UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

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MEMORANDUM

SUBJECT: CENR Subcommittee on Toxic Substances and Hazardous and Solid Waste Revised R&D Strategy (10/5//94 draft)

FROM: Lisa S. Matthews
Lisa S. Matthews
Subcommittee Executive Secretary

TO: Subcommittee Agency Principal Representatives

Attached for your information is the revised Research and Development (R&D) strategy (dated 10/5/94) for the CENR Subcommittee on Toxic Substances and Hazardous and Solid Waste. This version reflects some of the comments that we received on the September 21st draft strategy and a final editing. This draft strategy was mailed to a group of external reviewers on October 6th, with comments requested by October 21st. We will incorporate external mail review comments and any remaining Subcommittee comments the weeks of October 24th and 31st. The final Subcommittee strategy, along with the implementation plan, is due to CENR by mid-November.

If you have any questions on the strategy, please call me at (202) 260-7993.

Attachment

DRAFT October 5, 1994

COMMITTEE ON ENVIRONMENT AND NATURAL RESOURCES
SUBCOMMITTEE ON TOXIC SUBSTANCES AND HAZARDOUS AND SOLID WASTE
RESEARCH AND DEVELOPMENT STRATEGY

STRATEGY FRAMEWORK

This strategy addresses federal research and development (R&D) related to managing toxic substances and hazardous and solid waste in the environment. Toxic materials* are of concern because they can cause harm to human health and ecological systems. The potential for this harm is typically expressed in terms of risk, so management of toxic materials involves assessing and managing risks.

Risk assessment is the basis for both policy and technical decisions regarding risk management. It is used to determine priorities for risk management (addressing the highest risks first) and to guide the actual process of managing the risks (such as determining appropriate cleanup levels for contaminated sites). Risk assessment is scientifically complex because it involves integrated steps of hazard assessment (hazard identification and dose-response assessment), exposure assessment, and risk characterization. The first part of this strategy addresses the research needed to provide the information and data required to perform scientifically credible and sound risk assessments.

Risk management is the objective behind waste management and other efforts to prevent or control the impact of toxic materials on human health and ecological systems. The R&D priorities in this strategy on risk management revolve around research, development, and demonstration of technologies and approaches for the monitoring, prevention, control, and remediation of toxic materials. These are the primary tools of risk management, but their use must be guided by a process that starts with risk assessment, involves decisions about appropriate levels of risk and costs of alternative ways to reduce risks, and incorporates other technical, legal, and social factors. Compliance with laws and regulations and minimizing civil liability are legal elements of risk management.

Social and economic factors play a key role in both risk assessment and risk management. This strategy highlights some of the research needs in these areas essential to improve our ability to make more effective risk management decisions. Fears, desires, and needs of local residents, concerns of regional and national interest groups, and those of

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* Throughout this document, the term "toxic materials" should be read to include the range of environmental toxicants including toxic releases to all media, new and existing chemicals, pesticides, biotechnology products, ionizing and nonionizing radiation, oil and chemical spills, and solid, hazardous, radioactive, and mixed wastes.

affected tribal, national, state, and local governments all should be considered in the decision-making process. Cost effectiveness, sustainable development, economic incentives, environmental justice, and public participation are some of the important social and economic considerations that are addressed in the strategy.

1.0 VISION AND GOALS

Environmental Vision: To understand, prevent, and reduce human and ecological exposure to toxic materials and their adverse human health, ecological, and social and economic consequences. Actions will be guided by principles such as sustainable development, community involvement, environmental justice, wise ecosystem management, and the risk of alternatives.

- Protection: Protect human health and the environment from adverse effects associated with exposure to toxic materials;
- Assessments: Ensure appropriate priorities and levels of protection through the use of scientifically sound and demographically sensitive assessments of risk and cost/benefit;
- Innovative Environmental Technologies: Develop and apply safer, faster, better, and more cost-effective technologies for reducing and monitoring exposures of humans and the environment to toxic materials;
- Pollution Prevention: Promote pollution prevention as a primary guiding principle for protecting the environment. Use regulatory and nonregulatory tools to instill a prevention-based ethic in all sectors of society;
- Sustainable Development: Demonstrate that a clean environment and economic growth can be mutually supporting. Achieve both environmental protection and economic growth through government and private sector collaboration;
- Communication and Community Involvement: Ensure that all stakeholders have access to reliable information about sources and levels of pollution in their communities and promote stakeholder involvement in all aspects of the environmental decision-making process;
- Environmental Justice: Assure that the benefits of environmental protection can be shared equitably by everyone in the society and that no specific group is at greater risk from environmental factors;
- Emergency Response/Unintentional Releases: Prevent and respond to oil and other hazardous substances spills and chemical incidents so as to minimize environmental injury and protect public safety and ecological integrity;

- Occupational Safety and Health: Reduce worker and household exposure and health and safety risks presented by waste, radioactive materials, and other toxic materials encountered in the workplace or carried home on workers' clothing and equipment; and

- Federal Facilities: Cost-effectively cleanup or contain toxic contamination at federal sites which pose a risk to human health and the environment. Assure federal facilities are in compliance with all environmental laws and regulations.

2.0 POLICY-RELEVANT QUESTIONS

The research priorities presented in this strategy directly support the development of policies for managing risks from toxic materials. Risk assessment as a whole is central to policy formation. But science cannot always provide clear, complete, and unambiguous answers for policy formation. Some of the more difficult policy issues that are impacted by the research priorities in this strategy are listed below:

- **How to use risk assessment for public policy decisions?**

- **How to deal with uncertainty in risk assessment?**

- **How to improve risk communication and public involvement in decision-making?**

- **How to use cost/benefit and comparative risk analyses in making risk management decisions?**

- **How to weigh health risks and risks to ecological systems for different endpoints in making risk management decisions?**

- **How to use cumulative risk in the risk assessment and management paradigms?**

- **How to incorporate environmental justice concerns in risk assessment and management?**

- **How to use federal government resources to promote development and application of environmental technologies?**

- **How to coordinate objectives among federal departments and agencies?**

3.0 SCIENTIFIC AND TECHNOLOGICAL GOALS

- **To advance the science of risk assessment, to support toxic substances and hazardous and solid waste management, including to:**

(1) understand the effects of exposures to toxic materials on human health and ecological systems, including the toxicological mechanisms that produce those effects;

(2) uncover processes for predicting and measuring exposure to humans and ecological systems, and the processes leading to those exposures; and

(3) estimate risk and characterize and communicate those estimates. ;

- To demonstrate and evaluate more cost-effective, innovative technologies for pollution prevention, control of toxic wastes and emissions, site characterization, remediation and restoration, in support of sustainability;

- To advance the science of monitoring and predicting environmental concentrations and effects, as well as the fate and transport of toxic materials;

- To collect data and develop evaluative methodologies for the social and economic consequences of pollution; and

- To disseminate and coherently explain risk/benefit information, so the public can participate in a meaningful way in environmental decision-making.

4.0 RISK ASSESSMENT OF WASTE AND TOXIC SUBSTANCES

Conceptual Framework

The assessment of risks to human health and ecological systems from toxic materials follows a widely accepted paradigm produced by the National Academy of Science (NAS) in 1983 and reiterated by the NAS in 1994 in *Science and Judgement in Risk Assessment*. The risk assessment paradigm is a framework for organizing analyses of pertinent data in a way that emphasizes the interdisciplinary nature of the work. The four elements of the framework are: (1) hazard identification; (2) dose response assessment (note that we refer to elements 1 and 2 as "hazard assessment" in this strategy); (3) exposure assessment; and (4) risk characterization. This section of the strategy is organized around this paradigm.

Hazard Assessment. Understanding the hazards of toxic materials to either human health or ecological systems involves the same fundamental scientific principles of chemistry and cellular biology. Assessment of human health is focused on one species of concern with many endpoints with differing impacts on individuals such as cancer, neurological effects, and reproductive effects. Ecological hazard assessment is directed towards many species with endpoints with differing impacts on populations and communities of populations. Much of hazard assessment depends on epidemiologic research and studies to understand fundamental similarities and extrapolate among species and situations. Research on variability of fundamental processes within the human species and among non-human species within a family or taxa must be conducted to support good assessments in the future.

Exposure Assessment. The exposure assessment element of the risk assessment paradigm asks the questions: "How many people are exposed? What are the routes and pathways of exposure? What is the extent, duration, and magnitude of exposure?" Exposure assessments generally are based on either direct monitoring of environmental concentrations of toxic materials, fate and transport models to predict exposure levels, or assessments of toxic materials in humans, wildlife, or ecological systems. There are differences in the exposures and effects from exposures among individuals and groups of individuals that must be identified and understood to develop appropriate protection strategies. It is also important to understand the environmental justice implications of: (a) the distribution of exposure levels in the population; (b) highly exposed segments of the population; and (c) more susceptible subpopulations.

Risk Characterization. Risk characterization is the communications transition point between assessment and management. It *integrates* results of the other parts of the assessment, *evaluates* strengths and weaknesses of the data and conclusions, and *communicates* these results and their implications in terms useful to the risk manager and others.

The integration of the individual characterizations of hazard, dose-response, and exposure describe who or what is at risk and why. The characterization must also provide an evaluation of the overall quality of the assessment and the degree of confidence the authors have in estimates of risk and the conclusions drawn. Important uncertainties and interpretation of data must be explained to the risk manager. A risk characterization should be alert to the potential for racial or cultural bias resulting in failures to gather data on minority or socioeconomically disadvantaged populations, or failure to correctly identify and count members of such populations in large samples.

Effectively communicating the results of the assessment to the risk manager, stakeholders, and the community is essential to their reaching a decision about what risk management action need be taken, if any. The results of the assessment must be explained in terms useful for these purposes. Executive Order 12898, addressing environmental justice, requires both the identification of communities disproportionately affected by environmental pollution, as well as the participation of community residents in conducting studies to assess and redress inequities. Consequently, the risk communication should be tailored to inform and aid in the education of community residents when appropriate.

4.1. CURRENT STATE OF UNDERSTANDING

4.1.1 Hazard Assessment

Human Health: Past efforts in the hazard identification of toxic materials have focused on cancer as the main endpoint of concern with other endpoints (e.g., neurological, reproductive, and developmental effects) receiving less attention. Efforts to establish dose-response relationships for carcinogens have largely been of a curve-fitting nature that make linear low dose estimates of response at lower exposures. For non-carcinogens, the approach has generally been to identify a "No Observed Adverse Effect Level" (NOAEL) or a "Lowest Observed Adverse Effect Level" (LOAEL). Uncertainty factors are then used to estimate a dose below which an unacceptable level of effects would not be expected to occur in humans.

Much of the information on toxic materials has come from animal testing on individual chemicals. Little is known about the hazards of chemical mixtures and mixtures of other stressors. Differences between animals and humans with respect to absorption, distribution, metabolism and excretion (toxicokinetics), and species susceptibility have made the extrapolation of effects seen in animals to the human situation problematic both qualitatively and quantitatively. It has also been difficult to extrapolate the results of lifetime animal studies or long-term occupational studies to environmental exposures lasting much shorter periods of time (e.g., childhood exposures for children living near Superfund sites).

Ecological: During the past 30 years, research on the ecological hazards of toxic materials has primarily focused on the development of empirical toxicological data with greater emphasis placed on aquatic rather than terrestrial systems. These data reflect the first generation of approaches that effectively contributed to the assessment of adverse impacts resulting from overt toxic effects (e.g., lethality and growth effects) caused by exposure to environmental chemicals. With some exceptions, extrapolations of toxic effects across species and endpoints were based on the empirical evaluation of existing data. For example, water quality criteria for the protection of aquatic life are based on the assumption that the variety of tested species are representative of the vast array of untested aquatic species. Comparable data for the protection of plant and wildlife species are very limited especially with regard to endangered species. It is clear that empirically-derived hazard data cannot be developed for each combination of chemical and species.

Human Health __and__ Ecological: In the past few years there has been an increasing emphasis on the development of new approaches using a mechanistic basis of extrapolating across species and chemicals. For example, understanding relationships between mechanisms of toxic responses and chemical structure have made possible the prediction of potency for untested chemicals that are based on modes of action. Although these newer models have proven effective for predicting the acute toxicity of many xenobiotics, there remain significant uncertainties in predicting metabolic activation and chemical reactivity, which are the processes that underlie the chronic toxicity of the most potent environmental chemicals.

There has also been increasing concern that the first generation of approaches are not adequate for assessing the chronic effects of persistent bioaccumulative chemicals such as dioxins, furans, and those compounds suspected of acting as endocrine disruptors. In the context of extrapolating across species, the recent development of physiologically-based toxicokinetic (PB-TK) models for animal to human and for aquatic organisms reflects an important step towards a predictive capability. Initial linkage of PB-TK models with mechanistic research provides a rational approach to identifying critical toxicokinetic and toxicodynamic processes that underlie the differences in responses of species to chemicals. There is currently a paucity of data for developing these models.

4.1.2. Exposure Assessment

Procedures have been reasonably well developed to monitor environmental media and provide point estimates of mean exposure levels. While basic data on human behavior are used in modeling, genetic and cultural differences are not accounted for. Simple fate models are generally capable of predicting environmental concentrations, although with varying degrees of capabilities. There is, however, great uncertainty in many of these predictions. Generic transport and fate models are already widely available. While such models can be tailored to be used for small, site-specific problems, use at a higher scale, like watersheds, is limited by the complexity of the natural processes that must be linked together for large system models. The primary uncertainty of extrapolating laboratory hazard data to ecosystems in the field is the uncertainty about the actual chemical dose received by individuals.

Modern computing has removed many intractable hurdles in the science of modeling chemical behavior in the environment. While models are available to simulate transport of chemicals in the atmosphere, surface water, and groundwater, most models are limited in their ability to accurately simulate the impact chaotic weather events have on exposure, as well as the risk reduction which accompanies chemical and biochemical transformations. Models of resuspension of contaminated sediments, which control long-term risks of persistent chemicals, are in their infancy. Models of bioavailability are still in the conceptual stage even though the physical and chemical interactions that influence bioavailability are known. Soil/air interactions are largely unknown. Degradation models are seldom reliable, especially for industrial chemicals.

Reducing the uncertainty of exposure assessment will be accomplished by improving methods for measuring toxic forms of chemicals and developing more realistic information on the processes that control chemical transport and fate. Such information lags far behind the engineering of the computer frameworks for the models. Studies of fundamental ecosystem processes need to be designed in the context of the risk paradigm and with a new prospective from the modeling frameworks already developed. For example, current progress in exposure assessment has shown that most transport occurs during storm events. While sediment chemistry is becoming understood, sediment physics with respect to the energy of resuspension is a critical knowledge gap. Metal speciation has been modeled from a chemistry perspective, but not in the context of bioavailability or toxicity. Persistence and natural assimilation capacity of ecosystems for toxic materials are essential to making strategic choices in risk reduction and pollution prevention. In addition, biomarkers and other more diagnostic methods of measuring exposure are needed.

4.1.3. Risk Characterization

Risk characterization has long been overlooked as an area of research, the most common reasoning being that if the other two parts of a risk assessment were done correctly, the risk characterization would follow in a relatively straightforward manner. Experience has shown this to be presumptuous. Much of the criticism of risk assessments can be traced to inadequate risk characterization.

Although we currently do integration of hazard, dose-response, and exposure for carcinogen assessments where simplifying assumptions have been made (dose linearity, simple exposure scenarios, etc.), it is much more difficult to see how these pieces fit together in ecological assessment or in non-cancer health assessments. Complications such as mixtures, cumulative risk, short-term vs. long-term exposures, and the effects of biological variability have been dealt with in crude ways (or not at all) in assessments. Moreover, the effects of racial or ethnic differences and of economic disadvantages have been neglected until recently. The research necessary to properly integrate the parts of a risk assessment in all but the most simple cases has not been performed. Basic research and methods development is required for a better understanding of risk assessment and risk management.

There has been some recent research into risk-related uncertainty analysis, but it has not yet developed to the point of being second nature to the assessors themselves. Quantitative statistical treatments of uncertainty are well founded and established, but the application and adaptation of these techniques to risk assessment still needs some research. Presentation of the qualitative aspects of risk assessment uncertainty has not been well studied or developed. Before risk characterization can routinely present the confidence of the assessment to the risk manager, research must be done and methods established for both the qualitative and quantitative aspects of uncertainty.

Research is needed to develop both the statistical basis for presentation of results and the ability to clearly and concisely express results in terms needed by the users of the assessments, including the general public. Efforts to involve affected communities should include a risk communication strategy that involves community leaders in its definition. At the very least, the communication strategy, as well as the content of the study, must be made understandable by, and presented to, the public.

4.2. RESEARCH PRIORITIES

4.2.1. Hazard Assessment

Although ongoing research is making important advances, there remain significant uncertainties in predicting hazards of toxic materials, including dermal exposures, dose-response relationships, and species susceptibility. These uncertainties are especially noteworthy in the context of chronic endpoints, such as reproduction and development and for those chemicals with complex modes of toxic action. In addition, it is essential that data and models be developed that will allow the prediction of health endpoints in humans and endpoints that can be used in ecosystem studies to predict the sustainability of sensitive populations of aquatic life and wildlife. For example, endocrine disruptors are generally thought to have receptor-based mechanisms that affect reproductive success and, therefore, could have an effect on population dynamics. Thus, in addition to life-cycle studies, research on these chemicals must be conducted at the organ, cellular, and subcellular level to identify toxic mechanisms and receptors. This information is necessary to quantitatively predict responses for untested chemicals and establish the critical physiological and biochemical properties that underlie differences between species.

For human health, much more information is needed to understand the effects of short-term exposure that the risk assessor must often address. Most of the population is not exposed to toxic materials from any one source for their entire lifetime because of changes in address or changes in habits/lifestyles or introduction/reduction of pollution sources throughout life. Certain populations definable by cultural patterns, socioeconomic status, or race may, on the other hand, have lifetime or nearly lifetime exposures because they stay in one locale. Studies of effects of chronic exposure give information that is more relevant to stable than to mobile parts of the population. Most of the health effects studies from which we draw our information on toxic materials are studies of effects of chronic exposure.

The ability to extrapolate from tested species to untested ones must be improved. This improvement in extrapolation requires information on the physiological and biochemical similarities and differences between species in the context of the underlying toxicokinetic and dynamic processes. This knowledge coupled with the development of PB-TK and biologically-based dose-response models will assist in predicting dose-to-target organs and the resultant effects when empirical data are not available. Federally funded research over the past several decades has demonstrated that the only realistic option for information needs is to refine advanced animal extrapolation models which permit a minimum toxicological data set to predict effects for many other species. Developing species-to-species extrapolation methods for fish, wildlife, and birds is not only more cost-effective than expanding animal testing programs, this strategic approach is the only one to protect endangered species which cannot be tested.

For ecological assessment, the effects of chemicals on survival, growth, reproduction, and development of organisms can be an important component in protecting sustainable populations of aquatic life and wildlife. The development of tools that predict population dynamics in the face of natural forcing functions (e.g., temperature, rainfall, light intensity), chemical stressors, physical modifications, and biological interactions is needed to integrate the vast array of information that is becoming available.

There is very little information available on the variation in susceptibility to chemicals within the human species or among other species and taxa. Improved understanding of the variation in response to toxic materials would reduce the uncertainty of risk estimation and allow for a better evaluation of the "conservativeness" of existing approaches. Knowledge of mechanisms of action of toxic materials at the subcellular level would shed much light on these differences in response.

The assessment of chemical impacts in natural systems typically involves complex mixtures. Although advances have been made in developing a mechanistically-sound basis to interpret and predict acute toxicity, there are very limited data and techniques available for addressing the chronic effects of mixtures. Mixtures of persistent bioaccumulative chemicals are of particular concern. A strategic choice is to focus on the effects of reactive chemicals and persistent bioaccumulative chemicals thought to have receptor-based mechanisms of action. These have the potential for great hazard as well as great uncertainty in current predictive power. Some sections of the country may experience unusually high concentrations of toxic materials due to factors such as proximity to hazardous waste and Superfund sites, industrial pollutants, and landfills. As a consequence the communities in these areas may bear greater risk of health effects from cumulative exposures to multiple chemical stressors. These disproportionately affected communities should be targeted for priority risk management to reduce risk of their exposures.

The strategic research needed includes the following:

- Improved understanding of the biological basis for toxicity and development of biologically-based methods for extrapolating effects between species;

- Improved knowledge of the range and distribution of individual and interspecies variability in susceptibility to toxic materials;

- Effects of short-term exposures to toxic materials at different chronological ages of life;

- Increased data base on the non-cancer effects of toxic materials;

- Better understanding of the toxicokinetic and metabolic differences between species;

- Develop data base of relevant physiological and biochemical characteristics of organisms for extrapolation of effects;

- Develop predictive models of population dynamics for selected ecological or societal species of interest;

- The effects of dermal exposures on cancer and non-cancer endpoints; and

- Improve the understanding of the effects of complex mixtures given other environmental stressors in a disproportionately affected population.

4.2.2. Exposure Assessment

The same basic scientific principles generally apply in assessing human and ecological exposure to environmental contaminants. Both types of assessments must consider the activity patterns of the organism of concern and the different ways that contact can occur with contaminants. Both types of assessments are also aimed at evaluating various indicators of impact. Most human assessments focus on endpoints, such as body burdens or health effects. Ecological assessments can also look at health effects in animals or alternative indicators of ecological impact, such as species diversity or population trends.

The following discussion analyzes the knowledge gaps in the exposure area and proposes areas of research to address them in the future. The overall goal of this research is to generate the basic information that risk managers need to identify and analyze opportunities for reducing exposure to environmental contaminants and associated risks. A dual track strategy is proposed to develop the needed exposure related information:

- One approach is to focus on sources of environmental contaminants and work prospectively along the pathways of transport and dispersal.

- The second approach is to start with human body burdens (or other direct measures of exposure) or analogous ecological endpoints and work retrospectively through the process of bioaccumulation and uptake.

At some point these two lines of inquiry should meet to give us a much more complete understanding of the process and properties of exposure. The key elements of these two tracks are presented in the table below.

Dual Track Strategy for Exposure Assessment Research

Prospective Approach	Retrospective Approach
Gather data on release rates of contaminants from sources.	Gather data on levels of contaminants in humans/wildlife and data on indicators of ecological hazard such as species diversity, population trends, etc.
Gather data on levels of contaminants in media potentially impacted by sources.	Gather data on the levels of contaminants in media contacting humans or animals.
Develop fate models to predict media levels based on source releases.	Gather data on rates which receptors contact environmental media and develop models to predict uptake in organisms from food, air, etc.
Use media data to validate and improve fate models.	Use media data to validate and improve uptake models.
Extend models to cover bioaccumulation through the food chain and attempt source-to-receptor validation. Design exposure sampling methodologies for integrating small concentrated subpopulations and small diffuse subpopulations in health data collection research	Link uptake models to food chain models and attempt source-to-receptor validation. Evaluate geographic trends in data on body burdens and sources to see if links can be made. Focus health effects research resources on communities disproportionately affected by environmental pollution.

The "prospective track" would include the following efforts:

- More data are needed on contaminant release rates from sources and contaminant levels in the environment media impacted by sources. These data can be used to identify geographic and temporal trends. Geographic trends can be useful for identifying sources and mechanisms of impact. Temporal trends can be used to help evaluate effectiveness of regulatory programs;

- Understanding abiotic processes that control the transport, persistence, and bioavailability of chemicals in soils, natural waters, and sediments;

- Understanding bioaccumulation and metabolic processes that control biodegradability of chemicals in microbial populations in soils, natural waters, and sediments;

- Validation work is needed to test the effectiveness of existing fate models and guide further development efforts; and

- Understanding the health outcome of exposures to complex mixtures by poor and disadvantaged populations.

The "retrospective track" would include the following efforts:

- More diagnostic methods and biomarkers for defining the route of exposure and exposure history. This would include surveys of contaminant levels in tissues and other direct measures of exposure;

- More data are needed on human activity patterns to help develop distributions of exposure factors, such as food ingestion rates, time spent in various settings, etc.;

- Better procedures are needed for assessing dermal exposure, especially to contaminants in soil. Experimental protocols need to be developed and validated to determine dermal absorption properties of chemicals in various matrices and for various races;

- Better procedures are needed to assess complex exposure scenarios involving multiple sources/chemicals and multiple pathways of exposure and populations of varying class, race, and ethnicity. This would include developing procedures using biomarkers and other direct measurement techniques for assessing exposure. Direct measurement techniques include use of various types of monitors, such as personal air samplers, to measure individual exposure as it occurs. These approaches are well suited to assessing complex exposures involving intricate behavior patterns and spatially variable contaminant levels; and

- Investigative methods to collect exposure data from minorities, socioeconomically disadvantaged populations, or other diproportionately affected groups (e.g. such as subsistence fishermen, children, women, and elderly). Investigations should also be sensitive to the need for community involvement at all stages of research.

4.2.3. Risk Characterization

In order to make risk characterization the effective tool that it needs to be, immediate attention needs to be paid to the research necessary to develop the science:

- Methodological research is needed on how hazard, dose-response, and exposure can be integrated in more complex cases (ecological assessments, mixtures, cumulative exposures, etc.);

- Methods for both the qualitative and quantitative aspects of uncertainty analysis must be specifically applied to risk assessment, and the resulting methodology made a routine part of risk characterization;

- A specific effort is needed to improve the way risk assessment is communicated to the public and the risk manager, including development of statistical and communications tools; and

- Research is necessary to know how to include cultural and behavioral aspects in research design. For example:

  (1) How do different cultural values affect models of risk analysis?

  (2) What are the implications for research findings owing to the measures used to quantify study results?

  (3) What types of exposure analyses and dose-response mechanisms would be of interest to different communities?

5.0 TOXIC SUBSTANCES AND WASTE RISK MANAGEMENT

Conceptual Framework

To reduce risks from toxic materials to humans and ecological systems we must either reduce exposure or reduce the level of toxicity. For many years the primary emphasis was placed on reducing exposure by "end-of-pipe" control, by storing or "disposing" of wastes through burying in landfills, placement in abandoned salt mines, injection into deep wells below the potable water table, or like methods. Leaving toxic contamination in place and restricting access or limiting possible future land uses is another approach that has been used in the past. Many of these methods are not viewed as effective in the long-term and are often seen as simply shifting exposure to future generations.

Much of the emphasis of the last several years has shifted to methods to prevent production of toxic materials and treatment methods that reduce mobility of toxic contaminants (and consequently exposure) or that permanently reduce levels of toxicity. In waste management and remediation, this has been a requirement of laws such as the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund) and the Resource Conservation and Recovery Act (RCRA). The primary focus of future R&D, as described in this strategy, is to provide technology and methods to minimize the further production of toxic materials and to treat and remediate already existing toxic materials through innovative technologies that provide greater permanent risk reduction at lower cost.

Policies and approaches for managing toxic materials in the environment require linking of technology options with risk assessments to ensure appropriate levels of risk reduction. A hierarchy of technology approaches should be considered that starts with prevention and includes control, remediation, and monitoring.

(1) *Pollution Prevention*. Pollution prevention is the preferred approach for managing risks from toxic materials. Generally, it achieves the greatest levels of reduction for both exposure and toxicity. Prevention can include use of less toxic inputs, use of less energy or raw materials, or use of more efficient, cleaner processes or better product design. Increased prevention will ultimately reduce needs for managing wastes and cleaning up contaminated sites.

(2) *Control*. End-of-pipe or end-of-stack control technologies have become the mainstay of pollution control over the last 20-30 years as federal laws and regulations have specified acceptable emission levels based on use of "best available control technology." This regulatory "lock-in" of existing technology has had a chilling effect on development and use of more innovative technologies that could achieve an equal or greater reduction in risk for less cost. In addition, many conventional control technologies have not permanently reduced toxicity, but have often shifted toxic materials from one media to another.

Over time, pollution prevention will reduce the need for end-of-pipe controls, so that research in this area should decline in the long-term in favor of prevention R&D. This must be phased, however, because existing and new regulatory requirements still rely heavily on these control technologies. New innovative technologies and practices are needed over the next several years to lower compliance costs and improve risk reduction associated with pollution control. (In addition, more flexible regulatory approaches must be put in place to encourage use of these innovative methods.)

(3) *Remediation*. The mismanagement of toxic materials in the past has left a legacy of contaminated soils, sediments, and groundwater. Consequently, while this strategy emphasizes a shift in emphasis in the long term to prevention R&D, increased emphasis must be placed for the next several years on demonstrating and evaluating innovative technologies related to controlling and removing the risks from these past problems.

The current and projected costs to remediate the vast number of contaminated sites in the U.S. are enormous. These costs, as well as the risk these sites pose to human health and the environment, can be reduced through deployment of innovative technologies that will provide more cost-effective identification, prioritization, monitoring, and cleanup.

(4) *Monitoring*. Monitoring of toxic materials in hazardous and toxic waste in all media is essential for both assessing and managing risk. Without cost-effective technologies it is not possible to either initiate the most appropriate remediation activity or determine whether real decreases in risk are being achieved by either control or pollution prevention approaches. Effective monitoring used as a benchmark for residual risk reduction is essential across all categories in the waste management strategy. In addition, more effective monitoring is key to moving from technology-based to performance-based controls.

Continuous monitors, remote sensors, and various markers can verify actual performance and provide incentives for more efficient controls.

In addition, some communities and sections of the country may experience unusually high concentrations of toxic materials due to factors such as proximity to hazardous waste sites and industrial emissions to the environment. As a consequence these communities may be at greater risk of health effects from cumulative exposures to multiple chemical stressors. These disproportionately affected communities should be identified and considered for priority risk management to reduce the risk of exposures. Development of innovative monitoring technologies will provide the edge needed in identifying disproportionately affected areas and in realizing more cost-effective cleanup, compliance, and pollution prevention.

Global population growth and economic development present major new challenges to our ability to manage solid, hazardous, and toxic wastes and maintain and improve the quality of the environment and protection of human health. Current projections are that by the year 2050, world population will roughly double, and world economic output will increase five-fold. This will lead to production and consumption patterns that can greatly increase both the quantities of wastes and the levels of toxic materials released to the environment.

This expected growth also poses economic and social challenges. The costs of conventional pollution control divert financial resources from more economically productive uses. Consequently, it is essential that we:

- Base management of wastes and toxic materials on high quality risk assessments, and set priorities based on risk; and
- Greatly improve the effectiveness and efficiencies of this management through emphasis on the development and use of innovative, cost-effective technologies to prevent, control, remediate, and monitor toxic materials in the environment.

The strategy for risk management R&D focuses upon the scientific and technological developments to directly address and achieve the goal of "sustainable development" and to indirectly provide support to the goal of "environmental justice." Sustainable development has been defined as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs." The term is also commonly understood to refer to simultaneous achievement of a clean environment and economic growth. Environmental justice means that the risks associated with toxic materials and wastes should be managed equitably across all sectors of society.

5.1. CURRENT STATE OF UNDERSTANDING

5.1.1. Pollution Prevention

Pollution prevention research is still relatively young in relation to other environmental technology areas. Research to date has generally focused on 3 areas: (1) tools and methods for analyzing prevention alternatives: (2) cleaner technologies and processes (including identification of less toxic inputs): and (3) information dissemination.

Tools range from practical guides for conducting assessments to sophisticated computer models for process design and toxic materials substitution. Life cycle assessment is perhaps the most fundamental tool. Further research is needed to complete development and refine all of these tools.

Designing cleaner technologies and processes is at the heart of research needs in pollution prevention. Examples of this research include development of new (cleaner) synthesis pathways for chemicals (such as photochemical or biochemical conversion), identification of less toxic substitutes for organic solvents, developing less polluting production technologies (such as non-chlorine bleaching of wood pulp, and painting and coating technique with reduced emissions of volatile organic compounds), and developing and demonstrating environmentally safe maintenance procedures (such as cleaning and degreasing). To date several individual technologies or unit operations have been developed, but comprehensive, manufacturing base-focused R&D is only beginning.

Information dissemination is a critical adjunct to R&D to bring about commercial application. Therefore, it must be included in the national research agenda. Much as been done, but more innovative and effective approaches are needed especially in communities with high illiteracy rates or where English is a secondary language. They range from establishing better integrated networks of technical assistance providers to utilizing electronic data transfer more effectively. The public in communities disproportionately affected by environmental pollution should be able to call on the local government and other institutions to access and promote pollution prevention information to polluting sources.

5.1.2. Control Research

Although a wide range of control technologies exist, many are not cost-effective, and may not reduce risks adequately. For example, current drinking water treatment depends heavily on chlorination and filtration to remove contaminants. Chlorination produces disinfection by-products that are themselves toxic. Furthermore, drinking water distribution systems can release toxic metals if proper pH controls are not maintained. Conventional treatment technologies for air emission and wastewater often shift and concentrate pollutants from one media to another with little toxicity reduction.

Development of the technology for containment and removal of spilled oils has been supported by the government and private industry for a number of years. Recently, as a result of the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund) and the Oil Pollution Act of 1990, it has become increasingly important to develop suitable control methods for hazardous and toxic material spills.

A need for innovation across all media to improve control for toxic materials is a certainty. This need is further driven by new regulatory requirements that are evolving. Suggested research priorities reflect areas believed to offer the greatest potential for further risk reduction.

5.1.3. Remediation and Restoration

Risks to humans from toxic materials in contaminated sites derive from contaminated groundwater and airborne particulates and from direct or indirect exposure to contaminated soils. For may sites, radioactivity and explosion or fire are also major risks. Most of these sites also release toxic materials to various ecosystems through direct contact, leaching, or runoff.

Groundwater contamination at these sites has been the most difficult technical issue and represents a large part of cleanup costs. Groundwater contamination is perceived by the public as a major health issue and may present high risks at specific sites. It is also of concern because it degrades a natural resource and reduces its future uses.

A recent NAS study found that groundwater cleanup is both expensive (estimates of up to $1 trillion over the next 30 years) and that existing technologies are generally not capable of effectively addressing the problem. (Dense non-aqueous phase liquids (DNAPLs), for example, are not readily removed by existing treatment methods.) The study recommended a major national R&D effort to develop more cost-effective groundwater cleanup technologies.

Another problem associated with many sites where a cost-effective technical solution is not within reach is mixed radioactive and chemical wastes. Many contaminated federal sites cannot be effectively remediated until technologies are developed and demonstrated to address this problem. A federal R&D focus is particularly important because of the uniqueness of managing mixed radioactive and chemical wastes for federal sites.

One of the principal ways to reduce both costs and risks during remediation is to treat contaminated soils in place (in-situ) without excavation. Methods for in-situ treatment are a major focus of current R&D efforts and should remain a priority into the future. In recent years, advances have been made in technologies such as bioremediation and soil vapor extraction, but further development of these and other technologies is needed.

The demonstration and evaluation of these innovative technologies is an essential step in the development process. Implementation of technologies to the field, with regulatory acceptance, can only be accomplished through this manner. The thrust of federal R&D, then, is to transition technology from the laboratory to the field, where cost savings can be realized.

5.1.4. Monitoring

Great advances have been made in the last decade in the science and technology associated with monitoring. New approaches for chemical, biological, and physical sensing have been developed. These new technologies must be exploited for environmental purposes and developed into practical cost-effective tools for managing toxic and hazardous waste if we are to achieve our goals.

These technologies include the design, development, and operation of monitoring instrumentation with associated quality assurance aspects. Monitoring systems encompass microsensors, chemical sensors, biosensors, ground-based mobile platforms for sensors, sampling services, automated systems for tracking pollutant levels, and advanced technologies for data collection and analysis, including biological and complex ecological assemblages.

For example, a significant cost in site remediation is site characterization and monitoring. Post remediation monitoring is also needed to demonstrate to regulating authorities that cleaned sites are in compliance with policies such as the Resource Conservation and Recovery Act (RCRA). Innovative methods that are non-intrusive, provide real time results, and improve detection capability need further development or field testing.

A critical site characterization issue with enormous future year costs and risks is the detection and identification of unexploded ordnance. The end of the Cold War has brought about a significant reduction in the military threat facing the United States. But an unfortunate legacy of years of military training and testing is the large number of unexploded ordnance on federal facilities. In addition, conflicts throughout the Third World have left an enormous number of mines scattered throughout the countryside, which continue to cause great harm and prevent productive use of the land. The critical step to addressing these related problems is the cost-effective detection and identification of these objects.

Development of in-process monitors are needed as part of new manufacturing and other industrial processes designed under tenets of industrial ecology. For control, continuous, low cost monitoring of waste streams is required for market-based and multi-media regulatory approaches. Legislation such as the Clean Water Act (CWA) and the Clean Air Act (CAA) are drivers behind the need to monitor hazardous chemicals in process effluents or emissions. Unique military disposal operations, resulting in hazardous emissions; release of volatile organic compounds from certain treatment processes; and hazardous air emissions and wastewater from plating and finishing processes are just a few of the areas requiring advanced or innovative monitoring technologies.

Global monitoring technologies and national monitoring programs are of interest as a means of conserving, protecting, and enhancing natural resources. Monitoring systems may be strategically established to provide information of broad international interest, such as climate change effects on a global or regional scale. Improved monitoring techniques can be used to track the concentration and impact of toxic substance releases to the environment.

5.2. RESEARCH AND DEVELOPMENT PRIORITIES

Achieving the R&D priorities set forth below will require an increase in resources. These resource investments will yield significant decreases to the much larger costs currently associated with remediation and environmental degradation caused by wastes and toxic materials. As new technologies are developed, incorporated into processes, and deployed into the field in the future, R&D expenditures may decrease somewhat until a steady state in dollars is realized. Over time, the environmental program will move from one based on remediation and control to one based on prevention, control, and monitoring.

For the public to reap the benefit of research and development in all four areas discussed below, technologies must transition from the lab into the field and be implemented and commercialized. The key to this transition is the proper demonstration and evaluation of new technologies. A priority in all four areas is thus to develop protocols for testing innovative technologies to develop scientifically credible data on cost and performance, and to use these protocols to verify performance.

5.2.1. Pollution Prevention

In order to reduce and eventually eliminate hazardous waste streams and develop proactive solutions, R&D priorities are:

- Develop and evaluate pollution prevention options that can be incorporated into federal regulations and in enforcement and compliance agreements;
- Develop and validate tools, such as life cycle analysis (LCA), and computerized process design models to incorporate pollution prevention into products and processes;
- Form partnerships with industry, academia, and government to develop a new generation of cleaner technologies and processes, focusing on specific industry sectors;
- Develop and evaluate new technologies to reduce pollution from agricultural chemicals and animals waste management with a special focus on protecting sensitive ecosystems;

- Disseminate information on pollution prevention approaches, techniques, and technologies; and
- Provide technical assistance to help small businesses evaluate prevention approaches to comply with regulations and reduce costs.

5.2.2. Control Research

R&D priorities for treatment of air, solids, wastewater and spill containment and removal include:

- Develop, demonstrate, and commercialize innovative, low cost, and low maintenance technologies for use by small communities in treating their wastewater and drinking water;
- Develop, demonstrate, and evaluate improved methods to reduce risk from disinfection by-products, lead, copper, bacteria, and viruses in drinking water;
- Develop, demonstrate and test approaches to address non-point source releases of toxic materials, including storm water runoff and combined sewer overflow;
- Develop practical and scientifically valid tools and new approaches to manage watersheds, including the impacts of sewage sludge, storm water discharges, non-point source pollution, toxic chemicals, contaminated sediments, and habitat modifications;
- Develop and demonstrate emerging control technologies for toxic air pollutants from combustion and incineration processes;
- Develop cost-effective controls for treatment of toxic wastes formed during chemical synthesis, manufacturing processes, and mineral extraction. Priority should be on high toxicity, hard-to-treat wastes;
- Develop and evaluate response technologies to mitigate the impacts of inadvertent spills or discharges and facilitate the expediency of cleanup efforts;
- Develop better methods to remediate environments impacted by oil spills or chemical releases; and
- Develop and evaluate technologies to mitigate underground leaks from pipes and tanks, including improved leak detection, and more cost-effective cleanup. The effectiveness of natural attenuation in managing petroleum plumes is also an R&D priority.

5.2.3. Remediation and Restoration

Effective cleanup of hazardous waste sites such that existing and future environmental quality objectives are met, can be realized through the following R&D priorities:

- Conduct field evaluations of technologies to obtain data on performance, cost of performance, environmental effects, and range of applicability for the remediation of radioactive wastes, mixed wastes, contaminated soils, and groundwater contaminated plumes;
- Develop a national federal test sites program to identify test sites at federal facilities and to support demonstrations and evaluations at these sites;
- Develop, demonstrate, and evaluate in-situ technologies, such as bioremediation, for remediation of contaminated soils, landfills, and subsurface plumes without excavation, transportation, or incineration;
- Develop, demonstrate, and evaluate innovative technologies for the characterization, identification, and remediation of energetic materials (including unexploded ordinances, chemical munitions, etc.);
- Develop technologies to characterize, model, monitor and remediate contaminant plumes in groundwater, particularly dense non-aqueous phase liquids (DNAPLs) such as certain chlorinated solvents;
- Develop new information management and quality assurance tools and procedures to improve the speed with which data are collected, tracked, interpreted, and reviewed at sites; and
- Coordinate development of robotics, waste separation, and characterization technologies that are applicable to high level waste, mixed wastes, landfills and contaminated soils, and groundwater contaminant plumes.

5.2.4. Monitoring

R&D priorities in the area of monitoring hazardous chemicals in process streams, emissions, and whole ecosystems are:

- Develop and demonstrate innovative field screening techniques which will allow for the rapid and cost effective assessment of contaminated sites;
- Develop innovative subsurface characterization and monitoring methods, with particular emphasis on DNAPLs in groundwater and unexploded ordnances;

- Develop tools for monitoring systems for the management of large areas affected by non-point source pollutants; and

- Develop low cost continuous monitoring systems for in-line industrial process controls, air and water streams, and the long-term monitoring of contamination sites.

6.0 SOCIAL AND ECONOMIC ASPECTS

Management of risks from toxic materials and wastes raises significant economic and social issues. The economic issues have at least two dimensions. One is that the costs of environmental compliance affect the profitability of private companies (and thus economic growth) and can also consume large amounts of public funds. The second is that the innovative technological solutions that can reduce these costs are often not developed or commercialized due to economic constraints such as lack of capital.

Although economic issues per se are not the primary focus of research under this strategy, they have important policy implications and drive the technical research priorities in certain directions. For example, economic considerations suggest that:

- pollution prevention research should be given high priority because of its link to sustainable development and importance as a strategy for promoting environmental justice;

- innovative technologies for control and remediation that can reduce risk at lower cost are essential;

- legislation, regulations, and other government policies must provide sufficient flexibility to allow innovation to occur and to allow innovative technologies to be used;

- financial support for R&D and commercialization, selectively infused, coupled with removal of other barriers to commercialization such as lack of test sites and performance verification, must be provided; and

- an effective federal program to catalyze and enhance environmental technology development can yield important gains in the position of U.S. companies in global markets.

Under these conditions, stringent environmental requirements can actually lead to enhanced competitiveness and economic strength.

Social issues also have at least two dimensions. One concerns <u>informing</u> the public and <u>involving</u> them in decisions about risk management. Meaningful involvement demands that the public have access to reliable and understandable information about sources and levels of toxic materials in their communities, their associated risks, and that they have the opportunity to participate in the decision-making process for managing these risks.

The second critical social dimension is equity. Although existing information is incomplete, it is generally accepted that involuntary risks from toxic materials and their management are not shared equally by all socioeconomic sectors in our society. For example, while the federal government is aware that dietary risk from pesticides varies across different income, ethnic, and age groups, present survey results cannot provide disaggregated dietary intake estimates for these groups from different commodities. Similarly, there is insufficient information correlating exposure from waste management with different socioeconomic groups. Examples such as these strongly indicate that significant new studies and surveys are needed to effectively carry out a national policy of "environmental justice."

Research Priorities

- Identify and pilot economic incentives to encourage private sector development and commercialization of innovative risk management technologies;
- Develop analytic tools for integrating environmental and economic decisions;
- Develop new approaches and tools to provide the public with quality data in a form that allows them to evaluate the role of toxic materials in their community and to participate in the decision-making process;
- Develop techniques to identify and survey "high end" behavior which impacts exposure levels across different socioeconomic groups, e.g., dietary consumption patterns for high pesticide residue commodities;
- Establish a standard, tiered evaluative process for screening jurisdictions for disproportionately adverse health effects from environmental contaminants, including baseline health evaluations for comparing exposure levels in the general population with those in subpopulations (e.g. biologically susceptible, socioeconomic subgroups of interest);
- Advance research at minority colleges and universities with expertise in environmental justice issues;
- Evaluate the peer review process for racial and cultural insensitivity, and include community review for projects conducted in communities;
- Identify factors to encourage community participation, and develop public participation models for conducting exposure and health effects studies (also for waste management facility siting);

- Examine geographic/racial distribution and disparities of inspection and enforcement rates and evaluate factors in attitudes and criteria that could lead to disparities;

- Evaluate the impact of market-based pollution controls on minority and socioeconomically disadvantaged populations;

- Evaluate state, tribal, and local government environmental justice initiatives and characterize conditions leading to their success or failure;

- Evaluate how cultural values and health conditions associated with race, class, and ethnicity, affect risk assessment processes and risk management decisions; and

- Develop and evaluate economic models to be used for cost/benefit analyses, including contingent valuation and life cycle methods, and non-cancer health and ecological effect valuation.

7.0 EXTERNAL INPUT

The following policy direction to federal agencies addresses external input and participation in developing and implementing the national environmental technology strategy. The guidance addresses industrial and stakeholder participation and is as follows:

- Leverage federal resources by increasing cost-shared partnerships with the private sector, states, and federal agencies for development and testing of innovative environmental technologies. Make access to federal facilities easier for federal, state, local agencies, and the private sector;

- Accelerate national use of innovative environmental technologies for cleanup of federal and state sites. Work across federal agencies to address institutional and regulatory barriers that inhibit public-private partnerships. Provide technical assistance for implementation of innovative environmental technologies. Increase the number of improved technologies/systems (bench, pilot, or full-scale) demonstrated that address major environmental problem areas; and

- Strengthen partnerships with stakeholders. Improve decision-making process so it is open and accessible, results in decisions that are technically and economically feasible, environmentally sound, health and safety conscious, addresses public values and concerns, and can be implemented. Increase stakeholder participation in decision-making process.

8.0 INTERNATIONAL DIMENSION

The following policy direction to federal agencies addresses the international dimension for innovative waste management technology and fully supports the Environmental

Technologies Exports: Strategy for U.S. Leadership, (Trade and Promotion Coordinating Committee, November 1993). The guidance is:

> The U.S. must lead in world environmental stewardship and in advancing the goal of sustainable development. Environmental technologies are central to achieving these goals. U.S. governmental export promotion will foster partnerships with U.S.-based private sector firms to expand opportunities and will improve financing mechanisms for exporters. U.S. firms should take full advantage of exploding world environmental remediation markets and assist in developing sustainable economies of the future.

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