and collecting small fibers such as asbestos; improving our knowledge of the mechanisms that lead to failure of underground storage tanks; and enhancing our ability to create more effective devices of this type.

Source Characterization

This area covers the research needed to characterize the pollutants (type, amounts and rate of release) from a variety of sources. This information is necessary to conduct risk assessments and to develop cost effective risk reduction alternatives. Although considerable knowledge exists about "conventional pollutants from common sources," much is unknown about toxic pollutants and microbial agents from many new sources. These sources need to be generically characterized by appropriate groups and classes, and emission factors and models need to be developed.

We recognize two general types of sources: (a) point sources such as industrial furnaces, effluent discharge pipes, and incinerators, and (b) areal or dispersed sources, such as agricultural and urban runoff and natural sources and sinks. The technologies, necessary skills, measurement equipment and even the manner in which one approaches characterization of these two kinds of sources varies somewhat.

The current program contains work on characterization of point source emissions from industrial furnaces, hazardous waste facilities, and municipal solid waste combustors. An expansion of this work will result in the capability to characterize pollutants from high to very low concentrations for organics, inorganics and microbials; to characterize the rate of release of pollutants from treatment/ disposal facilities; to characterize any changes in the composition of pollutants during release; and to predict emission and contaminant levels under different environmental/climatic conditions. This core research will lead to a better understanding of the composition and release rates of pollutants and improve efficiency in developing, evaluating and selecting risk reduction alternatives.

Very little work is underway to characterize emissions from dispersed area-wide sources. Research is necessary to develop an understanding of the chemical, biological and physical mechanisms that govern the release of gaseous and particulate materials from a variety of sources (nonpoint source agricultural runoff, methane gas from marshes, natural vegetation sources of volatile organic compounds, emissions of alkaline dust and ammonia, etc.). This core research will lead to a better understanding of the composition and release of areal pollutant sources. With this new knowledge, the uncertainty in risk assessments for global climate change, stratospheric ozone depletion, acid deposition, wetlands and other sensitive ecosystems, and ozone nonattainment will be reduced.

Emerging and Future Issues

	Year/$ M				
Current	1	2	3	4	5
4.5	4.5	5.6	5.6	16.8	21.0

Effective environmental protection depends on the timely development of reliable risk reduction solutions. Typically, research and development resources are not focused on risk reduction options until after an environmental issue has been defined fully. Delay in the availability of appropriate reduction strategies and technologies can result in risk reduction solutions which are insufficiently protective and/or overly costly. Long-term impacts may not be anticipated and alternative solutions to problems may go unexplored.

We must begin to address risk reduction alternatives much earlier in the evaluation process, once an unacceptable risk is suspected but before it has been fully explicated. If we wish to address emerging environmental issues more constructively than we have in the past, risk assessment and risk reduction research and development cannot be performed in a strictly sequential fashion. Risk reduction research must evolve as issue definition evolves, starting with generic and fundamental studies of the possible solutions.

Moreover, in order to identify future issues long before they become crises of public concern, we must focus efforts on analyzing environmental trends, tracking changes in ambient concentrations of environmental contaminants, and evaluating new production technologies and new products.

Following is a description of the two areas in which we plan to conduct core research:

Emerging Issues

Several emerging issues are receiving inadequate research and development attention. Research and development are necessary so that performance and cost information will be available.

Following is a short compilation of these issues:

A. *Municipal Solid Waste.* Research needs to address the many environmental questions that remain unanswered relative to landfill and incineration options; they include groundwater contamination potential from landfills and hazardous air and solid residues from incinerators. Resource recovery options also need to be carefully analyzed.

B. *Global Climate and Stratospheric Ozone Depletion.* Risk reduction research is needed to identify affordable technological and non-technological options to reduce emissions of CO_2, CFCs and other important contributors to global warming and/or stratospheric ozone depletion.

C. *Nonpoint Source Contaminants.* As urban areas grow and agriculture becomes more dependent on chemicals, nonpoint source contamination of ground and surface waters become more widespread. The Agency plans to work cooperatively with USDA, academia, and the private sector to identify and evaluate promising prevention options and transfer successful technologies to users.

D. *Medical/Infectious Waste.* Careless disposal of medical wastes could lead to unacceptable risks to public health. The Agency needs to establish a core research capability to evaluate the efficacy of various transportation, handling, and disposal options.

E. *Water Supply.* As population grows, especially in arid areas, there is increasing pressure to reuse finite water supplies. Focusing on reuse, the

Agency should expand its modest program to include the identification and evaluation of cost-effective water treatment technologies. Also, we need to evaluate new approaches for reducing water use and for obtaining alternative water supplies (e.g., desalination).

F. *Indoor Air.* Concern grows regarding the quality of the air within our homes and buildings. The current program for evaluating emissions from construction materials needs to be expanded. There is also a need to evaluate other sources including combustion appliances and household chemicals. A pollution prevention and control program must be initiated with the aim of providing mitigation guidance to the public.

G. *Alternative Fuels.* As the nation attempts to deal with its ground-level ozone and CO_2 pollution problems, pressure will mount to use alternative motor vehicle fuels such as methanol. Questions about the pollution that may result from the production of these fuels as well as from their use remain unanswered. Careful research attention must be paid to the implications of this switch to alternative fuels. Emission characterization of both the mobile sources and the production processes is necessary.

H. *Environmental Infrastructure.* The nation faces a major problem with the aging and decay of its infrastructure, including water delivery systems, sewers and wastewater treatment plants. The Agency plans to conduct research aimed at identifying opportunities for incorporating pollution prevention practices as the infrastructure is replaced. For example, water savings may be possible, allowing smaller sewers to be built into existing ones, yielding major savings in infrastructure replacement.

Future Issues

All too often, environmental issues are thrust upon EPA from outside by citizen concern, by Congress, or in some cases, by the academic community. Rarely is EPA the first to identify an issue as problematic. Yet early identification of issues should be central to EPA's mission. The earlier issues can be identifed, defined, and solutions found and implemented, the sooner EPA's mission to protect human health and the environment is realized. EPA can identify issues before they become crises of public concern, but it must focus on doing so. There are several ways of proceeding:

A. *Environmental trends.* Demographic, economic, infrastructure (e.g., transportation), foreign trade, and other trends can be analyzed to determine potential environmental impacts. Enhanced ability to predict the environmental impacts of major trends would allow us time to perfect technologies to either minimize negative impacts or enhance positive impacts. This type of research is and should continue to be conducted primarily by the Office of Policy Planning and Evaluation, in coordination with research activities and the program/regional offices.

B. *Ambient concentrations.* The ambient concentrations of pollutants in the environment can be tracked over time for insight into future trends. This subject is discussed in both the human health and ecological risk assessment chapters and is not generally in the purview of the risk reduction program. The trends identified in the environment would be used in targeting and planning the risk reduction research. Also, this program may allow monitoring of the overall effectiveness of various control options as they are implemented. Over the longer term, it is really the reduction in ambient concentration that is important, not the specific reduction in each point or nonpoint source.

C. *New production technologies and products.* New production technologies and products can radically affect both the characteristics and amounts of emissions and residues. Use and disposal of new products or products with new components can also create (or reduce) environmental problems. These technological trends can be monitored and characterized. The engineering community is best able to do this because of its day-to-day contact and familiarity with the industrial production community. Once production technology or product trends are characterized as significant producers of new contaminants or increased volumes of contaminants, further investigation of the potential risks can be conducted by others. The primary goal of this research is to identify and predict changes in releases of contaminants into the environment due to changes in production processes and products.

Information and Communication

Current	Year/$ M				
	1	2	3	4	5
1.2	1.2	2.5	2.5	3.0	3.0

The selection and implementation of viable, cost effective, risk reduction approaches is influenced by a variety of legal, scientific, economic, political, and social factors. Just having scientific information that an unacceptable risk exists or that a technology exists to reduce that risk to an acceptable level does not ensure that appropriate risk reduction actions will be taken.

Waste generation and waste management decisions are driven by non-technological forces including behaviors, incentives, and benefits. Behaviors are complex patterns of human activity that result from habits, beliefs, knowledge, and economic pressures. Behaviors may be altered when sufficient incentive exists to change habits, abandon beliefs, investigate new ideas, or pursue improved economic conditions. Perceived benefits to individuals, groups, corporations or industries can motivate altered behavior in ways that reduce waste generation or discharge. Therefore, information about behaviors, incentives, and benefits is a key tool to be used in directing the development and implementation of mechanisms for reducing the generation of pollutants and improving the management of waste. Research in these non-technological areas may reveal significant opportunities for reducing pollution.

Research areas will include:

A. *Risk Communication*. How people perceive risk and what that means for efforts to communicate risk information to the public and to decisionmakers will be studied. Research will focus on methods for placing diverse risks in perspective, the social and cultural content of communication about risk, the factors affecting the acceptability of a risk analysis, presenting uncertainty in information for the public and policymakers, and the factors impeding consensus among experts. This research would lead to improved policies and environmental decisions.

   Another important area of research that relates to risk communication is the need to develop consensus-based methods of problem solving and policy making. Examples include development of the regulatory negotiation process and the use of alternative dispute settlement techniques in the enforcement program and in the Superfund cleanup program.

B. *Incentives and Disincentives*. Risk reduction strategies are designed to induce changes in behavior leading to the prevention of pollution or the resolution of existing environmental problems.

   Research is needed to identify the factors bearing on the decision to comply (or not to comply) with regulatory requirements. Examples of this type of research include topics such as methods and motivation of corporate environmental management in their compliance with regulatory requirements, effectiveness of deterrence strategies for environmental regulation, importance of the availability (or lack) of information and resources that could be alleviated by improved education and technical assistance, organizational barriers to effective environmental programs, and use of decision theory and decision analysis to gain insight into likely corporate responses to environmental programs.

   Research must also address the relative effectiveness of alternative strategies. One principal topic is the effectiveness of such incentive approaches as marketable permits, emission fees or charges, taxes, or subsidies.

A third area will explore why people do or do not take action to reduce risks within their control and explains what factors influence these choices. Several emerging problems stress the importance of individual or group level behavior and the importance of a nontraditional, nonregulatory approach. These problems include residential radon and other indoor air problems, lead in homes, use of pesticides and other chemicals in homes, in farming, and other occupational practices. These problems highlight the need for research on understanding behavioral change in individuals and firms. A related area is research on understanding how to get people to reduce risk through exposure avoidance. This is important for environmental issues such as the protection of pesticide applicators and asbestos abatement workers, land use planning and industrial siting.

C. *Technical Information Dissemination.* The objective of this research is to explore new mechanisms and/or improve existing methods of delivering scientific and engineering information. Historically, technology transfer has been accomplished through written materials (reports, summaries, journal articles, design manuals, handbooks, workbooks) and orally through seminars, workshops, and training courses. Research is needed to evaluate innovative state-of-the-art mechanisms such as expert systems, computer animated graphics, computer-assisted instruction packages containing workbooks and computer disks, and laser disk technology. The end products will be (1) guidance on how to select the appropriate technology transfer approaches for particular types of technical information and for specific user communities and (2) the actual development of innovative technology transfer systems. Development and demonstration of these systems will be accomplished in partnership with the private sector.

D. *Commercialization and Utilization.* New technologies must be commercialized to be successful. A variety of incentives and disincentives work to either promote or inhibit this process. These include market size, competition, need for permits, resistance to first use, and information availability on these and other decision-making criteria. Research carried out in the core program will identify and analyze the relative importance of these incentives and disincentives and design strategies to control their impact. The major products from this research will be expert systems to assist developers to identify the necessary actions required for commercialization. Support for the environmental technology commercialization system will ultimately reduce the time it takes to get new or improved environmental technologies into the marketplace.

E. *Education and Training.* EPA must take the lead on integrating environmental protection goals into the nation's business, science, and engineering curricula. Traditionally, industrial process engineers have been taught to maximize productivity, optimize quality, and reduce costs of production. We need to instill as well an understanding of and appreciation for the environmental and human health impact potential of their products, processes, and residuals.

It is critical that EPA, private industry, trade and professional associations, and universities work together to develop materials that teach environmental management. We need to support the development and implementation of environmental education programs at all levels, i.e., from grade school, to graduate school, to on-the-job training.

Educational programs can help explain how each and everyone has a role in protecting our environment. Our educational process must include information on the environmental impacts of this society's actions. EPA should work actively with scientific and professional organizations to advocate including environmental considerations in all types of industrial, scientific, and engineering actions.

IMPLEMENTATION STRATEGY

Priorities for the risk reduction core research program are to begin a major effort in pollution prevention in year two, and add a significant increment in year three. This is because pollution prevention is the most effective long-term strategy for accomplishing significant additional reduction in risk levels. Initiation of a full program is critical if a multimedia effort is to be implemented across the three major pollution prevention components: technology evaluation, technology transfer, and data management and trends analysis. An expanded program will work with all Agency programs, including solid wastes, pesticides, toxic substances, wastewater, water supply, radiation, nonpoint sources, and air emissions.

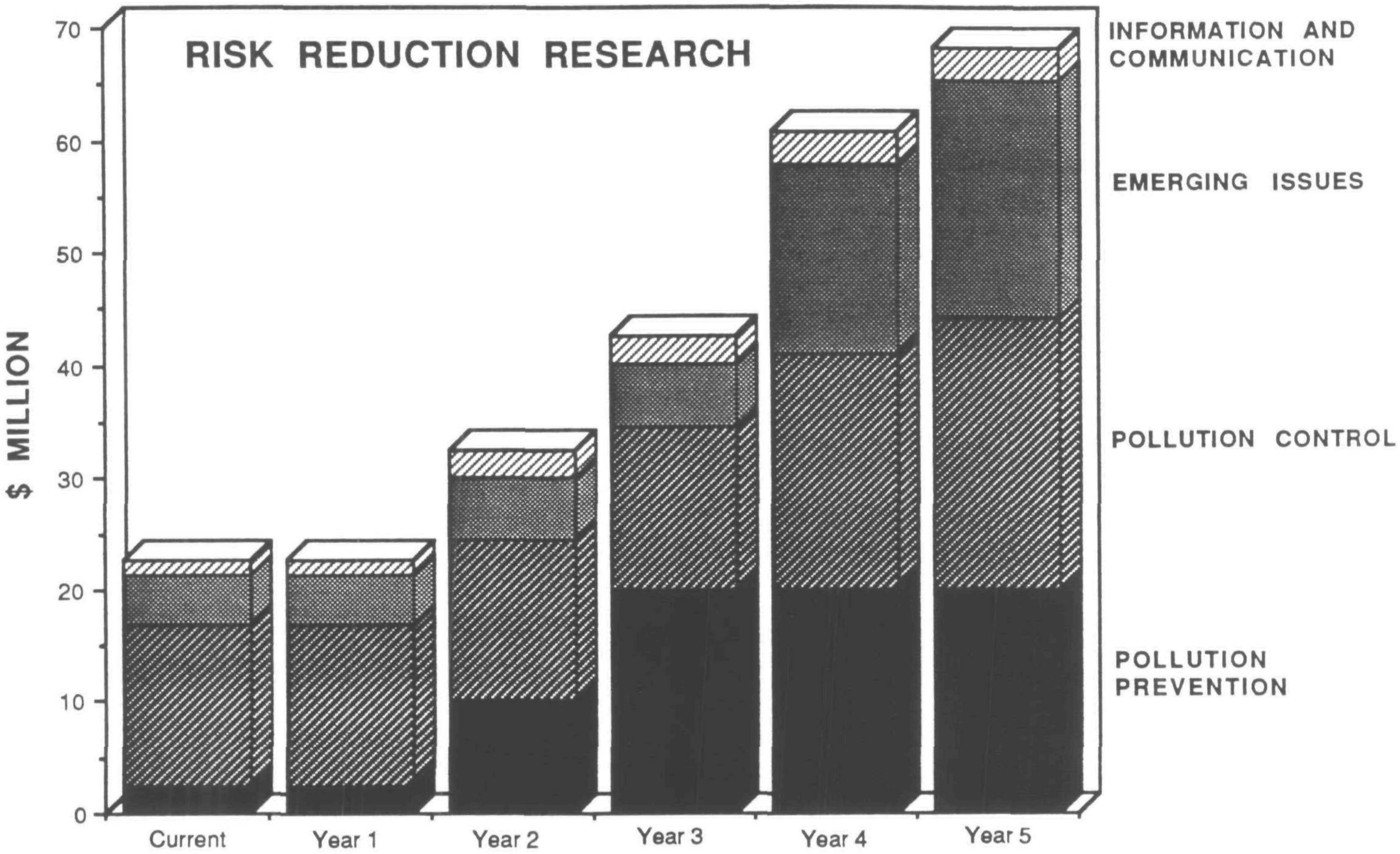
The next priority will be to expand significantly our capability in year two in the area of information and communication research and development. The primary areas for initial growth in the ORD program are research on new or improved methods for technical information dissemination, technology commercialization and utilization, and risk communication.

The work on emerging and neglected issues will begin to grow in year two and then expand rapidly in years four and five. An orderly expansion is planned. Work on municipal solid wastes and global climate will be increased early because of the apparent magnitude of these issues. Indoor air research and mitigation development will be next to receive focus. Medical and infectious wastes will also receive early attention. Work on nonpoint source contamination, water supply, energy conservation and alternative fuels, and environmental infrastructure will be fully in place by year five.

As indicated previously, opportunities in pollution control technology and in the identification of future environmental issues promise large dividends if sufficient resources can be applied. A major expansion is planned beginning in year four.

SUMMARY

The risk reduction research program must be expanded rapidly in the early years to initiate high priority work in pollution prevention. The identification of emerging issues and research on communication techniques will then begin steady expansion, followed by significant research on pollution control. The following chart depicts the estimated Office of Research and Development budget for risk reduction research for the current year and 5 years into the future. However, much of the research described in the information and communication area is performed by other Agency offices. We anticipate that expansion in these areas will be accommodated by budget requests outside the scope of this proposal.


RISK REDUCTION RESEARCH
$ MILLION
70
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50
40
30
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Current
Year 1
Year 2
Year 3
Year 4
Year 5
INFORMATION AND COMMUNICATION
EMERGING ISSUES
POLLUTION CONTROL
POLLUTION PREVENTION

EXPLORATORY GRANTS AND ACADEMIC RESEARCH CENTERS

INTRODUCTION

The single most important resource in our national environmental research and development strategy is the environmental scientists and engineers themselves. The proposals presented throughout this core research plan are predicated on the existence of a skilled environmental research community. To this end, EPA must assume responsibility for supporting and sustaining the nation's academic environmental research community and institutions.

As the Science Advisory Board stated in its recent report entitled *Future Risk: Research Strategies for the 1990's*, "The more the scientific community at large understands about EPA's scientific goals and projects, and the more EPA's scientists know about research outside the Agency, the greater the benefit to our national effort as a whole."

Exploratory Grants

	Year/$ M				
Current	1	2	3	4	5
8.0	18.0	30.5	38.0	50.0	50.0

One key mechanism for delivering this type of support is through investigator-initiated grants to the colleges and universities where these professionals receive their education and do their research. Previous experience demonstrates that our success in mounting large applied research programs depends on stable, reliable support for individual researchers, largely in academia. External grants programs are invaluable in stimulating the generation of fundamental knowledge from which applied programs derive new information. Without the steady infusion of new ideas, we run the risk of overmining our data base. Grants programs provide excellent training opportunities for young scientists and engineers in graduate and post-doctoral settings who are our future researchers and managers. And, finally, grants to academic environmental researchers increase the probability that problems and their possible solutions are discovered earlier, making remediation cheaper. When fully attained, the core program will provide approximately 200 new grants per year, with a total of 500 grants in place at any given time. Grants will be awarded in five environmental areas: health, biology, engineering, and chemistry and physics related to air and water. Maintenance at this new level of $50.0 million should ensure that researchers can commit themselves and their graduate students to research careers of interest and benefit to EPA, and be confident of extended funding if they perform well.

Academic Research Centers

	Year/$ M				
Current	1	2	3	4	5
4.5	4.5	4.5	7.0	10.0	10.0

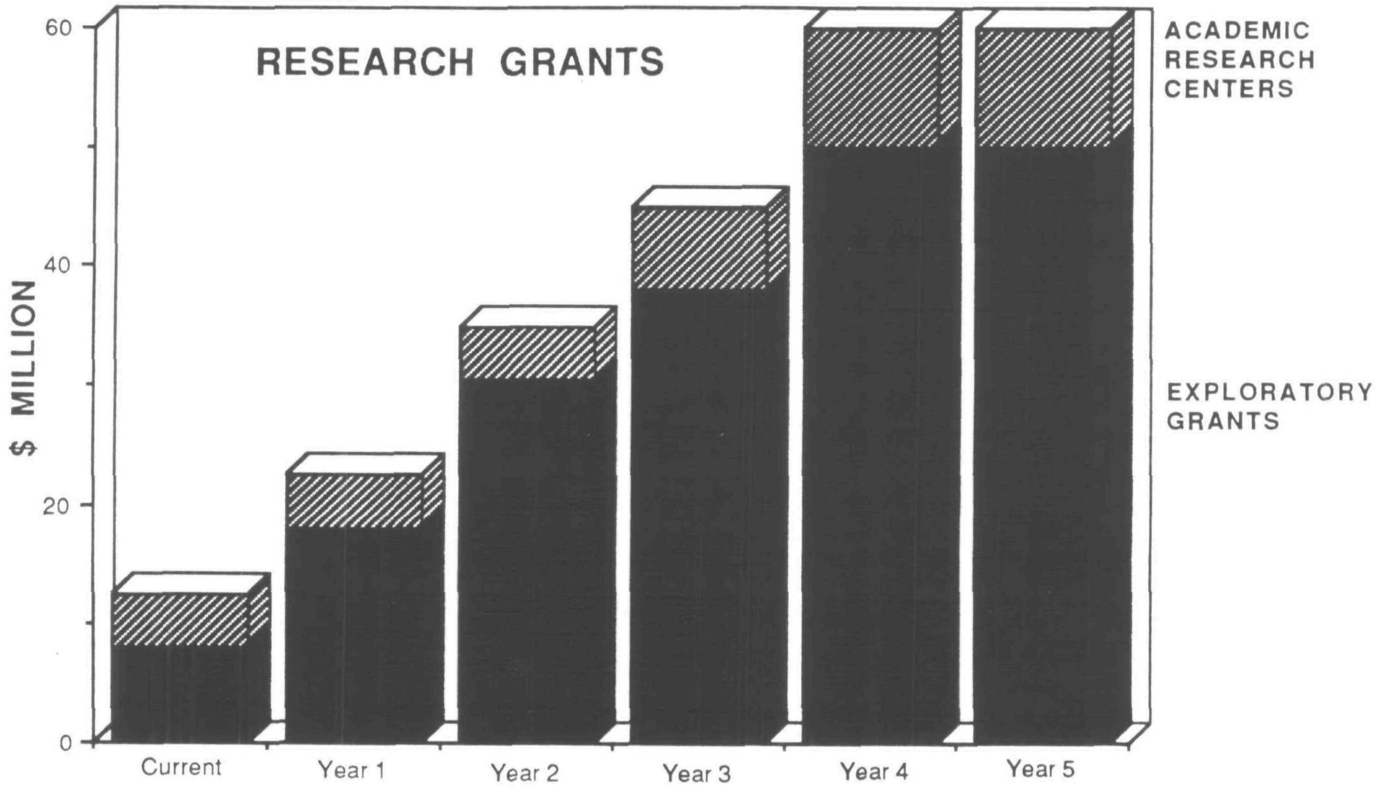
A concomitant element of our effort to strengthen EPA's links to the external scientific community will be to create additional academic research centers to address those areas of environmental research which are best served by longer-term institutional arrangements. In the past such areas have included ecological risk, coastal ecology, epidemiology, etc., where longer, larger, and more focused efforts have been required than could be achieved through grants to individuals.

Future centers will be focused on specific issues selected by EPA to complement and enhance the EPA research program, and to augment EPA expertise.

IMPLEMENTATION STRATEGY

The grants program we propose to mount will grow by significant increments in the first four years and then level off in year five at $50.0 million. The centers program will expand in both the second and the fourth years of this five-year scenario.

A graph depicting current and projected resources follows.



APPENDIX A
EXPOSURE ASSESSMENT
A CROSS-CUTTING ISSUE

INTRODUCTION

Exposure assessment has been termed the weakest link in risk assessment. The practice of exposure assessment attempts to quantify the real world contact (exposure) of agents and organisms and the subsequent absorption into the organism (dose) so that this information can be used in dose-response relationships to predict risk. The overall goal of the exposure assessment program is to provide accurate exposure information for Agency risk managers and decision makers to use in risk assessment and risk management.

Whenever risk-based decisions are made in the Agency, there is uncertainty associated with the risk estimates. Although the hazard identification and dose-response areas of risk assessment contain uncertainties, we often deal with certain chemicals in many different decisions, and the uncertainty in the hazard identification and dose-response for these chemicals will be consistent among decisions. For exposure assessment, on the other hand, each decision usually considers different exposure situations, forcing new evaluations of uncertainty for exposure for each decision. Furthermore, and perhaps even more importantly, all the Agency's risk reduction strategies involve the reduction of exposure either by reducing concentrations contacted or by modifying activities which result in contact, since toxicity and dose-response relationships for a given chemical are, for the most part, not modifiable. For these reasons, accurate exposure assessments provide the fundamental basis for the Agency's risk-based decisions, including risk reduction strategies used in risk management.

Many of the questions which Agency decision makers face daily have answers directly based on sound exposure assessments. Some typical examples are:

1. Will the risk to the surrounding community increase if an incinerator is sited here, and if so, by how much?
2. Which of the 15 known sources of this particular chemical should be controlled to most effectively reduce risk?
3. Have the people living in the area of this Superfund site been exposed to the hazardous substances at the site, and if so, how much?
4. How is the risk to the population in a given area changing over time, especially, have any of the controls I put in place succeeded in reducing risk?

CORE RESEARCH PROGRAM

This core research proposal outlines a program that will result in an integrated approach to exposure assessment, using real world data both directly and to derive validated relationships among several major approaches to exposure assessment: predictive, direct measurement, and reconstructive.

Exposure assessors have often used all of the major approaches to quantify exposure. The predictive approach characterizes the chemical and the organism separately, then estimates exposure by linking them through devices such as scenarios or microenvironments. The direct measurement approach uses measuring devices at the point of contact to monitor the intensity of contact while it occurs. The reconstructive approach uses measurements inside the organism after the exposure has occurred to try to reconstruct what the exposure and absorbed dose must have been at some time in the past. All of these approaches have particular strengths for answering certain types of questions of interest to the decision makers.

Predictive exposure assessments, when based on real world data and validated models, are best at answering "what if" questions such as question one above. Direct measurement data, in addition to providing an actual measurement of exposure, best answer questions about which routes of exposure (and ultimately, perhaps even which sources) are the most important in terms of the actual exposure received (e.g., question two above).

Reconstructive assessments offer proof that exposure and absorption have occurred and therefore are best at answering questions about the actual status of an individual's or a group's exposure (e.g., question three above). All these approaches, used together in an integrated approach to exposure determination, can be effective in helping answer some of the most difficult questions confronting the Agency both today and in the future (including questions such as the four above).

In addition to developing exposure assessment methods and gathering data, the core program proposes a major effort in the area of validation and uncertainty assessment, to help assure that the best data, models, and relationships are used in developing exposure information.

The program is described in terms of four topics: Predictive exposure assessments, direct measurement of exposure, reconstructive exposure assessment, and validation/integration/uncertainty. Each of the topics has issues associated with it. The program covers both human and ecological exposure assessments. As a crosswalk among the Human Risk Assessment, Ecological Risk Assessment, and Risk Reduction Core Research Programs, this presentation shows the relationships among the various exposure-related topics found in those programs.

Predictive Exposure Assessments

	Year/$ M				
Current	1	2	3	4	5
33.1	45.1	116.7	132.2	137.5	150.0

Predictive exposure assessments estimate the location and amount of chemicals or pollutants present (the "chemical" side) and combine them with estimates of the location, numbers, and activities of individuals or populations exposed (the "population" side). This combination can be achieved through the use of scenarios or other devices to arrive at quantitative estimates of exposure. In order to characterize the chemical, knowledge of sources, environmental fate, and concentrations in various media (or microenvironments) is necessary. Models are often used to interconnect these, but accurate characterization of the location and concentration of pollutants depends a great deal on real-world measurements. Models and environmental measurements work together in a predictive assessment; the models theoretically describe why the concentrations are what they are, and the measurements are the link to the real world.

The research involved in characterizing the "chemical" side of predictive exposure is the foundation upon which both the human and the ecological predictive exposure assessments are based and applies equally to human and ecological exposure.

Characterization of the location and activities of the exposed population (the "population" side of predictive exposure) can also use models, but again, observations or measurements of activities provide the real-world link.

Finally, exposure models in predictive assessments link the "chemical" and the "population." These models can use any of a number of devices for making that link, among them exposure scenarios, microenvironmental information, or Monte Carlo techniques.

Source Characterization

	Year/$ M				
Current	1	2	3	4	5
9.0	9.4	13.1	14.0	14.3	15.6

The current program contains some research for mobile sources and a minor amount of research for other sources. It is proposed that this be expanded to sources such as building materials, consumer products, and other indoor air sources as well as to outdoor sources such as incinerators.

Accurate release rates are important data in most fate models. Eventually, this research may lead to the ability to "fingerprint" sources.

Fate Processes/Models

	Year/$ M				
Current	1	2	3	4	5
6.4	7.4	9.4	11.2	12.0	13.0

Fate processes research and its practical application, fate models, have been the mainstays of predictive exposure assessment for many years. Many processes, however, are still poorly understood, and models are also needed in certain areas. The expansion of research in this area will emphasize metal speciation, partitioning processes (both physical and biological) for organics, and bioconcentration.

Media Characterization

	Year/$ M				
Current	1	2	3	4	5
12.1	22.1	85.3	90.9	93.0	98.0

This area contains analytical methods development and monitoring. Currently, the program is limited to monitoring in support of the air (hazardous air pollutants) program. The development of data for all the media has been neglected over the last decade and has become a critical gap in predictive exposure assessment. It is proposed that this area be the focus of a major new environmental research initiative: the establishment of an operational monitoring system for media status and trends. This system is discussed more fully under Ecological Risk. (See EMAP discussion pages 25 through 27.)

Microenvironmental Studies

	Year/$ M				
Current	1	2	3	4	5
0.2	0.5	0.9	3.5	4.5	4.5

This proposed research will develop data for use in the "chemical" part of microenvironmental models (see Human Exposure Models below). Currently there is very little work in this area. If the Agency is to have a predictive tool which can readily identify the relative media importance of chemicals, the data from these types of studies must be developed.

Population Activity Patterns

	Year/$ M				
Current	1	3	3	4	5
0.5	0.8	1.5	5.1	5.5	5.5

Research into activity patterns is the most critical gap in both microenvironmental and scenario models. Currently there is very little research in this area; it is generally recognized by exposure assessors to be the data gap which most seriously affects the assessors' ability to predict "real world" exposures.

Environmental Exposure Models

	Year/$ M				
Current	1	2	3	4	5
1.0	1.0	2.0	2.0	2.0	7.0

Currently, estuarine, water quality, terrestrial, and large lakes models are being developed. These models are not being routinely used by the Agency for ecological risk assessments, however. The research proposed will be an expansion to complete and test these models (and perhaps other ecological models) so that the Agency can better perform ecological risk assessments.

Human Exposure Models

	Year/$ M				
Current	1	2	3	4	5
3.9	3.9	4.5	5.5	6.2	7.0

Currently, both scenario models and microenvironmental models can be described mathematically but suffer from a need for realistic input data. Putting these models into the hands of assessors through PC-based, menu-driven programs, along with the backup data needed to run the models, is the goal here. Currently there is very little work in this area. Use of state-of-the-art technology (such as CD-ROM) may revolutionize the assessors' access to real data in the next few years, provided the data are developed.

Direct Measurement of Exposure

	Year/$ M				
Current	**1**	**2**	**3**	**4**	**5**
1.7	**2.2**	**4.0**	**12.0**	**14.0**	**16.0**

Direct measurement of exposure involves measuring the intensity of contact between a person and a chemical while the exposure is taking place. In addition to providing a major link to the real world by producing actual data, it provides the best way of determining which medium or pathway is the most important for exposure. Coupled with the source characterization "fingerprints" described above, this research could lead to a major improvement in our ability to determine what sources are causing exposures.

Instrumentation for Direct Measurement of Exposure

	Year/$ M				
Current	1	2	3	4	5
0.0	0.5	0.7	1.5	2.0	2.0

Currently, instrumentation exists to measure several dozen chemicals by direct measurement techniques, but there is specific research on only one other monitoring device. The number of chemicals that are important to EPA decisions requires that instrumentation be developed for many other chemicals.

Data Collection/Analysis/Management

	Year/$ M				
Current	1	2	3	4	5
1.7	1.7	3.3	10.5	12.0	14.0

Currently, there are data for a few dozen chemicals taken for populations in a handful of cities. In order to realize the potential for using these data to make more informed decisions, a much larger data base must be developed. In addition to helping answer questions about exposure directly, the data base would be used to develop a predictive tool which can answer questions about exposure of various segments of the population.

Reconstructive Exposure Assessment

	Year/$ M				
Current	1	2	3	4	5
0.8	2.4	7.4	8.0	8.4	12.1

Reconstructive exposure assessment involves taking measurements from inside an organism after exposure has taken place and relating the measurements (through pharmacokinetic relationships) to what exposure must have been in the past to result in these measured levels. Potentially, these assessments can be the best way to ascertain whether exposure has occurred.

Biomarkers of Exposure - Human

	Year/$ M				
Current	1	2	3	4	5
0.7	1.0	1.2	1.5	1.7	2.9

Although these biomarkers are potentially a direct test for exposure (obviating the need for worst case scenarios and bringing exposure assessment closer to actual exposures), there are few biomarkers now that can be used routinely for this purpose. Current research levels are small and are proposed to be greatly increased to do research into identifying potential biomarkers of exposure and determining the relationships between the biomarker levels and absorbed doses.

Biomarkers of Exposure - Ecological

	Year/$ M				
Current	1	2	3	4	5
0.0	1.0	5.0	5.0	5.0	7.0

Currently, there is virtually no work being done in this area, although potentially the use of ecological biomarkers of exposure could result in rapid assessment of actual exposure status of both plants and animals.

Pharmacokinetics/PK Models/Data

	Year/$ M				
Current	1	2	3	4	5
0.1	0.4	1.2	1.5	1.7	2.2

Pharmacokinetics is the key to reconstructive exposure assessment. Currently there is very little research being done; a few PK models have been developed but none of the necessary data (partition factors, local blood flow data, etc.) are generally available.

Validation, Integration, and Uncertainty

	Year/$ M				
Current	**1**	**2**	**3**	**4**	**5**
0.9	**1.3**	**2.0**	**5.6**	**8.6**	**11.8**

Model validation and uncertainty are perhaps the two most widely heard requests of risk managers when addressing exposure assessments. This is a critical gap which must be dealt with effectively and quickly if the exposure assessment program is to reach its goal of providing realistic exposure information to risk managers.

Model Validation

	Year/$ M				
Current	1	2	3	4	5
0.4	0.8	1.4	4.0	7.0	10.0

Currently, there are some projects to validate various fate models but no centralized validation program. A high priority of the exposure assessment program is the establishment of a centralized focus for getting validation data on the models we use. Validation is viewed as a process rather than a single step, and models used will be in various stages of this process for any specific use.

If established, the model validation program, can define terms, work through the backlog of most-used models (both the review of previous validation efforts and further field work, if necessary), and eventuallyprovide a working system for assessors to use to determine how much validation work has taken place for any given model.

Integrated Approaches

	Year/$ M				
Current	1	2	3	4	5
0.2	0.2	0.3	0.8	0.8	0.8

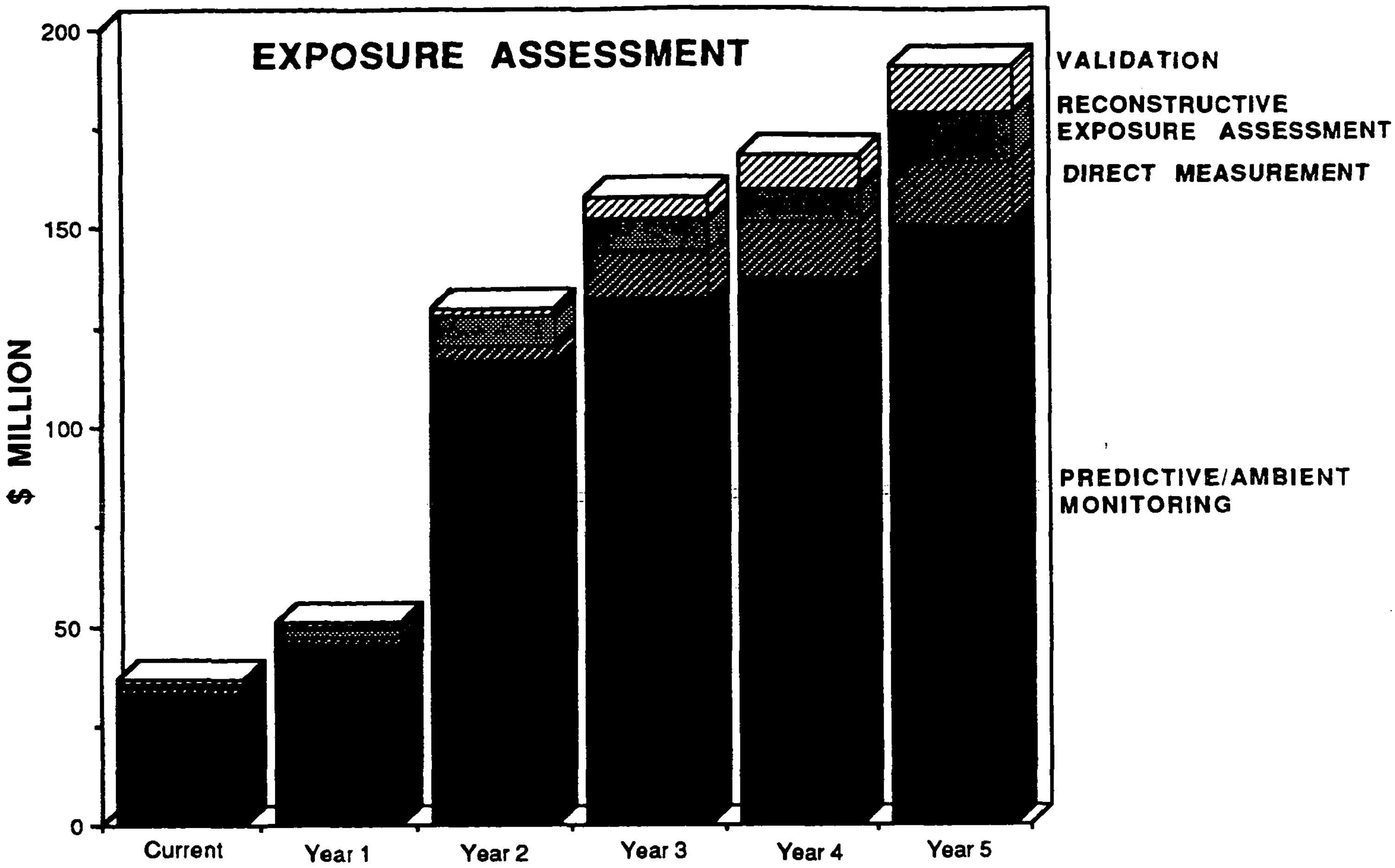
With three independent methods for determining exposure, the Agency has a unique opportunity to compare results from each method as part of a validation effort. This effort is currently operating at a very small level of resources and is proposed to expand somewhat in the future.

Uncertainty Analysis

	Year/$ M				
Current	1	2	3	4	5
0.3	0.3	0.3	0.8	0.8	1.0

The current program has a small effort in this area. The proposed program would expand the research into how uncertainty analysis can be used for exposure assessment and what the risk managers and decision makers want to see in the way of uncertainty analysis.

The following tables and chart depict budgetary resources in exposure assessment for current and ensuing years.


EXPOSURE ASSESSMENT
$ MILLION
200
150
100
50
0
Current
Year 1
Year 2
Year 3
Year 4
Year 5
VALIDATION
RECONSTRUCTIVE EXPOSURE ASSESSMENT
DIRECT MEASUREMENT
PREDICTIVE/AMBIENT MONITORING