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

January 16, 1987

Honorable Lee M. Thomas
Administrator
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

SAB-EC-87-17

OFFICE OF
THE ADMINISTRATOR

Dear Mr. Thomas:

The Science Advisory Board's Ecological Risk Assessment Research Review Subcommittee has completed its review of the Office of Research and Development's ecological risk assessment program and is pleased to forward its final report to you. This review is part of a series of SAB research program reviews that are intended to provide independent scientific advice on the objectives, relevance and quality of ongoing research, as well as an evaluation of the future needs and direction of individual programs.

The Subcommittee's major conclusion is that the overall concept of ecological risk assessment developed in this program is comprehensive and scientifically ambitious. It sets forth a research direction for the long-term (perhaps twenty years). In the short-term (five years), it is not achievable as planned, particularly because some of the key elements (density-dependent population, community and ecosystem mechanistic models) are based on an incomplete understanding of the fundamental mechanisms. However, the research staff have made a promising start in identifying some of the major issues this program should address. This, combined with some fine-tuning in the research plan, can produce both an innovative research program and one that can deliver shorter-term research products.

The Subcommittee enjoyed the complete cooperation of ORD staff and especially wishes to acknowledge the assistance of Dr. Rose Marie Russo, Director, Athens Research Laboratory. It wishes to express its appreciation of the opportunity to review this particular program and requests that EPA formally respond to the scientific advice contained in its report.

Sincerely,

G. Bruce Wiersma, Chairman
Ecological Risk Assessment
Research Review Subcommittee
Science Advisory Board

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

# REVIEW OF EPA'S ECOLOGICAL RISK ASSESSMENT RESEARCH PROGRAM

ECOLOGICAL RISK ASSESSMENT RESEARCH REVIEW SUBCOMMITTEE

SCIENCE ADVISORY BOARD

U. S. ENVIRONMENTAL PROTECTION AGENCY

January, 1987

# EPA NOTICE

U. S. ENVIRONMENTAL PROTECTION AGENCY

SCIENCE ADVISORY BOARD

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TABLE OF CONTENTS

Page

# I. Executive Summary

In general, the Subcommittee is impressed with the degree of progress made by the Agency in developing this research program in the past two years. This is particularly true of the ambitious conceptualization of many of the individual research projects, the talent and commitment of the scientific staff, and the degree of communication and cooperation achieved among the four ecological research laboratories involved in the program.

The primary goal of EPA's ecological risk assessment research program is to formalize and systematize scientific knowledge of the ecological risks of exposure in a way that will facilitate its use in the regulatory process. To meet this goal the program proposes the use of independent mathematical models, which are imbedded in a computer-based decision support system intended to provide flexible access to the array of tools and techniques that constitute the products of the research program.

The Subcommittee supports the research team's adoption of this overall goal and this general approach. In particular, the use of a modeling framework should help to guide the research effort as it progresses, while the modeling approach can provide a mechanism for incorporating the most current scientific knowledge in the regulatory decision making process. The research plan should place strong emphasis on the continuing need for improving the scientific basis upon which modeling efforts are based.

The overall concept is comprehensive and scientifically ambitious. It sets forth a research direction for the long-term (perhaps twenty years). In the short-term (five years), it is not achievable as planned, particularly because some of the key elements (density-dependent population, community and ecosystem mechanistic models) are based on an incomplete understanding of the fundamental mechanisms. However, the research staff have made a promising start in identifying some of the major issues this program should address. This, combined with some fine-tuning in the research plan, can produce both an innovative research program and one that can deliver shorter-term research products.

The Subcommittee's conclusions and recommendations on the major components of the research program include the following:

- Decision Support Systems

Decision Support Systems (DSS) constitute an important product generated by the ecological risk assessment program. There is, however, an underlying implicit emphasis (which is at times explicit) on computer programming, computational algorithms, and decision support systems. It is imperative that such decision support systems have a sound scientific foundation. Since resources for this program are limited, the Subcommittee recommends that EPA concentrate its research efforts of the development of the scientific bases for the decision support systems. The Subcommittee believes the use of the DSS should not occur at the expense of developing stronger scientific inputs.

- Environmental Transport and Fate

A necessary foundation for any assessment of environmental effects is reliable information on such questions as the nature of the sources of the toxic chemicals, amounts released, and temporal and spatial variability within and between the receiving media.

More emphasis should be placed on pollutant source characterization scenarios. Scenarios should include both steady state and single episode situations.

It is not always clear in the various projects whether the exposure conditions treat either or both of chronic or episodic exposures. The research plan should address both exposure scenarios.

- Terrestrial Ecotoxicology

The program as currently described insufficiently addresses ecosystem level models and experimental approaches, the food chain pathway and spatial heterogeneity. Ecological risk assessment deals with consequences at the levels of population, community and ecosystem. Ecosystem science has made enormous strides in the last five to ten years, and there are many operational models directly applicable to contemporary problems. These models represent a refinement of large models that have been streamlined on the basis of experience both in modeling and in the field. The research plan needs to better exploit the existing strengths of ecosystem models for ecological risk assessment. In fact, many of the extant ecosystem models are likely to be as useful, or more useful, than models at the other two levels of integration. The program staff should aggressively solicit advice from individuals and research programs in this country and around the world that can provide assistance with ecosystem level models and experimental procedures.

In addition to the development and application of the ecosystem models, validation of those models is essential.

- Aquatic Ecotoxicology

The projects on aquatic exotoxicology are well conceived and should produce valuable scientific results. The formulation and testing of models of toxicant uptake, clearance, deposition and metabolism in various tissues of aquatic organisms, as distinct from viewing the organism as a single compartment, is encouraged because these mechanistic approaches permit more confident extrapolation. The quality of scientific information and inference obtained from such models has been invaluable in other areas, such as human and other mammalian pharmacokinetics.

The Subcommittee is concerned, however, that the research plan does not exibit the necessary awareness of the considerable literature on pharmacokinetic models in other animals which EPA can draw upon to facilitate the rapid development of reliable toxicokinetic models.

The research on community and ecosystem effects is less clearly defined and developed than work on individuals and populations, but is no less important. It is imperative that state-of-the-art methods be used via consultation with appropriate experts. The Subcommittee doubts that models developed from this work during the next five years will provide predictive capability, but development of these models should result in greater understanding of ecosystem level effects and point to areas where further understanding is needed. The same set of observations can be applied to terrestrial ecotoxicology.

## II. Subcommittee Charge and Review Process

### A. Objectives and Charge of the Subcommittee's Review

At the request of the Deputy Administrator and the Assistant Administrator for the Office of Research and Development (ORD) the Science Advisory Board (SAB) Executive Committee agreed to carry out a scientific review of the Environmental Protection Agency's (EPA's) Ecological Risk Assessment Research Program. The Committee authorized the creation of the Ecological Risk Assessment Research Review Subcommittee to conduct the review. This action by the Executive Committee is part of a continuing series of SAB research program reviews that is intended to provide independent scientific advice on the objectives, relevance and quality of ongoing research, and to identify any needed modifications to the content and direction of individual research programs. This specific program review was requested by senior EPA managers because of their desire to obtain an expert evaluation of the capacity of this program to support the Agency's regulatory information needs and also because of the need to determine whether to modify what is still a very young program.

The SAB's Ecological Risk Assessment Research Review Subcommittee addressed four major issues in its review. These included:

- Assessment of the scientific adequacy of the conceptual design of the research program, and the internal EPA expectations for what programmatic and regulatory needs this program can fulfill.

- Evaluation of specific objectives of the research program in the areas of decision support systems for environmental risk assessment, environmental transport and fate, terrestrial ecotoxicology and aquatic ecotoxicology.

- Discussion of cross-cutting scientific issues and recommendations for future changes in the research program.

- Comments and recommendations regarding administration and management of the program.

B. Subcommittee Review Procedures

The Subcommittee met in public session on August 7-8, 1986 in Athens, Georgia at the University of Georgia's Center for Continuing Education and ORD's Environmental Research Laboratory, respectively. Notice of the meeting was published in the Federal Register on July 22, 1986 Volume 51, #40, page 26303.

The specific focus of the Subcommittee's meeting was the review of the "Research Plan for Ecological Risk Assessment," a document prepared by ORD's Environmental Research Laboratories in Athens, Ga., Corvallis, Ore., Duluth, Minn., and Gulf Breeze, Fla. Supplemental documents were provided to the Subcommittee at its meeting, in addition to oral presentations. Review and discussion of these materials furnished the basis of the Subcommittee's report. Members of the Subcommittee had the opportunity to question ORD scientific staff and research managers, and staff of the Office of Pesticides and Toxics Substances, as well as offer their own individual and collective views of the needs and strengths and weaknesses of the research program. The Subcommittee prepared its preliminary draft report on August 8, and revised subsequent drafts by mail. The Subcommittee's report was submitted to and approved by the SAB Executive Committee on January 15, 1987.

The Subcommittee enjoyed the full cooperation and support of EPA staff during the course of its review and wishes to express particular appreciation to Dr. Rose Marie Russo, Director, Environmental Research Laboratory at Athens, for her assistance in coordinating the Agency's preparation for this SAB review.

III. General Observations

In comparison with many EPA research programs, the origin of the ecological risk assessment program is very recent. Since its formation in 1985 both its scientific and administrative design have become more sophisticated. As with any new research program, some further modification in scientific direction and management are needed in order to ensure scientific success and to justify continuing budgetary support. The Subcommittee identifies and discusses such changes and formulates recommendations on these and other issues throughout the body of this report.

In general, the Subcommittee is impressed with the degree of progress made by the Agency in developing this research program in the past two years. This is particularly true of the ambitious conceptualization of many of the individual research projects, the talent and commitment of the scientific staff, and the degree of communication and cooperation achieved among the four ecological research laboratories involved in the program. The Subcommittee appreciates the challenges of achieving integration in laboratory activities, and cooperatively working toward common scientific objectives among both technical staff and research managers (including laboratory directors) and is very encouraged by the success demonstrated by the program to date. Similarly, the principal client office for the research provided through this program, the Office of Pesticides and Toxic Substances, has clearly stated its need and desire to provide continuing support for this research program.

In September 1985, the Environmental Research Laboratory at Athens convened a peer review to conduct an analysis of the Ecological Risk Assessment Program. That review was headed by Dennis Konasewich, and had as members Dr. Lev Ginsberg, State University of New York at Stony Brook; Dr. Harvey Gold, North Carolina State University; Dr. Alician Quinlan, Duke University; Dr. Curtis Richardson, Duke University; Dr. Thomas Yuill, University of Wisconsin, Madison; and Dr. G. Bruce Wiersma, Idaho National Engineering Laboratory.

The current Subcommittee and the ERL-Athens panel made overlapping comments in ten separate areas. These include:

- The program suffers from communication gaps between various researchers and tends to have a parochial outlook.
- Outside of the cooperation between the ecological research labs, there is a lack of integration and cooperation with other EPA laboratories such as air monitoring and health effects.
- There was a lack of integration of data base systems among the laboratories for support of the model development.
- There is the impression that the ecological modeling presented does not represent the state-of-the-art, particularly at the ecosystems level.
- There should be an effort to expand the end user of the product beyond the Office of Pesticides and Toxic Substances.
- The need for the integration and use of existing monitoring data bases in the ecological risk assessment program was pointed out.
- There is a need for a sound statistical basis in the program's design.
- Concern was raised that the funding level was inadequate.
- The time frame planned for the program is too short.
- The chemicals tested in the program should be consistent among the laboratories.

The planners and managers of EPA's ecological risk assessment program should play particular attention to these ten common points of criticism and comment from the two peer reviews.

## IV. Conceptual Design of the Research Program

### A. Objectives

The EPA's ecological risk assessment research plan presents the primary research goal as follows (page iv): "to formalize and systematize scientific knowledge of the ecological risks of exposure in a way that will facilitate its use in the regulatory process." To meet this goal the approach proposes the use of independent mathematical models, which are imbedded in a computer-based decision support system intended to provide flexible access to the array of tools and techniques that constitute the products of the research program.

The Subcommittee commends the research team for adopting this overall goal and general approach. In particular, the use of a modeling framework should help to guide the research effort as it progresses, while the modeling approach can provide a mechanism for incorporating the most current scientific knowledge in the regulatory decision making process. It is possible that, in a subject area as complex as ecological risk assessment, this framework may be the only effective mechanism over the longterm by which new scientific efforts contribute to the decision making process.

The overall concept is comprehensive and scientifically ambitious. It sets forth a research direction for the long-term (perhaps twenty years). In the short-term (five years) it is not achievable as planned, particularly because some of the key elements (density-dependent population, community and ecosystem mechanistic models) are based on incomplete understanding of the fundamental mechanisms. The result will be a theoretical construct that will:

- Advance understanding of population, community and ecosystem processes and the science of population, community and ecosystem modeling.
- Prove very controversial and subject to considerable disagreement and scientific debate.
- Be extensively challenged and tested for its utility in day-to-day decision making within the regulatory community.

### B. Integration

For the most part, the overall research plan is sufficiently integrated and the mechanistic modeling approach should be retained as the integrating mechanism. However, it is unreasonable to expect an immediate development of mechanistic models for use by the Office of Pesticides and Toxic Substances. Consequently, the research team should make every effort to integrate intermediate research goals that will provide research products that are more usable for Agency decision making over the short-term.

### C. Alternatives

The Subcommittee has identified several alternative approaches to the research plan. These include:

- Retain the mechanistic model as a guide for research and as a long-term (twenty year) goal for development of decision making tools.
- Adopt empirical models, where necessary, as the short-term product (within the next several years).
- Implement experimental pond/field plot studies to obtain data for both empirical and (in the long-term) mechanistic models, as well as to provide guidance to OPTS on acceptable pond/plot study designs for measuring population, community and ecosystem effects.
- Conduct field monitoring and research studies to obtain data to parameterize both empirical and mechanistic models, to validate models, and to provide guidance to OPTS on acceptable field study designs for measuring population, community and ecosystem effects.

In addition to considering such alternatives, the Agency should also sponsor Gordon Conference style efforts to debate the alternative approaches, e.g., mechanistic modeling of density dependent and ecosystem processes versus field studies and empirical models.

V. Specific Objectives

A. Decision Support Systems (DSS)

Decision support systems constitute an important product generated by the ecological risk assessment program. There is, however, an underlying implicit emphasis (which is at times explicit) on computer programming, computational algorithms, and decision support systems. The Foreword to the research plan states that "One of the strengths of the Decision Support System that is the ultimate product of this research is its plasticity: the process of ecological risk assessment can be redefined by the analyst using the system, in accord with the unique requirements of the regulatory problem at hand."

It is imperative that such a decision support system have a sound scientific foundation. The Agency needs to clarify whether emphasizing the DSS as the ultimate product necessarily implies de-emphasizing the imperative importance of the scientific basis of the DSS (the model, the dose-response functions, the input-output relationships, and the data base). The Subcommittee believes that use of the DSS should not occur at the expense of developing stronger scientific inputs. However, the research plan Forward states that one of the major characteristics of the models generated in every research project conducted under this program is "the generation of computational algorithms that will be encoded in computer programs in addition to the generation of mathematical formulations." This characteristic reinforces the concern about the centrality of the computer programming part of the DSS at the expense of developing scientific data. Furthermore, the encoding of mathematical models in computer programs connotes (or leads to the expectation of) a final product that can be readily used in the risk assessment process.

The quality and credibility of a DSS, and its usefulness, are provided by scientific data that can yield insights into transport and fate processes, dose-response functions and causality within the ecosystem. The software, computer programming and graphics enhance the technological capability for an effective DSS, but they never provide a sufficient condition for a scientifically credible DSS. The development of an effective DSS must be undertaken with the involvment of many parties -- cross-disciplinary researchers, computer programmers, and the ultimate users (where their input and guidance are imperative). In short, the DSS is merely a vehicle for the delivery of knowledge. If the knowledge is erroneous or lacks credibility, the vehicle serves no scientifically useful purpose.

The computerized environmental risk assessment system (CERAS) envisioned by the program managers seems ambitious, and its credibility is questionable without further clarifications and qualifications. The desire to develop a generic computerized environmental risk assessment system that is general for all assessments, applicable for different time and space scales (e.g., for a single river or region) for different biological scales and for different release scenarios, is legitimate. Whether such a system can be developed during the first five-year phase of this program is doubtful. The risk assessment component of CERAS calls for studying the randomness and the probabilistic nature of the forces that drive the ecosystem out of its natural balance. CERAS and other DSSs must ultimately incorporate the statistical outlyers in the overall model structure. More will be said on the probabilistic component of DSSs in subsequent sections of this report.

In the context of the goals and objectives of the ecological risk assessment program, one can identify several categories of users of the envisioned DSSs (developed within the program). These include:

- Scientists ---- who can contribute to and obtain understanding from the ecosystem dynamics through the interactive mode and nature of the DSS.
- Regulatory Analysts ---- who require answers on the risks, costs and benefits of the regulation of chemicals and other toxic materials released into the environment and the ecosystem.
- Policy makers - who evaluate policy options and the ecological consequences of these options.

B. Environmental Transport and Fate

A necessary foundation for any assessment of environmental effects is reliable information on such questions as the nature of the sources of the toxic chemicals, amounts released, and temporal and spatial variability within and between the receiving media. In some cases, such as pesticide applications, there is some degree of predictability of the nature of the release event. In other cases, such as accidential spills, there are infrequent pulses of toxicants, the intensity of which can only be estimated within broad limits. Chronic low level discharges may also be difficult to predict as a result of uncertainties surrounding the use and disposal characteristics of the chemicals. For example, leakage from landfill sites or fate in wastewater treatment systems may be very difficult to estimate.

The characterization and estimation of pollutant loadings represent a key and initial component of the assessment system, but this issue is not adequately addressed in the research plan. It is essential that the release scenarios, including steady or batch waste treatment, pesticide application, and accidential spills, be reasonable in intensity and frequency if the risk to ecosystems is estimated properly. The analyst using the DSS will require considerable guidance in this component.

It is not always clear in the various projects whether the exposure conditions treat either or both of chronic or episodic exposures. The research plan should address both chronic and episodic exposure scenarios.

EPA staff identified many areas, including water circulation and stratification, sediment transport, humic interactions, biodegradation and soil transport processes in which the Subcommittee concurs that there is a need for more fundamental science. In particular, transfer between sediments and the water column, partitioning of chemicals between solution particulates or bound phases in water (as, for example, affecting bioavailability) and wet and dry atmospheric deposition processes are processes that deserve particular emphasis because they may represent critical transport and hence exposure routes. The focus of exposure modeling projects (I-B-1 and II-B-2) is primarily to write better software using scientific findings developed elsewhere. The Subcommittee is concerned with the implication that the project will either not use the best scientific information available or will not generate new scientific information about these processes. There must be close liaison with environmental fate research projects in other parts of EPA and in other agencies.

C. Terrestrial Ecotoxicology

Several important points concerning terrestrial ecotoxicology will also be discussed in the context of food chain interactions and spatial heterogeneity.

Much of the research program emphasizes mechanistic population and community models. As stated elsewhere, this is a commendable long-term (twenty year) goal that can help guide the research program as it procedes. In the meantime, however, the successful application of such models in regulatory decision making is questionable because: (1) our basic understanding of population control mechanisms and density-dependent compensation phenomena is still very weak; (2) as a consequence, it likely will be necessary to make assumptions about key model parameters and functions;

(3) the range of reasonable model outcomes will likely be broad (i.e., the model outcome for a given application will depend heavily on the assumptions); and (4) the resultant debate about parameter values and model outcomes may impede rather than aid the regulatory decision making process. Because of this potential problem in applying mechanistic models as a regulatory tool, the Subcommittee believes that some of this effort should be re-directed to experimental work, empirical population and community models, and ecosystem models.

Experimental approaches are needed to gain data for both empirical and mechanistic models. However, they are also needed over the short-term to provide guidance to OPTS on acceptable designs for small field plot studies as well as full field-sized experiments to determine the effects of toxic chemicals on terrestrial organisms.

Empirical models appear to be incorporated in the research plan as short-term or intermediate goals that would be achievable and usable products prior to the availability of mechanistic/deterministic models. The Subcommittee agrees with this approach, but it believes that such empirical models may be the main achievable products during the next five years.

The program as currently described insufficiently addresses ecosystem level models and experimental approaches. Ecological risk assessment deals with consequences at the levels of population, community and ecosystem. Ecosystem science has made enormous strides in the last 5-10 years, and today there are many operational models directly applicable to contemporary problems. These models represent a refinement of large models that have been streamlined on the basis of experience both in modeling and in the field. The research plan needs to better exploit the existing strengths of ecosystem models for ecological risk assessment. In fact, many of the extant ecosystem models are likely to be as useful, or more useful, than models at the population and community levels of integration. The program staff should aggressively solicit advice from individuals and research programs throughout the country and around the world that can provide assistance with ecosystem level models. In addition to the development and application of the ecosystem models, validation of those models is essential.

The collection of data bases should be designed to answer specific questions, and not duplicate data bases existing in other agencies. Imaginative approaches should also be used to evaluate the data bases. An excellent example would be to use the appropriate data bases to address the issue of indicator species, taking into account, in a systematic manner, many attributes of candidate species.

D. Aquatic Ecotoxicology

The projects on aquatic ecotoxicology are well conceived and should produce valuable scientific results. The formulation and testing of models of toxicant uptake, clearance, deposition and metabolism in various tissues of aquatic organisms, as distinct from viewing the organism as a single compartment, is encouraged. The quality of scientific information and inference obtained from such models has been invaluable in other areas such as human and other mammalian pharmacokinetics.

The Subcommittee is concerned, however, that the research plan is "rediscovering pharmacokinetic wheels" by not exibiting as full an awareness as is needed of the considerable literature on pharmacokinetic models in other animals which EPA can draw upon to facilitate the rapid development of reliable toxicokinetic models. For example, there is considerable effort in the ORD Health Effects Research Laboratory, in the occupational health literature and in mammalian pharmacokinetics that can be exploited.

At present, effects on individual organisms are central to developing water quality criteria, and large data bases are available. In order to use this information to predict effects of new toxicants, or to predict effects on untested species,a more uniform theory of toxic action and taxonomic relationships among species is needed. It is important that the studies continue to be directed toward this result.

The development of a thorough understanding of toxicokinetics at the individual level should provide an understanding of population effects. The work on relating distribution of percentage of fat in populations to effects of toxicants on those populations is an example of this possibility. Also, examination of existing fisheries' models for predicting effects of toxicants on populations is worthwhile. However, there has been little success in achieving even moderately precise yield estimates for these models even in very well documented fisheries. Therefore, these models may be most useful in developing possible scenarios, i.e. simulations, to provide low resolution estimates of toxic effects in the site specific cases. EPA should consult experts on fisheries' population dynamics.

The research on community and ecosystem effects is less clearly defined and developed than work on individuals and populations, but no less important. It is imperative that state-of-the-art methods be used via consultation with appropriate experts. The Subcommittee doubts that models developed from this work during the five year period will provide predictive capability, but development of these models should result in greater understanding of ecosystem level effects and point to areas where further understanding is needed. The Subcommittee encourages EPA to pursue both empirical models and analytical models. The former, a black box approach seeking patterns in the outputs, should provide the most efficient means of identifying factors most sensitive to toxicants. Simultaneously, analytical models will provide some understanding of the causes of the observed effects.

EPA should devote efforts to relating organismal effects to ecosystem level effects. There has been considerable discussion within the scientific community of using indicator or keystone species, or groups of species, for assessing community or ecosystem effects. However, there is little information on how to identify these species. Sufficient information should be made available in the development of the data bases to aid in this identification. For example, the examination of synchrony in fluctuations in abundance of species in time series data may be very important.

## VI. General Discussion and Recommendations

### A. Omission of the Food Chain Pathway

The discussion of terrestrial transport and fate models under the topic of exposure analyses included a description of a toxics model and a pesticide model. Although the loading portions of these two models were different, the recipient portions of the four models were the same. The point of concern is that the receiving portion of the models included the following outputs: atmosphere, losses to surface water, ground water, and harvest. While there is a compartment entitled soil fauna, there appears to be no explicit mechanism for involving the movement of materials, e.g., pesticides or derivatives, from the plants or soil up the food chain through herbivores and carnivores.

Since previous experience has demonstrated this pathway is essential in considering the consequences of potentially hazardous materials, this omission is probably either an oversight in research planning or simply a deficiency in the pictorial presentation. Inclusion of such a pathway is, of course, essential to evaluating the process of biomagnification. Also, connections between the toxics and pesticides model with population, community, and ecosystem models will require this link. Though not a trivial task, there are numerous food chain models which could be readily incorporated into the two models.

The research plan also does not discuss the water-fish-bird-mammal food chain. Fish eating animals, such as gulls and otters can be invaluable sentinel species for determining the state of contamination of water bodies. The corollary is that they may be the first components of the ecosystem to be affected by discharges to the aquatic environment.

### B. Hierarchy Approach to Model Decisions

The ecological risk assessment program obviously must contend with choices among models at the population, community, and ecosystem levels. In addition, within each of these three levels, choices must be made among specific models and experimental procedures. One approach would be to examine each of the three levels, and then either develop new or adopt existing models. For each of the three cases, the best model would be chosen for that level, or the most appropriate organism or process to be evaluated. Choices in each of the three levels could be made independently, based on the desired outputs, thoroughness of understanding about the ecological processes, adequacy of the data base, and sufficiency of existing models. Judgments of success would depend upon the degree to which the ecological level was described and the confidence that one could predict for the consequences of a pesticide or toxic input.

An alternative approach is to expect that the three chosen levels are related and that the choice of models and experiments should be selected to result in the greatest cumulative information. In fact, hierarchy theory might provide some guidance in this design. The key issue is to select processes at each level that change only in extent and grain, that is, the spatial scale and the detail in which a process or phenomena is considered. The advantages of this hierarchial approach are that decisions about models or experimental designs at any one level are made in the context of the biological continuity from organisms to ecosystems, and that information obtained at one level is directly applicable to other ecological levels of organization.

C. Monitoring Data

The recommendations from the first peer review convened by the Director of the Athens Research Laboratory (24-25 September, 1985) stated that environmental monitoring was conspicuously absent from consideration in the ecological risk assessment program. The Scientific Committee on Problems of the Environment (SCOPE) has produced a report which outlines methods for estimating ecological risk. The significant difference between the SCOPE approach and the proposed EPA approach is the defined need for environmental monitoring. The SCOPE report states "exposures of animal and plant organisms and man to chemicals in the environment can be evaluated with most certainty by direct measurement of concentrations and fluxes...Monitoring and modelling programs are mutually supportive in that modelling studies suggest the most important measurements."

Mr. Mike Slimak of the Office of Pesticides and Toxic Substances emphasized in his presentation to the Subcommittee the importance of monitoring data in the risk assessment process. However, no other presentation to the Subcommittee addressed the issue of how existing monitoring data bases would be integrated into the overall ecological risk assessment methodology under development. Monitoring data not only can play a role as a data set for helping make modeling predictions, but well designed and implemented monitoring systems can be used in validating the developed models. The Subcommittee recommends that the research plan more explicitly articulate the role of monitoring data. The use of a technical advisor from EPA's multi-media Environmental Systems Monitoring Laboratory (EMSL) in Las Vegas would aid this effort.

D. Models and Data Base Interactions

Data bases constructed to be all inclusive or to meet all possible uses rarely achieve this goal. If a data base is used to build and implement models, the data base is best defined by the expressed need of that model. If a data base supports a class of models, the user must anticipate the data input requirements of those models. The greater the number of models the more cumbersome such a data base can become. For example, if one wishes to construct a data base on characteristics of species for the purpose of constructing an energy flow model of an ecosystem, the data base quickly becomes encumbered by great bytes of information on longevity, age distribution, growth rates, and population growth rates at several levels of phylogenetic development. Inconsistencies appear in the literature with how these different attributes are expressed among the different taxa (plankton population growth is expressed in turnover time, while fish population growth is expressed as changes in number per unit of time).

While developing a data base, it becomes more efficient to keep the data packages small and specific than to allow them to become large or too general. The Institute of Ecology (T.I.E.) performed a feasibility study on the production of an ecological data handbook for the National Science Foundation (1979-80) in which the problems encountered with expression of data are thoroughly discussed. EPA should refer to this study in planning its data bases.

E. Statistical Design

Two major components of the mission of the ecological risk assessment program include 1) quantifying the probability that adverse ecological effects may occur (or are occurring) as a result of exposure to pollutants, and 2) determining the significance of such adverse effects. The major problems in ecological risk assessment are the quantification of the probability and severity of adverse effects--the quantification of the probabilistic dose-response functions. The research plan places adequate emphasis on the quantification of the severity of adverse effects, but not adequate or sufficient emphasis on the quantification of the probability of adverse effects.

Most, if actually not all, disturbances to ecological systems are random in nature. Toxic spills, uncontrolled hazardous waste disposal, leakages from gas tanks and pipes, and acid rain are just a few examples. The randomness of these events--events that constitute an input (albeit an undesired input) to the environment and/or the ecosystem--must be understood, studied and incorporated into the modeling process in terms of their probabilistic nature. The statistical nature of these events cannot be overlooked, and must be studied and integrated within the entire program, including the data base and the data collection component of the program. In this regard, the data collection component and the maintenance of an adequate data base must incorporate and include the frequency, level (concentration), spatial distribution, source and time of these random events.

Once the randomness (probabilistic) nature of the "input" to the ecosystem is understood, then deterministic models currently developed within the program can and should be expanded to incorporate probabilistic inputs and disturbances. Only then would the word risk in the program's title be representative of and commensurate with the actual research envisioned for the program.

F. Validation and Calibration

The procedure for many of the modeling efforts is to assemble data and concepts from laboratory and microcosm studies into a large model. Calibration and validation of this model are necessary. This requires more resources than are currently available, but there may be other ways to implement a calibration and validation effort. For example, the ecosystem studies required of pesticides or other toxic chemicals could be used for validation. Funds could also be reprogrammed for validation in the future.

For validation of ecosystem models, large scale manipulations need to be carried out over relatively long-term periods. Perhaps low-levels of pesticides could be added to streams in existing experimental watersheds. EPA should also consider approaching other Federal agencies so that it could supplement funds to their research projects to, for example, allow one more watershed to be tested (and use made of an existing control stream). EPA's experimental watershed program (addressing acidification) could also aid model calibration and validation in the ecological risk assessment program.

G. Terrestrial - Aquatic Interactions

Too often, in the modeling of ecosystems, aquatic impacts are separated from the terrestrial impacts. This is unfortunate since the two ecosystem are closed linked. Feedbacks occur from aquatic to terrestrial ecosystems, but usually in a relatively minor (though sometimes possibly controlling) way. The aerial phase of riparian aquatic invertebrates serve to reintroduce the invertebrate propagules upstream; up to 25% of the nitrogen carried into some oxidation ponds is carried off the system as biomass.

Generally speaking, the contribution from the terrestrial to the aquatic ecosystem occurs indirectly through watershed processes (surface runoff and ground water), or directly as litter falls on the water surface. The Subcommittee advises that the research plan should formally recognize that: (1) terrestrial and aquatic models need to be linked; and (2) the transfer processes between the two ecosystems needs to be measured and modeled.

H. Spatial Heterogeneity

A major lesson in ecology from the last two decades concerns the importance of spatial heterogeneity. Most models are directed at the "average" square meter, or the model condition. This is a different issue from stochastic input data; rather, it recognizes that even small differences in habitat have major influences on the behavior of its system. This spatial heterogeneity crosses spatial scales from microhabitat to watershed and region. This concept was suggested in the discussion of the decision support system but has not been implemented in the individual models. Though there is a question about how much detail can be incorporated in these models, new advances are being made in analytical procedures for dealing with spatial heterogeneity. EPA should incorporate these new approaches in the project design.

VII. Administration and Management

A. Milestones and Products

The Subcommittee recommends that project by project milestones be developed, if this has not already been done, and that milestones for the overall risk assessment methodology be developed. In developing overall milestones, their relationships to specific research projects should be clearly stated in some systematic fashion. Milestones should be accompanied by the establishment of criteria to measure project and program success.

B. Interlaboratory and Research Center Communication

The ecological risk assessment program is an ambitious research undertaking with a broad scope. Because of the multi-media nature of the integrated exposure assessment methodologies, it demands a wide variety of scientific disciplines. A number of these disciplines exist outside of the four ecological research laboratories currently working on the program. The Subcommittee has already cited the example of the EMSL-Las Vegas in its discussion on monitoring data. Another example is the lack of participation in the program by scientists from EPA's air research laboratories. The Subcommittee also believes that a wealth of information on exposure assessment methodologies exists in EPA's human health research facilities. These methodologies might be adopted to good advantage in the ecological risk assessment program. The research plan and staff briefings provided no evidence that the ecological risk assessment program had made efforts to explore this possibility.

The EPA funded research centers should also be approached to determine if their specific research projects have applicability to the ecological risk assessment program. The staff should discuss these issues, in particular, with the U.C.L.A. intermedia transport center.

The Subcommittee applauds the interaction with U. S. Fish and Wildlife Service laboratories and encourages more such actions in the future.

C. Overcoming Parochialsm/Increasing Intellectual Manpower

The Subcommittee realizes that this overall program is very broad and needs a number of different skills. No single research group at an agency or at a university ever has adequate numbers of people to represent all the needed skills. For example, it appears that the program lacks anyone knowledgeable about terrestrial ecosystem models, but judgments about whether to construct such a model and what to include must be made. Some elements of the program are attempting to make measurements never made before and to construct models of systems never successfully modeled before. These parts of the program are working at the forefront of ecological science, and they must make every possible use of current research, knowledge, and insight to avoid duplication and to make rapid progress. A level of judgment about people (whom do you trust?) and ideas (what are the most useful directions?) is necessary that is not now available in the program.

The Subcommittee recommends continuing close cooperation among EPA research laboratories; making every possible use of centers of excellence; enlarging the visiting scientist program; sponsoring workshops, Gordon Conference like meetings on relevant topics, especially models; identifying what programs are underway at the National Science Foundation ecosystem analysis program; and initiating more aggressive efforts to obtain opinions about successful ecosystem and ecological models.

D. External Peer Review

The Subcommittee recommends that there be continuing review of the program to determine how well it is meeting its scientific goals. To accomplish this review, EPA laboratories should establish such a continuing peer review process with some continuity in the participation of the individual scientists.

There are a number of options for setting up this review. It could be a subcommittee of the Science Advisory Board, or through a cooperative agreement with a professional society or a university. Such a review committee could report only to the Program Director, or to other EPA officials.

E. Encouraging and Documenting Divergent Points of View

Any scientific research program will profit from divergent thoughts and ideas. In fact, this stance should be openly fostered, despite the propensity in programs with limited funding to present a more homogeneous approach. Furthermore, these divergent thoughts should be documented and considered in managerial decisions, and divergent or parallel studies should be simultaneously supported under some circumstances. Finally, products from these divergent point of view should be incorporated in descriptions and the eventual products of the ecological risk assessment program.

F. Potential for Serendipitous Results

The Subcommittee recognizes that many of the most significant scientific advances occur as "spin-offs" from research programs. By its very nature research cannot be fully planned. The Subcommittee believes that, in several subject areas of this program, innovative and creative thinking, and perhaps unplanned "breakthroughs" can occur. For example, in the design of the computer architecture of the design support system, in structure activity relationships, and in sensing ecosystem responses, there may be fertile ground for innovative thinking. The Subcommittee suggests that the investigators be specifically encouraged to pursue innovative ideas, even to the extent of allocating some additional percentage of resources to such endeavors.

G. Selection of Chemicals

EPA should employ a greater commonality of chemicals selected for its studies. It increases the difficulties of technical evaluation, when reviewing the combined results of a comprehensive research program, to find insufficient commonality in chemical selection. EPA should explicitly state its criteria for selecting chemicals in its research planning documents. EPA should also implement a consistent, peer reviewed data base of properties as well as document the analytical methods.

H. Funding Consistency and Amount/Broader Agency Application

This program has the potential of producing significant results that will facilitate and economize the implementation of a series of risk management decisions. It is a program that can have a broader application among the program offices including Water, and Solid Wastes and Emergency Response, in addition to the major client office, OPTS. Above all, the funding level should remain stable, and a long term commitment and the intellectual capital that has been committed should not be lost through attrition or resource reductions.