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AN SAB REPORT: REVIEW OF THE PROCESS AND RATIONALE FOR DEVELOPING ECOLOGICAL RISK ASSESSMENT GUIDELINES

**PREPARED BY THE ECORISK
SUBCOMMITTEE OF THE
ECOLOGICAL PROCESSES AND
EFFECTS COMMITTEE**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

August 11, 1992

OFFICE OF
THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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Mr. William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

RE: SAB Review of the Process and Rationale for Developing Ecological Risk Assessment Guidelines

Dear Mr. Reilly,

The Ecorisk Subcommittee of the Ecological Processes and Effects Committee (EPEC) of the Science Advisory Board (SAB) has completed its review of the Risk Assessment Forum's (RAF) proposed ecorisk assessment process and plan for developing ecorisk assessment guidelines. The Subcommittee met on March 26-27, 1992 to conduct this review.

The RAF requested that the SAB review their preliminary plans for developing guidelines which include the generation of issue papers and case studies. In particular, the RAF requested comments on the suitability of using their proposed process for structuring ecological risk assessment guidelines and on the adequacy of the list of issue papers and case studies. In the past the SAB consulted with the Forum on concepts that should be covered in the Agency's approach to ecological risk assessment, and EPEC has received periodic briefings on ecorisk guideline activities. Further, EPEC has identified Ecorisk Assessment and Guidelines Development as major topics for long-term consideration.

The Subcommittee commends the Agency for its development of a "Framework for Ecological Risk Assessment" (Framework) as a basis for ecorisk guidelines. The concepts

described in the Framework are well-conceived and broad enough in scope to include current Agency ecorisk activities. However, as defined by the RAF, guideline development depends on input from the issue papers and case studies that will be developed in the future. Ecorisk assessment is in its infancy in terms of development and, as such, the guidelines program and all of its components need to remain flexible and capable of incorporating new findings. In order to clarify that process, it would be most helpful if the Framework included some explanation of what is meant by ecological risk beyond the definition. It would be most instructive to discuss who or what is at risk and discuss some examples of both a narrow definition of ecorisk related to particular species or ecosystems and a broader definition such as the risk of irreversible departure from a healthy sustainable condition. Such an exposition may fit into the discussion of the conceptual model and in the future, it could be illustrated by the case studies.

We understand that the intent and desire of the evolving risk assessment effort is to provide managers and scientists with quantitative tools for making risk-based decisions. The Framework must define the steps in the assessment process, the roles of the assessors and managers, and encourage them to help the risk takers understand the consequences and the alternatives for mitigation associated with those risks. In order to achieve these objectives, the Agency must provide additional staff time and resources because progress has been slow to date and the most significant tasks still lie ahead. For the short term, the Agency may need to rely heavily on the technical input from outside experts. In addition, Agency managers and the RAF itself must recognize that the Forum has a key role in communication of risk assessment approaches and coordination with risk managers through the development of guidelines to assure that all needs are considered. The Subcommittee believes that RAF should also have a role in the promotion of research on critical ecorisk issues.

Today, most ecological risk assessments are at best semi-quantitative or qualitative statements patterned after either the chemical-based approach for human health or a broad environmental impact assessment which lacks specific endpoints. Risk assessment procedures as we know them today are data intensive and costly to perform. The RAF must strive to simplify the procedures and reduce costs.

The Subcommittee recommends that the framework document and the implementation strategy be revised to make the process more interactive and iterative and to expand its ecological focus on non-chemical stressors, including biological stressors. The Subcommittee has also included a number of specific comments and suggestions to clarify the structure and ultimate use of the guidelines as well as a request to more fully reflect comments of scientists

outside EPA and other groups. The Subcommittee is concerned that the process diagram as presented in the framework document is flawed because it does not clearly show the level of iterative and interactive processes which may occur between the components of the ecorisk assessment. Likewise, the Subcommittee recommends that the RAF modify the exposure assessment component to be called the "stressor-exposure assessment". The SAB recommends that a similar modification be made for the term in human health risk assessment paradigm. The implementation strategy needs further emphasis on guidance for non-chemical stress, mechanisms for meeting ecorisk research needs, and procedures for building technical links with critical Agency programs such as EMAP (especially for integration and assessment and indicators), the Great Lakes Initiative, Habitat Protection, and Global Climate Change. The Subcommittee recommends that these revisions be made within one year, so they can be reflected in future activities of the RAF and the Agency regulatory programs that apply the concepts.

The Subcommittee endorses the step of developing a conceptual model as part of the planning phase of each risk assessment. The RAF should encourage that such models be developed by multidisciplinary teams and guidance should be provided for use of conceptual models in an issue paper. The public should also be involved in the formulation of the model. The analysis of risks through exposure/stress characterization and effects characterization should provide feedback to the model. Unfortunately, the Agency has relatively few tools available to characterize the risks associated with non-chemical stressors, multiple stresses, or cumulative effects of stress. Research to develop these tools is urgently needed and the Subcommittee believes that RAF should have a role in identifying and promoting those needs.

The Subcommittee also supports the development of Technical Issue papers, as described at the meeting. More effort is needed to ensure that the development of technical issue papers and case studies proceed with a high degree of coordination and communication. Results of case studies should strongly influence the outcome of issue papers and thus maximize their contribution to the development of risk assessment guidelines. We recommend that additional specific topics be considered: development of the conceptual model, natural variability (distinct from ecological significance), data acquisition, predictive and retrospective analysis, a comparison of ecorisk assessment and environmental impact analysis, and ecorisk research needs. Finally, the number of case studies should be increased and an additional effort should be made to show how case studies support and relate to guidelines.

The Subcommittee recommends that the RAF seek early peer review and input on its future products in their formative stages so that relevant comments can be incorporated into the final documents. We are particularly interested in how the RAF will address our recommendations for changes to the Framework and for the integration of human health risk assessment under the broad concept of ecological risk assessment. The Subcommittee looks forward to the continued development of the ecological risk assessment process and hopes to see constructive iterations in the concept. We look forward to future opportunities to review the products of the case studies and issue papers.

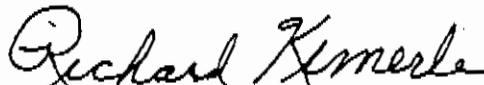
Sincerely yours,



Raymond Loehr, Chair
Executive Committee
Science Advisory Board



Kenneth Dickson, Chair
Ecological Processes and
Effects Committee



Richard A. Kimerie, Chair
Ecorisk Subcommittee

DEDICATION

On August 1, 1992, Dr. Allan Hirsch, a member of the SAB's Ecorisk Subcommittee, died unexpectedly. Throughout a prolific career that included service in the private and public sectors, Dr. Hirsch distinguished himself as an uncommon man of vision and principle, consistently calling attention to our responsibility to meet the ecological challenges confronting this--and future--generations.

Those of us on the Science Advisory Board benefitted from his presence and will be inspired by his memory, to which we dedicate this report.

ABSTRACT

The report represents the conclusions and recommendations of the U.S. Environmental Protection Agency's Science Advisory Board regarding a strategy for developing ecological risk assessment guidelines. The Ecorisk Subcommittee met on March 26-27, 1992 to conduct this review. The Subcommittee found that the Ecological Risk Assessment program had developed useful guidance to address important issues and recommended that the Agency increase its efforts to develop issue papers and expanded case studies. The Subcommittee agreed that the current framework should be viewed as evolving and that its focus must go beyond traditional chemical stressors dose-response approach of and it should be revised to effectively include biological stressors. Further, they recommended that the Forum serve as a major coordination point for scientists within the agency and in other Federal Agencies. Coordination is particularly important with EPA programs for EMAP, Geographic Initiatives using ecological criteria, Habitat Protection, and Global Climate Change. The Subcommittee also recommended that RAF activities should also be used to stimulate research on ecological risk assessment methods, assessment techniques, the selection of endpoints and indicators, and assessments of multiple stressors and cumulative impacts. The Framework should also be expanded to include biological stressors, data acquisition and public input to the formulation of the conceptual model.

KEY WORDS: Ecological Risk Assessment, Guidelines, Case Studies

U.S. ENVIRONMENTAL PROTECTION AGENCY

NOTICE

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1. EXECUTIVE SUMMARY

The Ecological Processes and Effects Committee (EPEC) formed a Subcommittee which conducted a review on March 26-27, 1992 of the EPA Risk Assessment Forum's program to develop Ecological Risk Assessment Guidelines. The major findings, conclusions, and recommendations of the Subcommittee are as follows:

- A. The Ecological Risk Assessment Guidelines program is viewed as a critically important Agency wide effort. The existing plan, accomplishments to date, and action items for the future were judged as appropriate to attain the goal to better understand, maintain, and protect the ecological resources of the nation. However, for this to happen it will be necessary for the Agency to continue to (1) strive for a sound scientific foundation in the Guidelines, (2) continue to sensitize and communicate to both the public and the decision makers the importance of our ecological resources, (3) seek the support and cooperation of other groups within EPA and outside agencies, (4) provide appropriate support in funding and personnel, and (5) proactively look to the future on what the real ecological threats are and what needs to be done to address them. The Subcommittee perceives that the ecological risk assessment guideline program is an excellent start towards developing a much needed, comprehensive approach for assessing the significance of ecological stressors. It is currently well focused and positioned to provide significant guidance that could influence most future regulatory initiatives within the Agency. Unfortunately, the Subcommittee finds that the program is moving very slowly, and lacks the visibility and support within the Agency to address critical technical issues. The link between the Risk Assessment Forum and the research program appears too limited for successful resolution of the technical issues they must face to manage and coordinate the development of ecological risk guidelines.
- B. The Subcommittee commends the Agency for the effort and resulting program plan that is emerging in the "Framework for Ecological Risk Assessment" and "Plan for Developing Ecological Risk Assessment Guidelines". The primary components of the program (Framework, Technical Issue Papers, Case Histories, and Guidelines) were judged as appropriate but they need to be carried out in a more interactive and iterative manner. The Subcommittee also agreed that a clearer more descriptive model should be presented on content and use of the Guidelines to help focus other program efforts.

- C. The organizational structure presented in the Framework document of Problem Formulation, Analysis, and Risk Characterization was judged as a useful alternative to the ecological components which were originally considered.
- D. The Subcommittee believes that the Problem Formulation phase needs an even stronger central emphasis by developing a conceptual model of planning; problem scoping; communication across agencies; involvement of the risk assessor, the risk taker, risk manager, and the Public where appropriate; and identification of stressors, endpoints, ecological boundaries, predictive and protective parameters, and data quality needs. Within the overall model there needs to be a strong concept that links stressors, endpoints, and boundaries to the purpose of the assessment and the alternatives to mitigate the risk.
- E. The Analysis phase is based upon the appropriate model of exposure/stress, impact or effects delineation, and risk characterization. Deficiencies were noted by the Subcommittee in this section. There is, it appears, a continuing insistence by the Agency to use the term "exposure characterization" which implies individual chemical exposure to many scientists and managers. The Subcommittee recommends that the Agency use the concept of "stressor-exposure characterization" which includes non-chemical stressors. This term should apply to both human and ecological risk assessments. Ecological risk assessments of the future will have to deal with this more difficult area of non-chemical stressors, including biological stressors, if ecological risk assessment is going to fulfill its expectations for the future.
- F. Additional points identified as needing inclusion in the Analysis phase were (1) include the relevant data acquisition, verification, monitoring steps inside the analysis box and (2) expand beyond chemical and physical stressors and include biological stressors.
- G. The Framework document section on Risk Characterization provides the needed flexibility for both qualitative and quantitative risk assessments. The Subcommittee thought that greater attention could be given to the details of (1) interactions and effective communications in the problem formulation phase between the risk assessor and risk manager, (2) how the output of risk characterization will be used by the risk manager, (3) predictive and retrospective risk assessments, and (4) the role of scientific judgement in the risk characterization process.

- H. The concept of developing Technical Issues Papers was supported by the Subcommittee. This step will provide the opportunity to keep the science of ecological risk assessment guidelines technically evergreen as the science evolves. Several additional topics deserving consideration for technical papers were added to the list: conceptual model development with an expanded scope, data acquisition, predictive versus retrospective risk assessment; natural ecosystem variability (separate from ecological significance); and a comparison of ecorisk assessment and environmental impact analysis. These papers and clarifications of other issues proposed by RAF, should provide the direction for research funding.
- I. The Subcommittee concurred with the RAF and placed a high value on the role of Case Studies in the overall guideline development process. In fact, it was felt that more case studies should be developed. Some of these case studies can be taken from the published literature, to illustrate the breadth and applicability of the guidelines to all parts of the Agency. In addition, case studies that are simple examples of ecological risk assessments, based on limited data sets, should be included. It is most important that an effort must be made to demonstrate more clearly how the case studies support and are linked to the Guidelines.

2. INTRODUCTION

The Science Advisory Board (SAB), was asked to review the process, status, and usefulness of the EPA's efforts to prepare risk assessment guidelines under the direction of the Risk Assessment Forum. In the past, the SAB consulted with the Forum on the concepts that should be covered in this Agency program. In addition to the consultation, the Ecological Processes and Effects Committee (EPEC) has also received periodic briefings on the status of the ecorisk guideline activity. The Committee has recognized the importance of Ecological Risk Assessment Guidelines not only to the EPA, but to other government agencies. With the current worldwide increased interest in protecting the integrity of our ecosystems this EPA effort to develop ecological risk assessment guidelines is critically important. The SAB is very interested in supporting the development of scientifically defensible and useful guidelines and has thus formed an Ecorisk Subcommittee under the direction of the EPEC to conduct reviews on this and any future related reviews.

2.1 Charge for the Review

The Risk Assessment Forum (RAF) requested that the SAB review their preliminary plans for developing guidelines including the development of issue papers and case studies. The Risk Assessment Forum was particularly interested in SAB comments on two issues:

- A. Is the ecological risk assessment process as described in the Framework Report suitable to structure EPA's first Agency-wide ecological risk assessment guidelines? Are the three major categories of (1) generic principles and methods for problem formulation, (2) analysis, and (3) risk characterization an appropriate way to structure future guidelines? Additional guidance specific for particular ecosystems, stressors, endpoints and other areas would be developed as feasible in the first guidelines or in subsequent stages of the overall guidelines development program.

- B. Are the eight issue paper topics listed below and detailed in the plan for guidelines development useful and sufficient to provide technical guidance for the ecological risk assessment process and the development of guidelines? Should any topics be added or deleted?
 - 1. Stressor-Ecosystem Interactions
 - 2. Endpoint Selection

3. Characterization of Exposure
4. Characterization of Ecological Effects
5. Risk Integration Methods
6. Uncertainty Analysis
7. Ecological Recovery
8. Ecological Significance

2.2 Subcommittee Review Procedures

The Subcommittee was provided a report entitled "Framework for Ecological Risk Assessment" describing the basic terminology and elements of the ecological risk assessment process, a "Plan for Developing Ecological Risk Assessment Guidelines", and the charge for the review. The Subcommittee also received copies of the "Peer Review Workshop Report on A Framework For Ecological Risk Assessment", and the "Report on the Ecological Risk Assessment Guidelines Strategic Planning Workshop". These latter two documents were the product of two workshops conducted in the spring of 1991 and were published along with the Framework Document following the review. EPA initially considered structuring ecological risk assessment guidance primarily around ecosystems, levels of ecological organization, or stressors. However, as a result of the Risk Assessment Forum's 1991 peer review workshops, participants recommended that the first Agency-wide ecological risk assessment guidelines be structured around the major phases of the ecological risk assessment process as they are now outlined in the Framework Report: these categories are problem formulation, analysis, and risk characterization. The Subcommittee met on March 26-27, 1992 in Washington, D.C. to review these materials and discuss the charge. The Subcommittee also provided comments on the Framework document and the needs for RAF involvement in the research planning process. At the conclusion of the meeting, the Chair summarized the preliminary comments of the Subcommittee for the public and the Agency. A draft report was prepared by the Subcommittee and provided to the Executive Committee for concurrence. The reviewers from the Executive Committee offered several comments, including the suggestion that human health risk assessment should be integrated with ecorisk assessment which the Subcommittee chair has adopted.

3. EVALUATION OF THE ECORISK ASSESSMENT PROCESS

3.1 Suitability of the Process for EcoRisk Assessment Guidelines

3.1.1 Overview of Ecorisk Process

The Subcommittee commends the Agency for its efforts in the development of a "Framework for Ecological Risk Assessment" as a basis for development of Agency-wide ecological risk assessment guidelines. The Framework Report with the three phases of (1) problem formulation, (2) analysis, and (3) risk characterization provides a useful conceptualization of the ecorisk assessment process. Each of the phases are broad enough in scope to include the various types of ecological analysis and assessments currently being used. Guideline development will, however, also require input from the yet to be developed Issue Papers as well as the compilation of Case Study reports. The Subcommittee believes that the ultimate success and usefulness of the Agency's Ecological Risk Assessment Guideline program will be improved if the Framework document and implementation strategy considered incorporating the items discussed in this report.

The Subcommittee agrees with the approach of using issue papers and case studies to assist with the development of guidelines, but the former must be scoped and have criteria for consistency and the case studies must be linked to the issue papers. While the Subcommittee understands the need for Agency guidelines and commends the effort of dealing with diverse needs, the guidelines/framework should represent primarily a synthesis of existing literature. The Subcommittee lists several important issues that need to be addressed and which will determine how well we can perform ecological risk assessments; these include data acquisition, comparison of ecorisk assessment and environmental impact analysis, and issues for ecorisk assessment research. They also recommended that several proposed papers be modified; two papers should be combined to discuss the development and scoping of conceptual models, natural ecosystem variability should be treated separately from ecological significance and the paper on uncertainty analysis should be expanded. The Subcommittee also recommends that EPA significantly expand the number and type of case studies to illustrate the applicability of risk assessment across the Agency.

Ecorisk assessment is in its infancy in terms of development and as such, the program and all of its components need to remain flexible and capable of incorporating new finding. The model as presented in the Long Range Plan has three components: Technical Issue Papers; Case Histories; and Guideline Development. The Subcommittee does not view these

as a linear process and recommends that the components be presented as an interactive and iterative process as shown in Figure 1.

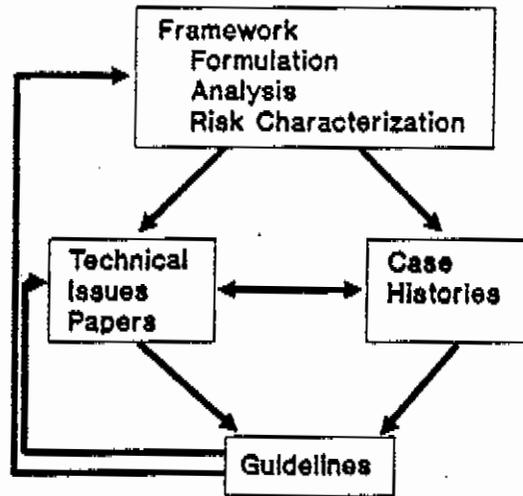


Figure 1 Relationships of Ecological Risk Assessment Components

At this time the Ecological Risk Assessment Guidelines documents are not well defined. The Subcommittee agreed that additional effort is needed to better define in the Framework document many of the potential issues surrounding Guideline development such as their nature, scope, intent, structure, and use. There is a need to focus on a better description of the Guidelines so that the path to get to them is clearer.

Success will also be contingent upon numerous other factors. There will be a need to maintain the scientific input that is currently planned through use of workshops and meetings. Related to this is the important need to solicit and involve other governmental agencies at the state and federal levels. Without their cooperation and involvement as partners in the entire

program, it will not be utilized to its full beneficial potential. Other issues such as adequate funding and sufficient time for full program development will help assure a valued and useful product.

3.1.1.1 The relationship between human health risk and ecorisk assessment

The foundation for Ecological Risk Assessment Guidelines probably emerged from the Human Health Risk Assessment Guidelines program, which may in fact be a simpler challenge than ecological risk assessment. The Subcommittee finds many similarities between the programs, but ecorisk assessments may involve a variety of levels of biological organization and interactions which are not considered in single species model human health risk assessments. The most basic reason is that for the assessment of human health risks, data from many species are used to estimate effects in one species - humans. Data from simpler levels of organization (molecular - cellular - tissue/organ - organism) are used to assess potential effects in the human individual; and in this case, humans are obviously at the highest level of organization in the assessment matrix. In the development of criteria for the protection of ecosystems, we are attempting to use data from lower levels of organization (molecular - cellular - organism) to predict effects on higher levels of organization (individual organism -population - community - ecosystem), where humans are only one species within a complex ecosystem. Fortunately, human health risk assessment provides a well developed model for the species level assessment which can be incorporated into the ecorisk assessment process. The large body of knowledge on human health risk assessment has often been considered as a model for ecorisk assessment. Actually, human risk assessment is a component of ecorisk assessment, just as man exists within the environment. In some cases, man's activities and choices pose the most significant risks to other species, populations, communities, and ecosystems. The Subcommittee recommends that RAF consider developing this type of approach, to build on past experience, harmonize the various forms of risk assessment, and find new opportunities to balance and communicate relative risks.

From a historical perspective, EPA's water quality criteria program and human health risk assessment guidelines required several revisions in scope and methods over many years as new technology changed. Therefore, the Subcommittee agrees with RAF that the ecorisk assessment process is one that is very likely to evolve to new levels of understanding and thus the guidelines, case studies, and issue papers. The Subcommittee further believes that the Framework will need to be reviewed and updated periodically.

3.1.1.2 Simplification of the Process and Graphics

There is a need to simplify and modify the level 2 diagrams in the Framework document. The level 2 descriptions of the Risk Assessment process shown as Figure 3 and Figure 4 in the Framework document are confusing (Appendix 1). Many boxes with redundant contents should be combined. In Figure 3 the boxes identified as Exposure Profile and Stressor-Response Profile can be eliminated or shown more appropriately as outputs of the analysis. The associated text discussion can also be eliminated or at least condensed into the Stressor-Exposure Analysis and Ecological Response Analysis Phases.

Figure 4 is confusing and should be simplified. In the Risk Description box, the process of "Ecological Risk Summary" adequately captures what occurs and should include the "Interpretation of Ecological Significance". The "Interpretation" box should be eliminated.

3.1.1.3 Coordination within the Agency

In order for the agency to have an effective risk assessment program, related activities within the agency need to be coordinated with an emphasis on the technical staff or scientist level not just upper/middle management level. This is especially important as the agency develops activities oriented towards nonchemical stresses (i.e., wetlands protection, global change, life cycle analysis, habitat loss, environmental quality criteria for geographic initiatives, Environmental Monitoring and Assessment Program). The Risk Assessment Forum should serve as a coordination point and implement this coordination through the risk framework document and guidelines development (especially in the issue paper process). Management needs to stress a cooperative rather than competitive atmosphere; there is more than enough work to go around and much of the data and tools required for risk assessment can be used throughout programs within the agency (see comments on need for R&D for assessment methods).

It is not apparent that the agency has an effective strategy for:

- A. Moving rapidly enough to consider non-chemical stress areas (other agencies such as FWS and BLM may provide useful experience)

- B. Securing R&D funds to support ecological risk assessment needs (the development of assessment methods should be given high priority and RAF should have formal input to the list of needs).
- C. Building strong links among technical staff and among closely associated activities such as EcoRisk Research, Wetlands Protection, the Great Lakes Initiative, EMAP (esp. integration and assessment and indicators), Habitat, Global Change. Such coordinated activities will allow development towards the goal of holistic ecosystem risk assessment.

Cooperation needs to become an operational philosophy/ state-of-mind with both technical staff and managers, and good cooperation needs to be rewarded.

The SAB commends the Forum staff for an excellent start in assembling the Framework Document. The exercise is bringing the long-needed Agency focus to the ecological risk assessment process. It should be recognized across the Agency for its future impact on all activities and regulatory initiatives. Clearly its importance can not be overemphasized. It should be explicitly stated that the framework can be applied to both predictive and retrospective assessments. To ensure maximum applicability for Agency needs, the Subcommittee feels that even more involvement should be encouraged of other Agency staff and management. The framework will eventually evolve into guidelines which will ostensibly be used to guide ecological research and regulatory initiatives across the Agency. To be most effective, the Forum needs to expand to include representatives from all segments of the Agency.

3.1.2 Framework Problem Formulation

The SAB applauds the inclusion of this phase in the ecorisk assessment process. It provides the opportunity for up-front planning, problem scoping, conceptual model development, and communication between the risk assessor and the risk manager. The importance of this phase is often overlooked with the result that the risk assessment is not properly formulated or focused. In order to facilitate communication with the risk manager, the problem formulation step should also consider alternatives to avoid or mitigate the risk.

The Subcommittee strongly endorses the use of a Conceptual Model in the Problem Formulation Phase of ecological risk assessment. The development of the conceptual model is a critical activity that influences both the risk analysis and risk characterization. The

Subcommittee recommends that the Framework document Figure 2 be modified to emphasize the central role of conceptual model development which is discussed in a later section. The whole activity of Problem Formulation can be viewed as conceptual model development. The remaining phases of the risk assessment process are built upon this component. It is essential that it be formulated correctly and early in the process. Figure 2, page 10, of the Framework Report needs to be modified to show that endpoint selection is an output of the conceptual model not an input to the conceptual model.

The Subcommittee urges that the Framework Document be revised to specify that development of the conceptual model should involve a multi-disciplinary team of engineers, physical scientists, chemists and modelers, in addition to ecologists and biologists. The conceptual model development should be the subject matter of a technical issues paper. The paper should include: stressor identity, ecosystem boundary, ecological effects expectations, and endpoints as proposed in the long range plan, and also include predictive and protective parameters and specific data quality needs.

The Subcommittee recommends that the concept of public involvement be incorporated into the Formulation phase. This is often critical to endpoint selection and model development. The public is really EPA's primary client and their needs should be considered in this phase.

3.1.3 Framework - Analysis

The SAB is pleased to see that the analysis phase considers not only exposure (although they prefer the term stressor) and effects characterization, but it also includes the interaction of the ecosystem (ecosystem characterization) on these two components. This reflects the interaction between the ecosystem, the stressor, and the effects which is often overlooked in ecorisk assessment. The inclusion of this interaction term strengthens the ecological risk assessment approach.

The analysis phase of the framework contains two major components--exposure/stress characterization and effects characterization. The preliminary results of the analysis phase need to feed back to the conceptual model for refinement (perhaps show an arrow back to this phase).

The framework adequately outlines the general components of the risk assessment process; however, the ability of the agency to perform the "ideal" type of quantitative risk

assessment is dependent on the immediate initiation and appropriate funding of methods development for risk assessment (including uncertainty analysis), especially in nontraditional areas such as habitat loss and animal distributions. It is anticipated that exposure and effects characterization is basically an outline of the tools the risk assessor has at his/her disposal and includes both empirical and process modeling approaches. The ability to perform exposure characterization for non-chemical stressors is a developing discipline that will utilize Geographic Information Systems, remote sensing, and new ecological concepts coming out of the discipline of landscape ecology such as habitat fragmentation and metrics to quantify and detect change. Also, techniques to integrate or link models for multiple stressors with regard to multiple endpoints is a critical need (i.e., cumulative effects). A better understanding is needed of the critical ecological processes that operate at regional scales. Applied models are needed that can address these scales and can then easily be used in risk assessments. Guideline development will not need ecosystem process models requiring input data that has little likelihood of ever being available. The Subcommittee concurs that issue papers should identify areas of critical research and added that the RAF should have direct input to funding decisions.

The Framework, as written, is explicitly limited to physical and chemical risks and does not address the risk of biological stressors. This is a serious omission - risks associated with introduction or use of organisms are important ones, and are currently a major cause of stress in many ecosystems. Further, with the growth of biotechnology, new kinds of risk assessments will need to be conducted. Since the framework is intended to provide a broad set of principles for future ecological risk assessments, it is important that it incorporate risks associated with biological stressors.

Subcommittee members continue to be concerned that the tenor of the Framework reflects a continuing emphasis on chemical risk assessment (e.g., dose-response relationships and protection of individuals), that is not consistent with the Science Advisory Board's recommendations nor those of the previous peer review panel workshops that the Agency broaden its efforts on ecological issues, including physical habitat alteration, biodiversity, and global change. The Subcommittee recognizes that the framework is intended to address the full array of ecological risks, but believes the effort to adhere to the human risk assessment paradigm has resulted in terminology and approaches that convey a more narrow approach than is desirable. As just one example, there is the continued use of the terminology "characterization of exposure". While the term "exposure" includes biological, physical, chemical and other stressors, apparently the term conveys only chemical toxicological mechanisms of cause and effects to many scientists. In view of this strong perception and

recommendations of previous peer reviews of the Framework which emphasized stressors, both chemical and non-chemical, the Subcommittee generally believes that the term "exposure" should be called "stressor exposure" to clarify that it is an assessment or characterization of exposures to stressors with both chemical and non-chemical considerations. For consistency, the SAB also recommends that RAF adopt the same terminology for human health risk assessment since exposure to more than one type of stressor may occur.

The Subcommittee recommends that the terminology used in the Analysis Phase be revised to be consistent with the concept of stressor characterization and stressor analysis to avoid the implication that the risk assessment process is principally chemical oriented, focusing mainly on individual toxicological endpoints. It is particularly important in this phase because it is at this point that the stressor data are analyzed the most intensively. Figures 1 and 3 in the draft Framework Document were inconsistent with that recommendation. The figure implies that the risk assessment process separates the stressor and effects data during the Problem Formulation and Analysis phases. In practice this is not always the way the data are handled. A minor change in the Framework is recommended.

It is also recommended that the data acquisition, verification and monitoring steps (box) be incorporated in a more formal way into the three phases of the Framework (Figure 3). The Subcommittee believes that these steps are a critical part of the risk assessment process. They also believe this is an iterative process that occurs at many points throughout the risk assessment process and is integral to the process. The Subcommittee recommends therefore that the data acquisition, verification and monitoring box be moved inside the lines of the Ecological Risk Assessment box.

Ecological impacts caused by human activities, such as habitat loss, result in major environmental impacts for some species and their populations. The interaction of humans with their environment represents a serious risk to many ecosystems. Yet, this is an area that is not extensively analyzed from the viewpoint of risk assessment and risk management. It is recommended that the Agency give careful consideration to the development of risk assessment procedures for impacts from human activities and review the Framework to insure that it adequately incorporates non-chemical stressors. There is a serious need for society to deal with the major risks to our environment for if we spend all our time studying minutiae we may find the ecosystems we wish to protect have disappeared or has been drastically modified.

3.1.4 Framework - Risk Characterization

The Subcommittee supports the flexibility of the Framework Document to include both qualitative and quantitative approaches to risk assessment. Greater recognition needs to be made for the importance of integrated, regional (holistic) ecological risk assessments of ecosystems. Guidelines must also clearly recognize and provide assistance for both predictive and retrospective ecological risk assessments. The Subcommittee recognized that there are many different kinds of risk assessments that are needed by the Agency ranging from simple to complex. The Framework Document recognizes this need and allows use of a variety of approaches ranging from the quotient method to very quantitative probabilistic risk assessment methods. The guidance provided in the Framework Document on the use of scientific judgement is important. Likewise, the Subcommittee endorses the weight of evidence concepts outlined in the document. Inclusion of all these above considerations and concepts allows flexibility yet provides important guidance to risk analysts.

3.1.5 Risk Management Interface

The risk assessor and the risk manager both have very complex and responsible roles which have been repeatedly highlighted by the NRC and recent EPA Administrators. In their roles, the assessors are supposed to deal with the relationships between stressors and effects, including their uncertainty (with a clear indication as to whether these are protective, predictive, prospective or retrospective risk assessments). The risk manager should contribute to the development of the conceptual model and when the assessment is complete, the risk manager should amplify the risk assessment to include political, societal, economic and other considerations. The risk managers and assessors should define the risk and the risk taker as the first step in each case and define their problem and select endpoints that can lead to considerations of risk minimization.

The output of the Risk Characterization is fed to the Risk Management box. Discussion of the significance of this step is addressed in a limited fashion in the framework document. This is clearly unacceptable. As written, the connection between assessment and management are disturbing. The risk assessment process needs to be appropriately separated from the risk management process, and there needs to be a safeguard that prevents the risk manager from over influencing the outcome of the risk assessment process. However, discussion is needed in this section to ensure readers that the output of the risk assessment is indeed useful to the user group, i.e., risk managers. Without this consideration, there is no check as to exactly when the assessment is complete or how well the process was done. The

Subcommittee strongly recommends the addition of a page or two of text to fully discuss the conceptual use of the assessment by the risk managers. In particular, the discussion should address the balance needed between risk management and risk assessment.

3.1.6 Status of the Framework

At the time of the SAB review, the Subcommittee was advised that the Framework Concept was evergreen, but that the Document would be published soon. During the discussion at the review, the Subcommittee asked if RAF could make changes to the framework, to reflect SAB comments on the figures, terminology, and introduction to the document. Later, the Subcommittee was advised that the framework was published without change. The Subcommittee believes that the Framework is an important document and recognizes that it serves as both a starting point and a broad outline to be modified in the future. The Subcommittee also believes that many EPA programs will adopt the Framework as the foundation for their guidance to staff in the states and EPA regions to perform ecological risk assessments. Once programs develop such guidance, it will be difficult to modify or correct the practices of the field staff and to advise them of changes. Therefore the Subcommittee recommends that the RAF modify its Framework to reflect significant comments from the SAB as soon as possible and further the RAF should develop a mechanism, such as newsletter, to keep managers and staff in programs and field components aware of evolving changes in the framework and the status of guideline development.

3.2 Issue Papers

The Subcommittee judged the inclusion of the Issue Papers concept as a valuable adjunct to other components in the ecological risk assessment guideline program. It appears to be an excellent format to address technical and implementation issues through the use of expert panels in workshops. The Subcommittee strongly urges the Agency to develop the technical issue papers presented in the charge as well as those identified below. Brief guidelines should be developed that describe what should be included in each Issue Paper, and case studies should be tightly linked to issue papers. A prioritization process should be used for develop Issue Papers that focus the most effort on the weakest areas so they can be addressed by research early in the guidelines development process.

3.2.1 Conceptual Model Development

As indicated in Section 3.1.2, this subject probably deserves an Issue Paper of its own. The Issue Paper should discuss examples of conceptual models and show how they affect the collection and evaluation of data. It should cover examples of both chemical and non-chemical stressors (especially biological stressors) and discuss the types of inputs that the risk manager should have in developing the conceptual model. Finally, the paper should explain how the conceptual model was addressed by the risk assessment and discuss how it could be modified by feedback from the risk assessment process.

3.2.2 Natural Ecosystem Variability

The Subcommittee recommends that the Forum consider the inclusion of an Issue Paper delineating the difference between anthropogenic stressor effects and natural ecosystem variability separate from the one proposed for ecological significance. Attempts to project laboratory-derived fate and effects data into the real world are most typically frustrated by the high intrinsic rate of natural variability seen in aquatic and terrestrial ecosystems. Subtle effects of man-made stressors are often impossible to measure, given the magnitude of changes in populations due to natural meteorological events, predation, and disease. A full consideration of ecosystem variability and the detection of the significant stressor impacts will be very useful to the ultimate use and application of ecological risk assessment guidelines.

3.2.3 Data Acquisition Issue

It would be appropriate for data acquisition to be dealt with in an Issue Paper. The Subcommittee viewed this subject as critically important as was evident by their previous recommendation to move it plus verification and monitoring inside the analysis box. This is a topic that requires team building and coordination both within the Agency (EMAP, Ecorisk Research, and Permit/Regulatory monitoring) and outside the Agency.

3.2.4 Ecological Risk Assessment and Environmental Impact Analysis

There is a fundamental need to clarify the relationship between risk assessment and environmental impact assessment. For the past two decades, widespread use of environmental impact assessment, principally under mandates of the National Environmental Policy Act, has led to an array of approaches and methods for predicting the environmental consequences of various environmental stresses. Some of the concepts and unresolved issues

in environmental impact assessment overlap ecorisk assessment; others do not. In some cases, formal risk assessments are incorporated within environmental impact assessments. Further, the terms "environmental impact" and "ecological risk" overlap, but are not synonymous. Conceptually, the Environmental Impact Statement approach should provide a valid ecological risk assessment which evaluated the relative risks of all alternatives to the proposed project. The framework document does not address these important relationships. Failure to do so creates confusion, and also may overlook important contributions to each approach that can be made through closer interactions. For example, the alternatives may identify ways to avoid risks or mitigate the impacts. The Subcommittee recommends thorough exploration of these relationships in an Issue Paper.

3.2.5 Uncertainty

The Subcommittee recommends that this very important topic, which has already been identified by the Agency as needing an issue paper, be explored and clearly set forth the categories of uncertainty that result in environmental risk, including:

- o Lack of basic scientific information about cause and effect, and ecosystem behavior
- o Probabilistic behavior of natural systems, such as floods, droughts, or earthquakes
- o Probabilities of technological failure or accidents, such as nuclear accidents
- o Uncertainties stemming from imprecision in sampling, toxicological testing, and analysis that all contribute to uncertainty.

Each of these categories imposes different requirements on risk assessment. It is important to clearly structure risk assessments to reflect these different causes of uncertainty, and to convey the nature of the uncertainty/risk to the risk manager.

In their most general terms, assessments of ecosystems involve the evaluations of Structural variables (e.g.: topography, soils, species present), State variables (e.g.: population density, temperature, contaminant concentration), and Rate variables (e.g.: population changes, climate changes). None of these are constants. It is imperative to

differentiate their normal ranges from that which could be induced by external influences, whether these be chemical, physical or biological in nature.

Many of the uncertainty issues cited here relate to an analysis of the different types of uncertainty that are encountered in the natural variability of ecosystems, accuracy and precision of measurements, and uncertainties introduced by the use of surrogate measurements. The treatment of these uncertainties becomes critical during the risk assessment phase. If the purpose of the assessment is the description of the present state of the ecosystem or a prediction of the future fate of the ecosystem, then the assessment is expressed in terms of central or most likely values with their associated uncertainties. If the purpose of the assessment is to establish a level of protection, then the uncertainty is converted to a bias applied to the stressor quantity (often in terms of uncertainty factors, safety factors, or modifying factors).

3.2.6 Linking of the Issue Papers with the Case Study Papers

In the process of Guideline development the issue papers and case studies are proposed to proceed on separate and parallel tracks. Actually, the Issue Papers will rely upon case study data to develop the topics. Therefore, it is clear that they need to be linked and coordinated (Figure 1). While this activity may not require an separate issue paper task, the authors of issue papers must be assigned a communication task to ensure dialogue with the case study authors. Outlines should be developed for both the issue paper and case study task to ensure coordination between the issue paper authors and case study authors.

3.2.7 Highlight Research Needs

We recommend that there be a continuing and formal effort to inform the Office of Research and Development of the research needed to fill identified gaps. Thus a separate task should identify and summarize these needs based on all the issue papers. Some of the subjects discussed by the Subcommittee included issues such as: (1) tools to assist in the data assessment necessary to perform the risk integration, (2) risk integration phase data which ranges from single quotient measurements to probabilistic assessment and complex model evaluation, (3) probabilistic approaches to risk assessment, (4) complex model assessment, and subjects that reflect an ever changing world. It is the research program that will provide the long term foundation for ecological risk assessment.

3.2.8 Predictive and Retrospective Risk Assessment

The Subcommittee recommends that RAF add an issue paper to discuss the similarities and differences between predictive and retrospective risk assessments. This issue paper could rely on the topology of EPA risk assessment needs, suggested earlier, and the case studies. These are standard terms which appear in the published literature, along with studies of an epidemiological nature.

3.3 Case Studies

3.3.1 Potential Benefits

The Subcommittee viewed the role of case studies as useful and crucial to the overall strategy of the Ecological Risk Assessment Guidelines. In fact it is suggested that the Agency should consider significantly expanding the number and types of case studies proposed for inclusion in the program. A need also exists to expand on exactly how they are to be used in the development of the guidelines. Many more case studies, some of which can be quite simplistic, will add significantly to how well the guidelines will apply to the wide range of issues faced by the Agency. Better use of existing, published literature will also simplify the effort and minimize potential for redundant effort. This is also an activity that can highlight some of the useful assessment methods developed under the National Environmental Policy Act.

It is not clear to the Subcommittee how the case studies are going to be specifically used in the ultimate development of Risk Assessment Guidelines. The Subcommittee feels that they have much to offer by identifying the types of risk assessments performed by EPA and other Agencies. The Subcommittee suggests that they may provide insight into the kinds of ecological guidelines needed. However, since they are based on current and old issues faced by the Agency, they may not represent the emerging issues challenging the Agency. A careful balance must be maintained between using case studies to identify the types of risk assessment guidelines needed and the evolution of EPA's risk assessment activities in the future.

Some of the case studies, e.g. the Chesapeake Bay study, are data intensive and costly, and therefore not routine. These studies should not be suggested to be the norm. Nevertheless, these studies can be used to establish the relationship between data-rich and

data-poor studies. The data-rich studies can be retrospectively decomposed into partial data poor studies which can then be assessed with respect to their power to predict the actual findings in the data-rich studies.

The RAF should develop a typology from the case studies and Issue Papers of the types of risk assessments that the Agency will need to prepare. Once this is available, the RAF may develop guidelines to address the specific categories of risk assessments that the Agency will need to address. Such an approach would guide the risk assessor through the steps in the context of the particular issues they need to address (e.g., cumulative impact analysis which may be appropriate for habitat loss assessments may have different guidelines from the Premanufacturing Notice assessment for TSCA).

3.2.2 Additional Case Studies

The Subcommittee developed the following list of potential case study subjects that should be considered.

- o Biotechnology
- o Radionuclides
- o Programs that calibrate predictive laboratory data with real world ecosystem data
- o Biotic stressors, introduced species and loss of species diversity

The Subcommittee concurs with the RAF selection of the following case study topics they should be closely coordinated with to assure they meet the needs for examples from the issue papers:

- o Evaluation of ecological resources
- o Habitat loss and disruption
- o The irrigation and drainage program (in addition to the Kesterson Wildlife Refuge example proposed)

- o Toxic Substances Control Act Premanufacturing Notices (additional examples would be useful) and test rules for pesticides under the Federal Insecticide, Fungicide, and Rodenticide, Act (these could focus on cumulative effects and non-target wildlife populations)

4. SUMMARY OF RECOMMENDATIONS

- a. The Subcommittee believes that the ultimate success and usefulness of the Agency's Ecological Risk Assessment Guideline program would be improved if the Framework document and implementation strategy considered incorporating the items discussed in this report. The Subcommittee also feels that the RAF should plan on periodic reviews and updates of these documents.
- b. The Subcommittee recommended that several additional issue papers be developed for issues which will affect how well EPA can perform ecological risk assessments; these include conceptual model development and natural ecosystem variability as distinct papers and new topics for data acquisition, ecorisk research needs and a comparison of ecorisk assessment with environmental impact analysis. The Subcommittee also recommends that EPA establish a priorities to assure that issue papers are developed for the areas of greatest uncertainty first so they may be addressed by research early in the guidelines development process.
- c. The Subcommittee strongly supports the use of case studies and recommended that the EPA significantly expand the number and type of case studies to illustrate the applicability of risk assessment across the Agency.
- d. The Subcommittee recommended that the Framework should define the potential issues for the development of guidelines such as their nature, scope, intent, structure, and use. This revision should be done as soon as possible so that it can affect the development and planning of the intermediate steps (issue papers and case studies) leading to guidelines.
- e. The Subcommittee strongly endorses the use of a conceptual model in the formulation phase of ecorisk assessment and recommends that the Framework document Figure 2 be modified to emphasize the central role of conceptual model development. The Subcommittee also urges that the Framework Document should indicate that development of the conceptual model needs to involve a multi-disciplinary team of engineers, physical scientists, chemists and modelers in addition to biologists and ecologists. The Subcommittee recommends that the concept of public involvement be incorporated into the Formulation phase. It is also recommended that the data acquisition, verification and monitoring steps (box) be incorporated in a more formal way into the three phases of the Framework (Figure 3).
- f. The Subcommittee continues to be concerned that the tenor of the Framework reflects a continuing emphasis on chemical risk assessment, that is not consistent with the Science

Advisory Board's recommendations. The Subcommittee believes that the term "exposure" should include the concepts of exposure to both chemical and non-chemical stressors. The Subcommittee recommended that the terminology used in the Analysis Phase be revised to be consistent with the concept of characterization of the exposure to stressors and stressor analysis to avoid the implication that the risk assessment process is principally chemical oriented, focusing mainly on individual toxicological endpoints. They also recommended that the same term, stressor-exposure assessment, be used for human health risk assessment.

g. The Subcommittee recommends that the framework discuss the use of risk assessments by risk managers and the balance between risk assessment and risk management.

h. The Executive Committee proposed and the Subcommittee concurred that the concept of ecological risk assessment should include human health risk assessment, build upon the human health model for species risk assessments, and harmonize the two approaches.

APPENDIX 1. COPIES OF FIGURES 1-3 CITED FROM THE "FRAMEWORK FOR
ECOLOGICAL RISK ASSESSMENT" EPA/630/R-92/001

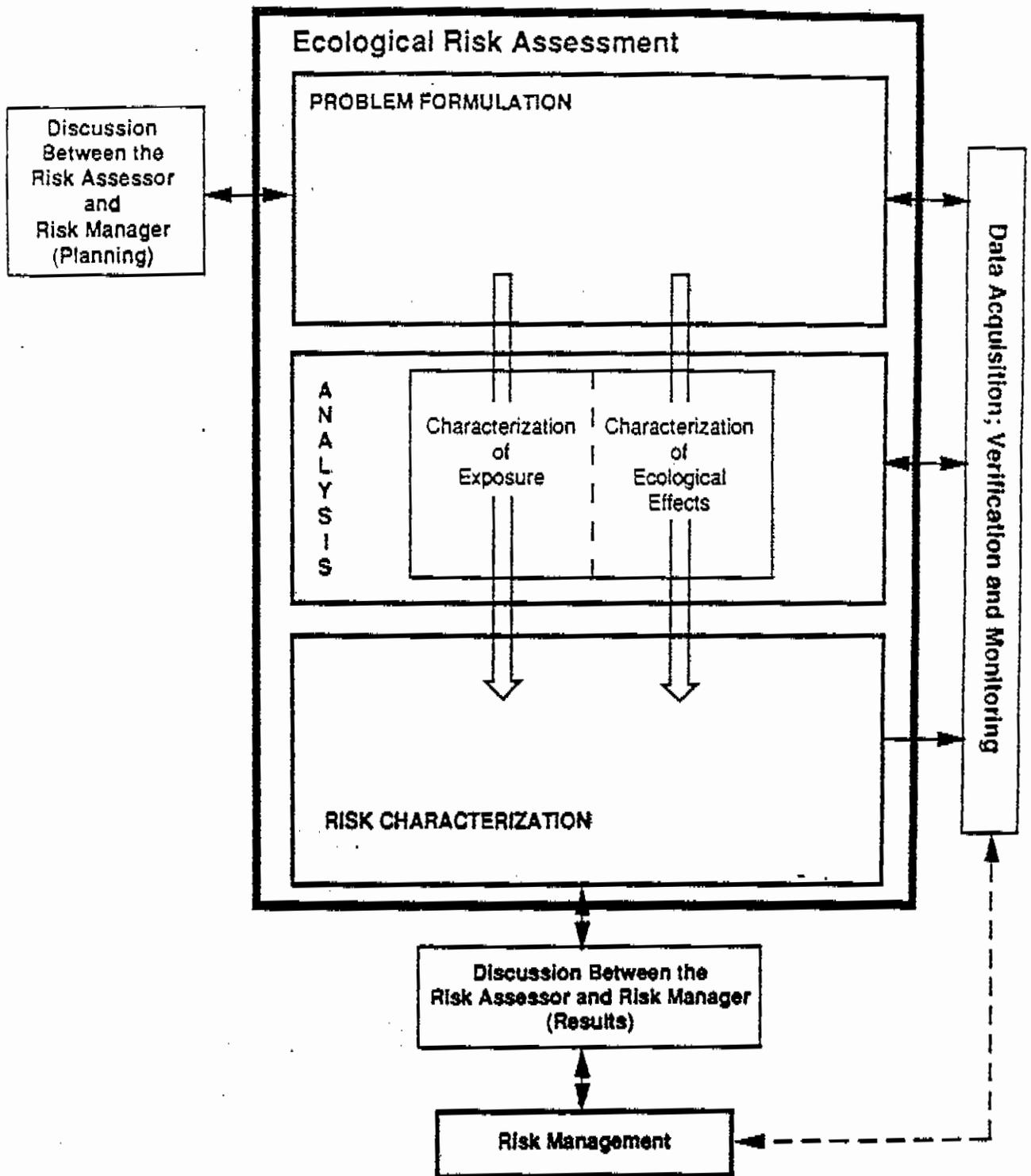


Figure 1. Framework for Ecological Risk Assessment

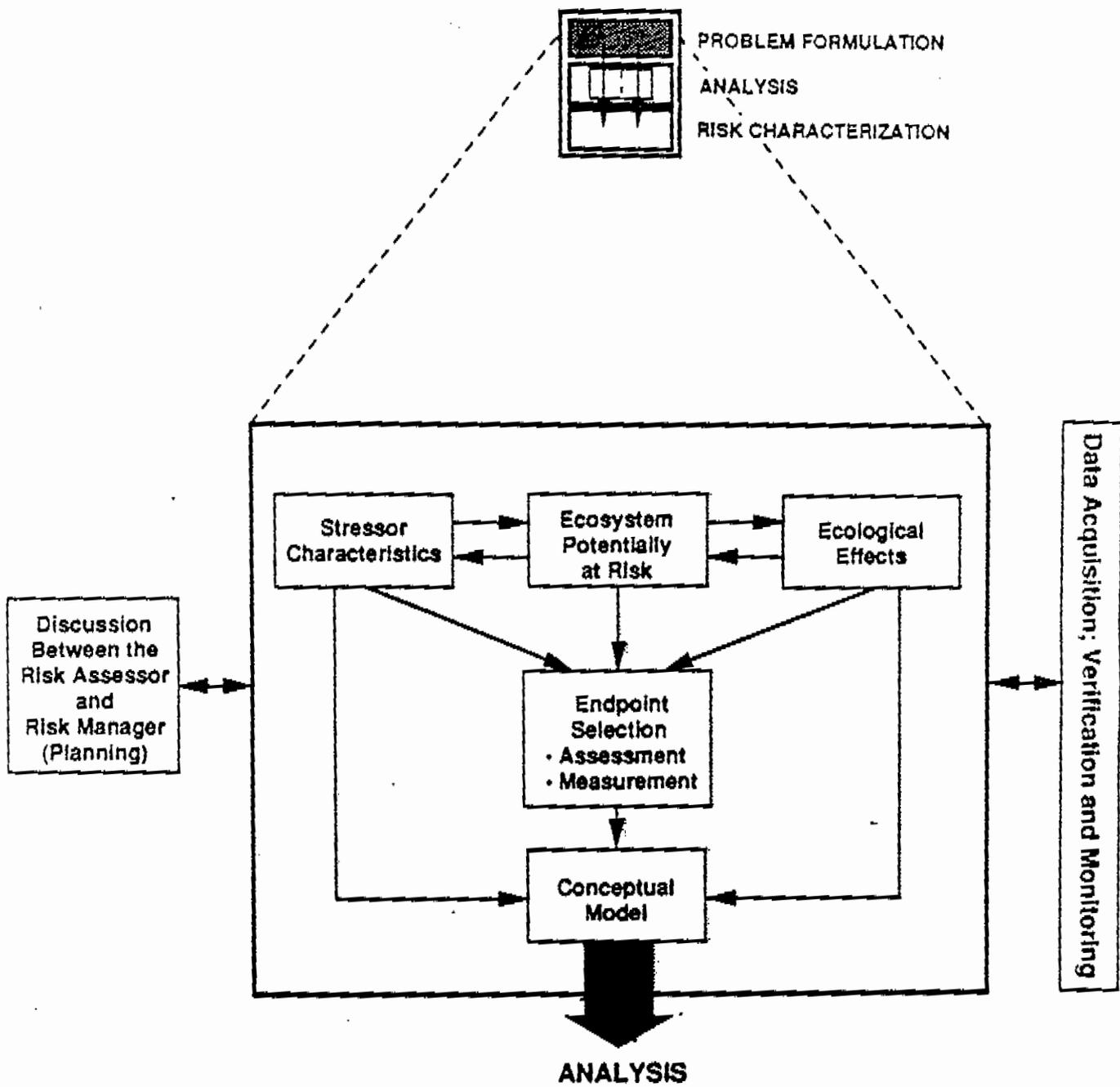


Figure 2. Problem Formulation

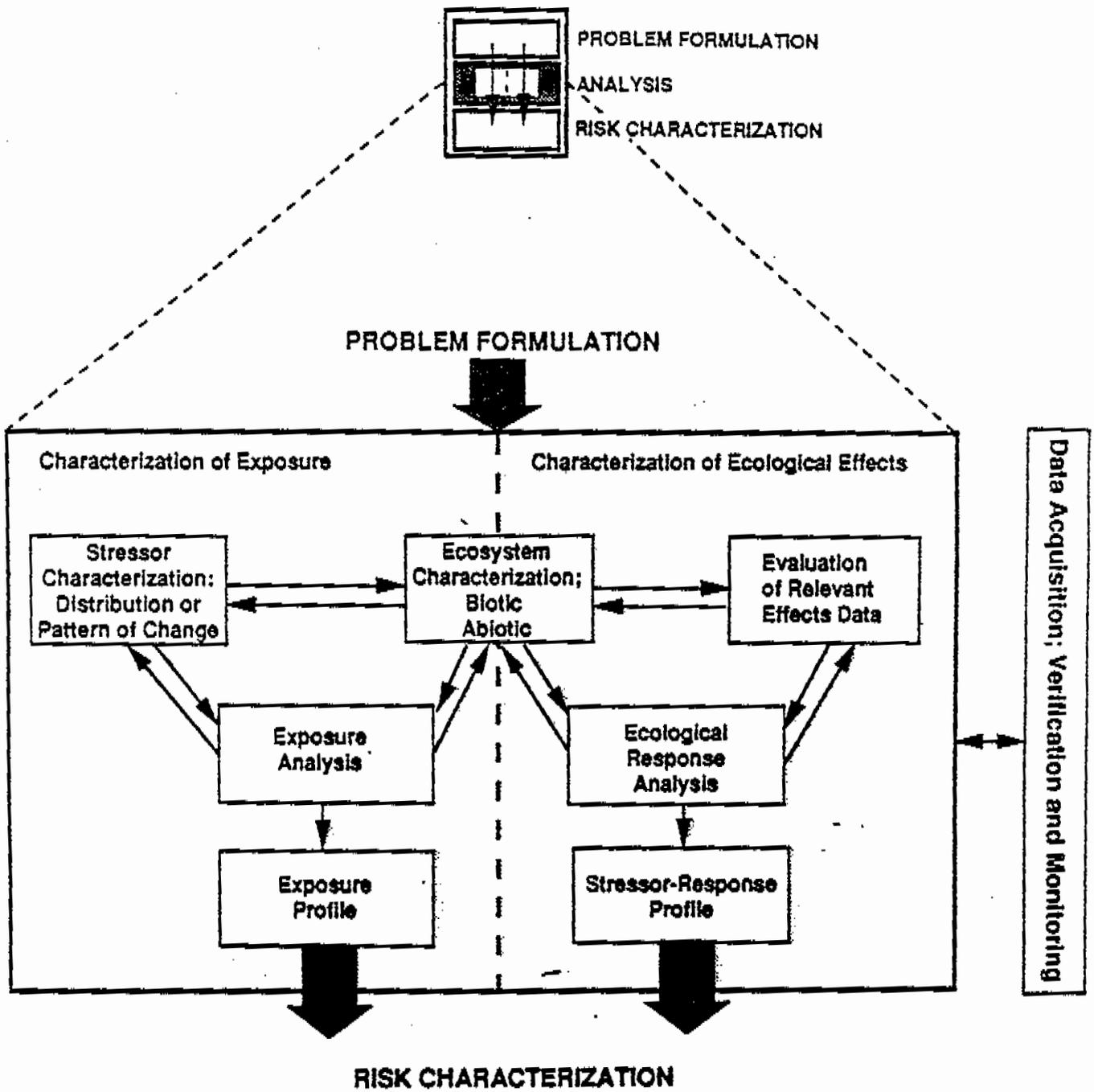


Figure 3. Analysis

Distribution List

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