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EPA

# AN SAB REPORT: EVALUATION OF EPA'S ECORISK ASSESSMENT RESEARCH PROGRAM

## PREPARED BY THE ECORISK RESEARCH SUBCOMMITTEE OF THE ECOLOGICAL PROCESSES AND EFFECTS COMMITTEE

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

OFFICE OF
THE ADMINISTRATOR

EPA-SAB-EPEC-92-006

November 20, 1991
Mr. William Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

SUBJECT: Science Advisory Board Evaluation of EPA's Ecological Risk Assessment Research Program

Dear Mr. Reilly:

The EcoRisk Assessment Subcommittee of the Ecological Processes and Effects Committee of the Science Advisory Board met on 20-22 May 1991 at Callaway Gardens, Georgia, to review the Agency's Ecological Risk Assessment Research Program. The title of the Research Plan is misleading, because the program currently functions primarily in support of the Office of Pesticide Programs and Toxic Substances (OPTS). However, it is the only research program within EPA that is addressing the complex and essential issues of ecological risk assessment and it could provide useful insights for planning broader and more general plan for the Agency as whole. The objectives of the review were to examine ORD's five-year plan for EcoRisk research for: the consistent use of sound scientific methods; the effectiveness of project integration; the mix of on-site versus university research; the contribution to EPA and other agency ecological risk assessment needs; consistency with developments in the ecological risk assessment paradigm; optimal allocation of resources in light of priorities; and its adequacy for addressing extrapolation issues.

The Science Advisory Board's Reducing Risk report concluded that ecological concerns should be given parity with human health issues and that risk reduction should be a key criterion to evaluate program progress and eventually to allocate resources. Taking note of your personal support of these conclusions as operational principles for the Agency, the Subcommittee evaluated the EcoRisk Research Program in this broader, Agency-wide context. The major conclusions and recommendations of the Subcommittee are as follows:

a) The Agency needs to develop scientifically sound methodologies and data bases for conducting ecological risk assessments on the diversity of anthropogenic stresses and ecological systems of the United States. The current budget for the ORD EcoRisk Research Program is grossly inadequate to address the scientific issues that must be resolved to meet that need. EPA should provide the level and consistency of funding for research to improve EcoRisk assessment methodologies commensurate with the importance of this need.

b) ORD should revise the EcoRisk Research Program to reflect the fundamental role of ecorisk throughout the Agency. The EcoRisk Program requires a broader scope than it presently derives from the limited program office clientele.

Further, the Ecorisk Research Program should:

c) Develop research projects that explore techniques and methods to quantify uncertainties associated with ecological risk assessments;.

d) Conduct research to systematically quantify uncertainties associated with each element of ecological risk assessment to provide the primary basis for prioritizing research and allocating resources in the EcoRisk Research Program;

e) Significantly enhance research to advance population-, community-, ecosystem-, and landscape-level ecological risk assessment methodologies to yield a more appropriate balance of projects designed to address higher levels of biological complexity, multiple stresses, and extrapolation issues;

f) Establish effective interactions with other research or risk assessment efforts within the Agency (such as EMAP and the Risk Assessment Forum);

g) Focus on the development and testing of new methods for ambient monitoring of ecological responses of communities and ecosystems. This effort should be coordinated with the development of an ecological indicator research program; and

h) Conduct research on risk characterization that would include statistical treatment of data, uncertainty analysis, and integration of data. This characterization should also be linked to research on ecological valuation. Finally,

i) EPA should establish an integration and synthesis task and an intellectual or think-tank component to develop new ideas for ecological risk assessment methodologies. Most of the research plan lacks the degree of innovation that is commensurate with the research needs or the importance of ecorisk research to Agency-wide decision-making. The extramural research program, based on scientifically peer-reviewed proposals, should be expanded and all research conducted by on-site contractors should be peer-reviewed.

We look forward to your response to our recommendations. We particularly offer our assistance to you in facilitating significant increases in funding for ecological risk assessment research and in institutionalizing the Ecorisk Assessment Research Program as a part of the Core Ecological Research Program within ORD. We also look forward to the development and future review of an Agency-wide EcoRisk Research Plan.

Sincerely yours,

Raymond C. Loehr

Dr. Raymond Loehr, Chairman
Executive Committee
Science Advisory Board

Kenneth L. Dickson

Dr. Kenneth Dickson, Chairman
Ecological Processes and
Effects Committee

Mark A Harwell

Dr. Mark Harwell, Chairman
EcoRisk Research Subcommittee

Enclosure

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## ABSTRACT

This report presents the conclusions and recommendations of the U.S. Environmental Protection Agency's Science Advisory Board following a review of EPA's Ecological Risk Assessment Research Program. The Subcommittee considered that the Ecorisk research program was fundamental to support the Agency's extensive need in ecological risk assessment; however, they felt that the funding and the scope of the current program were inadequate. They recommended expanded efforts on methodologies for population, community, ecosystem, and landscape level assessments and on quantifying uncertainty of risk estimation. Overall, they recommended that the Agency expand support for this research to cover all of the Agency program offices.



**KEY WORDS:** Ecological Risk Assessment; Ecorisk; Uncertainty Analysis; Risk Characterization.

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# 1. EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD) began a multidisciplinary research program in 1985 to develop scientifically defensible methods to assess ecological risks. This program, known as the EcoRisk Research Program, is primarily in support of the Office of Pesticide Programs and Toxic Substances (OPTS); however, it is the only research program within EPA that is addressing the complex and essential issues of ecological risk assessment. A five-year (FY92-FY96) research plan was prepared by ORD and subjected to review by the EcoRisk Research Subcommittee of the Science Advisory Board (SAB) Ecological Processes and Effects Committee. The objectives of the review were to examine the program for: the consistent use of sound scientific methods; the effectiveness of project integration; the mix of on-site versus university research; the contribution to EPA and other agency ecological risk assessment needs; consistency with developments in the ecological risk assessment paradigm; optimal allocation of resources in light of priorities; and its adequacy for addressing extrapolation issues.

The Subcommittee met on 20-22 May 1991 at Calloway Gardens, GA. Presentations by ORD staff and background materials provided by the EcoRisk Research Program provided the bases for deliberations by the Subcommittee. The Subcommittee answered the specific questions in its charge and reached consensus on several key issues.

The conclusions and recommendations of the Subcommittee are as follows:

a) The development of scientifically sound methodologies and data bases for conducting ecological risk assessments on the diversity of anthropogenic stresses and ecological systems of the United States is a critical need for the Agency and the nation. The current budget for the ORD EcoRisk Research Program is grossly inadequate to address the scientific issues that must be resolved to meet that need. The Subcommittee strongly recommends that EPA provide the level and consistency of funding for research to improve EcoRisk assessment methodologies commensurate with the importance of this need.

b) The Subcommittee recommends that ORD revise the EcoRisk Research Program to reflect the fundamental role of ecorisk throughout the Agency. The EcoRisk Program requires a broader scope than it presently derives from

the limited program office clientele.

c) Uncertainty analysis is a critical aspect of ecological risk assessment that is inadequately addressed within the research plan. The Subcommittee recommends that research projects be developed that explore techniques and methods to quantify uncertainties associated with ecological risk assessments.

d) The Subcommittee strongly recommends that a systematic quantification of uncertainties associated with each element of ecological risk assessment be undertaken. The Subcommittee further recommends that such an evaluation constitute the primary basis for prioritizing research and allocating resources in the EcoRisk Research Program, i.e., selecting research activities to reduce the most important uncertainties most effectively.

e) The Subcommittee recommends that the EcoRisk Research Program significantly enhance research to advance population-, community-, ecosystem-, and landscape-level ecological risk assessment methodologies. This emphasis should result in a more appropriate balance of projects designed to address higher levels of biological complexity, multiple stresses, and extrapolation issues.

f) The Subcommittee recommends that the EcoRisk Research Program establish effective interactions with other research or risk assessment efforts within the Agency (such as EMAP and the Risk Assessment Forum).

g) The Subcommittee recommends that the EcoRisk Research Program focus on the development and testing of new methods for ambient monitoring of ecological responses of communities and ecosystems. Existing data sets (such as NAPAP and EMAP) may provide the most comprehensive and useful information for such testing. This effort should be coordinated with the development of an ecological indicator research program.

h) The Subcommittee recommends that the EcoRisk Research Program conduct research on risk characterization that would include statistical treatment of data, uncertainty analysis, and integration of data. This characterization should also be linked to research on ecological valuation.

i) The Subcommittee is particularly concerned that most of the research plan lacks the degree of innovation that is commensurate with the research needs or the importance of ecorisk research to Agency-wide decision-making. The Subcommittee highly recommends the establishment of an integration and synthesis task and an intellectual or think-tank component to develop new ideas for ecological risk assessment methodologies. The Subcommittee further recommends significant enhancement of an extramural research program that is based on scientifically peer-reviewed proposals, and recommends significant increase in the use of peer review for research conducted by on-site contractors.

# 2. INTRODUCTION

The U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD) initiated in 1985 a multidisciplinary research program to develop scientifically defensible methods to assess ecological risks for use by the Office of Pesticide Programs and Toxic Substances (OPTS). This initial program (known as the EcoRisk Research Program) has been the subject of two external peer reviews and one previous EPA Science Advisory Board (SAB) review; the latter occurred in 1987. While the EcoRisk Research Program has direct ties to the EPA Office of Pesticides and Toxic Substances programs, it also serves as the only research program within EPA that is addressing the complex and essential issues of ecological risk assessment.

Based on the experience of the Agency and projected needs of OPTS, a new five-year research plan for the ORD EcoRisk Research Program was developed for FY92-FY96. Before implementing this research plan, the Agency sought review by the SAB. The EcoRisk Research Subcommittee of the SAB Ecological Processes and Effects Committee convened a review workshop during 20-22 May 1991 at Calloway Gardens, GA. The present report provides the findings and recommendations of the Subcommittee as determined in its review.

This report details the charge to the Subcommittee and the specific responses to each of seven questions provided in the charge. The report then includes a discussion of the findings of the Subcommittee organized around eight key issues identified at the workshop. Finally, a summary of recommendations is provided.

## 2.1 Charge to the Subcommittee

The Office of Research and Development requested that the Science Advisory Board review its research plans for the next five years in the area of ecological risk assessment. In a letter to the SAB dated 30 April 1991, Dr. Courtney Riordan, Director of the Office of Environmental Processes and Effects Research, requested that the SAB EcoRisk Research Subcommittee address the following questions as part of the charge for its review:

a. Has the ongoing program been consistent in the use of sound scientific methods, e.g., selection of projects with testable hypotheses, development of appropriate experimental designs, and choice of field-sampling protocols?

b. Have the research results demonstrated an effective level of project integration, i.e., an interconnectedness that enhances the opportunities for scientific innovation and productivity?

c. Does the program have an appropriate mix of on-site and university research?

d. How does the review panel see this program contributing to the ecological risk assessment needs of EPA or other federal research programs like the Global Change Research Program and Environmental Monitoring and Assessment Program (EMAP)?

e. Considering current approaches to ecological risk assessment, vis á vis the traditional 1983 National Academy of Science (NAS) risk assessment paradigm, is the research plan consistent with the state of the science? Is there appropriate balance in research devoted to the components of ecological risk assessment or should changes be considered (e.g., more/less hazard identification work, more/less exposure work, more attention to higher levels of biological organization)?

f. The research plan has been developed to conform to anticipated resources available over the next five years (Level I). Are knowledge gaps appropriately identified? Have critical projects (i.e., those of immediate need to the regulatory program or those recognized as necessary "first stages" in a long-term project) been identified and appropriately prioritized?

g. Does the research, as presently planned, adequately address extrapolation issues, e.g., laboratory-to-field, single species responses to population- or community-level effects?

## 2.2 Subcommittee Review Procedures

The Science Advisory Board accepted the charge for the review and assigned it to the Ecological Processes and Effects Committee (EPEC). EPEC established the Ecorisk Research Subcommittee, which conducted the review.

The Subcommittee met on 20-22 May 1991 at Calloway Gardens, GA. Background materials were provided to the Subcommittee prior to the meeting, and briefings were

presented at the review by the EcoRisk Research Program team and were discussed by the Subcommittee. The meeting, briefing, and background materials provided the bases for deliberations by the Subcommittee. The Subcommittee answered the specific questions in its charge and reached additional consensus on several key issues.

# 3. RESPONSE TO THE QUESTIONS OF THE CHARGE

## 3.1 Use of Scientific Method in Project Selection, Design, and Protocol Development

Because of the large number of projects, the limited time for the review, and the primary focus of the review process on larger issues, the Subcommittee did not undertake a detailed project-by-project review and thus is not able to respond in depth to this charge. However, sufficient information was presented to the Subcommittee for it to make some comments. It is clear from the presentations and provided material that the scientific rigor and quality of the individual research projects vary considerably. In many cases, the precise hypotheses to be tested were not carefully stated and did not appear to have been well-defined in the research plan. Often protocols were presented only in summary fashion. Some projects clearly were well-defined and do reflect state-of-the-science research; other projects appeared to be much weaker in conceptualization, scientific rigor, and implementation. The Subcommittee strongly recommends that a more consistent and intensive set of external peer reviews of individual proposed projects and ongoing activities be established, as discussed more fully later in this report.

## 3.2 Project Integration

The Subcommittee concluded that in general there is an inadequate level of project integration, and that opportunities for scientific innovation and significant advancement of the state-of-the-science of ecological risk assessment are being missed in the presently designed EcoRisk Research Program. In only a very few projects is there an explicit attempt at integration (one positive example is Project MM-2, which proposes to use GIS to connect biogeographic and ecologic databases in risk assessments).

In general, the critical research issues associated with explicit linkage of projects from contaminant/stress introduction, through transport, fate, and stress regime characterization, to characterization of effects on ecological assessment endpoints are lacking. The Subcommittee strongly recommends that the EcoRisk Research Program incorporate a significant activity to establish this integration and linkage, in order that systematic uncertainty analyses can be used to identify critical research needs (i.e., those uncertainties that have the greatest consequence on the ecological endpoints and on regulatory decision-making). This systematic exercise, if conducted periodically, would provide the basis for prioritizing research on

ecological risk assessment methodologies and would provide the basis for evaluating the efficacy of ecological risk assessment methodologies available to the decision-maker at any point in time. These issues are more fully addressed later in this report.

### 3.3 On-site Versus University Research Activities

Within the limits of the information provided in this review, it appears that the use of extramural versus on-site researchers is intended to strike a balance between the need to maintain a focus for the research program and the need to take advantage of specific skills and experience not available in the EPA environmental research laboratories. It is not clear to the Subcommittee how extramural groups fit into the overall EcoRisk Research Program. It would have been very interesting and informative to have seen the geographical distribution of off-site contractors, their relationship to particular EPA laboratories, and their areas of research expertise and responsibilities.

A major concern of the Subcommittee involves the level of peer review and quality control imposed on the on-site contractors that represent basic operating agreements (BOA) and contracts. Most of the individual laboratories participating in EcoRisk research activities allocate 40% to 60% of EcoRisk research funds to on-site contractors to conduct the actual research. Many of the EPA laboratory scientists are in fact program managers and are not directly involved in the research, to the detriment of the overall program. Moreover, there appears to be little external peer review of the individual research proposals prior to assignment to the on-site contractors. This is especially true of the field-oriented ecological experiments. The Subcommittee believes that this lack of sufficient external peer-review of the technical elements of the EcoRisk Research Program detracts from the quality of the research and its perceived value in the outside scientific community. The Subcommittee recommends that external peer review be established for each proposed research activity, whether conducted by the laboratories, on-site contractors, or extramurally, and that the opportunities for university and other extramural scientists to participate in the EcoRisk Research Program be significantly increased.

### 3.4 Contribution to Broad EcoRisk Needs of the Agency

Most of the presently designed EcoRisk Research Program is concerned with the specific needs and objectives of OTS and OPP. For this reason there is heavy emphasis on

research to validate the hazard assessment approach, as opposed to research aimed at developing needed methodologies for conducting ecological risk assessment on higher-level ecological systems and on non-chemical stresses. Ecosystem-level risk assessment research must take into account higher-level interactive processes between various components of ecosystems. This should include knowledge of rates of processes, causality and feedback mechanisms, and networks and hierarchies. On the other hand, OPTS deserves credit for sustaining this effort, because there is no other active research on developing ecological risk assessment techniques.

Both the EMAP and the EPA Global Change Program are concerned with detecting potential deleterious changes in ecosystem structure and function. Each of these programs is intended to examine the nation's ecological resources in a geographic context that eventually may be related to perturbations at the population, community, ecosystem, and landscape levels of ecological organization. EMAP is focusing on developing a monitoring strategy, whereas the Global Change Program is directed at understanding ecosystem processes and interactions in relation to temperature and precipitation change and the global carbon dioxide budget in response to anthropogenic alterations of the atmosphere. Research on ecological consequences of global climate change is also concerned with understanding and quantifying linkages and dynamics of higher-order ecological processes as well as providing input to global carbon cycle and vegetation models.

If the EcoRisk Research Program is to contribute scientifically to these major programs, it must put more emphasis on utilizing real-world field monitoring data and on development of methodologies to relate anthropogenic stresses to ecological effects. As noted elsewhere in this report, the present EcoRisk modeling effort bears little relation to population, community, ecosystem, or landscape problems, yet it is at those levels that we are primarily concerned about impacts on the environment. With the present level of funding and current research direction for the EcoRisk Research Program, it is the opinion of the Subcommittee that the program will have minimal impact on meeting the needs of the major EPA interests and priorities reflected in the EMAP and Global Change programs or those reflected in the SAB Reducing Risk reports (SAB 1990a, b). In this sense, it bears little relationship to ORD's Core EcoRisk Research Program outlined in their 1991 research plan entitled Ecological Risk Assessment Program.

Nevertheless, the EcoRisk Research Program has the potential to contribute to these programs for a variety of reasons. It has a core of scientists experienced with the methods and techniques of linking stresses with biological effects. The bottom-up approach historical-

ly used by the EcoRisk Program, with careful delineation of hypotheses for experimentation, could contribute to the understanding of the mechanisms and causes of the change that is identified through a top-down approach in programs like EMAP and Global Change. Finally, the EcoRisk Program could contribute to the identification of ecological endpoints and measurement indicators around which ecological risk assessments can be developed.

### 3.5 Consistency with State-of-Science

The current EcoRisk Research Program is consistent with the NAS paradigm (NRC, 1983), which suggested that risk assessment consists of a combination of hazard assessment (evaluating the inherent ability of a chemical to cause harm) and exposure assessment (evaluating the dose to individual organisms). However, through the present EPA Risk Assessment Forum activities, that risk assessment paradigm is being modified and expanded to be more appropriate for ecological risk assessments, rather than human health risk assessments, and to be more capable of addressing non-chemical as well as chemical stresses (Fava et al. 1991; Harwell et al., in preparation). Discussions at the workshops included, as one possibility, an ecological risk assessment paradigm with three substantive additions to the health risk paradigm: 1) exposure assessment is expanded into a stress characterization process; 2) hazard assessment is expanded into an ecological effects characterization process; and 3) the ecological effects characterization component accounts for ecological recovery processes. The first two elements proceed in parallel, with inputs and feedbacks occurring at several stages; this approach contrasts with the traditional health risk assessment paradigm in which hazard and exposure elements are independent and only combined at the end of the process in the risk characterization step.

A second important difference is recognition of the multitude of different endpoints that may be appropriate in differing circumstances, reflecting different types of ecosystems, different components that are ecologically or societally important, and different types and combinations of anthropogenic stresses. The ecological risk characterization component involves sequential stages of assessment, utilizing a diversity of specific stress-response analysis methodologies or data bases that explicitly account for ecological recovery processes. The ecological risk assessment process is designed to provide ecologically relevant information in a form understandable by non-scientists for appropriate weighing with other factors affecting the environmental decision.

The Subcommittee recommends that the EcoRisk Research Program take cognizance of the evolving methodology for ecological risk assessment and explicitly examine modifica-

tions in the proposed research activities to be more in accord with current ideas. As one example of this, the Subcommittee believes that more attention should be given to the relationship between lower and higher levels of ecological organization (extrapolation and calibration issues) to increase our confidence that use of lower-level studies in fact reflects higher-level effects. Another example is emphasis on developing methodologies for conducting ecological risk assessments in toto following the ecological risk assessment paradigm discussed at recent workshops of the risk assessment forum, rather than the present strong emphasis on conducting traditional laboratory experiments on toxic effects on organisms from exposure to individual chemicals.

### 3.6 Identification of Knowledge Gaps and Critical Projects

In general, the Subcommittee feels the EcoRisk Research Program does not reflect the important strategic distinction between the value of incremental progress and the value of substantive resolution of specific issues. The resources available fall short of the needs for the proposed research by a factor of at least 10 (and possibly as much as 100), if the research program is to make substantive advancements in the understanding of stress ecology necessary for conducting ecological risk assessments. This discrepancy magnifies the importance both of setting correct priorities and recognizing what can realistically be accomplished with a given commitment of resources and time. The level of committed resources in itself indicates that such a realistic appraisal has not been done. In 1987, the Society of Environmental Toxicology and Chemistry (SETAC) published the results of a workshop which recommended the establishment of a 10 year, $75 million/year research initiative in Ecological Risk Assessment (SETAC, 1987). A research initiative of this magnitude is still needed.

The evident priorities in the research plan do not reflect what is needed and what is feasible. The Subcommittee believes that priorities must be established by looking at the full process for ecological risk assessment and explicitly examining the uncertainties at each step (e.g., dose-response data, extrapolation across species, extrapolation to higher levels of organization, implications of multiple stresses and multiple endpoints, etc.). The Subcommittee identified four pressing needs for advancing ecological risk assessment: 1) development of a standard risk assessment protocol that quantifies and uses estimates of uncertainty in each step in the assessment of risk; 2) development of a standard protocol for model validation to apply to the models that are being used in the course of risk assessment; 3) identification and justification of specific higher-level (community and ecosystem) endpoints for characterizing the ecological components that might be at risk and that, if adversely

affected, would constitute harm to the environment; and 4) quantification of the performance (false positives, false negatives) of proposed testing and screening procedures for conducting risk assessment. Needs (1), (2), and (3) are not identified as foci of specific projects in the present EcoRisk Research plan. Need (4) is addressed in the research plan, but with a limited emphasis (i.e., "validating the quotient method") that impresses the panel as inadequate and inappropriate, and on a scale (sample size of cases examined, linkage to monitoring) that is insufficient to answer the question at an acceptable level of statistical certainty.

### 3.7 Extrapolations and Interrelationships to Other Levels of Biological Organiza tion

The Subcommittee noted that whereas most of the research activities within the EcoRisk Research Program are on lower levels of organization (and on chemical stresses), decision-makers and the public primarily are concerned about anthropogenic impacts on higher levels of organization (populations, communities, ecosystems, and landscapes). The Subcommittee believes that bridging the gap between the information being collected and the ecological assessment endpoints and anthropogenic stresses of primary concern is inadequately addressed by the EcoRisk Research Program.

A considerable focus in the research plan is on questions, phrased in presentations to the Subcommittee in terms that would allow "yes/no" answers, about the validity of a long list of assumptions that are part of present practice of conduct in routine risk assessments on pesticides and toxic substances. Such yes/no answers are not likely to be very useful advances, since we already know that the assumptions stated in the research plan (e.g., is the quotient method valid for ecological risk assessment? are effects from multiple stresses simple combinations of effects from individual stresses?) are not true. The real questions should be more refined, such as: What is the frequency distribution of the actual deviations from these assumptions? How will these deviations affect the frequency distribution of the effects in terms of ecological endpoints of concern? Is there an acceptably inexpensive and simple modification of present practices that will yield better performance?

The Subcommittee noted that much of the proposed research is in the nature of case studies. The number of cases to be examined, however, is very limited. Each case study is necessarily very specific with respect to variables such as site, subject organisms, and pollutant. For this reason, each case study is essentially only one "data point" from a very large and multi-dimensioned space to be sampled. In this situation, there are severe difficulties in extrapolating or generalizing from a handful of case studies to the larger universe of the myriad of chemicals and stresses for which ecological risk assessment must

be conducted. The presentations seemed not to be sensitive to this sample-size problem, and the plan seems overly optimistic about the breadth of the conclusions that can be drawn from the proposed case studies.

# 4. CRITICAL ISSUES AND COMMENTS

While the Subcommittee recognizes that the ORD EcoRisk Research Pro-gram has stated goals to improve the ability of the Agency to conduct ecological risk assessments in the broader context of diverse ecosystems, diverse ecological endpoints, and complex human-induced stress regimes, the actual proposed re-search program, with its emphasis only on toxic chemicals and pesticides and emphasis on traditional methods of ecotoxicology, falls well short of those goals and of the emerging needs of the Agency. Indeed, the Agency has indicated, through endorsement of the SAB Reducing Risk reports (SAB 1990a, b) and in other forums, that managing for risks on real-world ecosystems imposed by the many different types of anthropogenic activities is a, if not the, critical priority over the next several years. Unfortunately, the consensus of the Subcommittee is that the scientific basis for meeting this priority does not exist at present and will not exist in the future if the EPA ecological risk assessment research program is limited, as the present program is, in its perspective, its scope, and its resources.

The Subcommittee's review and discussions covered a wide range of issues concerning ecological risk assessments, uncertainties, the present proposed research plan, and the full range of research needed to implement a defensible and effective ecological risk assessment capability. These discussions are summarized below in sections that reflect the key issues identified by the Subcommittee. Consequently, a central recommendation of the Subcommittee is to expand the scope of the Ecorisk research Program to be Agency-wide, long-term, and anticipatory, while recognizing the continued need for program-specific and shorter-term research on ecological risks.

## 4.1 Uncertainty

Uncertainty analysis is a critical aspect of risk assessment. By definition, risk assessment has a probabilistic dimension. While the current state-of-the-science in ecological risk assessment may in many cases preclude probabilistic statements regarding the likelihood that an effect will be observed, the quantification and reduction of uncertainty in assessing ecological risk should be a central goal of the EcoRisk Research Program. The program should conduct research that addresses the areas of greatest uncertainty in stress characterization and effects characterization assessments. Thus, the Subcommittee strongly feels that the EcoRisk Research Program's individual projects should be chosen and prioritized based on their potential contributions to quantifying and then reducing uncertainties. While uncertainty is discussed throughout the EcoRisk Research Plan, there is almost no information on how it

will be estimated, how it is propagated across extrapolations or through models, or how it is used in ecological risk assessments in interpreting risk assessments or setting research priorities.

The Subcommittee noted that the proposed EcoRisk Research Plan contains no projects specifically addressing the area of uncertainty analysis. This appears to be a critical deficiency of the proposed plan. An uncertainty analysis research component should address the following issues/topics:

a. estimation of uncertainties
   - from sample variability
   - from expert judgment
   - from model lack-of-fit

b. error propagation methods
   - Monte Carlo simulation
   - first-order error analysis

c. use of error estimates
   - in risk assessment
   - in setting research priorities

d. other
   - estimation of covariance terms
   - fitting distributions (probability models)
   - sample estimators of center and dispersion

It was evident to the Subcommittee that the EcoRisk Research team has only limited expertise or experience in the area of uncertainty analysis. Adding such expertise to the program is critical to the development of a sound research program on ecological risk assessment. The research plan should include projects that specifically explore techniques and methods to quantify uncertainties.

The Subcommittee has two specific recommendations related to uncertainty: 1) the EcoRisk Research Plan should be designed specifically, and as its primary goal, to quantify and then reduce the uncertainties associated with ecological risk assessment; and 2) proposed research projects should be chosen and prioritized based on the contributions they will make to quantifying and reducing uncertainty.

### 4.2 Total Funding and the Allocation of Funds Across Levels of Biological Organization

EPA is to be commended for developing a strategy of emphasizing ecological risk assessment research programs for regulatory purposes under OTS and OPP and the Office of Research and Development (ORD). Recognition of the importance of maintaining the integrity of our terrestrial and aquatic ecosystems is an important direction for the Agency to take and a most worthwhile result to work toward. However, the Subcommittee concluded that the scope of the stated goals (and needs of the Agency) of the EcoRisk Research Program is completely out of proportion to the available budget. For this reason it is necessary to be much more specific in the statement of goals to distinguish between an expectation of incremental progress and an expectation of actual resolution on a particular issue. Actual resolution can realistically be expected only if all the resources are concentrated on one or at most two items. Distribution of resources over more items, as in the presently designed research program, makes it unrealistic to expect more than slight incremental progress. The EcoRisk Research Plan does not seem to recognize this constraint, and the presentations to the Subcommittee did not make the strategic distinction to allow weighing the value of marginal progress versus substantial resolution of unresolved issues.

EPA experienced an exciting change in its mode of operation when Administrator William Reilly embraced the SAB recommendations that ecological concerns be given attention on a parity with the human health, and that risk reduction is to be utilized as the diagnostic endpoint of regulatory activities. Consequently, technologies needed to evaluate ecological risk assessments in all programs throughout the Agency must now fundamentally cross the various levels of structural hierarchy (individuals, populations, communities, and ecosystems). The EcoRisk Research Program must service the whole of the Agency, not just the traditional OPP, OTS, and portions of the ORD programs. Furthermore, the EcoRisk assessment research activities must include the development and validation of new methodologies, as well as a new technology transfer and support to the regulatory programs. This requires a scope and vision for the EcoRisk Research Program that substantially transcends the present perspective within the program, i.e., addressing the immediate needs for chemical reviews under TSCA or FIFRA.

The proposed FY92-FY96 research plan includes a variety of activities that the Subcommittee classified into levels of organization (individuals/populations and community/ecosystem) and into types of activities (laboratory, field, modeling). These are presented in Table 1 (below), indicating the proposed level of funding and, thus, reflecting present operational priorities. Data for this table were supplied to the Subcommittee by ORD during the review. Given the increasing levels of complexity and the resulting increasing costs per experimental effort as one increases the level of biological complexity, it is obvious that most of the proposed activities remain at the individual and population level. This reflects the traditional level of toxicological risk assessment and will not, by itself, support ecological

risk assessments at the community and ecosystem level. The Subcommittee recommends the program be appropriately modified to increase its emphasis on issues related to the uncertainty of risk assessments at the community and ecosystem levels of organization.

Table 1 Average Yearly Research Expenditures (proposed $K)

| Organizational level | Laboratory | Field | Model | Total |
|---|---|---|---|---|
| individual & population | 900 | 800 | 700 | 2,400 |
| community & ecosystem | 100 | 650 | 550 | 1,300 |
| total | 1,000 | 1,450 | 1,250 | 3,700 |

The Subcommittee agreed on two major recommendations involving future funding responsibilities:

a) The programmatic funding base should reflect the new fundamental role of ecological risk assessment within all programs at the Agency. EPA should develop an Agency-wide research program to develop ecological risk assessment methods. The ORD funding should not be justified only by OPP and OTS needs, but should be supported by the full range of EPA Program Offices. The program should be based upon a clearly identified strategy that cuts across Agency needs for long-term development of ecological risk assessment capabilities. The program should draw upon resources from all media, and should be designed to develop theories and mechanisms that can be applied in concert with ecological risk assessment guidelines to reduce risk at all levels of ecological organization.

b) The level of support must be substantially increased to allow the development and field validation of population-, community-, and ecosystem-level risk assessment methodologies. The research recommendations identified in the 5-year plan, if all were funded, total in the many millions of dollars. A policy team, representing the program offices and other clients (including EMAP), should be charged with developing a funding strategy commensurate with the development and validation needs to implement ecological risk assessment research. Because of the complexity of abiotic and biotic components at the ecosystem level and the current lack of methods to test ecosystems directly and economically, the present research activities emphasize effects at the individual level and seek to establish adequate protection by extrapolating to the ecosystem. The approach is simplistic and does not establish a conceptual linkage of effects noted at the individual level with effects that may occur at

the ecosystem level. The exposure component has relied mostly upon predicting chemical concentrations with models recently developed by the Agency. Toxicity effect models have not progressed to the state of exposure models, except at the QSAR level for individual chemicals on populations. Virtually no models have been developed for ecosystemlevel effects.

A need exists for the EcoRisk Research Program to maintain a balance in support for simple laboratory studies of individual and populations with the more complex community--level and ecosystem-level activities. In addition, because of the present and likely future reliance upon lower-level studies, the Agency must calibrate these tests against ecosystem effects. There is also a need to validate the accuracy of all predictive exposure models and toxicological effects tests against the existing monitoring data from the real world. A critical research need is to focus on the linkages of lower levels of organization to higher levels of organization. These linkages need to be exploited in the construction of a better ecological risk assessment paradigm. This also implies a research strategy that addresses the problem of "top-down" (ecosystem to individual) as well as the "bottom-up" (individual to ecosystem) espoused in the EcoRisk Research Plan. We simply must establish for ourselves (the scientific community), as well as demonstrate to the public, that we understand the predictive power and utility of environmental assessment tools.

### 4.3 Communication

Communication problems between ORD and the OTS and OPP Program Offices have been cited by previous reviews and continue to be a major issue of concern to the Subcommittee. Since the inception of EPA, a dichotomy and competition between the Agency's R&D community and regulatory program offices have existed. The R&D laboratories must build their research strategies upon guidance from the program offices as to how resultant data may be used to enhance the development of new regulatory initiatives or improve the application of existing regulations. The program offices must look sufficiently far into the future to identify fundamental research needs for decision-making and support them through a significant, anticipatory exploratory research program in ORD and user workshops in the program. In programs such as OTS and OPP which have a large scientific staff, some program-specific needs (e.g., compiling databases, assessing Type I and Type II errors, the utility of endpoints, or compiling an inventory of regulatory decision criteria) can perhaps best be accomplished within the program. However, in such cases, ORD and OPTS must routinely coordinate and collaborate among scientific staff to avoid the distrust that comes from isolation and parochial work habits.

The proposed EcoRisk Research Program appears to be a three-dimensional matrix--managed program, involving laboratory projects and headquarters programs. This arrangement poses difficult communication problems, in part because there is no single source of accountability. Under such circumstances, much potentially productive effort is dissipated because the time of so many individuals is required simply to maintain communications among all components of this overly complex system. It is not surprising that project

investigators have little opportunity for building outreach and connections to other programs, such as EMAP or Global Climate Change, each of which could contribute substantive intellectual input and opportunities to the EcoRisk Research Program.

This issue of communication has consistently been a key topic recommendation from numerous previous extramural and SAB program reviews, yet the problem remains today. Clearly, a more formalized network providing for regular working session meetings is needed to focus development and application of R&D programs for EcoRisk.

Another area of interaction is among researchers on larger multi-disciplinary research projects. Some of the proposed projects reflect an integration of activities associated with effects and exposure. This integration is encouraged because it helps to provide an iterative feedback loop on ways to improve the research as it progresses. For example, recognition of how a stress behaves in the environment provides insights on where and how to focus effects research. Clearly, the closer the researchers on exposure and effects work together, the more likely the research results will be useful as tools to enhance EcoRisk assessments and to advance our understanding of the risks of anthropogenic stresses in the environment.

The Subcommittee recommends that the Agency encourage research projects that integrate stress characterization (i.e., exposure) and ecological effects characterization (i.e., hazard) elements within larger multi-disciplinary projects. For this reason, it is critical that ecological risk assessment should be accomplished through a team approach that identifies and brings together the correct technical expertise to perform the assessment. The EcoRisk Research Program should reflect this basic philosophy.

### 4.4 Risk Communication

The continued emphasis on the States as the dominant permitting and regulatory authority has given rise to a wide range of standards and permit authorities among the 50 States. It appears that in many instances, State regulatory initiatives are being promulgated without the benefit of the body of experience, data, or literature available from the Agency's R&D community. Often, these State and regional initiatives are launched by well-meaning but ill-informed citizen groups. Clearly, a void exists between the scientific R&D community and public perception of ecological risks, as demonstrated by the SAB Reducing Risk reports (SAB 1990a, b). A well-focused and directed effort to communicate ecological risks to the public is essential if the findings and precepts of EPA's EcoRisk program are to gain public acceptance.

### 4.5 Monitoring and Lessons From Other Research Programs

The primary mission and goal of the EcoRisk Research Program are to improve the technical bases for ecological risk assessments. In order to accomplish this, the Subcommittee believes that there must be an increased emphasis on the role of monitoring. By contrast, many of the projects and much of the staff time and fiscal resources in the EcoRisk Research

Program are currently directed toward minor or very subtle corrections of existing fate-and--effects methods. Experience has proven that real-world receiving-water communities and terrestrial environments are highly variable and subject to significant spatial and temporal oscillations. It is more important to gather real data on these large-scale variations rather than to fine-tune unrealistic equilibrium models.

Previous peer reviews in 1985, 1986, and 1990 have also pointed out the need for and importance of monitoring. However, the EcoRisk program has to date failed to respond to this advice. We believe this failure has resulted in slowing the rate of attainment of the ultimate program goals and has resulted in a situation where real-world data were missed (e.g., Department of Defense data on modeling of atmospheric spray dispersion or data from States on biological integrity of streams) that could have provided guidance and needed mid-course corrections to the program. The Subcommittee hopes that this same recommendation from a fourth peer-review panel will not be ignored.

This is a particularly important issue today because of the existence of the National Acid Precipitation Assessment Program (NAPAP) data base and the more recent implementation of the Environmental Monitoring and Assessment Program (EMAP). There is no more complete and comprehensive data set that relates stress to higher-level ecological response than that developed under auspices of NAPAP. Although the program has completed its assessment as required under the law establishing the initial assessments, there remain many opportunities to examine or reexamine data on communities and ecosystems that cover a wide variety of ecosystems types at landscape, regional, or in some cases, national scales. The Subcommittee recognizes the opportunity to utilize real-world monitoring data, collected under specific protocols with defined resources at risk, that could be reexamined in the context of the ecological risk assessment paradigm.

Similarly, the Subcommittee could detect only the weakest of links between the EcoRisk research program and EMAP. This is highly regrettable, since both programs have much to offer to one another. It seems reasonable to the Subcommittee that an effectively designed and implemented EMAP program (see NAS [1990] for guidance on monitoring systems design), could act as an effective safety net for evaluating the tier system employed in OPTS. The Panel believes, as discussed in the next section (4.6), that additional research should be conducted to improve upon risk characterization procedures, only one of which is the quotient method.

EPA research programs continue to evolve without consideration of how an international perspective could significantly improve real-world predictability and applications. As one important example, since the goals of many of the EcoRisk Research Program activities are to develop better physical and mathematical models and to measure and predict fate and effects of applied stress agents, a closer examination of existing highly stressed ecosystems from Eastern Europe could prove useful (cf., Grodzinski et al. 1990). Cooperative programs to examine structure and function of these highly stressed terrestrial and aquatic ecosystems

would provide extremely useful data on ecosystem response and recovery from chronic stress agents.

### 4.6 Risk Characterization

Risk characterization is the essential end-product of the scientific component of an ecological risk assessment. It is the output from the risk characterization process that is input to decision-makers for risk management consideration. Only when the component pieces of the process are put together in a risk characterization can we can judge whether these pieces are adequate, which pieces are missing, and what the influence is of component uncertainties on the overall uncertainty of the actual risk assessment.

In this light, an understanding of risk characterization is as important as the risk analysis components (i.e., stress characterization and response characterization). Many of the ecological risk characterization efforts by the Agency for single chemicals have used the quotient method (i.e., comparing exposure assessment and single-species toxicity measurements). As such, this does not constitute a quantitative estimate of the magnitude of risk. Because of this limitation in the quotient method and overall state-of-development of risk characterization procedures in ecology, additional research on the risk characterization component of ecorisk is critical.

The importance of risk characterization is not emphasized in the EcoRisk Research Program Plan and is allocated in the proposed budget less than one-tenth of the funds. The Subcommittee recommends that the Agency expand research activities in the area of risk characterization to enhance and complement research on stress characterization and effects characterization.

Additional efforts for interpretation of information (e.g., statistical treatment of data, probabilistic assessment, uncertainty analysis, and innovative ways of integrating and presenting data) are also needed. This should be linked to research on ecological valuation, to develop a metric for expressing the ecological cost component of risk.

Much of the emphasis of the EcoRisk Research Program described in the Plan is directed at attempting to obtain predictions in situations where historically predictions have not been feasible, and where, for theoretical reasons, we should expect predictive power to remain limited. This means that risk characterization research should devote attention to developing an assessment procedure that copes with uncertainty, i.e., incorporates uncertainty in a realistic and, insofar as possible, quantitative way, rather than just wishing that the uncertainty would go away. In fact, though there was mention of probability and uncertainty in the presentations to the Subcommittee, none of the proposed research activities addresses explicit quantification of probabilities and uncertainties. Since there seems not to be a professional consensus on what the protocol should be for uncertainty analysis, development of such a protocol should be a high priority in an ecological risk assessment research

program. In particular, the discipline of decision theory should be explored as a model for the formalization of risk characterization.

### 4.7 Research on Mechanisms and Processes

A review of the research projects in the EcoRisk Research Program Plan lead the Subcommittee to several conclusions. One is that although the client offices, OTS and OPP, have different core functions, their needs, relative to ecological risk assessments, are essentially the same. While a specific project may be considered of primary importance by one office and of secondary importance by the other, it is still needed by both. Once the similarities are recognized and conveyed to management, there may be more opportunities for close coordination and collaboration between ORD and program offices. For example, the laboratory and field data available to OPP could be used to calibrate the models and structure-activity predictions used by OTS for a few specific compounds.

Collaboration should also lead to the coordinated development of standardized methods for evaluating biological effects and provide justification for obtaining critical data on chemicals under the Pre-Manufacturing Notice and Toxic Release Inventory. If a minimum data set of analytical properties and biological effects information is available for chemicals covered by TSCA (see recommendation in the SAB report EPA-SAB-EPEC-91-0-04, November, 1991, entitled "Evaluation of Research on Expert Systems for Predicting the Environmental Fate and Effects of Chemicals"), collaborative efforts could be extended to other program offices within EPA. The Subcommittee recommends that the research plan include a strategy to encourage data sharing and the use of standardized effects testing methods between OPP and OTS. The OPP data could be used to validate some of the OTS evaluation tools, and the use of standard methods among the programs would improve the chemical review process in both offices.

The Subcommittee concluded that the majority of the proposed projects that focus on effects or hazards will not lead to a fundamental understanding of cause-effect relationships. This, in turn, will require that in the future, chemicals will continue to need to be tested one at a time by some standardized set of bioassay protocols. The major pitfall with this approach is that standardized bioassays appropriate to determine important ecological effects, such as inhibition of primary productivity, do not exist. It is only through a fundamental understanding of the modes of action on individual organisms and ecological effects at higher levels of biological organisms that a more credible approach can be developed.

The existing funding base for EcoRisk research is so limited that coordination between and among projects must be maximized and redundancy minimized. Further, it is essential that EcoRisk projects be selected on the primary criterion to quantify and reduce uncertainties in ecological risk characterizations to the extent possible. This is only possible when ecological stress-response models are based on realistic understanding of processes and on causality mechanisms. It is obvious that this is not the case in the present program. A careful evaluation of the projects relative to these points should be conducted and corrections

(e.g., delete, modify, or add projects) made as necessary. However, by having the goal of quantifying and reducing uncertainty in ecological risk assessment as the foundation of the EcoRisk Research Program, the limited funding can be put to the optimal use, the potential for good science can be increased, and the benefits to the client offices maximized.

The Subcommittee recommends that the EcoRisk Research Program not continue to "micrometer a brick". Many of the proposed laboratory activities continue to be directed toward subtle refinements of laboratory fate-and-effects methods. In many cases, it appears that principal investigators have not taken full advantage of the published literature or parallel research activities developed by State and regional agencies. It is essential to recognize that the results of the many research programs presented will at best result in only subtle changes in model parameters too small to be of any realistic advantage or use when applied to real-world ecosystems where processes not even included in the model come to play a major role.

### 4.8 Research on Multiple Stresses and Complex Mixtures

A major shortcoming in our ability to characterize environmental risk from human activities is the inability to ascertain the hazards of chemical mixtures or multiple stresses. Rarely is an organism, population, community, or ecosystem exposed to only a single chemical or stress. Rather, hundreds of substances and/or a variety of physical perturbations in the environment may affect the well-being of the ecological system in question. Often exposure to stress will occur near human population centers, where there are multiple sources, or in areas where contaminants concentrate because of natural physical and chemical factors. Examples of the latter are the accumulation of hydrophobic substances in areas of fine-grained sediment in water bodies or in the turbidity maximum of estuaries.

The complexities of standard environmental toxicity tests increase exponentially as multiple chemicals and/or stresses are employed. The often-used bioassay endpoints of survival, growth, and reproduction are not sufficient to provide the mechanistic understanding required to predict effects and to avoid the Herculean task of multiple chemical/perturbation bioassays. A fundamental understanding of the biochemical and physiological interactions of hazardous chemicals and stresses with individuals is necessary. For instance, rather than trying to determine the effect of polyaromatic hydrocarbon compounds (PAHs) on finfish reproduction by conducting hundreds of egg-to-egg bioassays on each chemical, a much more efficacious approach might be to understand the mechanisms that result in the effect (e.g., the induction of hepatic enzymes by PAH and the resulting potential for adverse impacts on reproductive hormones that could diminish the animals ability to reproduce and how this relates ultimately to alterations in ecosystems). Therefore, the Agency should make a larger investment in research on the mechanisms of toxicity and stress at all levels of biological organization

This approach will require a focused research program, involving university and Agency personnel, and a commitment for long-term funding and support. The long-term

benefit of this investment will be that the Agency could shift from a purely reactive role in processing applications for pesticide registrations and Pre-Manufacturing Notices for toxic chemicals to an anticipatory, strategic role in identifying risks to the environment and in stimulating human activities that minimize ecological and health risks.

As an example, the Subcommittee noted that there is apparently only one research project proposed to focus on modes of action/toxicity in either terrestrial, freshwater, or estuarine/marine systems. It is unlikely that this effort is sufficient to advance of the state-of-the-science beyond single chemical- single species toxicity tests.

### 4.9 Research on Community-, Ecosystem-, and Landscape-Level Processes

The mandate to conduct ecological risk assessment at the community and ecosystem levels of organization is relatively new to ORD. Many of the proposed projects in the EcoRisk Research Program assume that one can simply extrapolate effects upward from observations made on individuals. However, the emergent properties arising from organization and structure and the feedback controls and processes that exist at higher levels of organization produce new characteristics (often unexpected responses) that can not be predicted by simple extrapolations.

Our ecological landscape models are often based on theory and extrapolations because of inherent complexities in ecosystems and natural stochasticity in the environment. There have been, however, an array of ecosystem- and landscape-level experiments, some designed (e.g., Hubbard Brook Experimental Forest) and some uncontrolled (e.g., fire in Yellowstone National Park), which may provide valuable case studies to understanding ecosystem-level responses to and recovery from stress. These studies should be utilized to identify hypotheses concerning interspecific interactions and biogeochemical feedbacks that constitute the important processes occurring at higher levels. These mechanisms should be incorporated into the ecosystem risk assessment models and tested with direct field experimentation.

### 4.10 Innovation

An overall issue identified by the Subcommittee concerned the need for innovative research to address the fundamental issues of ecological risk assessment. With some exceptions, the activities proposed or underway in the ORD EcoRisk Research Program lack the degree of innovation that is commensurate with either the research needs (i.e., complexity of the issues) or the importance of the research to Agency-wide decision-making. There is a general consensus among the Subcommittee members that too many projects are proposed, scattered across the research landscape without sufficient attention to advancing the state-of-thescience in areas of particular need or generic applicability.

Development of methodologies for ecological risk assessment should be anticipatory, that is, not merely responding to present, immediate needs, but also to the environmental issues that will face the Agency in the next years and decades. As discussed previously, the

SAB reports on relative environmental risks (SAB 1990a, b) clearly identified stresses of primary concern that are not chemical in nature. Moreover, even for chemical stresses, addressing the set of scientific issues required to be incorporated into a genuine ecological risk assessment considerably exceeds the present single chemical-single species emphasis. Interdisciplinary approaches are required, as are integrated activities linking the stress regime component of ecological risk assessment with the ecological effects component. Both stress and ecological effects characterization, the two central components of ecological risk assessment methodology which have been discussed during the ecorisk guidelines workshops (Fava et al. 1991; Harwell et al. in preparation), require examination of issues cutting across scales of time and space, across ecosystem types and stress types, and across levels of ecological organization, from individuals through populations and communities, to ecosystems and landscape levels. This fundamentally requires significant advances in understanding ecological systems and their interactions with human activities, an understanding transcending the so-called "ecotoxicity" approaches of the past. As the core research activity for ecological risk assessment methodology development, the ORD program must take the lead in developing innovative approaches to these complex problems. That innovation is presently lacking for the overall program.

It should be noted that there are several research efforts that contribute to the ecological risk assessment research program and deserve special mention because of their high caliber. The research on bioaccumulation based upon pharmocokinetic principles is well conceived, scientifically sound, and innovative. Likewise, the QSAR studies of various classes of chemicals have provided important insights and should be pursued further. Both of these programs have been active for some time, and clearly preceded the current ecorisk research initiative. These examples point out the pay-offs that can result from long-term research that is well conceived.

The many other individual components of the EcoRisk Research Program need to attain a comparable level of scientific innovation. More importantly, the Subcommittee strongly feels that the overall research program as an integrative effort requires new and innovative thinking. One approach, presently lacking, would be to establish an explicit task on integration and synthesis that would evaluate research and identify needed research and targets of opportunity. Perhaps a scientific advisory committee to function as a think-tank to the Program could be convened periodically.

As an example of innovative approaches that could significantly enhance the program, opportunities should be sought for the EcoRisk Research Program to function in a lead or coordinating role for evaluations of ecological effects from human activities in the real world. Rather than investing small funds into tasks that piggy-back onto other ongoing research, such as the wading bird habitat study, the EPA program should function as a focus for leveraging and coordinating research funded by other federal agencies or regional/local interests, directed broadly toward ecological risk assessment research needs. These field studies can significantly improve the understanding of the extrapolation issues discussed previously, and offer top-down bases for identifying specific causal relationships and specific

hypotheses to be tested in laboratory and model experiments. Local and regional studies should be used as examples to identify needs for the ecological risk assessment research program. Advancing the state-of-the-science on characterizing stress and ecological effects uncertainties, both qualitatively and quantitatively, warrants a separate research task, discussed elsewhere in this report. Until one understands the relative magnitudes and nature of the uncertainties, it is impossible to know what level of confidence to assign to decisions based on the assessment.

A number of groups within EPA have struggled for some time with the development of risk assessment methodologies and with attempts to define uncertainties. The Environmental Criteria and Assessment Office (ECAO) in Cincinnati has addressed these issues for human health. Although the risk assessment methods for human health have limited applicability to risk assessment for ecosystems, the experience in dealing with extrapolation problems should be utilized.

Similarly, the issue of model validation, which is mentioned in several proposed project descriptions, should be addressed as a separate research task. Here the points of concern are that simulation models are often quite detailed and have many parameters, yet field data are scarce; as a result, all parameters are not sufficiently estimated from the field data. If properly and rigorously researched (including such components as statistical tests of goodness-of-fit, statistical tests of robustness and power, development of innovative graphical techniques, and systematic examination of previous applications of the model in other situations), model validation can provide graphical and statistical representations of model performance under a variety of conditions that are essential to have confidence in the model results. But this is a massive undertaking, which must be planned and funded accordingly.

Advancing the scientific understanding of higher-level ecological effects is central to developing a risk assessment capability that truly addresses the regulatory or assessment endpoints of concern to humans. The research program should include a focused task on evaluating existing methodologies and identifying new approaches that should be explored. As one component of this, there should be considerably greater reliance on multidisciplinary approaches. While we are not recommending that disciplinary-focused activities be replaced or eliminated, the Subcommittee does recommend that they be significantly supplemented by multidisciplinary and interdisciplinary activities. These are required to address such issues as the transformation and partitioning of chemicals in the environment, interactions of chemical with other chemicals and with physicochemical conditions in the environment, population dynamics of exposed and affected species, and the interactions of biological populations, among many other issues. Present resources will not allow addressing all of the full range of issues in an interdisciplinary approach; yet significant research must be undertaken to advance the state-of-thescience in interdisciplinary ecological research if EPA is ever to go beyond its very limited predictive capability for ecological risk assessment.

# 5. SUMMARY OF RECOMMENDATIONS

The Subcommittee reviewed the information provided and developed responses to the seven questions in the charge and developed further comments on eight issues. The principal recommendations from these comments are summarized below.

a) The development of scientifically sound methodologies and data bases for conducting ecological risk assessments on the diversity of anthropogenic stresses and ecological systems of the United States is a critical need for the Agency and the nation. The current budget for the ORD EcoRisk Research Program is grossly inadequate to address the scientific issues that must be resolved to meet that need. The Subcommittee strongly recommends that EPA provide the level and consistency of funding for research to improve EcoRisk assessment methodologies commensurate with the importance of this need.

b) The Subcommittee recommends that ORD revise the EcoRisk Research Program to reflect the fundamental role of ecorisk throughout the Agency. The EcoRisk Program requires a broader scope than it presently derives from the limited program office clientele.

c) Uncertainty analysis is a critical aspect of ecological risk assessment that is inadequately addressed within the research plan. The Subcommittee recommends that research projects be developed that explore techniques and methods to quantify uncertainties associated with ecological risk assessments.

d) The Subcommittee strongly recommends that a systematic quantification of uncertainties associated with each element of ecological risk assessment be undertaken. The Subcommittee further recommends that such an evaluation constitute the primary basis for prioritizing research and allocating resources in the EcoRisk Research Program, i.e., selecting research activities to reduce the most important uncertainties most effectively.

e) The Subcommittee recommends that the EcoRisk Research Program significantly enhance research to advance population-, community-, ecosystem-, and landscape-level ecological risk assessment methodologies. This emphasis should result in a more appropriate balance of projects designed to address higher levels of biological complexity, multiple stresses, and extrapolation issues.

f) The Subcommittee recommends that the EcoRisk Research Program establish effective interactions with other research or risk assessment efforts within the Agency (such as EMAP and the Risk Assessment Forum).

g) The Subcommittee recommends that the EcoRisk Research Program focus on the development and testing of new methods for ambient monitoring of ecological responses of communities and ecosystems. Existing data sets (such as NAPAP and EMAP) may provide the most comprehensive and useful information for such testing. This effort should be coordinated with the development of an ecological indicator research program.

h) The Subcommittee recommends that the EcoRisk Research Program conduct research on risk characterization that would include statistical treatment of data, uncertainty analysis, and integration of data. This characterization should also be linked to research on ecological valuation.

i) The Subcommittee is particularly concerned that most of the research plan lacks the degree of innovation that is commensurate with the research needs or the importance of ecorisk research to Agency-wide decision-making. The Subcommittee highly recommends the establishment of an integration and synthesis task and an intellectual or think-tank component to develop new ideas for ecological risk assessment methodologies. The Subcommittee further recommends significant enhancement of an extramural research program that is based on scientifically peer-reviewed proposals, and recommends significant increase in the use of peer review for research conducted by on-site contractors.

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