PB95-252490

United States
Environmental Protection
Agency

Office of Research and
Development
Washington DC 20460

EPA/630/R-94/008
November 1994

Peer Review Workshop Report on Ecological Risk Assessment Issue Papers

RISK ASSESSMENT FORUM

EPA/630/R-94/008
November 1994

PEER REVIEW WORKSHOP REPORT ON ECOLOGICAL RISK ASSESSMENT ISSUE PAPERS

Risk Assessment Forum
U.S. Environmental Protection Agency
Washington, DC 20460

DISCLAIMER

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

CONTENTS

CONTENTS (Continued)

FIGURES

ACKNOWLEDGEMENTS

This report represents the efforts of numerous individuals who served as issue paper reviewers, authors, and in other capacities at the Ecological Risk Assessment Issue Paper Peer Review Workshop. Special recognition goes to Richard A. Kimerle, workshop Chair, for directing this productive meeting. The following eight Work Group Leaders also made significant contributions to the workshop report: William J. Adams, John Bascietto, Gregory R. Biddinger, James A. Drake, Jeffrey M. Giddings, James R. Karr, A. Frederick Holland, and Kent W. Thornton. William H. van der Schalie and John H. Gentile, the Risk Assessment Forum coordinators for ecological effects, coordinated all workshop and issue paper development activities. David P. Bottimore of Versar, Inc., an EPA contractor, worked on all phases of the project, providing technical, administrative, and logistical support. Other Versar personnel making significant contributions to the workshop included Stephen W. Duda, Margaret J. Wilson, and Patricia H. Wood.

FOREWORD

On August 16-18, 1994, the U.S. Environmental Protection Agency's (EPA's) Risk Assessment Forum convened a 3-day workshop in Alexandria, Virginia, to peer review eight ecological risk assessment issue papers. Development of these issue papers was part of a long-term effort to develop Agencywide ecological risk assessment guidelines for EPA. Preliminary work on guideline development began in 1989 and included a series of colloquia sponsored by EPA's Risk Assessment Forum to identify and discuss significant issues in ecological risk assessment (U.S. EPA, 1991). Based on this early work and on consultations with EPA's Science Advisory Board, EPA decided to develop ecological risk guidance in stepwise fashion, starting with definitions of terms and concepts and continuing with the development of source materials for the guidelines. The first product of this effort was the report Framework for Ecological Risk Assessment (U.S. EPA, 1992a,b), which proposes basic principles and terminology for the ecological risk assessment process. Since that time, other materials have been developed, including suggestions for guideline structure (U.S. EPA, 1992c), ecological risk assessment case studies (U.S. EPA, 1993a; U.S. EPA, 1994), and the draft issue papers peer reviewed at this workshop (U.S. EPA, 1993b).

The issue papers were developed to help provide scientific and technical information that EPA scientists could use along with other materials to develop ecological risk assessment guidance. EPA did *not* ask the issue paper authors to provide guidance, to write a "cookbook" or "how to" of methods, or to resolve differences between the papers in terminology or approach. Rather, EPA asked for a document of limited scope that would highlight important principles and approaches relevant to the ecological risk assessment framework that EPA scientists should consider in preparing guidelines. Synthesis and integration of the issue papers, framework principles, case studies, and other materials are deliberately reserved for the guideline writers and subsequent peer reviewers and public commenters.

This report summarizes discussions at the workshop, which was chaired by Dr. Richard A. Kimerle of Monsanto Company. Included in the report are recommendations for revising the draft issue papers, an identification of cross-cutting issues and future research needs, and suggestions on possible structures for EPA's ecological risk assessment guidelines. These suggestions will be very useful to EPA as it begins the challenging task of developing ecological risk assessment guidelines.

William P. Wood, Ph.D.
Executive Director
Risk Assessment Forum

1. INTRODUCTION

The Ecological Risk Assessment Issue Paper Peer Review Workshop was held on August 16-18, 1994, at the Radisson Mark Plaza Hotel in Alexandria, Virginia. The purpose of the workshop was to provide the U.S. Environmental Protection Agency with:

- Recommendations on revisions to the eight issue papers on ecological risk assessment (see text box for a list of the issue papers);
- Identification of "cross-cutting issues" in the eight issue papers;
- Suggestions for development of ecological risk assessment guidelines; and
- Recommendations on future research and development needs to improve the science of ecological risk assessment.

The Eight Issue Papers

- *Ecological Significance*
- *Conceptual Model Development*
- *Characterization of Exposure*
- *Effects Characterization*
- *Biological Stressors*
- *Ecological Recovery*
- *Uncertainty in Ecological Risk Assessment*
- *Risk Integration Methods*

Twenty-five scientists from academia, industry, and State and Federal agencies participated as peer reviewers (appendix A). Also attending the workshop were the authors of the issue papers (appendix B) and observers (appendix C). The workshop began with plenary sessions to review the history behind the development of the issue papers, to provide the charge to the reviewers, and to discuss the agenda for the meeting (appendix D). Breakout sessions, organized according to the eight issue papers, facilitated teamwork between the reviewers and the authors. Following these working sessions to formulate the revisions to the issue papers, participants focused on identifying the cross-cutting issues, discussing potential structures for the ecological risk assessment guidelines, and identifying future research and development needs to improve the science of ecological risk assessment.

The major outputs and recommendations from the workshop are summarized below.

- All eight issue papers are suitable for publication upon revision based on the comments provided. All eight papers (and one additional paper, "Public Values Affecting Ecological Significance") will be published together in one EPA document in fall 1994.

- An introductory chapter to the issue paper document will be added by the Risk Assessment Forum that summarizes the objectives, scope, limitations, and intended use of the issue papers.

- Several cross-cutting issues were identified in some of the eight issue papers. It was decided that some of these cross-cutting issues would not be addressed in the issue papers and should be considered by EPA in the development of ecological risk assessment guidelines. Some of these cross-cutting issues include:

  -- Terminology—A dictionary or glossary is needed; definitions of multiple uses of the terms also should be included.
  -- Examples/Case Studies—The issue papers are not intended to be "how to" manuals, but should have examples to help illustrate concepts. Therefore, the guidelines will need to include illustrative examples to demonstrate concepts.
  -- Data Quality Assurance and Adequacy—The data quality objective (DQO), process can help risk assessors determine the level of confidence needed by risk managers to make a decision.

- Ecological risk assessment guidelines should build on the EPA report Framework for Ecological Risk Assessment (Framework Report, U.S. EPA, 1992a), with components that are common to any endpoint, application, media, or data source. Some conceptual diagrams from the Framework Report should be revised to reflect the current thinking that ecological risk assessment is an iterative process.

Section 2 of this document contains summaries of the keynote presentations on the objectives of the workshop by Dorothy E. Patton, Chair and Executive Director of EPA's Risk Assessment Forum (RAF), and Richard A. Kimerle, Chair of the workshop. Provided in section 3 are summaries of recommendations given to the authors for revisions to the issue papers. Section 4 describes the cross-cutting issues identified by the reviewers for consideration in revising the issue papers and in formulating guidelines on ecological risk assessment. Sections 5 and 6 present suggestions to EPA on formulating ecological risk assessment guidelines and on future research needs, respectively.

1.1. Background

In 1989, the RAF initiated a multiyear program for developing Agencywide guidance for ecological risk assessment. Ecological risk assessment is defined as a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. Drawing on experience from EPA's human health risk assessment guidelines, the RAF developed a range of materials to be used by Agency scientists in developing ecological risk assessment guidelines. A first major result of this process was the 1992 publication of the Framework Report, which proposed a simple, flexible structure, or framework, for ecological risk assessment. The framework developed for ecological risk assessment is illustrated in figure 1. Following publication of the Framework Report, EPA sought to bridge the gap between the simple structure of the framework and the future guidelines through development of case studies and issue papers. EPA solicited advice and expertise of the academic community, industry, and other scientists in applying these concepts to a series of ecological assessment case studies (U.S. EPA, 1993a; U.S. EPA, 1994). In 1993, EPA asked nationally recognized experts to prepare a series of eight issue papers identifying scientific issues for the phases of the ecological risk assessment process as defined in the Framework Report. The eight issue papers include:

- Ecological Significance
- Conceptual Model Development
- Characterization of Exposure
- Effects Characterization
- Biological Stressors
- Ecological Recovery
- Uncertainty in Ecological Risk Assessment
- Risk Integration Methods

The draft issue papers were made public in 1994 (for purposes of peer review) as one document (U.S. EPA, 1993b). The authors of the draft issue papers will revise their papers

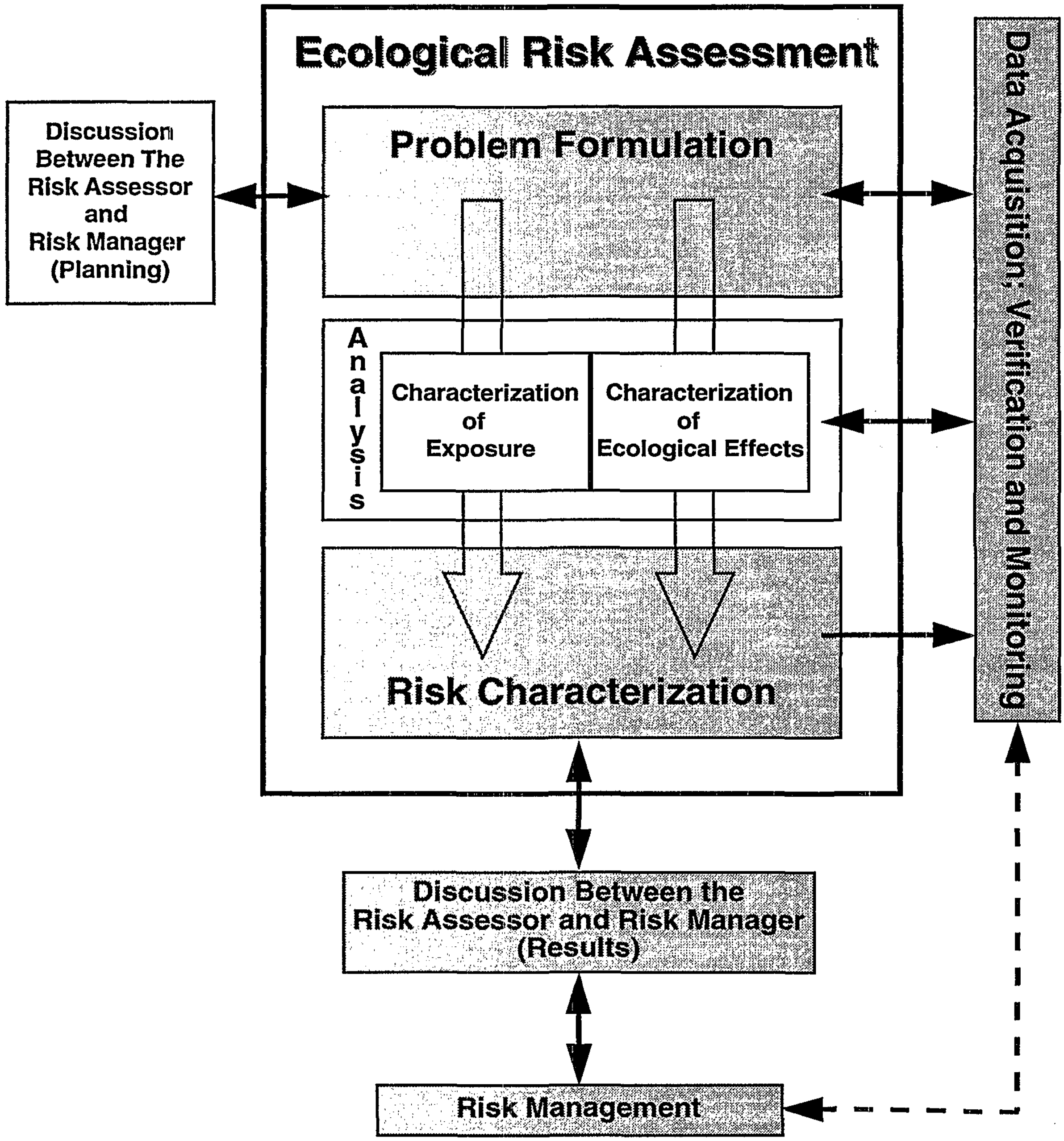


Figure 1. **The Conceptual Framework for Ecological Risk Assessment (adapted from EPA, 1992a)**

based on comments received at this peer review workshop. Revised issue papers will be published together as an EPA report and will be used as source materials to assist Agency scientists in preparing Agencywide ecological risk assessment guidelines.

1.2. The Peer Review Process

A panel of 25 experts in the field of ecological risk assessment was assembled by Versar, Inc., from academia, private industry, State government, and other Federal agencies to review the eight issue papers. Panel members were selected from more than 80 potential candidates identified and contacted through a process that included the use of professional societies, a literature review, and existing databases. The peer review panel (three reviewers per issue paper and a workshop Chair) was assembled for a 3-day workshop to provide the authors with comments on the content of specific papers as well as to identify cross-cutting issues common to a number of the eight papers.

Prior to the workshop, the reviewers were provided with the draft issue papers, the Framework Report, other background information, and a list of suggested review topics. The reviewers were asked to submit written comments on the issue papers before the workshop so that all of the comments could be compiled and provided to other reviewers and the authors before the meeting. Although initial discussions at the workshop were based on the pre-meeting comments (appendix E), the dialogue between the reviewers and authors expanded considerably because of the collaborative nature of the discussions that developed at the workshop. The recommendations provided by the reviewers on the issue papers are summarized in section 3, while appendix F contains the detailed comments.

1.3. Overall Highlights of the Workshop

This workshop was very successful from a number of perspectives. First and foremost, the scientific completeness and potential usefulness of the issue papers for the development of ecological risk assessment guidelines were enhanced by the format of the workshop. The strategies of providing written peer reviews before the workshop, having face-to-face discussions between authors and reviewers in the plenary and breakout sessions, and providing opportunities for dialogue between all workshop participants contributed to the success. In addition, presentations by the RAF staff describing the history of the guideline development process and the intended use of the issue papers helped to focus the peer review. Also contributing to the workshop's success was the genuine commitment on the part of all the participants and observers to make the issue papers as successful as possible, as a step toward ensuring success in the ultimate goal of guideline development.

Additionally, this workshop was somewhat unusual because of the wide diversity of valuable ecological expertise and experience represented, the willingness of participants to share their viewpoints, and the respect shown for the diverse viewpoints as participants listened and incorporated the many varied ideas into the materials. Numerous individuals commented on how their perspectives for assessing ecological risk were broadened as a result of the conversations with their scientific peers.

After the issue paper reviews were completed, an opportunity was provided for participants to contribute ideas on the Agency's use of the framework, case studies, and issue papers to develop ecological risk assessment guidelines. Once again, the diverse expertise and varied viewpoints of the participants from academia, industry, public interest groups, and State and Federal government agencies provided valuable input. The group was keenly interested in assuring that the subsequent effort to develop the ecological risk assessment guidelines would be performed in the most scientifically defensible manner possible.

2. KEYNOTE PRESENTATIONS

2.1. Welcome and Introduction

The meeting was opened by Dorothy E. Patton, Chair and Executive Director of the RAF, who provided an overview of the history of EPA's ecological risk assessment guideline development process. The Framework Report was the original document that established a flexible structure for assessing ecological risks. The framework defined a three-phase process composed of problem formulation, analysis, and risk characterization. This Framework Report was followed by the development of case studies and issue papers. The issue papers identified the scientific issues associated with the risk assessment process, while the case studies provided specific examples of the complexity of the ecological risk assessment process for a range of ecosystem types and scenarios. The case studies also represent an array of topics including data completeness, data quality, and types of assessments (e.g., qualitative vs. quantitative). EPA's overall process for development of ecological risk assessment guidelines is presented in figure 2.

The primary audience for the issue papers is EPA's guideline writers, while secondary audiences include EPA's Program Offices and others who conduct ecological risk assessments. The issue papers are not treatises or monographs, nor are they "how to" documents; rather, they review the current state of knowledge of issues associated with ecological risk assessment. They are designed to be used by the guideline writers as source materials along with the Framework Report, case studies, and scientific literature. Synthesis and integration of these materials will take place during the guideline development process through peer review and consensus-building with experts throughout EPA, academia, industry, environmental groups, consulting firms, State governments, and other Federal agencies.

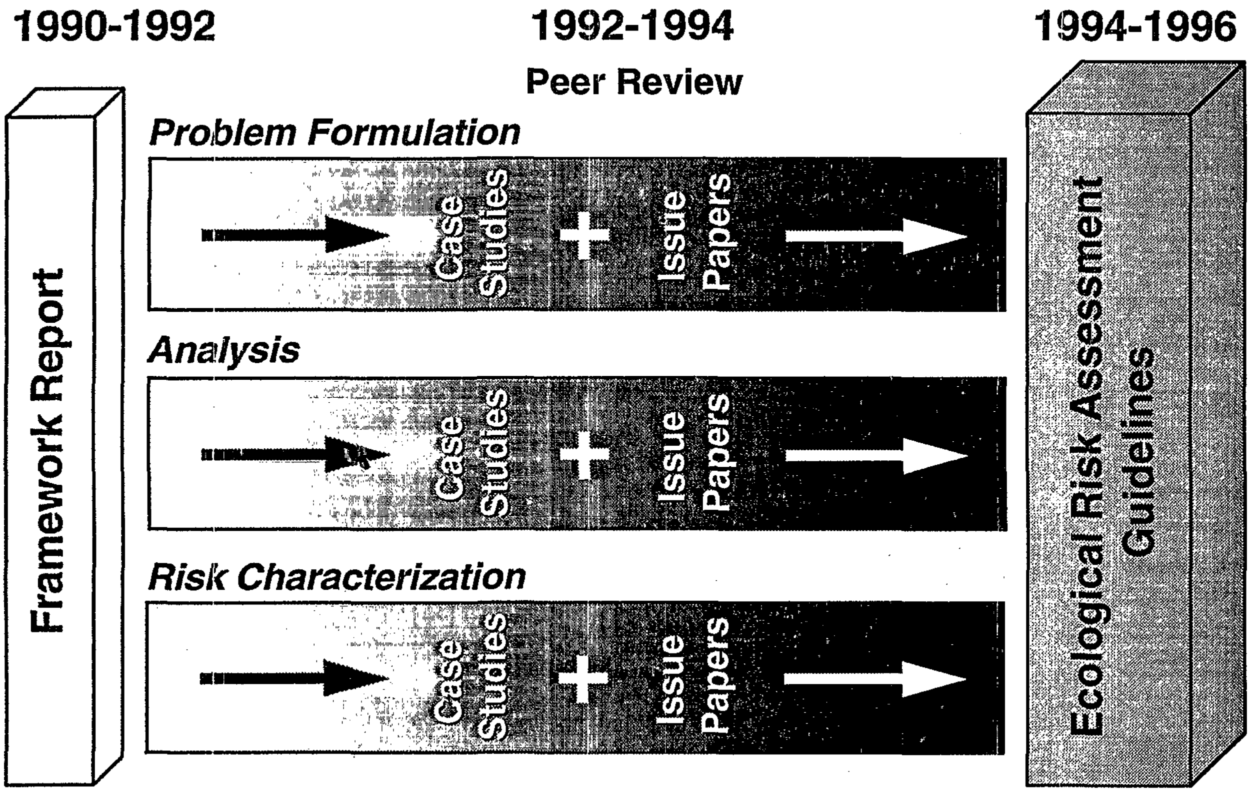


Figure 2. Development of Ecological Risk Assessment Guidelines

2.2. Workshop Objectives and Structure

Richard A. Kimerle of Monsanto Company, the workshop Chair, provided an overview of the need for "useful products" that can be used in ecological risk assessment. He stressed that although the topic is complex, a simplified approach is needed for risk assessors throughout Federal and State governments, industry, environmental groups, and the interested public. The Chair also presented the following workshop objectives and the charge to the reviewers:

- Provide recommendations to the issue paper authors so that the authors can finalize the issue papers, and, in the process, try to maintain a reasonable consistency between the Framework Report and the issue papers;
- Develop recommendations on the potential direction and structure of the ecological risk assessment guidelines; and
- Identify future needs and research areas, particularly for EPA's Office of Research and Development, that can fill data gaps and improve the science of ecological risk assessment.

In addition, several other objectives were detailed including:

- Identify and discuss cross-cutting issues (topics common to some or all of the eight individual issue papers); and
- Identify terminology needs and issues.

Because of the ambitious agenda and number of topics to be addressed, the Chair instructed the reviewers to focus on the immediate need to finalize the issue papers.

3. RECOMMENDATIONS FOR REVISION OF ISSUE PAPERS

3.1. Overview

The first day and one-half of the workshop was dedicated to developing detailed critiques of the eight issue papers and defining the revisions required to finalize the documents. Following the keynote presentations to set the tone for the workshop, the three reviewers for each paper and the issue paper authors met in breakout sessions to review the pre-meeting comments and to discuss revisions to the papers. This collaborative format for peer review was somewhat unusual. Scientists routinely use anonymous peer review to ensure the quality of publications for professional journals. However, for this workshop, the peer reviews were not anonymous and the authors and reviewers met face-to-face to discuss the pre-meeting comments and to define the revisions to the issue papers. If there were any pre-workshop concerns over this review process, they were quickly dispelled by the very professional atmosphere of cooperation. In fact, this format facilitated a spirit of collaboration between authors and reviewers.

In general, many initial concerns about the scope and content of individual issue papers were resolved by the recommendation that an introductory overview section be written for the issue paper document. This section, to be written by the RAF, will provide the context necessary for readers to understand the purpose, scope, limitations, and intended use of the issue papers. Issue paper-specific comments generally called for some reorganizing of sections within individual papers, clearer use of terminology, and incorporation of examples. Following revisions, nine issue papers (the eight original papers and one additional paper on "Public Values Affecting Ecological Significance") will be published as an EPA document.

Summaries of recommendations for revision of the eight issue papers that were developed during breakout work group sessions are presented below. The names of the authors and reviewers for each issue paper are included following the titles. Sections 3.2

through 3.9 present summary lists of recommendations from each group, while appendix F contains the detailed recommendations for revisions to the papers.

3.2. Ecological Significance

Authors: M. Harwell, B. Norton, W. Cooper, J. Gentile
Reviewers: K. Thornton, R. Bachman, T. O'Connor

Six recommendations were made to the authors of the Ecological Significance paper as follows:

1. Define ecological significance;
2. Reorganize the issue paper;
3. Incorporate the Public Values appendix into a separate issue paper entitled "Public Values Affecting Ecological Significance";
4. Expand discussions of attributes and criteria;
5. Incorporate additional examples; and
6. Incorporate specific pre-meeting comments, where appropriate.

3.3. Conceptual Model Development

Authors: L. Barnthouse, J. Brown
Reviewers: G. Biddinger, R. Kendall, R. O'Neill

Ten recommendations were made to the authors of the Conceptual Model Development paper as follows:

1. Provide basic information for a broader audience on the scientific method and the use of science to make management decisions;
2. Clearly state how conceptual model development focuses the study;
3. Include references identified by reviewers;
4. Include a third case study on a waste site;
5. Reduce the level of detail on characterization of stress;
6. Add statements of scope and purpose;
7. Discuss the importance of documentation and transparency;

8. Consider including a dictionary as an alternative to a glossary;
9. Include a process flow diagram; and
10. Ensure consistency with other issue papers.

3.4. Characterization of Exposure

Authors: G. Suter II, J. Gillett, S. Norton
Reviewers: W. Adams, L. Kapustka, F. Wagner

Five recommendations were made to the authors of the Characterization of Exposure paper as follows:

1. Follow the exposure characterization descriptions in the Framework Report;
2. Modify some terminology;
3. Revise the figures;
4. Restructure the issue paper; and
5. Provide recommendations on performing exposure characterization for chemical and nonchemical agents.

3.5. Effects Characterization

Authors: P. Sheehan, O. Loucks
Reviewers: J. Giddings, N. Beyer, W. Landis

Five recommendations were made to the authors of the Effects Characterization paper as follows:

1. Retain the emphasis in the introductory section on important general concepts;
2. Clearly state that risk assessments should not be based on simplistic "indices";
3. Include additional types of effects in the sections on individual- and population-level effects;
4. State that many ecosystem structure/function endpoints need more research and development before they can be routinely used in risk assessment; and
5. Discuss additional research and development needs.

In other respects, the reviewers stated that the paper is comprehensive and adequate without major revision; however, some minor editing is needed to increase clarity and to bring out the organization of topics.

3.6. Biological Stressors

Authors: D. Simberloff, M. Alexander
Reviewers: J. Drake, R. Orr, J. Thorp III

The reviewers stated that only a few changes were recommended to the authors because this is a well-written document. The changes include:

1. Clarify the community/ecosystem concepts; and
2. Include additional thoughts and guidance on practical applications.

3.7. Ecological Recovery

Authors: S. Fisher, R. Woodmansee
Reviewers: J. Karr, P. Brezonik, R. Wentsel

Eight recommendations were made to the authors of the Ecological Recovery paper as follows:

1. Consider the written pre-meeting comments of the reviewers;
2. Emphasize anthropogenic disturbance and the kind of variation it produces;
3. Stress the importance of monitoring to determine the success of recovery;
4 Stress the uncertainties that exist in recovery;
5. Include case studies to illustrate key concepts;
6. Remove the unnecessary references to ecological theory;
7. Expand coverage of different kinds of stressors; and
8. Include the proper range of disciplines in the discussion of risk assessors.

3.8. Uncertainty in Ecological Risk Assessment

Authors: E. Smith, H. Sugart
Reviewers: A.F. Holland, L. Ginzburg, and K. Rose

Ten recommendations were made to the authors of the Uncertainty in Ecological Risk Assessment paper as follows:

1. Provide more synthesis of the science of characterizing uncertainty;
2. Use a broader variety of examples;
3. Integrate discussions and recommendations with those in other issue papers;
4. Reorganize the introduction section;
5. Refocus the problem definition section;
6. Refocus the analysis-phase uncertainty section;
7. Expand and generalize the discussions in the risk characterization section;
8. Incorporate pre-meeting comments as appropriate;
9. Define terminology used; and
10. Reorganize the describing uncertainty section.

This issue paper defined most of the scientific issues associated with characterizing uncertainty in ecological risk assessment. It did not, however, bridge the gap between the general treatment of uncertainty provided by the Framework Report and the specific information required to develop Agencywide guidance for ecological risk assessment.

3.9. Risk Integration Methods

Authors: R. Wiegert, S. Bartell
Reviewers: J. Bascietto, J. Giesy, P. Van Voris

Four recommendations were made to the authors of the Risk Integration Methods paper as follows:

1. Revise section formatting;
2. Provide more balance in the discussion of different model groups;

3. Include a discussion of alternative model approaches; and
4. Include examples of each model approach.

4. IDENTIFICATION OF CROSS-CUTTING ISSUES

Concurrent with their review of the individual issue papers, the peer reviewers were asked to identify cross-cutting issues, those topics common to more than one of the eight issue papers. Numerous issues were identified in both the pre-meeting comments and during the breakout sessions. These issues were discussed in the plenary sessions and, to the degree possible, incorporated by authors into their issue papers or into the introductory chapter to be added to the issue paper document. Some cross-cutting issues were dismissed, while many were left to be considered by EPA in its future activities to develop guidelines for ecological risk assessment. The major cross-cutting issues discussed included:

1. Terminology—Each author was asked to define all terms used in the context of their issue paper. An alternative, which was rejected, is to create a glossary or a separate dictionary of terms where the various uses of terms would be defined. It was finally recommended that when ecological risk assessment guidelines are developed, a dictionary could be completed to help clarify and unify the terminology.

2. Uncertainty—There was general recognition that many sources of uncertainty exist in the science of ecological risk assessment, including uncertainty resulting from selection of modeling approaches and measurement endpoints; assumptions, extrapolations, and propagation of errors; separating anthropogenic from natural variation; and year-to-year natural variation in ecological processes. In addition to recognizing the importance of uncertainty by creating a separate issue paper, all authors dealt with uncertainty in the context of their papers.

3. Structuring Issue Papers Within the Current Context of the Framework Document—Some concern was expressed over fitting the issue paper material into the framework and whether the framework needs modifications. These discussions concluded that the structure of the framework (problem formulation, analysis, and risk characterization) was suitable and useful at this time but could, through the iterative process, undergo some modifications to provide better support for guideline development.

4. Research—During the review, participants were asked to identify future research needs within the context of each paper, but not necessarily as a whole. The focus of the workshop was on the technical quality of the papers to ensure their usefulness in guideline development. In the process of discussing the papers, future research topics were noted by the groups. Section 6 of this report summarizes the recommendations from the reviewers on future research needs.

5. <u>Quality Assurance</u>—General discussions were held on the importance of establishing mechanisms to ensure that the quality of data used in a risk assessment is known and maximized. Related to these discussions is the concept of data adequacy and the data quality objective (DQO) process where risk assessors work with risk managers to determine the degree of confidence needed to make a decision.

6. <u>Complexity and the Need to Simplify</u>—Both the ecological risk assessment process and the technical content of the issue papers were viewed as being complex. Workshop participants recognized the need for "simplification" of the ecological risk assessment process, including identification and use of the right "tools" for problems; communicating clearly among risk assessors, managers, and society; deciding which computer software to use to streamline documentation and decision making; use of an iterative or tiered approach to assessment; and avoiding conducting an ecological risk assessment beyond the level of ecological significance required.

5. RECOMMENDATIONS FOR DEVELOPING ECOLOGICAL RISK ASSESSMENT GUIDELINES

5.1. Background and Overview

Following the discussion on the revisions to the issue papers, workshop participants (reviewers, authors, and observers) were given the opportunity to make suggestions to help EPA formulate the ecological risk assessment guidelines. This "brain-storming" session was an open forum on the potential format, structure, and scope of the guidelines that EPA will be developing in the next year or two. The ecological risk assessment guidelines, much like the existing human health guidelines, will present the general principles and approaches that will be used by EPA programs. As such, the guidelines are intended to promote consistency in the conduct of ecological risk assessments across the Agency while being flexible enough to allow professional judgment to be exercised. The guidelines will not be textbooks, cookbooks, or rule books; rather, they will present the preferred procedures and rationales for an ecological risk assessment.

Workshop participants identified and discussed the value of a number of different approaches for development of guidelines. Approaches considered included those that rely on endpoints (e.g., mortality, reproductive and developmental inhibition, etc.); application type (e.g., new product assessment, land use decisions, dredging, etc.); media (e.g., aquatic, terrestrial, etc.); or data source (laboratory, field, or model estimation). In conclusion, the participants agreed that comprehensive guidance is needed now because relying on the aforementioned approaches to guideline development would be sequential and, therefore, would greatly lengthen the time required until comprehensive guidance would appear.

The group felt that the practice of ecological risk assessment would improve more rapidly if the focus of guidance is on the components of risk assessment that are common to any endpoint, application, media, and data source. Therefore, the recommendation from the group was that the *first* guidance document developed be built on the existing Framework

Report. Guidance on endpoints, applications, media, and data sources should be incorporated in this first round of guidance by the liberal use of examples and case studies.

Additionally, it was suggested that guidelines should address other critical elements of risk assessment such as (1) the definition of best assessment practices; (2) a more explicit process for setting assessment goals; and (3) the importance of recognizing that the risk assessment process is iterative. The best assessment practices should address the characteristics of a well-performed assessment, which defines the composition and responsibility of the assessment team; ensures appropriate study design, data adequacy, and analytical rigor; and builds in effective and clear communication of the process and the results. The problem formulation phase of the assessment guidelines needs to expand on the Framework Report, recognizing that assessment goals are selected in the context of social values and involve public input. In essence, the process of dialogue among the risk assessor, the public, and the risk manager should be more explicitly explored in the guidance for problem formulation. The guidelines should also reflect that assessments are more often a feedback process than a linear analysis, with the iterative nature explained and illustrated in the guidelines.

This section captures some of the suggestions provided on potential structures of the guidelines for ecological risk assessment. Section 5.2 presents the ideas of individuals (Group 1) assembled from several working groups. Section 5.3 provides an overview of the recommendations from Group 2 (also composed of participants from several working groups), while subsequent sections (5.4 through 5.9) summarize the recommendations of individual working groups.

5.2. Recommendations on Guidelines From Summary of Group 1

Basic Principle: If guidelines do not build upon the Framework Report, an alternative must be developed that is acceptable to EPA.

Both guidelines and guidance are needed, and two general models for development of guidelines/guidance are possible:

- Model 1—Develop holistic guidelines and fill in the details for the various elements of the ecological risk assessment process by preparing supporting documents that are periodically updated. (See outline in section 5.2.1 below.)
- Model 2—Use the Framework Report as holistic guidance and prepare detailed guidance for the various elements as stand-alone documents.

The subdivisions to Models 1 and 2 are essentially identical. An outline of Model 1 is presented below. Model 2 was disregarded and, therefore, was not fully developed for presentation. Model 1 was strongly recommended as the best approach at this juncture.

5.2.1. *Model 1 Outline*

1. Introduction

    1.1. Historical development of framework (Cube, SIQ^2C)
    1.2. Best assessment principles (SIQ^2C = Scale Independent Qualitative/Quantitative Classification)

2. Problem Formulation

    Note: Follow framework outline; use issue paper on Conceptual Model Development

3. Analytical Phase

    3.1. Ecosystem Characterization

    Note: This section may be better developed in problem formulation.

    3.2. Exposure Characterization

    3.2.1. Chemical Addition

    3.2.1.1. Chemical Stressors

3.2.2. Disturbance

3.2.2.1. Biological Stressors
3.2.2.2. Physical Stressors
3.2.2.3. Radiation

3.3. Effects Characterization

3.3.1. Individuals/Populations
3.3.2. Community and Ecosystem
3.3.3. Landscape and Region

4. Risk Characterization

4.1. Risk Estimation
4.2. Risk Description

Note: Rely on issue paper guidance.

5. Interaction Between Risk Assessment and Risk Management

5.2.2. *Additional Recommendations*

Additional recommendations on supplemental guidance documentation should be taken from individual Work Group discussion reports, especially those of Exposure and Effects Characterization. Other ways of approaching supplemental guidance would be to focus on a matrix that looks at information taken from laboratory, field, or models.

- Case Studies—A significant effort should be made to provide practical guidance through the incorporation of case studies into the guidance document. Such case studies will provide continuity through the steps. If case studies cannot be woven through the document, they should be provided as appendices.

- Framework History—In developing the guidelines, an effort to capture the history of how the outline of the Framework Report was determined would be beneficial. EPA has been considering an endpoint/habitat approach, referred to as the "cube" (see figure 3). The suggestion was made that moving to the Scale Independent Qualitative and Quantitative Classification Approach could benefit the novice.

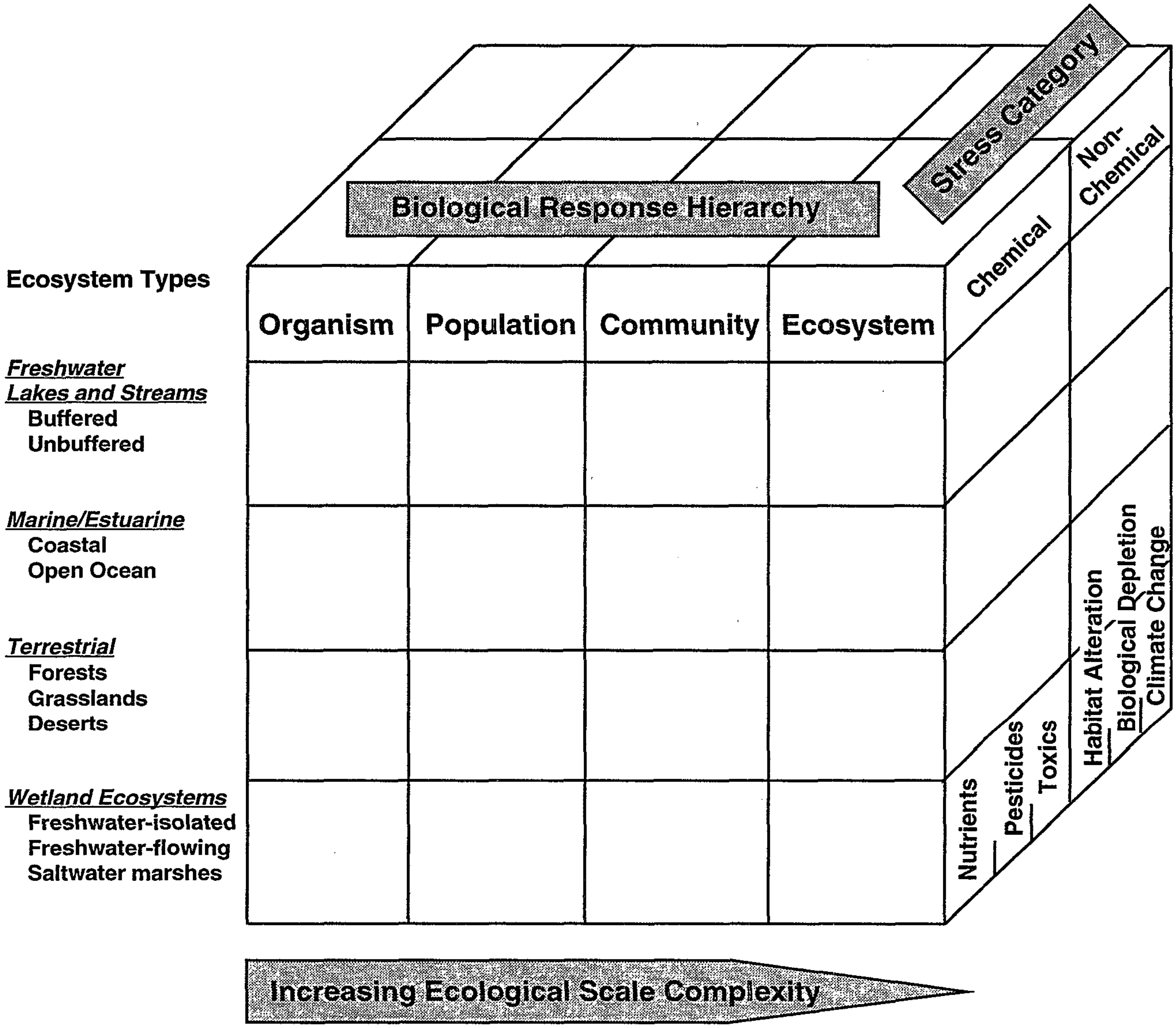


Figure 3. **The "Cube"—A Three-Dimensional Matrix of Ecological Risk Organizing Principles**

- Balance in Guidelines—The guidelines should seek a balanced level of depth in the various sections. Each section should provide adequate guidance to be useful without providing excess detail.

- Tiered Approach—Risk assessments are tiered and activities are often iterative in nature. This concept should be emphasized in the guidance. In particular, the fact that risk assessments can be used in a screening fashion will be an important guidance in focusing the use of risk assessment in pollution prevention programs. Also, it is important that the guidelines state that the risk assessment process need not be lengthy.

In conclusion, it was recommended that the guideline writers be familiar with the recommendations provided at the workshop before embarking on the first draft of the guidelines. They could also provide an outline of the proposed guidelines and guidance documents to a core group of experts from this meeting to obtain acceptance. Their help could be elicited in preparing a prioritized strategic plan to developing the guidance as well. The group could explore:

- Level of detail to pursue guidance;
- Mechanisms for developing supplemental guidelines; and
- Developmental opportunities for technology transfer of guidance.

5.2.3. *Best Assessment Practices*

Regardless of the model used for development of guidelines, a discussion of "best assessment practices" should be included in the guidelines that defines:

- Composition and process for assembly of the assessment team;
- Responsibilities of the assessment team;
- Elements of the assessment process;
- Documentation of design assumptions and decisions;
- Communication with risk managers and the public; and
- Other topics related to the mechanics of the process that need to be defined.

Best assessment practices should not include detailed guidance on practices for modeling and analysis methods, data quality determinations, or other technical aspects of the ecological risk assessment process that have been addressed comprehensively by other organizations (e.g., the American Society for Testing and Materials). It should simply refer to the documents prepared by these other organizations.

5.2.4. *Goals and Uses of Ecological Risk Assessment*

A process for identifying the goals of an ecological risk assessment needs to be incorporated into the existing Framework Report. This process must incorporate a procedure to include societal values in selection of endpoints and assessment goals. In this manner, the ecological risk assessments will be conducted with humans as a part of the ecosystem, not apart from it.

The need for, and goals of, ecological risk assessments are broad and the guidelines must be flexible for such diverse uses. The reasons for not constraining ecological risk assessments to regulatory goals and adopting a "new" ecological goal development process are: (1) regulatory goals do not allow EPA to be proactive and avoid "train wrecks" or surprises; (2) the EPA Science Advisory Board Future Risk Report (U.S. EPA, 1988) identified the major problems facing the nation as ones that were *not* being effectively addressed by existing regulations, including biodiversity, habitat modifications, integrity of ecosystems, etc.; and (3) the public is ready for a new paradigm that makes them a part of EPA's assessment process and that is both logical and credible. Involving the public in the process provides some of the credibility needed.

Because the causal links between changes in ecosystem state and changes in human welfare cannot be established and modeled, it is essential that the goals generated be operational applications of social values. These goals should be selected using an interactive process that involves scientists and the public using a process of value articulation and conflict resolution. Important points about the goals include:

- Goals for ecological risk assessment must be formulated at the appropriate scale; there is no "one size fits all."

- Goals must make risk assessment part of a broadly focused program of adaptive management and assessment (i.e., they must be challengeable).

- Development of goals for ecological risk assessments should be made in a consensus-building atmosphere (Holling, 1978). The various groups interested in the risk assessment should be brought together, and common goals identified and expanded.

- Goals should be articulated in terms of the endpoints of the ecological risk assessment to be conducted.

The existing framework could be modified to include a step for defining ecological goals and valued ecosystem attributes during the problem formulation stages (i.e., the diagram should explicitly contain an ecological goal development box). This step should include a feedback loop to risk managers and the conceptual model development elements. Steps in the development of guidelines and modification of the Framework Report should be taken incrementally.

5.3. Recommendations on Guidelines From Group 2 (Ecological Significance, Uncertainty, Risk Integration Groups)

1. Specific guidelines on problem formulation and conceptual model development:

    - Be explicit on the contents of the conceptual model, especially on endpoint selection criteria.

2. Develop several example assessments to illustrate how the principles, concepts, and issues identified in the issue papers can be applied:

    - Include a broad range of examples and problem types;
    - Use real world examples when possible; and
    - Use hypothetical data if necessary so one can proceed through an entire example assessment.

3. EPA Program Offices will develop the guidance documents.

4. Guidelines should be developed for planning local- and State-scale risk assessments as well as at State and national scales.

5. Tool development should proceed in parallel with guideline development so the two are not out of phase, so that when guidelines are developed (i.e., in a 10 to 20-year timeframe, similar to health risk assessment), tools will be available.

5.4. Conceptual Model Development

1. Provide guidelines on conceptual model development that are explicit and instructional.

   A. Be explicit about the elements to be considered in a conceptual model (e.g., include a checklist); "beef up" issue paper introduction.

   B. Develop guidelines on conceptual model development with application-specific examples. This could be effectively accomplished either with a manual or software to support:

      - Training; and
      - Online documentation of decisions.

2. Future guidelines should aim for continuity by using common case studies/data sets.

   Note: The case studies/data sets could be "representative" (e.g., merged case studies or created data).

3. Ensure that terminology is used consistently and clearly in the guidelines.

4. Do not tinker with the framework. Accept its value in defining basic concepts and definitions, establishing consistency in ecological risk assessment, and as a communication tool for the nonscientist, but capture and address the conflicts/ controversies in the guidelines.

5.5. Characterization of Exposure

1. Develop a set of "best assessment practices" for exposure characterization that provides hands-on or "how to" guidance for key portions of the characterization (i.e., the exposure profile).

2. Incorporate in the exposure characterization guidelines the concept of tiers and additional screening-level approaches for determining when a sufficient amount of data have been collected and the exposure characterization is adequate.

3. Separate the guidelines for exposure characterization into chemical, physical, and biological approaches for assessing exposure.

5.6. Effects Characterization

1. The framework exists as an adequate *generic* risk assessment guideline. To go beyond what is already captured in the framework will require a series of topical reports. Topics could include:

    - Problem formulation (including a "key" to designing the risk assessment, possibly evolving into an expert system);

    - Exposure (broken down into chemical/physical/biological, air/water/soil);

    - Effects (many possible subtopics, perhaps as separate documents, including):

        — Effects of multiple stressors,
        — Integration of multiple endpoints,
        — Qualitative structure-activity relationships (QSAR),
        — Data analysis and modeling, and
        — Physical models (microcosms and mesocosms);

    - May need separate guidance on chemical and physical stressors; may need separate guidance for aquatic, marine, and terrestrial systems;

    - Data quality and adequacy;

    - Risk characterization (including uncertainty); and

    - Case histories (unlimited number; illustrate fitting tools to problems).

2. Throughout the guidance documents, the issue of *scale*—spatial, temporal, and ecological—should be addressed. This includes the problems of extrapolation across scales, among taxa, and among ecosystem types.

3. The plan for multiple volumes—topical guidance documents—is based on the vision of a "toolbox" or "bookshelf." It was the general view that the framework (modified and improved with age, perhaps, but in essentially its current format)

constitutes a generic guideline, the issue papers help to flesh out the guidelines in a generic way, and the next step has to include more specifics.

Other possible schemes for breaking down the mass of specifics were discussed and discarded, including:

- By stressor;
- By ecosystem type;
- By endpoint; and
- By application (i.e., by problem, or programmatic need).

However, breaking the process down into its components—problem formulation, exposure and effects analysis, and risk characterization—creates the need for guidance on fitting the pieces together. Case histories become useful here; they illustrate how the individual stages and specific tools are applied to particular problems.

5.7. Biological Stressors

A study that examines the effect of a stressor at all salient levels of scale would help eliminate the pitfalls caused by "academic blinders." For example, evaluate how a stressor influences the:

- Individual;
- Deme;
- Population;
- Metapopulation;
- Community;
- Metacommunity; and
- Regional landscape.

The Biological Stressors group preferred not to make a distinction between community and ecosystem; after all, "ecosystems" without species and "communities" without flows and flux do not exist.

5.8. Ecological Recovery

1. The term "exposure" should be used in the final guidelines with caution. To many readers it implies the stressor is *only* a chemical agent, when most often the stressors are:

   - Physical;
   - Chemical;
   - Biological; or most likely
   - A combination of a variety of stressors.

2. The guidelines should consider that a range of land use alternatives exists, from protected wildlife reserves to areas intensively harvested, all of which require wise management and can benefit from the use of ecological risk assessment methodologies. Although different uses have different management goals, all of the land use alternatives are concerned with protecting the integrity of natural systems.

3. Any action taken to minimize an ecological risk will have secondary and tertiary effects as well, and these should be anticipated. The guidelines should encourage risk managers to consider all potential effects of any action, especially those that may have a narrow focus to resolve a specific target problem.

4. The guidelines should encourage risk managers to be proactive and not just reactive in dealing with environmental problems. Whenever possible, efforts should be made to avoid future problems.

5. While the framework is a good starting point, especially in its inclusion of a broad set of ecological goals, it may have some limitations in that its conceptual approach is based on human health assessments. The specific ecological resources and conditions that societies wish to protect need to be defined independently of the current administrative, regulatory, and conceptual structures within ecological risk assessment. The media approach (air, water, soil) or the regulatory approach (drinking water, ground water, etc.) should not restrict the conceptual approaches to protecting ecological resources.

5.9. Uncertainty in Ecological Risk Assessment

1. The guidelines should state that the first step of any ecological risk assessment should be to define the goals and identify the endpoints of the assessment.

2. The guidelines would benefit by including example assessments that apply and illustrate the concepts in the issue papers. The examples selected should be demonstrative, cover a range of problem types, and may use "hypothetical" data.

3. Guidelines should be developed so that they can be used as a planning tool.

6. FUTURE RESEARCH AND DEVELOPMENT NEEDS

6.1. Overview

All Work Groups were asked to prepare a list of future research and development needs as they prepared their comments and recommendations on revising the issue papers. In order for the ecological risk assessment guidelines to have the beneficial impact that is desired, the Workshop participants strongly recommend that the EPA Office of Research and Development carefully review the suggested areas needing more research. The research recommendations suggested by the participants should be prioritized according to the contribution each will make to the development of the guidelines. It will also be necessary to provide the resources necessary to accomplish the research tasks that are judged essential to the overall success of guideline development. All too often, identified research needs go unaddressed because resources are not available. Workshop participants encourage the Agency to take the research needs seriously to fill the gaps to improve the science of ecological risk assessment. This section summarizes the future research and development needs identified by the eight Work Groups.

6.2. Ecological Significance

The primary research needs for assessing ecological significance are the development of:

- Tools and guidance for valuing ecological attributes;
- Procedures for integrating information on ecological endpoints with societal values;
- The environmental risk decision square (the "cube") as a decision making tool;
- Procedures and approaches for translating and communicating ecological significance into the management/decision making/public arena; and
- Monitoring programs established to provide baseline and long-term trend information for assessing change.

6.3. Conceptual Model Development

The Conceptual Model Development group did not identify distinct research needs. They did, however, see the need for and value of stimulating the development of tools that could aid in the construction of the conceptual model. A computer-based tool would be useful to assist with (1) documenting assumptions used in classifying the problem; (2) summarizing the data on stressor and ecosystem boundaries; (3) selecting endpoints; and (4) constructing the conceptual model diagram.

6.4. Characterization of Exposure

The primary research and development needs for characterization of exposure are:

- Bioavailability models for chemicals other than nonionic organics;
- Data on interspecies transfer and transfer coefficients for chemicals;
- Better use of existing biomarkers as measures of exposure; and
- Improved ability to assess nonchemical stressors and to increase the exchange of ideas and information between disturbance ecologists and risk assessors.

6.5. Effects Characterization

Future research and development needs identified for effects characterization are:

- Methods and concepts for measuring and interpreting effects of stressors on

  — Ecosystem stability and equilibrium;
  — Nonlinear dynamics in ecosystems and populations;
  — Nutrient cycling;
  — Disease resistance;
  — Diversity; and
  — Biotic integrity.

- Methods and concepts for measuring and interpreting:

  — Effects of fluctuating exposure regimes; and
  — Combined effects of physical and chemical stressors.

6.6. Biological Stressors

Research and development needs for biological stressors are:

1. Organized research efforts, possibly funded by the National Science Foundation and conducted by doctoral students, into the basic biology and natural history of, risks from, and predictable effects of the introduction of nonnative species into ecosystems. It was suggested that a process similar to the Delphi method could be useful, wherein the experience with similar species will provide the best basis for researching risks associated with introduced species.

2. Basic microbial research to identify the specific characteristics of bacteria, fungi, alga, and protozoa that contribute to increased survival, proliferation, and dispersal. This information helps accurately predict the risks of introduced species.

3. Develop micro- and mesocosms to more correctly assess the potential dispersal of microorganisms through air and biological vectors. Even though these are the two major means of dissemination of microorganisms, there is as yet no technology to assess this phenomenon.

4. Develop in vitro tests, based on microbial traits essential to a successful invasion (described in #2 above), to correctly assess the impact of introduced species of microorganisms on major host species. Research in human and veterinary medicine and plant pathology has identified those traits that indicate a microorganism's pathogenic potential and which species are likely to be affected. Similar research needs to be conducted to develop those abilities for evaluating environmental impacts of microorganisms.

5. Organized research and cataloging should be conducted on the possible processes and commodities that serve as "corridors" for invasion by many different species of biological stressors. An example is the current research into ballast water and commercial logs as invasion means.

6.7. Ecological Recovery

Until focus is placed on the ecological goals as discussed and described above and in comments during the workshop, it was suggested that the most important research priorities cannot be clearly defined. Ecological sciences have a lot to contribute to this; however, it is very important that the interests and desires of ecology as a science and the components of ecology that are most critical to protection of human societal interests in ecological/biological systems be distinguished. The energies and ideas of ecology and ecologists need to be more effectively tapped to accomplish this goal. Further, a variety of societal constituencies needs to be vested in this process.

6.8. Uncertainty in Ecological Risk Assessment

The following research needs were identified for the topic of characterization of uncertainty in ecological risk assessment:

- Evaluation of the effect of the independence assumption on the propagation of errors;
- Evaluation of nonprobabilistic tools on measuring uncertainty in risk assessments; and
- Evaluation of structural uncertainty using multiple model types.

6.9. Risk Integration Methods

The following research needs were identified for risk integration methods:

- Develop electronic and visual tools (e.g., Terra Vision Model) that will facilitate easier communication of ecological risk assessment issues, analyses, and results to policy and decision makers and the public.

- Prepare a document to summarize the best contributions from the discipline of ecology to the field of ecological risk assessment. Answer the following: What information can be derived from working at the different levels of biological and ecological organization, or from working at different trophic levels?

- Develop and analyze the functional models for ecological risk assessment that have policy implications. For example:

  1. Nature as a backdrop to human activity—
     Objective: maintenance of equilibrium/homeostasis.

  2. Systems are dynamic (covers shorter timeframe, i.e., successional issues)—
     Objective: maintain the system states within their "natural boundaries."

  3. Systems are evolutionary (covers biodiversity over the much longer term)—
     Objective: maintain opportunities for evolutionary adaptation.

7. REFERENCES

Boesch, D.F.; Schubel, J.R.; Berstein, B.B.; Eichbaum, W.M.; Barber, W.; Hirsh, A.; Holland, A.F.; Johnson, K.S.; O'Connor, D.J.; Speer, L.; Wiersma, G.B. (1990) Managing troubled waters: the role of marine environmental monitoring. National Academy Press: Washington, DC.

Holling, C.S., ed. (1978) Adaptive environmental management and assessment. John Wiley and Sons: Chichester, England.

Rose, K.A.; Cook, R.B.; Brenkert, A.L.; Gardner, R.H.; Hettelingh, J.P. (1991) Systematic comparison of ILWAS, MAGIC, and EDT watershed acidification models. 1. Mapping among model inputs and deterministic results. Water Resour. Res. 27: 2577-2589.

Suter, G.W.; Barnthouse, L.W.; Bartell, S.M.; Mill, T.; Mackay, D.; Paterson, S. (1993) Ecological risk assessment. Lewis Publishers: London.

U.S. Environmental Protection Agency. (1994) A review of ecological assessment case studies from a risk assessment perspective, Volume II. EPA/630/R-94/003, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1993a) A review of ecological assessment case studies from a risk assessment perspective, Volume I. EPA/630/R-92/005, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1993b) Draft ecological risk assessment issue papers. EPA/630/R-93/004A, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1992a) Framework for ecological risk assessment. EPA/630/R-92/001, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1992b) Peer review workshop report on a framework for ecological risk assessment. EPA/625/3-91/022, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1992c) Report on the ecological risk assessment guidelines strategic planning workshop. EPA/630/R-92/002, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1991) Summary report on issues in ecological risk assessment. EPA/625/3-91/018, Risk Assessment Forum, Washington, DC.

U.S. Environmental Protection Agency. (1988) Future risk: research strategies for the 1990s. SAB-EC-88-040, Science Advisory Board, Washington, DC.

APPENDIX A — REVIEWERS

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Reviewers

Workshop Chair:	Dr. Richard A. Kimerle, Monsanto Company
Work Group Members:	
Ecological Significance	
Work Group Leader:	Dr. Kent W. Thornton, FTN Associates
General Reviewer:	Dr. Robert A. Bachman, Maryland Dept. of Natural Resources
General Reviewer:	Dr. Tom O'Connor, National Oceanic and Atmospheric Administration/NOS
Conceptual Model Development	
Work Group Leader:	Dr. Gregory R. Biddinger, Exxon USA
General Reviewer:	Dr. Ronald J. Kendall, Clemson University
General Reviewer:	Dr. Robert V. O'Neill, Oak Ridge National Laboratory
Characterization of Exposure	
Work Group Leader:	Dr. William J. Adams, ABC Laboratories
General Reviewer:	Dr. Lawrence A. Kapustka, Ecological Planning and Toxicology
General Reviewer:	Dr. Frederic H. Wagner, Utah State University
Effects Characterization	
Work Group Leader:	Dr. Jeffrey M. Giddings, Springborn Laboratories
General Reviewer:	Dr. Nelson Beyer, U.S. Dept. of Interior, National Biological Survey
General Reviewer:	Dr. Wayne G. Landis, Western Washington University
Biological Stressors	
Work Group Leader:	Dr. James A. Drake, University of Tennessee
General Reviewer:	Dr. Richard Orr, U.S. Dept. of Agriculture
General Reviewer:	Dr. James H. Thorp III, University of Louisville

Reviewers (Continued)

Ecological Recovery

Work Group Leader:	Dr. James R. Karr, University of Washington
General Reviewer:	Dr. Patrick L. Brezonik, University of Minnesota
General Reviewer:	Dr. Randall Wentsel, U.S. Senate Committee on Environment and Public Works

Uncertainty in Ecological Risk Assessment

Work Group Leader:	Dr. A. Frederick Holland, South Carolina Marine Resources Research Institute
General Reviewer:	Dr. Lev R. Ginzburg, Applied Biomathematics
General Reviewer:	Dr. Kenneth A. Rose, Oak Ridge National Laboratory

Risk Integration Methods

Work Group Leader:	Dr. John Bascietto, U.S. Dept. of Energy
General Reviewer:	Dr. John P. Giesy, Michigan State University
General Reviewer:	Dr. Peter Van Voris, Battelle-Pacific Northwest Laboratories

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Reviewers' Names and Addresses

Dr. William J. Adams
ABC Laboratories
7200 East ABC Lane
Columbia, MO 65205

Dr. Robert A. Bachman
Director, Fish, Heritage, and Wildlife Administration
Maryland Dept. of Natural Resources
Tawes State Office Building
580 Taylor Avenue, E-1
Annapolis, MD 21401

Dr. John Bascietto
U.S. Dept. of Energy (EH-231)
1000 Independence Avenue
Washington, DC 20585

Dr. Nelson Beyer
National Biological Survey
Patuxent Wildlife Research Center
12011 Beech Forest Road
Laurel, MD 20708-4041

Dr. Gregory R. Biddinger
Exxon USA
Benicia Refinery
3400 East Second Street
Benicia, CA 94519

Dr. Patrick L. Brezonik
University of Minnesota
Water Resources Research Center
1518 Cleveland Avenue, Suite 302
St. Paul, MN 55108

Dr. James A. Drake
University of Tennessee
Dept. of Zoology and Graduate Program in Ecology
125 Austin Pey Building
Knoxville, TN 37996-0910

Dr. Jeffrey M. Giddings
Springborn Laboratories, Inc.
790 Main Street
Wareham, MA 02571

Dr. John P. Giesy
Michigan State University
Dept. of Fisheries and Wildlife
163 Natural Resources
East Lansing, MI 48824-1222

Dr. Lev R. Ginzburg
Applied Biomathematics
100 North Country Road
Setauket, NY 11733-1345

Dr. A. Frederick Holland
South Carolina Marine Resources Research Institute
217 Fort Johnson Road
Charleston, SC 29422

Dr. Lawrence A. Kapustka
Ecological Planning and Toxicology
5010 S.W. Hout Street
Corvallis, OR 97333-9540

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Reviewers' Names and Addresses

Dr. James R. Karr
University of Washington
Institute for Environmental Studies
Engineering Annex, FM-12
Seattle, WA 98195

Dr. Ronald J. Kendall
Clemson University
The Institute of Wildlife and Environmental Toxicology
One Tiwet Drive, P.O. Box 709
Pendleton, SC 29670

Dr. Richard A. Kimerle
Monsanto Company
800 North Lindbergh Boulevard
St. Louis, MO 63167

Dr. Wayne G. Landis
Institute of Environmental Toxicology and Chemistry
Environmental Sciences Building
Room 518
Western Washington University
Bellingham, WA 98225-9180

Dr. Tom O'Connor
National Oceanic and Atmospheric Administration/NOS
SSMC4, 10th Floor
1035 East-West Highway
Silver Spring, MD 20910

Dr. Robert V. O'Neill
Oak Ridge National Laboratory
Environmental Sciences Division
Building 1505
Oak Ridge, TN 37831-6038

Dr. Richard Orr
Animal and Plant Health Inspection Service
U.S. Dept. of Agriculture
Federal Building
6505 Belcrest Road, Room 810
Hyattsville, MD 20782

Dr. Kenneth A. Rose
Environmental Sciences Division
Oak Ridge National Laboratory
P.O. Box 2008, Building 1505, MS 6038
Oak Ridge, TN 37831-6038

Dr. Kent W. Thornton
FTN Associates
3 Innwood Circle, Suite 220
Little Rock, AR 72211

Dr. James H. Thorp III
University of Louisville
Biology Dept.
Louisville, KY 40292

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Reviewers' Names and Addresses

Dr. Peter Van Voris
Battelle-Pacific Northwest Laboratories
900 Battelle Boulevard, MS K4-12
Richland, WA 99352

Dr. Frederic H. Wagner
Ecology Center
Utah State University
Logan, UT 84322-5205

Dr. Randall Wentsel
Committee on Environment and
Public Works
415 Hart Senate Office Building
Washington, DC 20510

APPENDIX B — AUTHORS

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Issue Paper Authors

Ecological Significance
- Mark Harwell, University of Miami
- Bryan Norton, Georgia Institute of Technology
- William Cooper, Michigan State
- John Gentile, EPA/ORD/ERL, Narragansett, RI

Conceptual Model Development
- Lawrence Barnthouse, Oak Ridge National Laboratory
- Joel Brown, University of Illinois at Chicago

Characterization of Exposure
- Glenn W. Suter II, Oak Ridge National Laboratory
- James W. Gillett, Cornell University
- Sue Norton, EPA/ORD/OHEA

Effects Characterization
- Patrick J. Sheehan, McLaren/Hart
- Orie L. Loucks, Miami University, OH

Biological Stressors
- Daniel Simberloff, Florida State University
- Martin Alexander, Cornell University

Ecological Recovery
- Stuart G. Fisher, Arizona State University
- Robert Woodmansee, Colorado State University

Uncertainty in Ecological Risk Assessment
- Eric P. Smith, Virginia Polytechnic Institute
- H.H. Shugart, University of Virginia

Risk Integration Methods
- Richard G. Wiegert, University of Georgia
- Steven M. Bartell, Senes Oak Ridge, Inc.

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Authors' Names and Addresses

Martin Alexander
Professor, Dept. of Soil, Crop, and Atmospheric Sciences
Cornell University
708 Bradfield Hall
Ithaca, NY 14853

Lawrence Barnthouse
Leader, Environmental Risk Group
Environmental Sciences Division
Oak Ridge National Laboratory
P.O. Box 2008, Building 1505, Mailstop 6036
Oak Ridge, TN 37831-6036

Steven M. Bartell
Vice President and Director
SENES/Highwood Farm
Old Gobey Road
P.O. Box 688
Wartburg, TN 37887

Joel Brown
Assistant Professor of Biology
Dept. of Biological Sciences
University of Illinois at Chicago
845 West Taylor Street
Chicago, IL 60607-7060

William E. Cooper
Professor, Institute for Environ. Toxicology
Michigan State University
C-231 Holden Hall
East Lansing, MI 48824-1115

Stuart G. Fisher
Professor, Dept. of Zoology
Arizona State University
University Drive (1501)
Tempe, AZ 85287-1501

John H. Gentile
Environmental Research Laboratory—Narragansett
U.S. Environmental Protection Agency
27 Tarzwell Drive
Narragansett, RI 02882

James W. Gillett
Professor of Ecotoxicology
Dept. of Natural Resources
Cornell University
16 Fernow Hall
Ithaca, NY 14853-3001

Mark Harwell
Associate Professor
Marine Biology and Fisheries
Rosenstiel School of Marine and Atmospheric Science
University of Miami
4600 Rickenbacker Causeway
Miami, FL 33149

Orie Loucks
Eminent Scholar of Ecosystem Ecology
Dept. of Zoology
Miami University
212 Biological Sciences Building
Oxford, OH 45056

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Authors' Names and Addresses

Bryan Norton
Professor, School of Public Policy
Georgia Institute of Technology
Atlanta, GA 30332

Sue Norton
Office of Health and Environmental Assessment
U.S. Environmental Protection Agency
401 M Street, SW (8601)
Washington, DC 20460

Patrick Sheehan
Principal Toxicologist
ChemRisk Division
McLaren/Hart Environmental Engineering Corporation
1135 Atlantic Avenue
Alameda, CA 94501

H.H. Shugart
WW Corcoran Professor
Dept. of Environmental Sciences
University of Virginia
Clark Hall
Charlottesville, VA 22903

Daniel Simberloff
Robert O. Lawton Distinguished Prof. of Biological Science
Dept. of Biological Science
Florida State University
109 Conradi Building (B-142)
Tallahassee, FL 32306-2043

Eric P. Smith
Dept. of Statistics
Virginia Polytechnic Institute and State University
Blacksburg, VA 24061-0439

Glenn W. Suter II
Research Staff Member
Environmental Sciences Division
Oak Ridge National Laboratory
P.O. Box 2008, Mailstop 6038
Oak Ridge, TN 37831-6038

Richard Wiegert
Professor of Zoology
Dept. of Zoology
University of Georgia
Biological Sciences Building
Athens, GA 30602

Robert Woodmansee
TERRA LAB
315 West Oak Street, Suite 101
Fort Collins, CO 80521

APPENDIX C — OBSERVERS

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Observers' Names and Addresses

Don Barnes
U.S. EPA/SAB
401 M Street, SW
Washington, DC 20460

Kristin Brugger
E.I. Du Pont de Nemours & Company
Experiment Station, Building 402
Wilmington, DE 19880-0402

Joseph Dulka
E.I. Du Pont de Nemours & Company
Agricultural Chemicals Products Division
Wilmington, DE 19880-0038

Scott Dyer
Procter & Gamble
5299 Spring Grove Avenue
Cincinatti, OH 45217

Barbara Elliott
Environment Canada
Commercial Chemicals Branch
351 St. Joseph Boulevard, 14th Floor
Hull, Quebec K1A0H3

William Fisher
Office of Assistant Sec. of Navy
Crystal Plaza 5, Room 236
2211 Jefferson Davis Highway
Arlington, VA 22244

Andrea Hall
Thompson Publishing
1725 K Street, NW
Washington, DC 20006

Arlene Hamburg
DowElanco
9330 Zionsville Road
Indianapolis, IN 46268-1053

Kristine Hooks
Compliance Services International
2001 Jefferson Davis Highway
Suite 1010
Arlington, VA 22202-3603

Paul Jacobson
Versar ESM Operations
9200 Rumsey Road
Columbia, MD 21045-1934

Elle Kalketenickri
MARAD
400 7th Street, SW
Washington, DC 20024

William Kappleman
Environ Corporation
4350 N. Fairfax Drive
Arlington, VA 22203

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Observers' Names and Addresses

Donna Kostka
National Biological Survey
MS 3660
1849 C Street, NW
Washington, DC 20240

Tony Maciorowski
Office of Pesticide Programs (7507C)
U.S. EPA
401 M. Street, SW
Washington, DC 20460

Suzanne Marcy
Office of Water (4303)
U.S. EPA
401 M Street, SW
Washington, DC 20460

Dave Mauriello
Environmental Effects Branch (7403)
U.S. EPA
401 M Street, SW
Washington, DC 20460

Corey McDaniel
Los Alamos National Laboratory
K-555
Los Alamos, NM 87544

Tom Parkerton
Exxon Biomedical Services
P.O. CN2350
Mettlers Road
East Millstone, NJ 08875

W. Bruce Peirano
U.S. EPA
26 W. Martin Luther King Drive
Cincinnati, OH 45268

Kevin Reinert
Rohm and Haas
727 Norristown Road
Springhouse, PA 19477

Bill Richards
Woodward Clyde Federal Services
904 Wind River Drive, Suite 100
Gaithersburg, MD 20878

Don Rodier
Office of Pollution Prevention and Toxics (7402)
U.S. EPA
401 M Street, SW
Washington, DC 20460

Anne Sergeant
U.S. EPA
401 M Street, SW
Washington, DC 20460

Charles O. Shore
Sciences International
1800 Diagonal Road
Alexandria, VA 22314

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994

Observers' Names and Addresses

Susan Snider
American Forest and Paper Association
1111 19th Street, NW, 8th Floor
Washington, DC 20036

Ralph Stahl
E.I. Du Pont de Nemours & Company
1007 Market Street, B-12212
Wilmington, DE 19898

Dave W. Thompson
General Electric
640 Freedom Business Center
King of Prussia, PA 19406

Bob Vatne
DowElanco
9330 Zionsville Road
Indianapolis, IN 46268

Jennifer Wurzbacher
Hunton & Williams
200 Pennsylvania Avenue, NW
Washington, DC 20006

Paul Zubkoff
Office of Pesticide Programs (7507C)
U.S. EPA
401 M Street, SW
Washington, DC 20460

APPENDIX D — AGENDA

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994
Radisson Hotel, Alexandria, VA

Agenda

TUESDAY, AUGUST 16

7:30 am Registration and Check-in

Plenary Session

8:30 am Welcome and Introduction
Dorothy Patton, U.S. EPA, Risk Assessment Forum

8:45 am Workshop Objectives and Structure
Richard Kimerle, Workshop Chair

Individual Issue Papers

9:00 am Highlights of Pre-Meeting Comments
Work Group Leaders

10:30 am Break

Concurrent Working Sessions (8)

10:45 am Individual Issue Paper Discussions
Work Group Leaders and Reviewers; Authors Present to Clarify/Discuss Issues

12:00 pm Lunch

1:30 pm Discussion (continued)

3:15 pm Break

3:30 pm Discussion (continued)

4:00 pm Session Review and Wrap-Up

5:00 pm Adjourn

The Eight Issue Papers

- *Ecological Significance*
- *Conceptual Model Development*
- *Characterization of Exposure*
- *Effects Characterization*
- *Biological Stressors*
- *Ecological Recovery*
- *Uncertainty in Ecological Risk Assessment*
- *Risk Integration Methods*

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994
Radisson Hotel, Alexandria, VA

Agenda

WEDNESDAY, AUGUST 17

8:30 am	Breakout Sessions Continuation of Discussions of Issue Papers
10:00 am	Break
10:15 am	**Plenary Session** Recommendations for Authors *Work Group Leaders*
11:15 am	Observer Comments on Issue Paper Recommendations
12:15 pm	Lunch
1:30 pm	**Plenary Session** Introducing Cross-Cutting Issues *Workshop Chair*
2:00 pm	Breakout Sessions on Cross-Cutting Issues
3:30 pm	**Plenary Session** Highlighting Cross-Cutting Issues *Work Group Leaders and Workshop Chair*
4:30 pm	Observer Comments on Cross-Cutting Issues
5:30 pm	Adjourn

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 16-18, 1994
Radisson Hotel, Alexandria, VA

Agenda

THURSDAY, AUGUST 18

8:30 am	**Plenary Session** Ecological Risk Assessment Guidelines *Dorothy Patton, U.S. EPA, Risk Assessment Forum*
9:00 am	Ecological Risk Assessment Guidelines Discussion Chair, Work Group Leaders, and Authors (Breakouts if needed)
10:30 am	Observer Comments
11:30 am	Lunch
12:30 pm	**Concurrent Working Groups** Chair and Work Group Leaders: Write Workshop Report Authors: Discuss Revisions to Issue Papers and Schedule
4:00 pm	Adjourn

APPENDIX E — PRE-MEETING COMMENTS

Prior to this workshop, each issue paper was evaluated by a team of three peer reviewers. This appendix contains both the reviewers' pre-meeting comments and the charge to the reviewers containing suggested topics for consideration during their review. Versar and EPA encouraged the reviewers to provide their frank and candid views so that the authors would have the information needed to complete their papers. Using these written comments as a starting point, the authors and reviewers collaborated at the workshop and were able to reach agreement on the necessary revisions for each of the eight issue papers. (See appendix F.) The revised issue papers are now being compiled and will be published separately.

Compilation of Pre-Meeting Comments

Contents

Compilation of Pre-Meeting Comments

Contents
(continued)

Issue Paper Review Topics and Format for Written Comments

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Peer Review Workshop
August 1994

Background

EPA's Risk Assessment Forum is developing Agency-wide guidance for conducting ecological risk assessments. The first step in this process was the 1992 publication of EPA's "Framework for Ecological Risk Assessment (Framework Report - copy is provided in Section 5 of this notebook), which proposed a simple, flexible structure, or framework, for ecological risk assessments. The eight issue papers were written to help provide a basis for expanding the framework into a more substantive guidance document. The issue papers authors will be asked to revise their papers based upon comments and recommendations from this peer review.

The success of this workshop depends on participation of the reviewers. EPA has asked for your input on the critically important issue of ecological risk assessment. In order for this to be a fully productive workshop, we will be compiling written comments from all reviewers prior to the workshop. You will have approximately 10 days to prepare your written comments and subsequently you will have 10 days to review all of the comments prior to the workshop.

Areas for Review

Each individual issue paper has a three-person review team that includes a Work Group Leader and two General Reviewers. Although the full set of issue papers has been provided to each reviewer for information purposes, General Reviewers are expected to provide comments only **on their assigned paper**. Each Reviewer is asked to consider the following two areas for his or her paper:

- General Areas for Consideration (e.g., completeness; examples, etc.); and

- Questions Relevant to Particular Issue Papers (e.g., how well does a figure illustrate the concept, are the examples adequate, is there too much detail on a specific area or not enough?).

In addition, the Workshop Chair and the Work Group Leaders are asked to examine all the issue papers and comment on:

- Cross-Cutting Issues (e.g.,use of terminology, areas of emphasis, etc.).

Instructions for Submission of Pre-Meeting Comments to Versar (due by July 29)

Content: The suggested review topics are intended to guide you in your review of your issue paper. While we ask you to consider the suggested issues and questions because they reflect specific areas of interest, you should focus on those topics you feel are most important, and you are welcome to comment on other topics concerning your paper as necessary. **However, while General Reviewers may comment on issue papers other than their assigned paper, such work is not assigned and neither Versar nor EPA will reimburse any such work.**

Format: To assist the authors in incorporating comments, please refer to the Review Topic Numbering System (see below) and the page number of the issue paper.

Where appropriate, please include full citations for references that you think the authors should consider in revising their papers. Please follow the citation format used in the Framework Report, for example:

McKim, J.M.; Bradbury, S.P.; Niemi, G.J. (1987). Fish acute toxicity syndromes and their use in the QSAR approach to hazard assessment. Environmental Health Perspectives 71:171-186.

Submit a hard copy of your comments, and, *if possible*, a disk copy of your comments saved in Wordperfect 5.1(or higher) format.

Due Date: Friday, July 29, 1994 -- It is *essential* that Versar receive comments by the due date so that the comments can be complied and sent to all workshop participants to allow for review of all the comments prior to the workshop.

Instructions for Submission of Pre-Meeting Comments (continued)

Review Topic Numbering System

In an effort to facilitate discussion of particular topics the suggested review topics are given a two-part number as follows:

The first part of the number refers to the to which the topic refers:

G-	=	General Area;
2-	=	Issue Paper Number (refer to page numbers); and
C-	=	Cross-Cutting Issues.

The second part of the number refers to the specific number of the topic as presented in the following list of topics:

G-**6**	=	Topic #**6** listed in the General Area topics (i.e., "Examples")
2-**2**	=	Topic #**2** in Issue Paper Number 2 (Ecological Significance); and
C-**1**	=	Topic #**1** in Cross-Cutting Issues ("Terminology").

General Areas for Consideration

Reviewers should consider the following factors:

G-1. Clarity of purpose and scope. Comment on the utility of the introduction as a "road map" to the organization and major emphasis of the paper.

G-2. Completeness of coverage. Ideally, each paper should address issues spanning the full range of ecological risk assessments (different stressors, ecosystem types, levels of ecological organization, and spatial and temporal scales). Without necessarily expanding the volume of the report, which of these areas (or others) deserve more (or less) coverage?

G-3. Clarity and consistency of terminology. Comment on the definition of terms and the need for a glossary.

G-4. Current capabilities vs. future needs. What areas should be expanded (or condensed) so that the paper covers both current scientific capabilities (the "givens") and future research needs? While key literature references should be cited, descriptions of background information already in the literature should be minimized. Promising approaches that will require additional research should be clearly separated from presently available techniques.

G-5. Relationship to EPA's Framework for ecological risk assessment. How could the authors improve discussion of the applicability (or inapplicability) of the framework approach?

G-6. Examples. Where could additional examples be useful for clarifying or illustrating the application of principles?

Questions Relevant to Particular Issue Papers

Preliminary review and discussion of the issue papers identified many areas where additional work was required. The time available for revision was quite limited, and some papers were completed with more unresolved issues than others. Consequently, the number of questions provided below for each paper is also variable. Reviewers are encouraged to provide their views on the questions relevant to their assigned paper as well as to identify other areas where the issue papers can be improved.

2. Ecological Significance

2-1. Comment on the balance between ecological and social aspects of this paper.

2-2. Should a glossary be provided with this paper? If so, what terms should be included?

2-3. What additional criteria, if any, could be provided to help differentiate between ecologically significant and insignificant changes?

2-4. At what additional places in the paper, if any, could examples be used to illustrate concepts?

Questions Relevant to Particular Issue Papers (continued)

3. Conceptual Model Development

3-1. Comment on how the balance of the paper should be changed in the following areas, if at all. Please be specific on what should be added or deleted.

3-1a. Chemical vs. non-chemical stressors.

3-1b. Perspectives from different levels of biological organization - individual, population, community, and ecosystem levels.

3-1c. Stressor characterization vs. ecosystem at risk, endpoints, and the conceptual model.

3-2. How might the case study examples be better integrated into the paper to illustrate the concepts discussed?

3-3. What additional clarification is required (if any) for the terms "stress regime," "disturbance regime," and "regulatory endpoint?"

3-4. Comment on the adequacy of discussion of the time scale to be addressed in an ecological risk assessment.

Questions Relevant to Particular Issue Papers (continued)

4. *Characterization of Exposure*

4-1. Terminology has been a controversial area especially for this paper. Which exposure-related terms are most appropriate for the range of chemical and non-chemical stressors encountered in ecological risk assessment? (See text box for one set of alternative terms. Also, refer to Figure 1 in the paper).

4-2. The discussion of disturbances is short compared with chemical exposures. What technical issues should be covered in more detail in the disturbance section (e.g., fragmentation or natural disturbance characterization)?

4-3. How well do figures 2 through 6 reflect the structure used to assess exposure? What other types of exposures are not addressed?

4-4. Page 4-13 lists three primary exposure considerations during problem formulation. What modifications, if any, do these considerations require?

4-5. Page 4-22 lists three primary objectives of the exposure assessment in the analysis phase. What modifications, if any, do these objectives require?

4-6. Page 4-26 states that the objective of most chemical exposure analyses is to estimate the concentration of chemicals in different media at equilibrium. What modification, if any, does this objective require?

4. *Characterization of Exposure* (continued)

One Set of Alternative Exposure Terms

The terms listed below were synthesized from discussions among the issue paper authors and from a consultation with EPA's Science Advisory Board (SAB). The terms differ in varying degrees from those in the Framework Report and the Exposure issue paper.

Source: An entity or action that releases to the environmental or imposes on the environmental a chemical, physical, or biological agent.

Agent: The physical, chemical, or biological entity that is first released to or imposed upon the environment from a source. An agent does not necessarily directly induce adverse responses but may generate "secondary" stressors that can induce such responses.

Stressor: Any physical, chemical, or biological entity that can induce an adverse response. The stressor may be the agent or may be derived from interactions between the agent and the ecological system.

The use of the terms agent and stressor was not clearly resolved in the discussions. Our interpretation is that while the terms are very similar, they differ in connotation as described above.

Stress Regime: The exposure and/or disturbance that results from interactions of stressors with ecological components. Stress regime is defined in terms of spatial extent, intensity, duration, and frequency, and is used in place of "Characterization of Exposure."

Exposure: Co-occurrence of or contact between an ecological component and a stressor added to an ecological system. Stressors included in this definition may be chemical, physical, or biological additions (e.g., thermal discharge to a stream, exotic species introductions).

Disturbance: Co-occurrence of or contact between an ecological component and a stressor that modifies or deletes part of an ecological system. Such stressors may be physical (e.g., habitat destruction or alteration in natural fire or hydrologic cycles) or biological (e.g., species removal by harvesting).

There is not an absolute distinction between exposure and disturbance. For example, sedimentation in a stream may be considered as an addition-type stressor or as a modification to stream morphology.

4-7. Section 3.2 provides considerable detail on chemical fate and transport. Which areas, if any, should be deleted?

4-8. Page 4-9 discusses prospective and retrospective assessments; page 4-18 discusses effects-driven and source-driven assessments. Are these classifications appropriate and useful for consideration of assessment types?

4-9. Knowledge gaps are listed on page 4-49. What gaps, if any, should be added to or deleted from this list?

Questions Relevant to Particular Issue Papers (continued)

5. Effects Characterization

5-1. What changes, if any, should be made in the relative emphasis on different levels of biological organization - individual, population, community, or ecosystem?

5-2. How should the paper be modified, if at all, to better reflect present capabilities vs. areas for future research and research needs?

Questions Relevant to Particular Issue Papers (continued)

6. Biological Stressors

6-1. Comment on the balance in the paper between discussion of genetically-engineered microbes and exotic species "macrobes."

6-2. Risk assessments of biological stressors will have to be done even though, as the paper indicates, our present ability to make accurate predictions may be very limited. What more could be added concerning how such risk assessments should be approached now and what future research needs are in this area?

Questions Relevant to Particular Issue Papers (continued)

7. Ecological Recovery

7-1. What additional examples of recovery in ecosystem types not described in this paper, if any, could be added to illustrate specific points in the text?

7-2. What more could be added concerning recovery from anthropogenic (as opposed to natural) stressors?

7-3. What additional tools and methods available to risk assessors to analyze whether recovery has occurred, if any, could be included in this paper? What are the relative strengths and weaknesses of these approaches?

7-4. How well does the paper address the socio-economic factors that affect the likelihood of recovery?

7-5. What additional information, if any, is available on recovery at the landscape level?

Questions Relevant to Particular Issue Papers (continued)

8. Uncertainty in Ecological Risk Assessment

8-1. This paper tends to focus on quantitative estimates of uncertainty. What is the proper balance between qualitative, quasi-quantitative, and quantitative uncertainty estimates in the risk assessment process? What additional examples could be provided to illustrate these approaches?

Questions Relevant to Particular Issue Papers (continued)

9. Risk Integration Methods

9-1. Physical and experimental models are included as risk integration tools. Is this correct, or should these models be considered as analysis phase methods?

9-2. What examples can be provided regarding the application of fuzzy set theory to ecological risk assessments?

9-3. How (if at all) should the paper be changed to better differentiate current capabilities from future research needs?

9-4. What should be added (if anything) to the discussion of the weight of evidence approach (section 5.3)?

9-5. What changes, if any, should be made in the balance between the various sections of the report?

Cross-Cutting Issues

These topics (and others to be identified by workshop participants) will be discussed during the second part of the workshop. The Risk Assessment Forum is especially interested in comments and recommendations that will assist writers of future Agency-wide ecological risk assessment guidelines to address these difficult issues.

Exposure Terminology

C-1. The Characterization of Exposure issue paper proposes one set of exposure terms, the text box associated with question 4-1 shows another, and the Framework Report provides a third. Which terms are most appropriate for the range of stressors encountered in ecological risk assessment? Why? (See also figures 1 through 6 in the Characterization of Exposure issue paper for examples of a range of situations that exposure terminology should address).

Modifications Recommended by the SAB to EPA's Framework Process Diagrams

Note that terminology changes associated with exposure discussed in question C-1 are repeated here. Figures are those found in the Framework Report.

- Overall Process (figure 1)

  Move the data acquisition, verification, and monitoring box inside the overall ecological risk assessment box.

  Extend the box with the dotted line separating exposure and effects into the problem formulation and risk characterization phases, and eliminate the vertical arrows extending from problem formulation into risk characterization.

- Problem Formulation (figure 2)

  Modify the diagram to emphasize the central role of conceptual model development. Show endpoint selection as an output of the conceptual model, not an input to it.

  Use "ecological system" instead of "ecosystem."

  Use a two-way rather than a one-way arrow between risk characterization and the data acquisition box.

- Analysis (figure 3)

  Eliminate the boxes for exposure and stressor-response profiles, or show them as outputs of the process.

  Show a feedback arrow from the analysis phase to the conceptual model.

- Risk Characterization (figure 4)

  In the risk description box, eliminate the "Interpretation of Ecological Significance"; this subject is described by "Ecological Risk Summary."

Cross-Cutting Issues (continued)

EPA's Framework for Ecological Risk Assessment

C-2. The basic pattern for the issue papers is derived from the Framework Report. EPA's SAB and others have suggested modifications in the framework (see text box on previous page). Which changes, if any, would improve either the consistency among the issue papers or the general applicability of the framework to the full range of ecological risk assessments?

C-3. Comment on the applicability of EPA's framework for biological stressors. What modifications to the framework, if any, are required?

C-4. Are prospective, retrospective, effects-driven, and source-driven assessments adequately differentiated and discussed?

C-5. Are the dimensions of exposure adequately discussed (e.g., from the standpoint of experimental design)?

C-6. What, if anything, should be added concerning the issues of bioavailability and environmentally-realistic exposure in toxicity tests discussed?

C-7. Should there be increased emphasis on anthropogenic disturbances? How and where could this be incorporated into the issue papers?

If you have any questions or need additional guidance regarding any matter pertinent to submission of your comments, please contact:

David Bottimore, Versar
703/750-3000 extension 378

Ecological Significance

Workgroup Leader:	Dr. Kent W. Thornton FTN Associates
General Reviewer:	Dr. Robert A. Bachman Maryland DNR
General Reviewer:	Dr. Tom O'Connor National Oceanic and Atmospheric Administration/NOS

REVIEW COMMENTS

Issue Paper 2 on Ecological Significance

Authors: M. Harwell, University of Miami
B. Norton, Georgia Institute of Technology
W. Cooper, Michigan State University, and
J. Gentile, US EPA ERL-Narragansett

Reviewer: Kent Thornton, FTN Associates, Ltd.

INTRODUCTION

The review follows the general format requested by EPA and Versar. However, two additional sections, **General Comments** and **Specific Comments**, have been added prior to the Cross-Cutting Issues. These sections include review comments that are considered germane to the Issue Paper but can not be satisfactorily incorporated under General Areas for Consideration or Specific Questions. These comments refer primarily to general organization, clarification of specific Issue Paper statements, and/or alternative considerations or points of view. I recognize the short time frame for revision, the need to minimize major reorganizations to the Issue Papers, and that many of these comments might not be addressed in this Issue Paper, but could, perhaps, be considered during guideline development.

GENERAL AREAS FOR CONSIDERATION

G-1. Clarity of Purpose and Scope

The Introduction clearly states there are no formulas or guidelines for determining ecological significance. It also identifies some of the factors that influence ecological significance, but there is no clear definition or definitive statement of ecological significance. Because this is such a difficult subject or issue to address, a working definition should be provided in the Introduction. The two attributes of ecological significance listed in the third paragraph on page 2-9 might be revised to provide this working definition. Ecological significance also is used differently throughout the text. This is discussed further below. The Introduction does provide a list of central themes that will be discussed in subsequent sections, but the central themes identified on page 2-10 do not correspond to the following sections. Revising these bullets to reflect the content of the subsequent sections would assist the reader. A possible revision might be:

- Introducing the concept of ecological significance and interaction of scientific and societal values during problem formulation
- Attributes of stressors, exposures and effects that contribute to ecological significance that should be considered during analysis
- Integrating societal values, analysis results and uncertainty in assessing ecological significance, and
- Providing information on ecological significance to decision makers.

G-2. Completeness of Coverage

In general, the Issue Paper is relatively complete in its coverage. It does discuss different stressors, ecosystem types, levels of ecological organization and spatial/temporal scales. It has a nice discussion of natural and anthropogenic stresses and the importance of considering both in determining ecological significance. The discussion of levels of ecological organization in Section 3.2.1.1. identifies populations, communities, and ecosystems, but does not contain a paragraph on landscapes. Landscape ecology and its importance for assessing ecological significance is discussed throughout the text, but it is not specifically identified as an important level of organization. For completeness, this paragraph should be added. A table summarizing the important attributes of each organizational level would be a useful addition. Given the importance of habitat alteration as a major stressor, the authors might want to include a few additional sentences on physical stressors.

Reference or baseline conditions are introduced in Subsection 3.2.2 Recovery (last paragraph in Subsection, p 2-37, just preceding Subsection 3.2.3). Reference or baseline conditions might be expanded and introduced in earlier sections as another metric for assessing ecological condition. This might include the substitution of space for time in providing baseline or reference conditions on various seres or successional stages of ecological systems. Establishing or identifying reference sites might be considered part of problem formulation, while also contributing to the analysis and risk characterization phases.

There is considerable redundancy in the Issue Paper. Clearly, reiterating points emphasizes their importance and reinforces these factors for the reader. However, the authors might consider reducing the text during revision to eliminate some of this redundancy. There are also some areas where the paper might be shortened. For example, Section 2. Problem Formulation could be shortened and still maintain its salient points, particularly if the Appendix is retained as part of this Issue Paper.

G-3. Clarity and Consistency of Terminology

As stated above in Comment G-1, a definition of ecological significance should be provided in the Introduction. The elements and factors contributing to ecological significance are provided throughout the text, but it should be defined initially. There are some places in the text where ecological significance appears to be synonymous with scientific significance and other places where it appears to be determined only by societal factors. These discrepancies should be resolved.

There are several terms that are used in the text that should be defined in a glossary. All of the terms used in Table 2 should be defined, if the table is retained in the Issue Paper. Additional terms might include fungible, intergenerational equity, resistance, ecological endpoints, assessment endpoints and measurement endpoints.

In several subsections, the critical point(s), which are quite good, are made at the end of the paragraph or subsection (e.g., last sentence of middle paragraph on p 2-31; last paragraph on **Community level**, p 2-32; last paragraph on **Ecosystem level**, p 2-33; last paragraph on **3.2.1.4. Timeframe for Change, p 2-35**; middle paragraph on p 2-40 in **4.1 Societal Values**). I personally think the Issue Paper would be strengthened if these critical statements were used to initiate the paragraph or section. I would suggest the authors review their respective sections during revision to see if there are other important statements or paragraphs that could be moved to the beginning of the section/subsection, followed by the illustrative examples.

G-4. Current Capabilities vs Future Needs

The Issue Paper states in the Introduction that there currently are not formal or accepted guidelines or approaches for assessing ecological significance. There is some discussion of how economists assess significance and selected discussion of current approaches for assigning value to different factors contributing to ecological significance, but there is limited discussion of how ecological significance is currently assigned to various ecological changes and impacts. An area that could be strengthened in the Issue Paper would be a subsection on how ecological significance is currently determined and how this information is used in the decision-making process. This discussion also should include the relation of ecological significance to policy and decision-makers perspectives and endpoints. The Issue Paper develops criteria and factors that should be considered in determining ecological significance and presents some excellent examples of how these individual criteria or factors have been applied. Supplementing this with a brief subsection on how these factors are currently integrated in the Risk Characterization phase to assess ecological significance or how ecological significance is currently transmitted to the decision maker/manager would be useful.

In general, the Issue Paper does not explicitly identify Future Needs. Two exceptions are a statement of the need to develop the risk typology structure and Subsection 5.4, Research in Support of Decision-Making, which has only two generic research areas listed. Clearly there are other areas where research is needed to assess ecological significance such as the establishment of ranges of nominal and subnominal scores for various measurement and assessment endpoints, procedures for associating or integrating ecological and economic criteria, the importance of establishing cause-effect relationships in assessing ecological significance or formulating the hyperspace or hypervolume of the risk typology structure in assessing ecological significance.

G-5. Relationship to EPA's Framework for Ecological Risk Assessment

The Issue Paper clearly relates ecological significance to the EPA Framework for Ecological Risk Assessment and each of the 3 primary phases. This relationship, in part, has resulted in considerable redundancy among Sections because many of the same factors are discussed in Problem Formulation, Analysis and Risk Characterization. One possible approach to reduce this redundancy, albeit at the expense of reorganizing the Paper, would be to have Section 2 specifically define and discuss ecological significance and the need for assessments for different stressors, ecological types, levels or organization, etc; Section 3 discuss the factors that are important in determining or influencing ecological significance; Section 4 relate these factors to the three phases of Ecological Risk Assessment; and Section 5 discuss the input of ecological significance to decision-making.

G-6. Examples

The authors have done an excellent job of providing examples in the text that illustrate why various factors/criteria/attributes are important in determining ecological significance. I do not think additional examples are required in the text. However, the figures and tables should be revised for greater clarity. In particular, the captions on most figures and tables do not provide an explanation of the illustration. Specific examples are:

- Table 2. Without a phrase providing a definition of these terms, it is not always clear why they are equivalent concepts.
- Figure 2. Without clarification in the caption, this figure eludes me. It also was not clear from the text how this hierarchy was formulated or what it meant.
- Figure 3. Again, the caption is critical. This is a center piece of Section 2 and raised again in subsequent sections. It should have an explanatory caption. In addition, it is not at all clear, from the figure or the text (the Appendix does provide the explanation) how time and space are incorporated in this figure.
- Figure 4. Expand the caption to explain the figure.
- Figures 5, 6. and 7. Personally, I would not include these in the Issue Paper. I don't think they provide a good illustration of the concept in the text and think they would require significant explanation for individuals to understand.
- Figure 8. This figure does not illustrate or clarify the concept presented in the text without further explanation. The immediate impression is that you have 5 independent pathways for the development of different climax associations, starting from an upland brush grass perennial system. It is not clear exactly what is intended from this figure.
- Figure 9. Without additional information in the caption, much of the information in this figure will be lost on the reader. For example, P/R is not defined, the 0.5 meters, 10 meters, ... 700 meters are not defined as stream width, CPOM, FPOM are not defined, changes in fish types are difficult to discern, etc.
- Figure 10. I am not sure this figure captures the significance of biogeochemical cycles that was intended in the text. There are better figures that describe the phosphorus cycle at multiple scales from an individual lake watershed to basin to

region to global cycle that would probably provide a better example. I will bring an example with me to the review meeting.

The authors identify a number of factors in each section/subsection that are important to consider in evaluating ecological significance. I think it would be useful to the audience if these could be summarized in a text table, with a brief paraphrase to refresh the readers memory on re-reading or provide the individual skimming the document with an overview of the important factors for each issue or topic. These could also be incorporated as text bullets, but the table would be preferred.

G-7 General Comments

While this section was not specifically requested, the categories identified above do not permit discussing aspects of organization and general content. There is considerable disparity among the general organization and content of individual sections. For example, the central theme is unclear in Section 2 and the concepts of ecological and social/societal significance are intermixed and confusing (in sharp contrast to the Appendix); Section 3 contains a number of "provocative" statements that are not referenced or fully supported through discussion; Section 4 is more clearly written with directed information and ideas; while parts of Section 5 are weak and not well-developed. The Issue Paper could be improved if a single author revised the document and developed each section similarly. Specific comments are presented in another section of this review.

QUESTIONS RELEVANT TO ISSUE PAPER 2: ECOLOGICAL SIGNIFICANCE

2-1. Balance Between Ecological and Social Aspects of Significance

This raises the issue discussed in G-1 and G-3 above. Ecological significance incorporates both scientific and social significance, as indicated in the text. The authors have provided a good, balanced discussion of the importance of considering not only the scientifically measured changes or impacts in ecological systems and their components but also the consideration of what this change/impact means from a societal perspective. However, there is limited discussion on the relationship of ecological significance from a policy or decision-makers perspective. The difficulty of integrating multiple perspectives to develop a statement of ecological significance also is well-documented in the Issue Paper.

2-2. Glossary and Terms

This was discussed in G-3 above.

2-3. Additional Criteria for Differentiating Significant vs Insignificant Change

The Issue Paper identifies a number of criteria that might be used to differentiate significant from insignificant change. The Issue Paper is strongly oriented toward sustainability, which is not necessarily a problem, but sustainability as a unifying principle is subject to debate in the scientific community.

2-4. Existing and Additional Examples
This was addressed in G-6 above.

SPECIFIC COMMENTS ON ISSUE PAPER 2: ECOLOGICAL SIGNIFICANCE

Specific comments on Issue Paper 2 are raised in the chronological order noted in the text.

1. p 2-6, 2nd line. Is risk assessment only a construct in which the risks from human activity can be assessed or does it also included the concept of relative comparison (i.e., relative risk) and differentiation of natural causes or sources?
2. p 2-6 to 2-7. The four bullets listed do not have equivalent footing for supporting the basic emphasis on significance. The first two are essentially truisms; the third is conjecture; and the fourth is the premise on which the paper is based. Little uncomfortable presenting these as having the same factual basis.
3. p 2-7 to 2-8. Ecological significance is comprised of two components: societal values (judgements) and scientific information, I think, is what is intended in the text on pages 2-7 and 2-8. You might be able to combine these two paragraphs, or abbreviate them with this initial statement.
4. p 2-8 to 2-9. What I might infer from this text on statistical versus ecological significance is that statistics has no role in determining the significance of any outcome in ecological risk assessment (i.e., "Relying on stringent statistical tests is not compatible with this flexible paradigm."). There is little disagreement that statistical significance is not necessarily required for ecological significance and vice versa, but there clearly is a role for statistical tests, analyses, and statements in ecological risk assessment and in support of ecological significance. There is nothing magic about a 95% CI and making decisions. Most wildlife management studies would never be published if they required a 95% CI to show statistical significance. Meta-analysis, while not firmly established in the literature, is an approach for combining multiple studies to provide additional weight of evidence. I think you can eliminate the discussion in the second paragraph on p 2-9 and not diminish the strength of your argument.
5. p 2-11. The Problem Formulation section discusses the importance of considering ecological significance at the initiation of the assessment. Absolutely agree. However, there is no discussion of the importance of problem definition, question generation and bounding the problem as part of focusing the assessment on the ecologically significant issues. There is no other Issue Paper on Problem Formulation. Is it worth a few sentences to acknowledge the critical importance of this phase of ecological risk assessment? This section also could be tightened and shortened, I think, without losing its salient points or diminishing the importance of the phase. This is particularly true if the Appendix is retained.
6. p 2-12. The analogy with human health is interesting and, as you know, controversial. I personally like the analogy, but others do not. If you chose to retain this analogy, there are two issues you might address. First, you state in the middle of the page that

ecological management is only vaguely analogous to health management, but then develop this analogy in the first paragraph of the next section on Science and Public Interaction. The preceding paragraph does not really support the use of this analogy. Second, you state that both societal values and science are involved in a physicians judgement regarding whether a patient is healthy or ill. Why do societal values influence a physician's judgement on health and illness? The Surgeon General's office rarely solicits public opinion on what constitutes public health, but does attempt to influence public opinion on what individuals should consider to be good public health. The analogy presented in the paragraph does not appear to be appropriate for assessing ecological health

7. p 2-18 to 2-20. The Risk typology is intriguing. It seems to imply that there is a sector somewhere in this hyperspace where criteria should be able to be defined so that there is almost universal agreement that further stress can not be assimilated/accommodated. Outside this minima, different societal values compete for use of the resource and societal values take on greater weighting than scientific assessments of impacts. Would be interesting to pursue as part of the guidelines.
8. p 2-21. The last paragraph represents a critical part of the Section. The authors should consider introducing this early in the section.
9. p 2-23, last paragraph before 3.1.2 "Natural stress, in essence, is divergence from the normal physical and chemical regime of an ecosystem; ecological significance results from such divergence". What does this mean?
10. p 2-29. Section 3.2.1.1 Ecological Components of Change and Ecological Endpoints. Why is this section included in Analysis? Identifying endpoints is an integral part of the Problem Formulation phase. Should this section not be moved to the Problem Formulation section? In addition, how are ecological endpoints different from assessment or measurement endpoints? I assume that these "ecological" endpoints embody and represent the information the public/decision makers/managers will use to reach a decision on significance. This is a critical part of problem formulation. There is a statement at the end of the first paragraph in this section that I do not understand. "If none of the stress-induced changes (direct or indirect) in an ecological system involve the selected ecological endpoints, then the change has ecological significance. If some endpoints are affected, however, then other considerations must apply for determining ecological significance". Please explain this.

11. p 2-34, Section 3.2.1.3. I like the subsection, but it is out of context with the other subsections. It says ecological significance increases with the area affected because: bullet, bullet, bullet. End of story. There are interesting contrasts in subsections throughout the Issue Paper. Having one author or a technical editor revise the document would be helpful.
12. p 2-42 to 2-43. 4.2.2 Uncertainty. There is no mention of sampling, interannual, measurement, analytical or other sources of error included in sources of uncertainty.

Was there a reason why these were not considered part of uncertainty? In addition, I would reinforce and emphasize the statement you make at the end of the paragraph immediately following the bullets - the risk manager must have a clear and comprehensive presentation of all the assumptions in the assessment. This is rarely done and almost never done well. Assumptions are inherent in every bit of information from a laboratory study to field data collection to the statistical/empirical/process model used in the analysis. I encourage you to emphasize the importance of this in assessing ecological significance.

13. p 2-46, 5.1 Weight of Evidence. The statement is made that risk communication is beyond the scope of this chapter. I think communication is similar to ecological significance; if it is not considered during every phase of ecological risk assessment, clear, concise and understandable information will not be provided as input to the decision maker. Can information be ecologically significant if the individual/parties receiving it can not understand it?

14. p 2-48 to 2-49. These three sections, 5.2, 5.3 and 5.4 are weak. I would suggest you consider adding some of the conclusions arising from the EPRI/EPA Joint Climate Project to Address Decision Makers' Uncertainties in place of sections 5.2. and 5.3. The citation is: Science and Policy Associates. 1992. Joint Climate Project to Address Decision Makers' Uncertainties. TR-100772. Electric Power Research Institute. Palo Alto, CA. The research needs should be enhanced to discuss the techniques, studies and procedures identified as part of the Issue Paper needed to develop useful guidelines for determining ecological significance.

Ecological Risk Assessment Issue Paper

Pre-meeting Comments

Reviewer: Dr. Robert A. Bachman

Issue Paper: Ecological Significance

General Areas for Consideration

G-1. The introduction clearly outlines the relationship of the paper to the Framework and the function of the paper.

G-2. The paper spans the full range of the ecological risk assessment process. Areas for further clarification are discussed under comments 2-1 and 2-3.

G-3. Terms appear to be sufficiently defined. No glossary needed.

G-4. The manner in which societal values are evaluated and incorporated into problem formulation is poorly articulated, perhaps because of the lack of understanding on just how this process can be objectively assessed. See more on this in comments 2-1 and 2-3.

G-5. The paper appropriately expands on the framework approach.

G-6. The examples are helpful and adequate to illustrate the principles discussed.

2-1. Except for some ambiguity regarding initial or benchmark conditions, the ecological or ecosystem function analysis appears to be fairly well articulated. It is unclear, however, just how the social aspects will ever be fully integrated into the risk assessment procedure. The authors acknowledge this on page 2-54.

It is unclear why the discussion regarding public values affecting ecological significance are included as an appendix to the issue paper instead of being incorporated into the main body of the paper. The authors correctly assert that "Defining what is ecologically significant partially involves the judgement of society-at-large..." (page 2-7). Because the question of whether the effect of a stressor matters or not so frequently depends upon the perspective or will of society, it raises the question of whether it is practically possible to formally incorporate this line of inquiry into the risk assessment process or not. For example, if society at large perceives human population growth and economic growth as desirable, a particular stress may be considered insignificant. On the other hand, if and when growth is perceived as undesirable, the same stress could be considered very significant indeed. Because most ecosystems can be considered as a "commons" in the Hardin (1968) sense, how is the risk assessor or risk manager to take this ambiguity into account?

2-2. No glossary needed.

2-3. The issue paper could be strengthened by more clearly defining baseline assumptions or sideboards for endpoint selection. For example, although the authors acknowledge on page 2-16 that the ecosystem's place on a continuum is important, there is little reference that many, if not most, ecosystems in the United States are in various states of disequilibrium. Most if not all, rivers and streams currently experience stormwater runoff events (floods) that are larger than the long-term events that shaped the morphology of the stream and river beds. Stream bank erosion from decades and even centuries of anthropogenic activity have set in motion physical stresses that will take further decades to check or restore. Other ecosystems, such as forests set aside for succession to old-growth systems are in various stages of recovery. The ecological significance of a stress may depend upon the definition of the ecosystem status and trend selected for assessment. If extant conditions are used as reference, the stress may be considered insignificant, whereas if pre-Columbian, or pre-human conditions are considered as the baseline condition, the same stress might be extremely significant.

2-4. Examples are clear, and adequate.

Reference:

Hardin, G. (1968) The tragedy of the commons. Science 162:1243-1248.

Review of Issue Paper on Ecological Significance
Thomas P. O'Connor

Introductory comment

The February 1992 Framework for Ecological Risk Assessment clearly states the need to set ecological endpoints as the essential first step in problem formulation. It defines such an endpoint as "an explicit expression of the environmental value that is to be protected." The words "ecological significance" do not appear until the second to last page of the Framework document in the context of communicating results of a risk assessment. Aspects to be considered are magnitude of effect, spatial and temporal scale, and recovery time. Two or three paragraphs are then devoted to each aspect. The EPA Scientific Advisory Board's August 1992 report reviewed the Framework, and a list of proposed issue papers. Other than recommending that the topic of natural variability be address separately, the SAB said nothing about the proposed issue paper on Ecological Significance. The SAB, though, was very keen on the way the Framework highlighted the importance of problem formulation. This leaves me convinced that the importance of defining endpoints is recognized, but wondering whether "ecological significance" comes into play when defining endpoints or only when communicating results. Since most people would prefer to not to be assessing the risk of insignificant ecological modifications, I will proceed on the assumption that considerations of environmental significance are part of problem definition. However, since the same considerations may well be covered in all the other issue papers, there may be no need for a separate paper on this topic.

G-1 Clarity

The reader is left with no more guidance to significance than what is already in the Framework where it indicates that considerations of magnitude of effect, spatial and temporal scale, and recovery time are central to its determination. I have not read any other issue papers but the Tables of Contents of four of them also specify these considerations. This issue paper repeats the list three times, once under the heading of "Problem Formulation", once under the heading of "Analysis", once again under the heading of "Risk Communication." These sections, themselves, are inappropriate because the topic at hand is not an entire risk assessment. It would be better to have one section for each of the criteria deemed necessary for a declaration of significance.

To some extent clarity is lost because, as stated on page 19, "While the goal of this chapter is to give more specificity to this criteria, we recognize that many particulars can only be filled in with ecosystem-specific information..." It is difficult to maintain a solely general discussion, and this may be why the authors have allowed themselves many digressions. There is a lot of space devoted to the decision process and to the utility of economics as a guide to public regard for the environment. All this diverts the reader from getting to guidance on determining ecological significance. Similarly there are all sorts of references to ecosystems with different spatial scales, different recovery times, different levels of resiliency, and so forth. This misses the mark, too, because it does not address the main question. The paper would benefit from being much shorter.

There are some insights that go beyond the Framework document. Figure 3 is helpful but axes should be identified On the horizontal axis, I think recovery time decrease from infinity at the left to zero at the right (it would be more conventional to have it increasing from left to right). On the vertical, spatial extent varies from very local at the bottom to global at the top Better still, using the notion on pages 25 and 34, the vertical axis could be 0 to 1 representing the fractional extent of an entire system. The idea on pages 19 and 28 that sustainability is a critical characteristic of an ecosystem deserving protection was not introduced in the Framework. Similarly, the concept of redundancy on page 35 brings out the fact that species shifts, in and of themselves, may not be significant.

G-2 Completeness

The main issue is to put some criteria on the intensity, scale, and recovery rate of an ecological change required to make it a "significant" change. Those criteria are not provided.

G-3 Clarity and consistency of terminology

I found no difficulties in this regard. Terms of jargon are either explained here or in the Framework document.

G-4 Current capabilities vs. future needs

The criteria for "significance" remain undefined.

G-5 Relationship to EPA's Framework for Ecological Risk Assessment

The paper clearly derives from the issue of "ecological significance" first raised in the Framework. However, it does not provide further guidance

G-6 Examples

It would help immensely if the authors could provide at least one example where the ecological significance of a man-made non-global environmental change is assessed. They should show how considerations of intensity, scale, and recovery time were brought to bear in at least one specific case not involving species extinction.

2-1 Balance between ecological and social aspects

I think that too much of this issue paper is devoted to social aspects. Certainly societal values determine what is going to be protected, but those endpoints are not necessarily ecological much less "ecologically significant". The risk managers, dealing directly with the public, have to consider every possible effect raised by the citizenry. If upon review, using the still-to-be-formulated guidelines, a non human-health endpoint is deemed "ecologically insignificant", the risk manager has to convey that conclusion to the public. In this arena science conflicts with public perception and the strength of the guidelines are tested. However, it is circular to require societal acceptance as part of the guidelines.

It easy to imagine public concern over effects that are not "ecologically significant" because they occur over small scales or are ephemeral or both. Even if public pressure forces a decision to be based on such a concern, it does not become "ecologically significant". Conversely, a century ago wetlands did not enjoy today's public sentiment toward conservation but that did not make them less ecologically significant. The first order of business is to set guidelines for "ecological significance" independent of societal perceptions.

2-2 Should glossary be included

No

2-3 What additional criteria

No criteria are provided.

2-4 At what additional places could examples be used

All Figures, save #3, can be deleted. Figures 1, 2 and 4 deal with decision making, not ecological significance. Figures 5, 6, and 7 concern details of population dynamics by themselves and in the presence of stress. The variables are not explained in the text, but even if they were, this is much too much detail on one type of response to stress. Figure 8 is like the previous three in being unexplained but also too detailed. Figure 10 on the biogeochemical cycle of elements is too far afield.

Conceptual Model Development

Workgroup Leader:	Dr. Gregory R. Biddinger Exxon
General Reviewer:	Dr. Ronald J. Kendall Clemson University
General Reviewer:	Dr. Robert V. O'Neill Oak Ridge National Laboratory

WRITTEN COMMENTS
ON
CONCEPTUAL MODEL DEVELOPMENT

GREGORY R. BIDDINGER

GENERAL AREAS FOR CONSIDERATION

G-1 Clarity of purpose and scope

The introduction of the issue paper is where I would expect to find the definition of the scope of information to be covered in the following pages and identification of the purpose for which the information is needed. I did not find that provided in the introduction. What the reader does get is a nice concise introduction to what the conceptual model is or accomplishes in relationship to the Problem Formulation phase of the USEPA *Framework for Ecological Risk Assessment".* The historical context is well presented and the reader is given a clear image of how the conceptual model fits in the framework, but not the road map to the rest of the issue paper. A one sentence purpose statement is provided.

> " The purpose of this chapter is to discuss the translation of agreed-upon values and goals into technically credible and cost-effective risk assessments."

In my estimation this statement is too cryptic to be a core idea that the reader carries with them throughout the entire issue paper. To me the purpose of the issue paper is more along the lines of the following:

The purpose of this review will be to explain the relevance of the conceptual model to a credible risk assessment, and to demonstrate (with 2 case studies) how the conceptual model changes in relationship to the stress regime , ecosystem components at risk and regulatory objectives.

This then could be followed with a statement of scope that says how it will be done.

In order to achieve these objective stressor characteristics and types of stressors will be reviewed to better understand how the conceptual model will change with different stress regimes. As well the importance of the regulatory context in which the risk assessment is performed will be reviewed to show how it influences the selection of endpoints and defines the bounds for the ecosystems at risk. All of which adds up to the potential for dramatically different conceptual models for the same set of environmental conditions.

Obviously, the authors can do a better job than I have done above, but the introduction could benefit from a concise statement of purpose and scope.

G-2 Completeness of coverage

I feel like the authors did a good job of coverage and with the exception of the limited number of examples selected (see comments in G-6 below) I have no objections with the breadth of materials presented.

G-3 Clarity and consistency of terminology

There were a number of ecological terms with which I was not very familiar(e.g. vagility) which were defined within the context of a sentence or example. This left me guessing at times about the *meanings. I don't think you should bog down the text with the definitions. I would suggest a glossary all* in one section or key term boxes through out the text in areas where they are used.

G-4 Current capabilities vs. future needs

The development of capabilities in conceptual model formation is really a function of our understanding of how the world works. The more we know about ecosystems and the way we perturb them the better we will be able to identify risks and how to estimate their probabilities.

What I might suggest would be worth pursuing would be the development of tools which could help the risk assessor assure that they have fully explored all the considerations impinging on the development of their particular conceptual model. This could be in the form of a set of rule-based questions which guide the modeler through a system of checks and balances flesh out their model. The conceptual model and the problem formulation phase in which it is imbedded deserve their own guidance document. The aforementioned rule-based questions could be developed as part of that guidance.

G-5 Relationship to EPA's Framework for ecological risk assessment

I believe the authors have been true to the framework in the development of the issue paper . Their terminology and presentation of the key concepts parallels the framework document

G-6 Examples

The examples chosen were useful in helping to see the way the conceptual model is shaped and the flexibility of the risk manager and risk assessor in performing a risk assessment . I would like to have had more examples of other kinds of stressors. If there is to be a guidance document on problem formulation then examples of conceptual models for each stressor type should be included.

In general, I approve of the way in which the examples where used to provide continuity through out the entire paper. One problem I did note with these specific examples was that neither had any selection criteria and quality assurance standards for the models and data used. Due to that fact the issue paper comes up short on its guidance in this area. The brief section (6.4) on page 3-53 is not very informative. At a minimum this section should be expanded and a example be included to address this critical element of the conceptual model.

3. Conceptual Model Development

3-1 Comment on how the balance of the paper should be changed in the following areas, if at all. Please be specific on what should be added or deleted.

note the comments listed below really address the issue of balance between sections and not specific points of difference I might take within specific sections. I will identify those issues separately and bring them to the workshop with me. If time allows I will share with authors and co-reviewers in advance of the workshop.

one major issue is that a glossary would be a great help. Whether each paper needs a glossary will depend on how papers are finally published; as a collection or individual documents.

3-1a Chemical vs. non-chemical stressors

There seems to be adequate balance between the two areas. In the first reading I thought there was more detail than I needed in the chemical stressor sections and the physical stressors was difficult to follow. In rereading it was obvious to me this was due to the fact I know more about chemical stressors than physical ones (e.g. habitat loss)

3-1b Perspectives from different levels of biological organization - individual, population, community, and ecosystem levels.

The issue of level of organization for the assessment was integrated effectively throughout the issue paper. On the other hand the treatment in section 4.2 on page 3-37 was very cursory and not very useful. Therefore a reader/user of the document will be disappointed if he/she expects to find that guidance in one location. If the sponsors want the issue papers to be that level of guidance then this section and others like it should be expanded.

3-1c Stressor characterization vs. ecosystem at risk, endpoints, and the conceptual model

In general I don't see any great imbalance among these sections each seems to lay out the details of issues to be considered.

3-2 How might the case study examples be better integrated into the paper to illustrate the concepts discussed ?

As I stated above in the general comments (G-6) I think the two case studies were systematically woven through the issue paper in an way which provide needed continuity. Also, as previously stated, the case studies were inadequate in supporting a clarification of the model/data selection criteria and quality assurance standards

3-3 What additional clarification is required (if any) for the terms "stress regime", disturbance regime", and "regulatory endpoint" ?

The term **stress regime** was not clearly defined as far as I could tell from reviewing the document. Section 3 on characterizing the stress regime did provide an adequate overview of what the aspects which define the regime. These aspects include the type of stressor, the source of the stress, and the pattern with which an exposure to the stress occurs. A clear definition in the introductory paragraphs would be useful. The sentence could be as simple as

The stress regime is the totality of stress related characteristics which include the type and source of the stressor; the stressors pattern of exposure (intensity, frequency, duration, and timing) and the spatial scale in which the stressor is operating

Although not directly stated in the text, my interpretation of the concept of a **disturbance regime** is that it is a specific type of stress regime which addresses physical stress effects (habitat loss or distruction). The text implies that it is unique from other stress regimes because there is a natural background level of disturbance which introduces a background risk load and it is the consequences of the incremental risk burden from anthropogenic disturbances that upset the balance. I believe that chemical stressors also have a background or even competing risk from compensatory mortality associated with disease, and predation. although we seldom consider this in our risk estimates.

Although, I couldn't find a separate definition of **regulatory endpoint** the definition was intuitive from the numerous reference though out text that the conceptual model would be effected by the regulatory context in which it was developed. From the discussion in section 5. it was apparent that a good regulatory endpoint was one which (1) was susceptible to the stressor; (2) demonstrated ecological relevance ; (3) satisfied the risk manager as support for regulatory policy and (4) was in alignment with societal values and public opinion.

3-4 Comments on the adequacy of discussion of the time scale to be addressed in an ecological risk assessment.

The related issues of exposure pattern, duration and timing where really dealt with at a very general level. They were very direct and a good encapsulation of the main considerations but with out any depth. I think if I were about to embark on the development of a conceptual model I could spend a few minutes reading through this and be reminded of some very key issues quite efficiently. But if I need to explore the influence of time scale on my specific assessment I would have to look elsewhere for help, and I am not sure that is not appropriate. .

RISK ASSESSMENT FORUM

ECOLOGICAL RISK ASSESSMENT ISSUE PAPER
PEER REVIEW WORKSHOP

August 1994

Comments provided by:

Ronald J. Kendall, Ph.D.
TIWET/Clemson University
Clemson, SC

on the Paper

"CONCEPTUAL MODEL DEVELOPMENT"

prepared by

Lawrence Barnthouse
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN

and

Joel Brown
Department of Biological Sciences
University of Illinois at Chicago
Chicago, IL

GENERAL COMMENTS and AREAS FOR CONSIDERATION

The Issue Paper, "Conceptual Model Development" by Barnthouse and Brown (1994) is a well written document that provides some appropriate examples of chemical and non-chemical stressors in the context of an ecological risk assessment. Overall, the paper reads very well and is relatively easy to complete in a short period of time. However, in consideration that this Issue Paper will provide some important guidance to future individuals that will be developing ecological risk assessments, at least one more example should be included for comparison. I would suggest that in addition to the (1) pesticide issues and birds and (2) the forest wetlands study, I would recommend including one additional example of a hazardous waste site ecological risk assessment. This will be explained more fully in my technical review of the paper. I also believe that the paper should be enhanced in terms of scientific style and presentation with appropriate citation of more peer-reviewed scientific articles. This would enhance the communication of technical information and, where appropriate, examples might be found for further clarification of the literature. I think that the paper entitled "Conceptual Model Development" by Barnthouse and Brown (1994) provides a good foundation for critical review and further refinement.

1. SPECIFIC QUESTIONS RELEVANT TO CONCEPTUAL MODEL DEVELOPMENT:

1a. Chemical vs. non-chemical stressors.

I think the carbofuran example in birds is a good use of a data rich pesticide example for wildlife exposure. Additional appropriate literature should be cited (Mineau 1993; Hudson, et al. 1984). In addition, I would suggest broadening the reader to include other pertinent examples of ecological risk assessment of pesticides (Avian Effects Dialogue Group 1989, 1994; Smith 1987). A good example is also represented by Kendall and Akerman (1992). In addition to the pesticide/wildlife issues, I would suggest an example in the "Conceptual Model Development" Issue Paper to include hazardous waste site exposure and food chain contamination in wildlife.

The Louisiana Forest Wetland Study example is valuable to present as a non-chemical stressor in the present document. With these three examples, one would be able to move through a pesticide-wildlife issue with a product that breaks down relatively quickly in the environment, next one could consider food chain contamination related to hazardous waste issues in both birds and mammals with appropriate questions asked, and then move into a non-chemical stressor in the example of the Louisiana Forest Wetland Study.

1b. Perspectives from different levels of biological organization - individual, population, community, and ecosystem levels.

In the present document entitled "Conceptual Model Development", reference is made to various levels of impact on biological organization, including on individual, population, community and ecosystem levels. In the carbofuran-bird example, there is not a very good tie between individual impacts in terms of mortality and population ecology. For this reason, I would refer the authors to the book by Kendall & Lacher (1994) entitled **"Wildlife Toxicology and Population Modelling: Integrated Studies of Agroecosystems"** that has a considerable amount of referenced information on individual impacts of pesticides in birds and other wildlife and investigation of the relationship between individual impacts and impacts at the population level. In addition, with the suggested hazardous waste study, the authors would be able to tie together food web contamination with impacts at the population and community levels. A good example would be Giesy, et al. (1994).

1c. <u>Stressor characterization vs. ecosystem at risk, endpoints, and the conceptual model</u>.

In the Issue Paper entitled "Conceptual Model Development", the authors do a relatively good job in tying together concepts such as stressor characterization versus ecosystems at risk and appropriate endpoints to measure in context with development of the conceptual model. I think the addition of one more example (e.g. hazardous wastes) would enhance the ability within the paper to communicate these concepts to a less informed reader. In addition, more discussion should elucidate appropriate endpoints and testable hypotheses as a function of the stressor characterization and concern for various ecosystems at risk. At the present time, this is somewhere between a blend of art and science and as much discussion and presentation of relevant examples as possible would enhance transforming this "art form" to a stronger scientific base.

2. HOW MIGHT THE CASE STUDY EXAMPLES BE BETTER INTEGRATED INTO THE PAPER TO ILLUSTRATE THE CONCEPTS DISCUSSED?

In regards to the question of how case study examples might be better integrated into the Paper, I think that the current two examples in the "Conceptual Model Development" Issue Paper are already well integrated. The additional example already suggested, including hazardous waste sites, would probably be best included as the second example among the three. The lead off example with carbofuran and birds as a pesticide case does well as a data rich scenario to be used as the first case example. The concluding non-chemical stressor paper, particularly the Louisiana Bottomland/ Wetlands Paper probably takes position number three in a lineup.

3. WHAT ADDITIONAL CLARIFICATION IS REQUIRED (IF ANY) FOR THE TERMS "STRESS REGIME," "DISTURBANCE REGIME," AND "REGULATORY ENDPOINT?"

All of these terms represent additional terminology which must be appropriately defined and consistently used. One of the difficulties in developing consistency in ecological risk assessment has been related to inadequate definition of terms and inconsistent use of even defined terminology. Just the topic "stress regime" is a relatively vague term, particularly in toxicological definition. For this reason, it will be extremely important for the authors to define and compare and contrast these various terminologies and how they are referenced and utilized in the "Conceptual Model Development".

4. In terms of comment on the adequacy of the discussion of the time scale to be addressed in an ecological risk assessment,

this can be debated against other issues of similar importance, including stressor intensity, frequency, duration, timing, scale and modes of action. These particular stressor characteristics are outlined well in the text; however, better referencing of these characteristics would improve scientific quality considerably.

5. SPECIFIC RECOMMENDATIONS.

1. On Page 3-5 on Line 6, remove "a concrete plan" and the sentence should read: "In short, the conceptual model serves as a focusing process for conducting the analysis phase of the assessment and defines the types and quantity of information available for risk characterization".

2. On Page 3-7, Line 11, I would suggest replace the word "illuminate" with the word "reveal".

3. On Page 3-22, in Section 3.3.1.1. "Pesticides", several references are made to "toxins" which are really poisonous substances derived from a natural origin such as the venom of a spider. "Toxics" more clearly describe a pesticide as a toxic substance.

GENERAL CONCLUSIONS and SUMMARY

In addition to inclusion of another case example in terms of the examples presented as case studies in the "Conceptual Model Development" paper, a stronger orientation to scientific referencing should be included in the document. For instance, there are some excellent literature sources for carbofuran ecological risk assessment for birds. In addition to scientific refereed material, there also exists several documents produced through the Avian Effects Dialogue Group of the Conservation Foundation and later Resolve which dealt with the issues of pesticide impacts on birds and their populations (Avian Effects Dialogue Group 1989, 1994). Kendall (1992) presents information on pesticide exposure in birds in context with ecological risk assessment which could contribute to the present manuscript. The figures in the Conceptual Model Development paper really do not add anything at present in terms of showing Conceptual Model Development and the moving from there to an analysis stage. I would suggest that the authors give consideration to more appropriate utilization of figures which would show the development of the conceptual model process and how one would use that information to move clearly into the analysis stage. This would enhance the reader's understanding of the use of the Framework Document for Ecological Risk Assessment that I believe EPA wants to elucidate with the Issue Paper. Overall, I believe the authors presented a good document to work from and to be utilized in the future harmonization of the ecological risk assessment process within EPA.

Respectfully submitted,

Ronald J. Kendall, Ph.D.

LITERATURE

Avian Effects Dialogue Group. (1989) Pesticides and Birds: Improving Impact Assessment. Conservation Foundation, Washington, D.C.

Avian Effects Dialogue Group. (1994) Assessing Pesticide Impacts on Birds: Final Report of the Avian Effects Dialogue Group. 1988-1993. Resolve, Washington, D.C.

Giesy, J.P., J.P. Ludwig and D.E. Tillitt. (1994) Deformities in Birds in the Great Lakes Region: Assigning Casualty. Environmental Science and Technology 28(3):128A-135A.

Hudson, R.H., R.K. Tucker, and M.A. Haegele. (1984) Handbook of Toxicity of Pesticides to Wildlife. 2nd ed. United States Department of the Interior Fish and Wildlife Service. Resource Publication 153. Washington, D.C.

Kendall, R.J. and J. Akerman. (1992) Terrestrial Wildlife Exposed to Agrochemicals: An Ecological Risk Assessment Perspective. Environmental Toxicology and Chemistry 11(12):1727-1749.

Kendall, R.J. and T.E. Lacher, Jr. Eds. (1994) Wildlife Toxicology and Population Modeling: Integrated Studies of Agroecosystems. Lewis Publishers. Boca Raton, 579 pp.

Kendall, R.J. (1992) "Farming with agrochemicals: The response of wildlife." Environmental Science & Technology. 26(2):238-245.

Mineau, P. (1993) The Hazard of Carbofuran to Birds and Other Vertebrate Wildlife. National Wildlife Research Centre, Canadian Wildlife Service, Technical Report CW69-5/177E. Ottawa.

Smith, G.J. (1993) Pesticide Use and Toxicology in Relation to Wildlife: Organophosphorus and Carbamate Compounds. United States Department of Interior, Resource Publication 170. C.K. Smoley, Boca Raton. 171pp.

COMMENTS ON 3. CONCEPTUAL MODEL DEVELOPMENT by Barnthouse and Brown.

Review by Robert V. O'Neill, ORNL

I intuit that the pupose of writing these papers was to fill out and make more practical the principles developed in the Purple Framework. The real danger is that the report becomes Grape handcuffs! I think all of the authors should consider whether they have taken this opportunity to push back the boundries of our understanding of Risk Assessment or merely filled in the blanks in previous thinking. Risk is a brand new baby - let's help it grow and develop, not define it so that it is constrained to remain a baby.

In chapter/paper 3, the development of a conceptual model is discussed as a process that helps focus thinking and makes explicit the stressors, the system, the endpoints, etc. Everything that follows in the risk assessment will fall back on this problem definition stage. So nothing may be omitted, nothing forgotten, at this formulation step.

The chapter is designed, therefore, to be comprehensive. The authors have done a very professional job in trying to encompass every eventuality in their presentation. But the task is a daunting one - they are essentially asked to write a textbook in ecology. The paper will be cross-examined for omission - anything that is omitted may damn the adequacy of what follows.

The problem is not unique to the chapter, it is implicit in the assessment task. The authors have approached this problem in a experiential manner: "The following example shows that a particular type of effect occurs, therefore, don't forget to include it in your thinking." Based on past experience, here is a way to proceed that does not repeat the mistakes of the past. But the most important information to be extracted from past experience is that new and unanticipated phenomena are arising continuously. You cannot include everything - you certainly cannot include what you don't know about! Society's responsibility is to act responsibly - not infallibly.

The most important aspect of the conceptual model phase is WHAT YOU LEAVE OUT!!! The paper currently attempts to list candidates for inclusion - I really wanted to see principles for leaving factors out. I think the chapter (and the preceeding one as well) would benefit by some discussion of how one decides to leave something out of the analysis - without violating the need to act responsibly.

So the problem becomes developing principles that ensure that all relevant processes and state variable are included. The authors' approach to this problem is encyclopedic: here is everything I have experienced or has occurred to me while I wrote this paper. Can we go past that? Instead of a checklist, can we develop principles? Would it be possible to catalogue the TYPES of effects propagation? Is there a taxonomy of effects types?

There is no discussion of more "esoteric" potential effects, such as moving the system toward a point of instability or bifurcation, even though changes in individual components of the system are within acceptable bounds. How about esoteric cumulative effects: habitat fragmentation that will at some point in the future make it difficult for the region to maintain species diversity even though the present project cannot be shown to cause this effect right now? Is it worth talking about several conceptual models: one with direct and secondary processes with impacts directly tracable to the project being assessed - and another level of analysis that might consider societal/economic changes that will cause a drift toward undesired endpoints or interactions with unrelated stressors? Just how far does the conceptual phase go? Non-violation of existing laws? No known impact (based on our experience)? Don't we need to go toward cost-benefit and quality of life? Where does it end? Should the conceptual model phase include evaluation of the costs of mitigating if the system eventually shows negative impacts? Should this be a cost to the developer? - maybe in escrow? Just where does the process end?

This paper and the preceeding one overlap in scope - both attempt to be comprehensive - both advocate that the broadest possible view be taken. Although I have not be given time to adequately go through the preceeding paper, I believe I detect significant overlaps that should be cleared up.

The only real defect in the paper is in section 3: Characterizing the Stress Regime. The material is too finely divided into subsections. Eliminate all paragraphs that contain a single declarative sentence followed by: "For example..." Much of the material can be tabulated. Focus on principles and not on details and examples. The outline of the section is fine, the execution is too tedious. The authors should aim at restructuring this section into 5 pages instead of 20.

Characterization of Exposure

Workgroup Leader:	Dr. William J. Adams ABC Labs
General Reviewer:	Dr. Lawrence A. Kaputska Ecological Planning and Toxicology
General Reviewer:	Dr. Frederic H. Wagner Utah State University

4.0 Characterization of Exposure

William J. Adams

General Areas for Consideration (as pertaining to exposure characterization)

G-1. Clarity of purpose and scope

Overall, the introduction provides a reasonable starting point for the paper on characterization of exposure. However, I believe it is lacking some organization that could improve its ability to serve as a "road map" to the organization and major emphasis of the paper. I believe the paper should strictly follow the major concepts and components of risk assessment provided in the Framework document. For example, characterization of exposure is predominantly dealt with in "Problem Formulation" under the headings of stressor characteristics and conceptual model and in the "Analysis" section of the risk assessment Framework (see Figure 3, page 18 of the Framework document) under the headings of stressor characterization, exposure analysis, and exposure profile. At a minimum, a summary should be provided which ties back to the Framework document and lists the same "headings" for characterization of exposure, i.e., Problem Formulation (stressor characteristics and conceptual model) and Analysis (stressor characterization, exposure analysis, and exposure profile). One could carry this further and organize the introduction around these headings although this is not essential. I feel very strongly that these same headings need to be used in the Table of Contents and as headings in the body of this paper. Most of them are currently there, but in a slightly modified form. I would like the road map to be more clear starting with the Framework document.

G-2. Completeness of coverage

I think the authors did a good job of laying down the basics for conducting risk assessments for multiple types of stressors and ecosystems. It is difficult to cover this subject in great detail in a few pages. Perhaps the paper could be enhanced by a further discussion of how characterization of exposure should be performed at the population and community level. I would also like a little more discussion on preparation of exposure profiles with an example or two.

G-3. Clarity and consistency of terminology

(1) The glossary is clearly needed and was nicely prepared, although I did comment on one or more definitions.

(2) There is a need for some standardization of terms not only in this paper, but in the Framework as well. The use of exposure characterization, stressor

characterization, exposure analysis, stressor regime, appear to be used interchangeably at times. Some standardization has to be established which cuts across all of the papers and the Framework. I suggest that EPA review the recommendations of the SAB, past and present workshop participants and prepare a standard glossary of terms and edit all documents to be consistent with these terms.

G-4. Current Capabilities Versus future needs

If you read the characterization of exposure paper from the view point of a scientist who wants to learn how to conduct an exposure characterization I think you would see this paper providing general guidance and concepts, but not details on "how to do it." This is alright, but the paper would be of greater benefit if literature could be cited and a few examples, including tables or figure, demonstrating how actual exposure data are compiled, and analyzed such that they become useful for constructing the exposure profile and are ultimately used to in conjunction with effects data to complete the risk characterization. I would like to see a little bit of "hands on/how to" provided in the paper. At a minimum, additional references on these subjects might be provided.

G-5. Relationship to EPA's Framework for ecological risk assessment

I think we have gone beyond the point of discussing whether or not the framework approach works or not. I do not see any need for this type of discussion in this paper. We could discuss that issue, if deemed appropriate, at the workshop.

G-6. Examples

I mentioned a couple examples in responding to the previous questions.

Additional General Comments

(1) Exposure components are listed in the paper (page 4-10) as intensity, time, and extent. Most of this discussion could be placed in section 2 instead of the introduction. The discussion in section 2 is limited to "extent"; what about intensity and time?

(2) On page 4-20 (second paragraph) there is a good example of how professional judgment is used to determine appropriate routes of exposure and how data might be aggregated to abbreviate or facilitate the exposure characterization. One or two more examples like this would be very instructional.

(3) I think there should be an expanded section on the need for uncertainty analysis and methods for performing this analysis.

(4) There is no summary at the end of the paper. Should there be one?

4.0 Characterization of Exposure

Specific Questions

4-1. Terminology selection relative to exposure characterization. Which terms are most appropriate?

(1) The EPA Framework document indicates on page 5 that the term "exposure" will be used instead of "characterization of stress.". The Framework document is inconsistent. On pages 18 (Figure 3) and 19 stressor characterization is frequently used. Within the same box on page 18 both terms are used. The Characterization of Exposure paper written for this workshop also does not use the term "exposure" in lieu of "stressor characterization." This is simply to point out that the EPA guidance given in the Framework document is not followed. I see nothing inappropriate with "stressor characterization" or "characterization of stress", so I am not recommending a change. It is obvious that there is not general agreement on the use of theses terms so I suggest that the glossary of terms lists them all and indicate that they are often used interchangeably.

(2) I reviewed the terms in the text box on the question page for the Characterization of Exposure questions against those definitions provided in the glossary at the end of the Characterization of Exposure paper. The definitions for the terms "Source, Agent, and Stressor" are similar. The term "stress regime" is defined quite differently in the two places and I do not agree with either definition! I think it is inappropriate to state that it can be used in place of "characterization of exposure." A stress regime is a series of exposures (co-occurrences of stressors and organisms). The definitions of "exposure and disturbance" in the "text box" are good and I prefer them to those presented in the glossary.

The key to successful use of terminology is consistency. Right now there is a need for careful editing to insure consistency between papers and between the papers and the Framework document.

4-2. What technical issues should be covered in more detail in the disturbance section (e.g., fragmentation or natural disturbance characterization)?

I thought the discussion on disturbances was a big improvement over previous summaries on this topic.

4-3. How well do figures 2-6 reflect the structure used to assess exposure? What types of exposures are not addressed?

Figures 2-6 are intended to be broad examples of the risk assessment process. As such they provide a useful summary of information. The figures appear to summarize most of the common exposure scenarios.

4-4. What modifications, if any, are required to improve the three primary exposure objectives used in problem formulation listed on page 4-13?

The following minor modifications are recommended: (1) the "Agent and source title" should be changed to "Stressor characterization" to be consistent with the Framework Document; (2) the Assessment endpoint section on page 4-13 might be revised to reflect that the assessment endpoint selection is primarily an effects related endeavor and that from an exposure viewpoint the selection of assessment endpoints would be driven by knowledge of the exposure regime and in particular, information about spatial, temporal distribution that would influence the choice of assessment endpoints.

4-5. What modifications, if any, are required to improve the three primary exposure objectives used in the analysis phase listed on page 4-22?

The only modification I would make at this time is to include a brief mention of the need to quantify uncertainty associated with exposure (stressor) measurements.

4-6. Does the statement on page 4-26 that "the objective of most chemical analyses is to estimate the concentration of chemicals in different media at equilibrium", need to be modified?

(1) The object of most chemical analyses is to determine the concentration of the analyte present in the matrix being analyzed! I phrased this in this manner to point out it is easy to confuse terms. A single analyses is probably not what is being discussed here.

(2) I don't believe that the objective of most exposure analyses are to determine chemical concentrations in different media at equilibrium. The goal is to determine the exposure and/or exposure regime as it currently exists or existed at some time in the past or future. It is true that equilibrium models are often used to assist in assessing exposure, but the goal is not to estimate concentrations of chemicals in different media at equilibrium.

4-7. Section 3.2 provides considerable detail on chemical fate and transport. Which areas, if any, need to be deleted?

I am not sure any of the areas need to be deleted. I believe the sections on Advective Transport, Transfer Between Media, and Transformations could be shortened to one page each, if one desired to do this.

4-8. Are the discussions on prospective and retrospective assessments (pages 4-9) and source driven and effects driven assessments (page 4-18) appropriate and useful for consideration of assessment types?

The comments on prospective and retrospective assessments are acceptable, but they probably don't belong in the introduction. The introduction is too long and needs to be shortened. Relative to source driven and effects driven assessments the comments on page 4-14 are sufficient. The additional comments on page 4-18 probably are not needed.

4-9. What additions or deletions should be made to the knowledge gaps listed on page 4-49?

(1) The issue of bioavailability was listed as a data gap. To be more specific, information is critically needed on methods for estimating bioavailability for compounds other than non-ionic organics and a few metals.
(2) A set of rules or guidelines could be developed to provide guidance on how to prepare and present exposure profiles. This document provides guidance on how to handle chemical analyses data and provide compilation, statistical, and graphical presentation information, but very little on actual details.
(3) Information is need on how to calculate uncertainty associated with all portions of the Exposure Analysis and Exposure Profile phases of risk assessment.

Issue paper

on

CHARACTERIZATION OF EXPOSURE

Glenn W. Suter II, James W. Gillett, & Sue Norton

Reviewed by Lawrence A. Kapustka

---

review format

---

cross cutting issues

Ecological Risk Assessment (EcoRA) means a variety of things to practitioners, managers, and the public. Clarifying what an EcoRA is and how one is developed is vitally important. The intense effort that led to the publication of the *Framework for Ecological Risk Assessment* (*Framework*) has elevated the visibility of EcoRA in the regulated community and the general public. The task at hand, as I see it, is to clarify ambiguous aspects of the *Framework* guidance, but equally important, to provide sufficient detail on the process so that uniformly high quality EcoRAs can be produced.

Three concerns emerged in my review of the various chapters that deserve serious attention during the workshop to guide subsequent revisions of the document.

1. focus -- The *Framework* correctly presents the importance of using an iterative process in producing an EcoRA. However, in emphasizing this "spiral" from the broad encompassing Scoping- and Screening-Tier assessment to the specific and tightly bound Final Tier, clarity was not achieved. The elements of Problem Formulation, Analysis, and Risk Characterization were presented with extensive cross-referencing to the multitude of interactive relationships. As a consequence, the important technical definitions required to convert the guidelines into operational steps are obscured. That tact of presenting an holistic view was acceptable for the *Framework*; at this stage discrete, formal discussion of implementation are needed. My impression of the issue papers (chapters) is that far too much discussion was devoted to the "other topics."

re***commendation***: Present succinct discussions of exposure in the exposure chapter, effects in the effects chapter, etc. If additional discussion of the holistic, interactive, and interative aspects of an EcoRA is warranted, make that a stand-alone chapter.

2. *consistency* -- Portions of the *Framework* were ambiguous, or perhaps unnecessary -- one candidate for modification being the apparent redundancy in the Risk Characterization section. Some of the confusion and redundancy might be reduced or eliminated by providing clear descriptions of intent. Where appropriate, definitions should be refined. Nevertheless, invention and redefinition of terms should be approached cautiously. Terminology and section headings should carefully track those presented in the *Framework*.

   Among the most troubling definitions offered in these issue papers is the term "agent." The merits associated with this proposed terminology are few and minor. Weighed against the loss of communication capability, this is a poor choice. There does not seem to be much difficulty among technical persons in any portion of environmental science, management, or regulation understanding what is meant by the separate terms entities of chemical, biological, or physical realms. Biological systems, be they individuals or ecosystems, respond differently to each realm. Serious analysis of exposure, response, effects, mitigation, monitoring, management, or any other aspect of human interest in the environmental arena requires distinction among biological, chemical, and physical variables. Grouping, and therefore losing the distinctive information that might be conveyed if dealt with separately, can only lead to greater confusion and less informed environmental action.

   The apparent drive behind this particular terminology has been the concern that EcoRA has dealt almost exclusively with chemicals and not adequately considered physical disturbance that lead to diminished habitat for certain high profile species. Encumbering and diminishing the language will not fix that problem.

   recommendation: Special effort should be devoted to retaining consistent use of terms as they are used in the technical fields.

   The readability, and instructional value, of the issue papers would also be enhanced if they tracked the specific topics introduced in the *Framework*.

3. *ecology & scientific rigor* -- The foundation of EcoRA is anchored by two broad support structures: ecology and toxicology. If either of these scientific constructs is misrepresented, the value of the EcoRA will be diminished. The very nature of risk assessment, (i.e., extrapolation beyond data ranges) challenges the technical, scientific limits. Ecology as a discipline has the distinction of operating without solid principles common to other natural sciences. In filling this void, the temptation to use paradigms as principles has been seductive. Simplistic and discredited explanations of effects responses, recovery, linear succession, restoration potential, have crept into the overall presentation of the *Framework* and some of the issue papers.

   recommendation: Take a hard look at the explicit and implicit ecological commentary in the Framework with an eye on updating the ecological information so that it more accurately captures the essence of ecology the science, rather than popular (non-science) ecology.

general impression of exposure chapter

The apparent instructions to the authors of all the issue papers were to cover their topic across the three phases of the *Framework* guidance: Problem Formulation, Analysis, and Risk Characterization. This approach has resulted in a series of issue papers that dilute and confuse the discrete elements needed to produce a quality EcoRA.

I did not get a sense of a clear description or explanation of the essential features of exposure *vis-a-vis* an EcoRA; rather, there was a great deal of discussion that blended with effects, consequences, and even expectations. The foundational relationships critical to conducting and interpreting EcoRA are not expressly presented:

1. without exposure, there cannot be a response attributable to the "agent;"
2. with exposure, there may be a response;
3. a response may manifest into an effect;
4. an effect at one organizational level (e.g., individual, population etc.) may be realized at other organizational levels.

The emphasis on "may" should not be diminished, given the great tendency to equate the potential for exposure with an actual ecological effect.

I wanted this issue paper on exposure to:

- discuss items 1 and 2,
- succinctly detail routes of exposure,
- present straightforward descriptions of techniques to assess or document exposure,
- provide a smooth transition for the "effects" issue paper, and
- build the foundation for subsequent procedural documents akin to ASTM Standards.

Against these prejudices, this issue paper comes up short.

specific technical issues

1. Introduction

2nd sentence -- ...or other system must be in contact with or co-occur...

Co-occurrence does not equate with exposure. Whereas co-occurrence may lead one to consider the potential for exposure, it should not be construed as being more than a potential. The logical extension of the statement as presented would be to accept a statistical correlation as confirmation of a cause-effect relationship.

1.1. Scope

1st sentence -- scope...

In framing the scope as uptake or interaction with the "ecosystem or its component that constitute the assessment endpoint ..." key features of exposure that are best evaluated in controlled laboratory settings are exempt. Surrogate systems, whether biological or chemical, that are used as measurement endpoints would not be included in this delineation of scope.

2nd sentence -- "... various human activities..."

It is inappropriate to restrict the description of disturbances to human activities. Whereas it may be the role of a regulatory body to issue or deny permits, levy fines, etc., there is a broader purpose for considering physical disturbances in an EcoRA. Non-anthropogenic disturbances should be factored into the ecological analysis of risk. If the goal is to assess risk and analyze consequences of any "agent" in an ecological context, it becomes imperative that one incorporates the key features of ecological relevance whether anthropogenic or not.

3rd paragraph -- "...separating biological agents..."

After reading the various segments of this issue paper, particularly the cumbersome diversions made to accommodate simultaneous discussion of physical and chemical agents, it would seem preferable to distinguish all three (biological, chemical, and physical) categories into separate chapters. At the risk of sounding as if ASTM has panaceic solutions, the approach of having an umbrella documents with annexes might be useful here. This would translate into a brief, cogent discussion of the critical, cross-cutting features of exposure without regard for the type of "agent," supported with three discrete discussions of biological, chemical, and physical "agents" respectively.

1.1.1. Sources and Agents

2nd paragraph.

There is an intriguing revelation of personal values in this chapter. Whereas a soy bean field has many ecological distinctions from a True Prairie or Eastern Deciduous Forest ecosystem, it is hardly equivalent to a parking lot. The tenor of this chapter is decidedly value laden and poorly grounded in scientific terms. The entire discussion of systems elimination tenuous. No area on Earth is permanently rendered sterile as implied in this paragraph. Apparently the span of time is cast in partial human life-span rather than ecologic or geologic reference. In doing so, the hypotheses generated as the product of a risk assessment can easily be challenged.

1.1.2. Types of Exposures

Figure 2.

It is not obvious in Figure 2., that "Exposure" is to be represented in terms of the magnitude <u>and</u> likelihood of convergence of the "agent" and the receptor. As presented, it becomes easy to assume the Exposure-Response relationship is unity and that exposure = effect. Consequently this figure presents an imperfect conceptual relationship and does not promote development of an operational strategy to conduct a valid EcoRA.

The flow through the six paragraphs illustrates the progressive merging of exposure and effects. From an analytical perspective, it is critically important to determine exposure independent of effects. The merging of indirect effects, secondary exposures, etc. should be handled in the Risk Characterization phase. If the merger occurs from the outset, the depth of analysis possible will be compromised.

2. Problem Formulation

3rd bullet "Ecosystem at Risk"

This should be stated as the "ecological resource at risk." Virtually all practitioners agree that EcoRA do not occur at the Ecosystem Level. What should define and EcoRA is the Ecological Setting or Ecological Context. This permits evaluation of exposure and effects in terms of ecological relationships and dynamics.

2.2.2. Extent Based on Effects

It is not clear how this section as written is relevant to the exposure chapter. The message can be simplified to cover three points:

1. overt symptomology may help define exposure areas, (e.g. herbicide drift and dead plants);

2. mobile organisms may disperse chemicals leading to secondary exposures;

3. slow acting effects may be manifested away from the exposure point.

2.4. Assessment Endpoints

p. 4-19

2nd bullet -- turtles

Would and organism such as a heron or osprey be a better example?

4th & 5th bullets

Change "...have the greatest exposure of ..." to "... have greater exposure potential of ..."

2.5. Causal pathways in Conceptual Models

1st paragraph

The sixth sentence is remarkable in being naive, fundamentally incorrect, and terrible guidance. For assessment of phytotoxicity and in evaluating exposure pathways considerable distinction among taxonomic groups or life-forms are possible.

3.1. Further Source and Agent Characterization

4th paragraph

Use full name for CFC.

5th paragraph

Adventitious exposure is a curious use of the term.

3.2.1.2. Transfers among media

1st paragraph.

It is interesting that special attention is given to methyl mercury as an example that may not be in equilibrium. It would be much more instructive to provide an example of some ecological setting that was in equilibrium. Are there any?

p. 4-28. last paragraph

The term "conservative" should be avoided in this context since it carries so many alternative meanings.

3.2.2.1. Transformations

Biotic Reactions

Purge the anthropomorphic representation of microbes as naive. Better terms are available.

3.2.2.2. Interactions with Ecological Processes.

1st paragraph

A closing sentence should be added, explicitly stating that as the complexity and length of pathway increases, the linkages become obscure, uncertainty increases, and plausible effects diminish.

3.3.1. Behavioral Attributes

p. 4-34 2nd paragraph -- "These exposure-related behaviors are best considered as effects per se, ..."

Considering exposure equal to effects violates the scientific basis of an EcoRA. It may be convenient for some purposes, but it is wrong. One should not lose sight of the "life" that such directives develop. This contributes to the tendency for desk-top assessments (i.e., not verified in the field), to incorporate worst-case scenarios that assume 100% bioavailability and 100% exposure. The result of such exercises is less ecological relevance. Don't assume perfect correlation between exposure and effects.

3.3.2. Routes of Contact

1st paragraph

Why assume equilibrium?

3rd paragraph.

Add explanatory information regarding the continuing controversy. Namely, the model is based on information gathered from hydroponic experiments only and as such presents an atypical exposure condition. Moreover, the model is not able to accommodate the pervasive influence of rhizosphere organism on root morphology (e.g., suppression of root hair development; the primary point of uptake in a hydroponicly grown plant), and root physiology that are extensively documented in plant physiological ecology writings.

3.3.4.2.

1st and 2nd paragraphs

These paragraphs emphasize biomarkers as effects measures. It would be more appropriate here to discuss the exposure aspects of biomarkers.

3.4. Implementation Issues

Clarify the separation: 1) the selection and use of models, 2) data acquisition. Analysis should be a part of both.

3.4.1.1. Validation

Use "Verify" not "Validate" in title and in paragraph.

3.4.2.2. Statistical Analysis

It was not clear to me what the two paragraphs provide in regard to exposure assessment.

4.1. Direct Disturbances

1st paragraph

There are few physical disturbances that are truly as complete and pervasive as implied in this paragraph. Change to reflect the typical, intermediate condition experienced.

second paragraph -- "... harmful and then quantifying the effective deletion ..."

This presentation as noted earlier is artificially bounded. First, value-laden terms like harmful present an inappropriate bias to the risk assessment process. Disturbance may be detrimental to some processes and resources while being quite beneficial to others. The Clementsian implications of this presentation is disturbing intellectually. It would also suffice to state the changes as modifications. This would account for deletions, additions, and alterations of a partial nature.

4th paragraph

The examples and implications (that highways are somehow more permanent and destructive than reservoirs) are not very sound. Many secondary road, a lot of railroad rights-of-way, and numerous ghost-town areas have reverted to non-managed status or have been transferred to be managed as ecological resource areas. I suspect that the such transitions occur more frequently and of greater spatial extent than that occurring from reservoir silt-in.

5th paragraph

The purpose and meaning of this paragraph is not apparent.

REVIEW OF RISK ASSESSMENT FORUM ISSUE PAPER

NO. 7.4: CHARACTERIZATION OF EXPOSURE

by Frederic H. Wagner

The authors have done a lot of work on this chapter. The following comments, based on three days' review, obviously do not come from the same amount of thought, and background research, and so may or may not be valid. But they are offered as food for thought, and hopefully will be useful.

General Areas for Consideration

G - 1

I am assuming that this entire document will become a procedural guide or manual for people engaging in risk analysis. Hence I think it should provide the user an understanding not only of the conceptual matters treated in this chapter, but as well a reasonably concrete sense of the assessment procedure including the sequence of actual steps taken. To a degree the sequencing of the topics and Figures 1-8 do this, but I think not concretely or completely enough. Hence I think one or more hypothetical (or real, if appropriate ones are available) step-by-step examples should be included in the treatment.

Let me show how the failure to provide this kind of concrete understanding and abstract nature of the discussion raise questions in my mind. One turns on the distinction between prospective and retrospective assessment (cf. Questions Relevant to Particular Issue Papers 4-8). Both of these procedures are mentioned several times in the chapter, and the distinction between them is touched on briefly on p. 4-9. But I think failure to describe them more fully and exemplify them leaves the assessor unalerted a priori to the very different operating procedures which the two imply.

My assumption is that prospective assessment must involve situations in which a decision, policy, or action is being contemplated that will affect the environment. The purpose of assessment is to predict that effect. This general perspective is stated or implied a number of times in the chapter (1.1.3, 2.5, 3.2.2). The procedure is largely a modelling one, and involves analyzing the magnitude and nature of the source and agent, and of the system to be affected. The established or known parameter values of these analyses are structured into a model which is then used to predict the effect(s) of the agent on the impacted system.

Retrospective assessment, if I understand it correctly, is more empirical and a posteriori. It must measure parameters of affected systems and compare them with parameters of similar but unaffected systems to detect, and quantify the magnitude of, effects. These are then related to agents that have been identified and measured. Establishing cause and effect might involve experimentation. This whole scenario is in essence a research project of some significant time period with associated personnel and equipment. I even ask whether it fits the description of risk assessment.

It seems to me that "source-driven" and "effects-driven" assessments (again Relevant Question 4-8) fit this same dichotomy, may be rough synonyms of prospective and retrospective assessments. And don't they have the same operational implications?

The same questions arise with model validation (cf. 3.4.1.1). This involves selecting key parameters of systems for which predictions are being made and measuring these periodically (monitoring) over time to determine whether or not predicted changes are taking place. There is an implied time, personnel, and equipment need here that may not be obvious to an assessor reading this Issue Paper. It needs to be spelled out before he/she commits to this action and embarks on it.

G - 3

Except for the above matters, I find the terminology consistent and clear. The glossary is helpful.

G - 6

See above comments re step-by-step scenarios.

Questions Relevant to Particular Issue Papers

4 - 1

I have commented above on terminology and generally feel that it is OK. But the *definitions in the text box are succinct, and the box, if included in the chapter text, would* be more convenient to refer to than paging back to the glossary.

4 - 2

I do think the discussion of disturbances is brief. There is a whole literature that deals with disturbance ecology. It explores such aspects as pulse vs. continuous disturbance, varying impacts on functional groupings (species, guilds, trophic levels, etc.), and on spatially different impacts. Perhaps not relevant for this chapter, but these considerations lead naturally into the subject of restoration.

I know there are space constraints, but subject to this, it might be worth including brief, generic discussion on the forms of disturbance: meteorological/climatological (flood, global warming), human mechanical (mining, agricultural, urbanization, logging, livestock grazing), etc. Can an agent (e.g. an anthropogenic chemical) that eliminates a whole species or combination of species become a disturbance thereby?

4 - 3

I have problems with Figures 1-7, and perhaps these are due to my entrainment on conceptual diagrams for modelling. Maybe these figures are designed for a much more general purpose, but even so I think they are ambiguous in places. So I'll make this comment and it can be ignored if not relevant.

In my experience with these kinds of diagrams, each symbol represents an explicit system entity. Boxes represent components of the system (chemical nutrients, biomass, individuals, populations, etc.) and are measured as point-in-time state variables. Arrows represent processes (metabolic, photosynthetic, natality, movement, decomposition) and are measured as rates. The constraints on the process rates are shown in varying forms, often as bow ties on the arrows. Models are constructed from rate functions expressing the process rates as functions of different values of the constraints, and predict changes in the state variables. Validation consists of measuring state variables over time to see if they change according to prediction.

In our present context, Fig. 8 (p. 4-70) is constructed in roughly this form: rectangles are state variables, processes are hexagons, and constraints are shown as arrows from the agents and disturbances on right impinging upon hexagonal processes on the left. In general, I think agent and disturbances function as constraints on processes (DO in respiration, toxicants on a variety of physiological processes, UV-B on plankton mortality).

In Figures 1-7, the boxes variously contain state variables (zooplankton), processes (zooplankton mortality), constraints (agents, pesticides), and functional relationships (exposure-response curves). In some cases they contain combinations: state variables and constraints (pesticides and birds), processes and constraints (UV-B and zooplankton mortality). I'm not sure on where "risk of effect" fits our conceptual framework. Arrows simply convey unspecified causal flow.

I suppose these diagrams are nothing more than starting points to begin conceptualization of the problem confronting an assessor. But the one(s) representing the final predictive model(s) that he/she uses will be very different. If Fig. 8 can serve both purposes, can't a similar approach for Figs. 1-7?

4 - 4

Re Agent and source. If source and agent are unknown, how can observed effects be attributed to any agent, and to what end does the assessor define potential sources and agents? It seems too hypothetical for any policy action.

4 - 5

It seems to me that this Analysis Phase (Section 3) is treated pretty thoroughly here. But it strikes me that this phase needs to be carried out in close association with Effects Characterization. It can't be known how complete the source characterization is unless the affected components and processes of the impacted system are known. Same with pathway analysis: A simple, exhaustive cataloging of all fate and transport processes could be an abstract effort. Attention needs to be focused on those fate and transport processes that lead an agent to the affected components and processes of the impacted system. Similarly, the interactions with ecological processes cannot be usefully detailed until the impacted system and its processes are known. Can "effective" concentration or dose be known except for specific system components and processes?

4 - 6

Why only at equilibrium? Many agents are increasing over time. Restoration aspires to reduce them.

Effects Characterization

Workgroup Leader:	Dr. Jeffrey M. Giddings Springborne Laboratories
General Reviewer:	Dr. Nelson Beyer National Biological Survey
General Reviewer:	Dr. Wayne G. Landis Western Washington University

Risk Assessment Forum
Ecological Risk Assessment Issue Paper Review

Issue Paper on Effects Characterization

Review comments by Jeffrey Giddings

The following are notes made as I read through the issue paper three times. They are in order as they appear in the issue paper, not organized in terms of the review questions we were asked to address. I did not have time to read all of the other issue papers, but I did look at the papers on Conceptual Model Development and Characterization of Exposure to address some of the cross-cutting issues.

Unfortunately, Federal Express will come for this package in less than an hour, and there is not time for me to summarize my thoughts on each of the review topics. My general reaction to this issue paper is that it is comprehensive, touches on most of the important points, and is reasonably well balanced. In some sections, as I have noted below, there is too much emphasis on what the Introduction calls "greatly improved theoretical and empirical foundations" for addressing large-scale ecosystem-level effects, at the expense of more practical, conventional approaches for addressing individual and population level effects. While I think the ecosystem approach is important and opens up many interesting questions for research, I think the current need is for clear, pragmatic guidance to those in EPA and elsewhere who are trying to develop scientifically sound risk assessment programs—even if that entails reliance on more pedestrian concepts and more ordinary sources of information. I don't think the ecosystem considerations should be left out of the document, but I think they should be brought into balance.

This comment is related to the issue of current capabilities vs. future needs. Perhaps the recent spate of books and manuals on ecological risk assessment are already filling the need for coverage of current capabilities, but I would like to see this issue paper provide a better perspective on tools and approaches that are actually in use, and less emphasis on exciting new concepts and areas for future exploration.

My apologies to the other reviewers and to the authors for leaving this review in its current state of disorganization, but the time allocated wasn't enough to include reflection and summarizing. I look forward to discussing these issues at the workshop.

Review Topic	Notes and Comments
G-1	Goal of chapter: "explore principles and data bases" used for characterizing ecological effects. Principles I understand; I'm not so sure what is meant by data bases.
E (Editorial)	Introduction has a couple of puzzling phrases: "level of resolution desired

from other ecological manipulations" (lines 2-3) and "quantify, in so far as that may be possible" (second paragraph, third line). These phrases don't seem to fit the sentences.

C-3 The introduction notes that biological stressors will be discussed in another chapter, not much in this one.

G-3 Section 2.1.1.—Definition of direct and indirect effects. "Direct effects are those that can be related causally to exposure of the stressor." Not a *clear definition—indirect effects are also related causally to stressor.*

"Indirect effects occur as a result of the changes induced ... by a stressor acting on the physical or chemical environment or on habitat quality, rather than as a direct response to the stressor." Again, not a very clear distinction here (unless the reader already understands the distinction). Implies that all effects of physical disturbance (dredging, etc.) would be indirect (since all involve stressor acting on the physical environment). "Habitat quality" apparently includes food supply and other ecological aspects—otherwise, this definition of indirect effects doesn't seem to include effects caused by reduction in food supply, for example.

The best way to convey the concept of direct and indirect effects is by example. The examples need to clearly illustrate the distinction. In the case of the aerial insecticide in Canadian prairies, be explicit: The insectide causes direct toxic effects on macroinvertebrates; it doesn't cause direct effects on ducklings, but the reduction in macroinvertebrate food supply causes indirect effects on recruitment of ducklings.

I wonder: how important, for the purpose of risk assessment, is the *distinction* between direct and indirect effects anyway? (I don't mean, how important are indirect effects—but is it important that we categorize them as indirect?)

5-1 Section 2.1.4—Levels of ecological organization. (Section title says "biological organization" but this should be changed.) The classical diagram of space-time scales (Fig. 1) is fine. But I like the comment (top of page 5-12): "the distinctions between levels of organization are not as real as they seem."

E Second to last sentence of long paragraph on p. 5-12: for clarity, change "longer than that for" to "longer than the scale for".

5-1 Section 2.2—Individuals and populations. Quibble, p. 5-14: I wouldn't call the LC50 an expression of population effect. The "population" of reference in an LC50 is simply the test population, not as ecological population (with associated emergent properties). The LC50 is a concentration that has 50% chance of killing an individual—concept seen clearly in the nearly synonymous term, TLm.

5-1 Section 2.2, p. 5-14, final sentence on the relevance of field studies. A very important point, seems to conflict with OPP's "new paradigm".

5-1 Section 2.2, general comment: Not very much attention paid here to population-level assessments (life table analysis, etc.). It comes out in later sections, but a brief discussion here would be appropriate.

E Section 2.3—Ecosystem structure. Second paragraph, first sentence: Meaning is very unclear. "...effects on ecosystems, rather than on the specific structure of the ecosystem itself...". What is the distinction? "...although, obviously, this is ecologically important as well...". What does "this" refer to?

G-3 Section 2.3, p. 5-15, second line from top of page: "Reductions in numbers, biomass, and taxonomic and trophic diversity indicate a short-term disruption in equilibrium conditions." Equilibrium conditions may not exist on the short-term; reductions may be due to natural fluctuations (this is the big problem of distinguishing stressor effects from natural variability, alreay referred to).

G-3 Section 2.4—Ecosystem function. Section is too concise. Need an overview of "ecosystem functions" (with examples) in this section on concepts and terminology. This is especially important in light of the emphasis on ecosystem properties later in the chapter.

5-2 Section 2.5—Pulsing and stability. Discussion is forward-looking, well beyond current capabilities. "Our understanding of these risks ... is still too incomplete to prescribe a standard methodology."

G-5 Presumably, all of Section 2 relates to Problem Formulation; Section 3 relates to Analysis; and Sections 4 through 7 relate to Risk Characterization. These correspondences could be made more explicit in the issue paper. So Section 2 should include a discussion of how these concepts are used in developing a conceptual model (ties in with chapter on Conceptual Model—revisit this after reading that issue paper).

G-5 Section 3.1—Endpoints. To correspond with Framework, this discussion would belong with Problem Formulation (Section 2).

G-3 Definition of "effect" in section 3.2 (first paragraph) might be better placed in Section 2.

5-1	Table 2 is extremely useful. Gives a great capsulated view of the different effect measurements at different levels of ecological organization.
	Section 3.2.1—Effects on individuals. Page 5-21, last line, mentions "growth of individuals is measured in toxicity tests for ... some algae". Not that I know of—all algal tests measure population growth (cell density, biomass).
G-2	I am not familiar with the review by Vouk and Sheehan (1983), but from the reference to it in section 3.2.1 I infer that it is mostly about higher animals. There should be some mention here, for the sake of completeness, about the very common aquatic invertebrate reproduction tests (daphnids, mysids, sea urchins).
E	Page 5-23, third line of first full paragraph begins "Several reviews of full life-cycle and other partial life-cycle tests ..."; I think this should be "reviews of early life-stage and other partial life-cycle tests ...".
M (Miscellaneous)	Last paragraph on p. 5-23 is too compact for me to penetrate its meaning. Exactly what is a global index? Why is it preferred for expressing toxicity test results for individuals? How would weight of young per female be calculated—total weight of all offspring at birth? Would this index be substantially more useful than total number of offspring per female (as commonly measured in chronic tests with invertebrates)?. The paragraph is puzzling, not illuminating.
G-2	Section 3.2.2—Populations. There could be some mention here (or reference to further discussion in section 5) of modeling approaches to interpret mortality and reproduction data (e.g., typical toxicity test results) in terms of life tables and population dynamics.
E	Section 3.2.2—last paragraph, second sentence: I think "generic composition" should be changed to "genetic composition".
C-3	Section 3.2.2, last paragraph addresses population genetics. This is a critical issue for release of genetically engineered organisms. More discussion is warranted.
5-1, G-4	Section 3.2, reviewing the types of effects data, includes 2.5 pages on individuals, 1 page on populations, and 4 pages on ecosystem structure and function. To the extent that the number of pages reflects the depth of discussion (and I think it does, pretty much), this indicates a heavy emphasis on the ecosystem level. However, available data and methods for interpretation exist mainly at the individual and population level. The first sentence of section 3.2.2 notes that the population is the focus of

most ecological assessments, and I agree. This section does get into some interesting and forward-looking science, but it lacks practical impact.

The discussion of diversity (Section 3.2.3) plays down the importance of this widely used parameter without explaining or illustrating its limitations. It may be true that air pollution effects on plants aren't reflected in diversity indices, but there are certainly situations (e.g., effects of metals or pesticides on aquatic invertebrate communities) where diversity is a sensitive and informative measure of effect.

On the other side of the coin, section 3.2.4 (Ecosystem Structure and Function) includes a long paragraph about effects on resistance to disease and insect attack. Some of the argument involves long chains of indirect effects—changes in photosynthesis or nitrogen availability affecting C:N ratios of primary metabolites, thus affecting production of secondary metabolites that confer disease resistance, thus increasing the incidence of disease, thus causing extensive damage to forests. The paragraph concludes by acknowledging that this is a "new dimension of risk assessment for which research is only beginning." I don't necessarily deny the potential importance of this phenomenon in nature, but I don't believe it will be a consideration in developing risk assessment guidelines for years to come. (Also, this topic might fit more appropriately in the section on effects on individuals.)

Contrast this paragraph with last one in section 3.2.4, on the Index of Biological Integrity. IBI is not considered useful in its present form because it can't be applied broadly across very different types of ecosystems. The specific shortcomings of IBI are not explained.

In short, Section 3.2 leans heavily towards novel, largely unexplored, systems level measures of effects and away from the measures that are the basis for most ecological risk assessments conducted today. I'm afraid that many users of this document will sense a certain ecological snobbery and anti-faddism, and will not find this section very helpful in designing assessments for everyday use.

G-2 Section 3.3.1—Data Quality. There is much more to quality assurance than the use of controls—proper documentation, maintenance and calibration of instruments and equipment, avoidance of bias in sampling and measurement (mentioned in section 3.3.3), prevention of cross-contamination, accuracy of calculations, training of personnel, and so on. I'll try to bring a few appropriate reference citations to the workshop.

C-5 Section 3.3.3—Representative Data. Mention is made of the difficulty in relating toxicity test data to environmental exposure, because the toxicity tests don't use relevant exposure methods. This is a very important point. In my experience with risk assessment of pesticides, for which real-world exposure patterns are much more complex than those used in acute and chronic toxicity tests, the connection between measurement endpoints and assessment endpoints is extremely uncertain; predictive assessments for regulatory purposes are forced to incorporate worst-case assumptions and large "safety factors". Since laboratory toxicity tests are likely to remain the most important source of data on ecological effects, a serious effort is needed to design more relevant exposure methods.

G-1, 5-1 Section 4—Analysis of Stressor Responses. The objective of this section isn't clear. Is it to present examples of quantified effects? That's a terribly broad objective, and not clearly differentiated from the previous section. Certainly section 4.1.1 (Direct Effects of Chemical Stressors) doesn't—can't—begin to cover the enormous amount of information that has been generated from laboratory and field studies. The treatment in this section (4.1.1) is unbalanced and disorganized: a paragraph citing several studies of effects on reproductive effects, a paragraph indicating that studies have linked chemical contamination to mortality, a paragraph mentioning that chemicals can affect population abundance, and a paragraph with three examples of effects on disease resistance.

G-3, C-5 Section 4.1.2—Indirect Effects of Chemical Stressors. The authors caution that "the concept of what is direct and what is indirect needs to be treated carefully" and I would concur. Some of the examples given in this section, especially the changes in soil chemistry brought about by acid precipitation, could be considered to be aspects of stressor characterization, not effects characterization. Is Al toxicity in plants a direct effect of one stressor (Al), or an indirect effect of another stressor (H^+)?

The two examples of indirect effects caused by reductions in food supply and by reductions in nesting habitat and cover are classic illustrations of what I consider to be indirect effects. Maybe it's because I'm an ecologist, not a chemist. In a simple situation, stressor A causes an impact on ecological receptor Y. If the change in receptor Y in turn causes an impact on receptor Z, I consider the effect on Z to be an indirect effect of stressor A. If stressor A causes a chemical change, it may create a new stressor B, which can cause an impact on receptor Y. I wouldn't consider this an indirect effect of A on Y, I'd consider it a direct effect of B on Y.

This issue is discussed in Chapter 4 (Section 1.1.2), using similar examples; the two chapters are not inconsistent, and an effort to harmonize the paradigm and the terminology would be fruitful.

G-6 Section 4.4—Multiple Stressors: Terrestrial Case Study. This is a fascinating example of indirect effects, but not a clear example of multiple stressors. If I understand it correctly, lower soil pH reduced the rate of litter processing by invertebrates, resulting in immobilization of Ca, reduction in soil Ca:Al, and impairment of tree growth. What are the multiple stressors? Perhaps this is another case where the distinction between stressors and receptors is not clear.

5-1 The introduction to Section 5 (especially pages 5-45 and 5-46) reflects a good balance between individual, population, and ecosystem level assessment models.

E At the top of page 5-46, "Leslie Matrix" is misspelled.

C-5 Section 5.1.2 and 5.1.3 (which could be conveniently combined into a single section) address time-concentration-response functions. It should be noted that time, in this analysis, refers to duration of continuous exposure to a constant concentration. Since concentrations are often not constant (see my comment above), more complex models (such as that of Mancini 1983 cited on page 5-45) are needed to predict effects.

5-1 Sections 5.2, 5.3 and 5.4 on system level modeling are well done. They properly begin with a caveat about the need for further development of ecosystem models, and give some good examples.

E Section 5.5, first paragraph, 7th line from top: refers to "frequency of some disease". From the context, I assume this can be generalized to any type of ecological effect.

C-4 Section 5.5—Evaluation of Causality—provides some much needed perspective. The nine factors reflecting causality are useful for retrospective assessments. The final paragraph addressing extrapolation to other conditions and ecosystems is applicable to predictive assessments. And the comment about the need for multiple lines of evidence is important for both kinds of assessments.

C-5 Section 6.2—Extrapolation from Laboratory to Field. The summary of limitations of lab tests is useful and highly relevant (it's a critical issue for pesticide registration under the "new paradigm", for example). The second paragraph notes that extrapolation models haven't been developed to address the influence of factors that affect availability of chemicals. I see this as an exposure issue, not a stressor-response issue; models do exist for predicting, for example, dissolved chemical concentrations in situations with high suspended sediment loads, allowing the assessment to deal with biological availability.

The fourth paragraph (page 5-56) addresses time-varying exposure—an issue I've commented on above. The first sentence seems to be missing a word: I think "continuous constant" should be inserted before the final word, "concentrations".

G-2, 5-2

There are several good reviews, and some recent workshop reports, addressing the use of microcosms and mesocosms. I'll provide some references at the workshop.

I agree with the general conclusion that field studies have shown that aquatic communities are less sensitive in many cases than would have been expected from laboratory data. I think this is partly a matter of bioavailability, partly of time-varying exposure, and partly a reflection of the inherent resiliency of complex natural communities. The strategy of protecting 95% of all species, for example, may be unnecessarily conservative—even when a larger fraction of the community is affected, the overall structure and function of the system can remain intact.

M

Section 6.4—Extrapolations across Spatial and Temporal Scales. The first paragraph is actually about extrapolation among ecosystem types, not across spatial scales, but it's a very useful discussion all the same. The second paragraph addresses extrapolation to long time frames, and suggests that the difficulty stems from lack of understanding about aging of long-lived species. I think a more important problem in long-term extrapolation is the cumulative uncertainty over time—the same phenomenon that makes it hard to predict next week's weather.

Nelson Beyer
Patuxent Environmental Science Center
July 27, 1994

Review of "Effects Characterization"

General comments

Ecological risk assessments are an applied part of the field of ecotoxicology, and the chapter on "Effects Characterization" will be most useful if it provides guidance on how best to carry out a risk assessment given the kinds of data likely to be available and our current level of understanding of ecosystems. Rather than describe what an ideal risk assessment would include, it would be better to describe what is currently achievable and explain to the reader how to go about it. Probably most ecotoxicologists would agree that although we know a lot about ecosystems, we are a long way from understanding how they function. It may be many years before we do have reliable models of ecosystems, but in the mean time we must do the best we can. Some of the concepts discussed in the chapter would be impractical to include in a risk assessment, and I think that using a more pragmatic approach would make the chapter stronger.

Some risk assessments are national efforts involving teams of scientists working together for years. Modelling global warming would be an example. I assume this chapter is also meant for the more common situation, the one in which regulators must decide what to do about a ten-acre lot on which unknown quantities of chemicals were dumped in an area that is already polluted, borders a marsh, and has a few species of wildlife. What should be sampled and measured to produce a modest risk assessment that the scientific community would consider acceptable? I kept these questions in mind as I read the chapter.

Much of the literature cited in the chapters discusses concepts that are in the process of development. Models were mentioned whose investigators suggest that they can link changes in populations to communities, or provide other links that would be useful in risk assessment. The reader wants guidance, wants to know more than just that someone is working on a model, but whether the model is workable, if it has been tested, and if it is acceptable to the scientific community.

Probably the most useful improvement to the chapter would be to include more methods from risk assessments that successfully handle some of the tough questions. For example, Table 1 suggests "significant decrease in tree canopy bird populations" as an assessment endpoint and a "dietary LD fifty for Japanese quail egg hatch and fledgling" as a measurement endpoint. How do we get from one to the other? This question must have been addressed in many risk assessments.

The discussion needs to be a bit more down-to-earth. For example, on page 5-58 the authors state that "Multivariate statistical tests could be used to estimate the probability that the ecosystems of interest belong to the same state space as the ecosystems used to develop the exposure-response model." Before getting into statistical tests, I would want to know the criteria that should be used to decide whether two ecosystems are the same. I fear that a dozen different biologists would have a dozen different opinions. In parts of the chapter, the discussion of statistics and models has gotten ahead of the more basic question of what we should measure and why.

The paper barely discusses biochemical indicators, pathology, and the use of chemical residues in tissues to estimate toxicity. Whether the authors agree or disagree with these approaches, they should give the reader some guidance, since these measurements have been basic to environmental toxicology. Consider the way in which biologists have evaluated DDT in raptors, for example. From field studies we know that some populations of raptors have declined and that the declines are related to eggshell thinning. From laboratory studies we know what residues in eggs are associated with eggshell thinning. Performing a population study, particularly of raptors, is generally well beyond the means of a local investigator. However, a biologist can put together a solid argument simply by collecting eggs from a site, analyzing them for DDT, and interpreting the results in view of previous studies. Should residue analyses of eggs be recommended as measurement endpoints for organochlorines? And what should be recommended about pathology? If the chapter had been written by a pathologist, lesions might have been emphasized. What kind of guidance can be given on indicators, such as ALAD for evaluating lead poisoning? A great deal of work is now being conducted on cytochromes P-450 and related enzymes. In section 3.4. phenol glycosides seem to be recommended. Are some physiological indicators legitimate measurement endpoints for risk assessments and what criteria are used to decide? I know this question is controversial, but I think the chapter should provide some guidance.

The discussions on the complexity of ecosystems could be shortened by referring the reader to the literature. Most biologists are aware, for example, that ecosystems can be viewed on different time and spatial scales. Rather than be reminded that ecotoxicology is complex, they want specific recommendations on how to deal with the complexity.

It seems that effects on populations or higher levels of organization are especially important according to this chapter. I fear that readers have different ideas of what constitutes a population. For example, if half the robins on a campus are killed by a pesticide, has the population been affected? If readers have different ideas of what is meant by a population they are going to perform quite different risk assessments. If we take the position that some mortality is significant and other mortality is not significant, where do we draw the line?

Predicting effects on ecosystems from effects on individuals is critical to this chapter. Several times the reader is referred to the "aggregating up paradigm" by Cai. The citation is to an abstract and poster presentation. Since this work seems to be so pivotal the authors should explain the process thoroughly.

Specifics

2.1, 2.1.1 The explanation is longer than necessary. If a stressor affects organisms or the abiotic environment, which in turn affects an organism being considered, the effect is called indirect. Toxicity from ingesting a lead shot would be an example of a direct effect, stunted growth from lack of prey killed by acid rain would be an indirect effect.

2.1.4 Delete

2.4 Unclear - What does "regulatory agents and rates magnify the linkage..." mean? What is recommended here?

2.5 "Transients outside the range of resilience for the system can be induced, creating a new, potentially degraded and irreversible equilibrium. The induction of undesirable alternate stable states, and possibly technically chaotic responses, is probable under some circumstances." What does this jargon mean? The section is too abstract for the audience. When I read about a transition to a new equilibrium I first want to know equilibrium of what. What kinds of measurements are being discussed?

3.2.1 Unlike some of the other sections, this section is written in a style that assumes too little of the reader, who already knows that successful reproduction is essential to populations and that shortening life spans can affect populations. Also note that LC fifty studies can be chronic, although they are less common than acute tests.

3.2.3 It may not be necessary here to introduce so much terminology - top-down control, cascading, multispecies population ecology, and species-sensitive ecosystem function research, since they are not mentioned later. I see why descriptions of ecosystem and community structures may be similar, but I would suggest avoiding calling them equivalent concepts.

3.2.4 (The first paragraph is unclear and I may have misinterpreted it.) I would be hesitant to insist that fine-scale changes must be related to productivity, since productivity may at times be unresponsive to drastic changes in the biota. Some stressors cause an increase in productivity.

Should changes in nutrient cycling be a measurement endpoint? Should an element have to be shown to be limiting before a change in cycling be considered biologically significant?

3.3.4. This section is weak. Could it be replaced with a brief comment, to the effect that when statistical results are not significant, investigators should report the power of the test. (ref.)?

4.3.1. The explanation of the joint action model is unclear. Why should the expression equal 1?

5.5 The concept of uncertainty should be reserved for statistical variability arising from data. If the investigator cannot determine a causal relation between an effect and a stressor, then a risk assessment should not be performed.

6.1, 6.2, 6.3 Give some recommendations.

7.1 Figure 5 seems to be an important model for the chapter. Unfortunately it shows axes of parameters without explaining which parameters are recommended and which would not be appropriate. It would be more helpful to include an example with real data from a risk assessment.

7.5 Effects Characterization-Review by Wayne G. Landis
General Comments

I apologize for the obviously rapid turnaround and lack of polish that accompanies this review. I hope that I am able to improve the section on effects and provide some additional literature. Attached are copies of some recent papers that may also aide the writers.

Although summarizing the potential for effects and means to measure them is a daunting task, this section misses much of the literature that has a direct bearing on this aspect of environmental toxicology. Much of the review could have been published in the mid-1980's after reviewing the citation list, yet there has been an incredible amount of literature published since the turn of the decade. The review also lacks a critical edge. Often statements are offered without references, I take it that these are the often unsubstantiated opinions of the authors. I realize that these statements are harsh , but there are also parts that I really do enjoy, such as the lack of confirmation in the use of the IBI, although a reference is important here. This is a critical document and needs to be held to rigorous standards. In some instances some of the conclusions of some of the references, such as Matthews 1982, are not accurately represented and have been greatly supplemented by more recent publications by the same author (see Matthews and Matthews 1990, Matthews et al 1991a, 1991b, Landis et al 1993a, 1993b, Matthews et al, in press and Landis et al 1994). There is an extensive literature that deals with the structure of ecological systems, much of it far removed from Odum and Cairns. I am also surprised that many of the classics of population biology and community structure are not included, nor a discussion of chaos and complexity theory as described by May (May and Oster 1978), Hassell et al (1991), or the important works of Kauffman (Kauffman and Johnsen 1991, Kauffman 1993). In the last ten years there has been an intense discussion of the meaning and existence of stability within ecological systems and this is missed in the discussion. Also striking is the absence of the work of David Tilman (1982, 1988, Tilman and Wielden 1991) that clearly describes the importance of resource ratios in predicting the structure of ecological systems and this work has also been applied to systems undergoing toxicant stressors (Landis 1986). The discussion found within this section relies too much on only a few papers and points of view, and the ecological literature is underrepresented.

Also missing are the multivariate approaches to determining the status and vector direction of ecological systems as published by Kersting (1988) and Johnson (1988). Recently, other methods have been published and used (Matthews and Hearne 1990, Matthews et al 1991a, 1991b, etc.) that detail a very powerful approach to measurements of effects at the system level. There are also other researchers attempting to elucidate the patterns found in ecological systems that are beyond the simplistic index snapshot approach.

Specific Comments

2.1.1. Direct and Indirect Effects.-A review of Wiegart and J. Kozlowski (1984) would useful here. I use perhaps simpler definitions in order to distinguish these types of effects:

> Direct Effects-those effects mediated directly by the molecular interaction of the toxicant and the receptor site.
>
> Indirect Effects-those effects not mediated directly by the molecular interaction of the toxicant and the receptor site.

Physical and chemical stressors also tend to have sites of action within the organism so these definitions also are useful in those cases. One of the points that is generally not made is that direct and indirect effects happen at the same time, even though the outcome of the indirect effects may be harder to determine. Indirect effects also tend to be long lasting and can persist long after the toxicant or other stressor has been left behind. Also misleading is the example used on page 5-9 where it is implied that indirect effects move up the trophic levels, Of course this is not the case. Indirect effects move more like a ripple with the pathways determined by the connections between that population and the rest of the populations within that species assemblage. Indirect effects can also be thought of at the organismal level. Selection for resistance to a particular toxicant also causes an increase in the frequency of genes linked to this resistance trait. These genes alter the gene pool of the population and may alter to outcome to a subsequent toxicant or other stressor event. Two examples come readily to mind. First, the receptor for TCDD is found in vertebrates, except apparently jawless fish, and is apparently an important mediator of early development. The divergence of vertebrates from other forms of animal life was at least 500 million BP and the jawed from jawless fish about 350 million bp. The occurrence of such a receptor unique to jawed vertebrates is likely due to a long ago stressor event that caused a population bottleneck, and the indirect outcome was sensitivity to a toxicant that did not exist until far into the future. The second example is the mitochondrial DNA sequences among Homo sapiens. These haplotypes apparently reflect population bottlenecks of various populations and apparently are region specific.

In order to distinguish between direct and indirect effects and to demonstrate how immediate and important the outcomes are, I use Figure 1 presented below. The figure is based upon the factors important in describing how organisms and populations use resources and respond to competitive interactions as described by Tilman (1982).

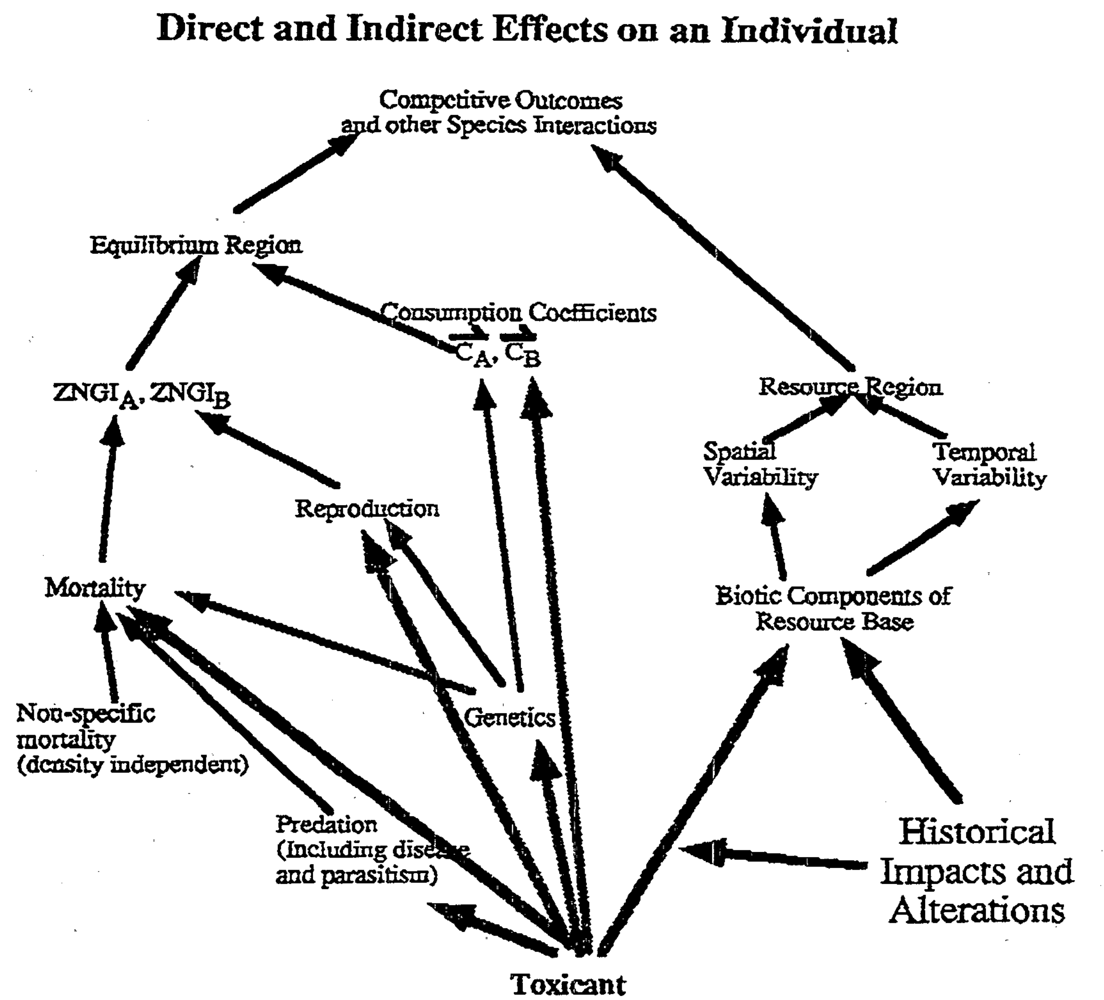


Figure 1. Direct and Indirect Effects using the Factors of Resource Competition Modeling.

I have found that this figure is useful and ties these types of effects into a mechanistic theory of species interactions. In general it would be better to include a more complete list of types of direct and indirect effects rather than the few examples presented in this section.

2.1.2. Distinguishing Ecological Effects of Chemical and Physical Stressors.-In this section there seems to be a lack of review of a variety of research attempting to describe population cycles, effects of disturbances, and an attachment to recovery. Only one reference is cited, yet there is contemporary research addressing the problems of environmental data analysis and interpretation, In fact, the concluding statement of this section is incorrect. Hypothesis can be tested about fluctuating systems, the data do not fluctuate. There are theoretical descriptions of these fluctuations and methods of examining the data.

While there are cyclic and stochastic changes in populations, there are now several documented instances of chaotic dynamics. Chaotic dynamics are deterministic and there is a great deal of classic research investigating their occurrence in ecological systems (May and Oster 1978, Hassell et al 1991, Hastings et al 1993, Schaffer, 1985, Schaffer and Kot 1985). There are also investigations that detail the long term variations in natural systems.

A recent investigation into variation with a set of natural systems has been conducted by Katz et al. Katz *et al.* (1987) examined the spatial and temporal variability in zooplankton data from a series of five lakes in North America. Much of the analysis was based on limnological data collected by Brige and Juday from 1925 to 1942. Copepods and cladocera, except *Bosmina*, exhibited larger variability between lakes than between years in the same lake. Some taxa showed consistent patterns among the study lakes. They concluded that the controlling factors for these taxa operated uniformly in each of the study sites. However, in regards to the depth of maximal abundance for calanoid copepods and *Bosmina*, the data obtained from one lake had little predictive power for application to other lakes.

Perhaps my biggest difficulty with this section and also the issue paper 7.7, Ecological Recovery, is that it is assumed that a disturbance-recovery dynamic is in fact a true representation of ecological systems. This has its root again in the Clementian notion of an ideal system for a particular environment. Yet ecology is moving towards a non-equilibrium viewpoint. Hutchinson (1961) invoked non-equilibrium conditions to explain the paradox of the plankton. Strong (1992) has prepared an excellent overview of non-equilibrium themes in contemporary ecology and should be summarized. I have problems with unproved and perhaps unprovable assumptions. If as Yodzis (1988) states, it takes over 2 turnover cycles through the longest track of the food web to realize a theoretical equilibria, in many ecological systems this exceeds greatly the historical record. Given the incidence of catastrophic events such as fires, floods, disease and evolutionary events on a much shorter time scale the opportunity of reaching an equilibrium must rare.

The return of a system to its pre-existing state, structurally, metabolically and dynamically, is a classical definition of recovery. The property that confers upon a system the ability to recover is stability. It has often been assumed the stability is a property of persistent ecological systems. It has even been suggested that the examination of stability and the measurements of resilience and recovery are the most appropriate attributes to be studied in multispecies toxicity tests (deNoyelles 1993). Even in situations where an equilibrium does not occur it is assumed that given more time that replicate systems will converge toward an equilibrium condition (Rosenzweig and Buikema 1994). As comforting as an assumption of ecological stability may be, there is an increasing amount of data that indicate that stable systems may be the exception.

In regard to populations, Connell and Sousa (1983) examined a great deal of the literature on population dynamics and found stability as return to original conditions extremely rare. Andrews (1991) in a study of tropical lizards found that the population dynamics are unstable. Hypothesized causes are the rapid population turnover and the complexity of a food web. Kauffman in a series of publications (1991, 1993) suggests that ecological systems need to operate on the edge between stability and deterministic chaos. Stable and the community can not adapt and a cascading collapse can occur. Chaotic and wild events happen, including extinction.

Our research and the analysis of a variety of data has led us to conclude that equilibria are illusions (Landis et al 1993b). There are many biotic and abiotic factors that govern the composition of an ecosystem after a stress event; substrate type, distance from colonizing sources, genetic variability of the resident population are but a few. Since each of the initial conditions are likely to be different from those that lead to the original system, it is unlikely that the subsequent system will be identical. Similarity, however, does not mean the same. In fact, similarity at the structural level may lead to an illusion of recovery.

First, the apparent recovery or movement of the dosed systems towards the reference case may be an artifact of our measurement systems that allow the n-dimensional data to be represented in a two or one dimensional system. In an n-dimensional sense, the systems may be moving in opposite directions and simply pass by similar coordinates during certain time intervals. Positions may be similar, but the n-dimensional vectors describing the movements of the systems can be very different.

The apparent recoveries and divergences may also be artifacts of our attempt to choose the best means of collapsing and representing n-dimensional data into a two or three dimensional representation. In order to represent such data, it is necessary to project n-dimensional data into three or fewer dimensions. As information is lost when the shadow of a cube is projected upon a two dimensional screen, a similar loss of information can occur in our attempt to represent n-dimensional data. The possible illusion of recovery based on this type of projection is diagramatically represented in Figure 2. In Figure 2a the dosed and the reference systems appear to converge, i. e. recovery has occurred. However, this may be an illusion created by the perspective chosen to describe and measure the system. Figure 2b is the same system but viewed from the "top". When a new point of view is taken, divergence of the systems occurs throughout the observed time period. As the various groups separate, the divergence may be seen as a separate event. In fact, this separation is a continuation of the dynamics initiated earlier upon one aspect of the community. Eventually, the illusion of recovery may simply be the divergence of the replicates within each treatment group becoming large enough, with enough inherent variation, so that even the multivariate analysis can not distinguish treatment group similarities. *Not every divergence from the control treatment may have a proximate causal effect.*

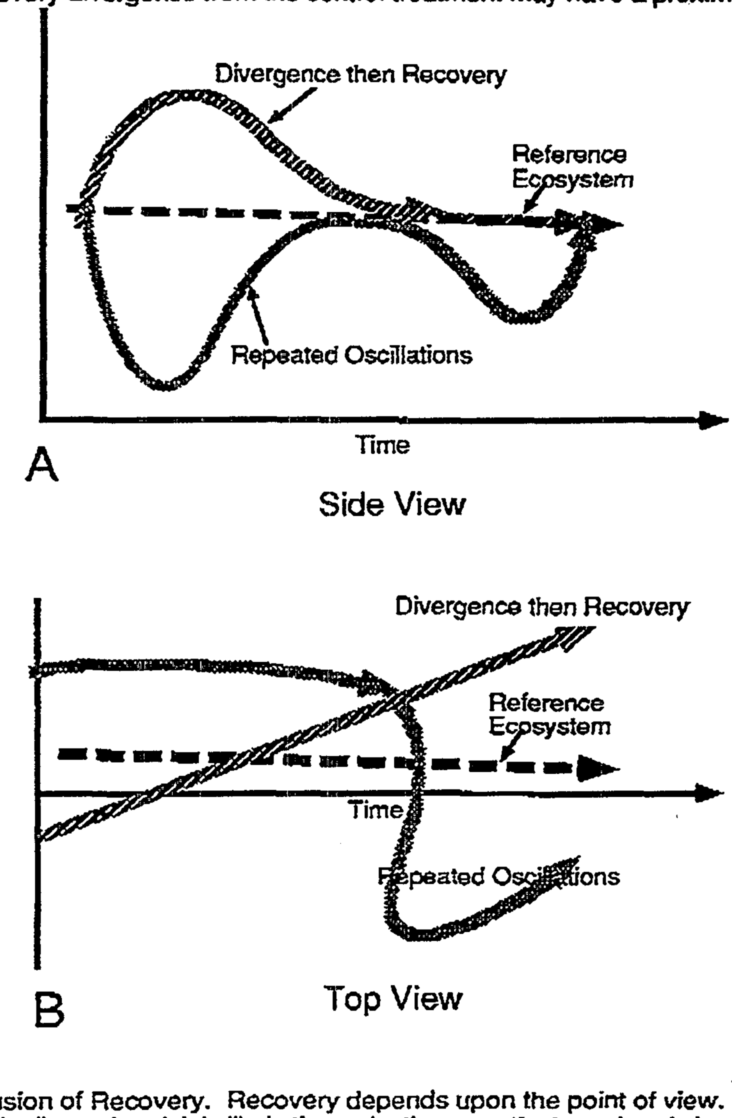


Figure 2. The Illusion of Recovery. Recovery depends upon the point of view. Since ecological systems are highly dimensional, it is likely that selecting a particular point of view will highly bias the interpretation of the dynamics.

Finally, there are data that demonstrate that the information about the prior state of an ecological system exists and even a very basic level. Experimental evidence for the importance of historical events has been found in other experimental systems. Drake (1991) assembled in varying orders the components of a relatively simple microcosms system. The structure of the system was highly sensitive to the order of the introductions. While stochastic explanations may seem to describe snapshots of ecological systems, knowing the historical dynamics elucidates mechanisms of species interaction and provides deterministic descriptions of the system. In one experiment, two systems that had different histories but were indistinguishable using the methods available, produced different outcomes upon an invasion by Cyclops. Recently (Drake et al 1993), these findings were further confirmed by using a set of microcosms set up as islands with an invasion (inoculation) scheme. Historical events, as in the timing, invasion success and persistence of the organisms lead to the development of systems in different regions of ecosystem space.

Conditioning of the ecological system following a stressor event has also been demonstrated in the work of Blank and colleagues (Blank and Wangberg 1988, Blank et al 1988, Molander and Blank 1992). Pollution induced community tolerance (PICT) is a phenomena in which populations of a toxicant stressed community evolve resistant organisms or are replaced by pollution tolerant invaders. This process has been demonstrated for several toxicants among a marine periphyton assemblage. The development of tolerance certainly depends upon historical factors, are there resistance genes in the population, rate of immigration by resistant organisms, and rates of sexual and asexual reproduction among many others. Not only would the development of resistance likely alter the outcome of a subsequent event, linked resistance genes or genes unrelated to toxicant decontamination would have the potential to affect responses to other types of stressors.

A record of historical events can also be maintained in the population genetics of resident populations. Murdoch and Hebert (1994) examined the mitochondrial DNA (mtDNA) of populations of bullheads found in the Great Lakes. Through the use of restriction enzymes that cut the DNA molecule in very specific sites, 42 distinct mtDNA haplotypes were identified. In pairwise comparisons of contaminated versus relatively clean sites, the population from the contaminated site had lower genetic diversity. All sites contained large populations of brown bullheads. No single mtDNA haplotype dominated the contaminated sites, implying that the mtDNA was selectively neutral. Murdoch and Hebert conclude that the reduction in diversity is due to a population bottleneck reducing the population to a few individuals and eliminating many of the mtDNA haplotypes from the population. Although the population levels are similar, the genetics of the populations are significantly different reflecting the historical bottleneck due to contamination.

Section 2.1.3. The Concept of Threshold and Section 2.2. Linking Stressors to *Individuals and Populations etc.*

These sections really address many of the same issues and consolidation should be considered. The concept of threshold is directly tied to the ability to detect effects.

If ecological systems were organisms then perhaps some sort of threshold before a stressor has an effect may be a valid concept. However, once the stressor can affect an organism to a point so that the survivorship of its genome is altered, then evolution kicks in. If environmental toxicology is to be consistent with biology as a whole then consistency with evolutionary biology must be maintained. Cairns (1992) states as the authors do that the threshold concept is objected to because it is seen as too permissive and therefore wrong is not a scientific argument. Neither is the concept of a threshold once an evolutionary event takes place. Cairns does argue that effects are hidden due to the inherent variability of ecological systems. This argument simply means that if it can not be measured using current techniques then the effect does not exist. Well, it is now possible to probe these types of dynamics using a variety of methods. Pimm and Redfearn (1988) examined the variety of population densities using spectral analysis. They actually discovered that the long term trend is divergence, not convergence towards an equilibrium state. Other methods are being used to explore effects in data with variation.

Lucassen and Leeuwangh (1994) did use canonical correspondence analysis to find a treatment related effect upon species composition. A major advantage of this approach is the attempt to examine the structure of the system as a whole and not piecemeal. The difficulties with using correspondence analysis in this context are the low abundance of some organisms and the lack of replication. Although the authors were tentative, the do suggest "it is thought that statistical methods that visualize long-term processes at community structure level might be helpful in describing the threat of toxic chemicals on ecosystems." The second exception is linear structural relations (LISERAL) (Johnson, Huggins and deNoyelles 1994). LISERAL is an attempt to test whether a hypothesized ecosystem structure fits the data, produces interaction coefficients between the components of the model and produces stability measurements. This method is multivariate and does attempt to analyze the system as an entity. LISERAL does have the bias in that it hypothesizes a knowledge of the structure of the ecological community, and its interpretation presupposes ecological stability. There are several other promising techniques.

Multivariate methods have proved promising as a method of incorporating all of the dimensions of an ecosystem. One of the first methods used in toxicity testing was the calculation of ecosystem strain developed by Kersting (1984, 1985, 1988) for a relatively simple (three species) microcosm. This method has the advantage of using all of the measured parameters of an ecosystem to look for treatment-related differences. At about the same time, Johnson (1988a, 1988b) developed a multivariate algorithm using the n-dimensional coordinates of a multivariate data set and the distances between these coordinates as a measure of divergence between treatment groups. Both of these methods have the advantage of examining the ecosystem as a whole rather than by single variables, and can track such processes as succession, recovery and the deviation of a system due to an anthropogenic input.

My colleagues and I currently uses a variety of techniques including metric and nonmetric clustering to detect effects within microcosm and field data. In order to compare dynamics we are experimenting with several new techniques but currently use projections that are called space time worms. These methods have now proven useful in detecting patterns in biomarkers in field experiments and the conditioning of microcosms. As described elsewhere in this review, typing of mitochondrial DNA and other markers will illuminate even basic evolutionary events.

As we as scientists get better at detecting effects the threshold question will eventually disappear as being one of the myths of environmental science. Apparent threshold is perhaps a better term if you must insist. However, there will come a point when decisions will have to be made on acceptable impacts, as we get better at measuring evolutionary events.

Apparent thresholds do not mean no effect. I can illustrate this point simply. In Figure 3, I have use a simple difference equation to model a species with non-overlapping generations. The initial start points are different by 2 points in 10,000. The populations oscillate in a stable fashion around the carrying capacity but a slightly out of sink. Without years of data, differentiating between this two circumstances will be difficult and the initial difference will probably fall below an Apparent Threshold. However, upon the application of a new stressor, the lowering of the carrying capacity by 20 percent, one population become extinct and the other starts to oscillate around the new carrying capacity. Since ecological systems are historical small events can have large consequences. Extinctions of isolated populations is probably a common event. Metapopulation dynamics often rescues such sites but the probability of rescue depends on the geometry of the patches and the dynamics within a patch. Wu (1991) illustrates these points in dramatic fashion.

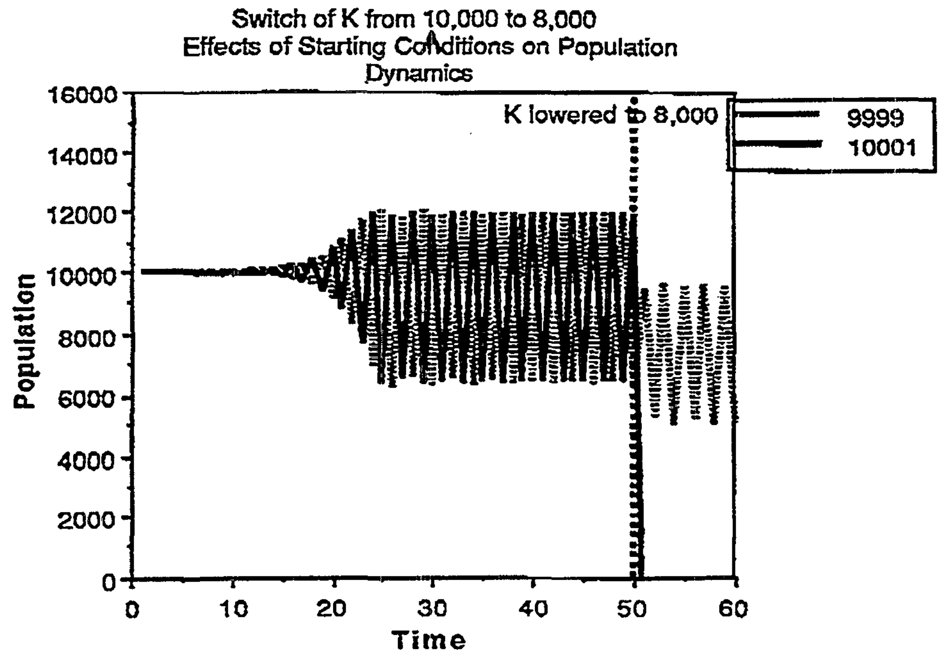


Figure 3. Different Outcomes from slightly different initial conditions. R is equal to 2.0, K is initially 10,000 and that is lowered at time 50 to 8,000. One population becomes extinct as the other cycles around 8,000.

Section 5. Ecological Response Analysis: The Role of Various Types of Models-Before attempting to incorporate models into the discussion, an in-depth review of Oreskes et al (1994) should be made. Essentially they state that models can not be validated or verified, merely confirmed. Although useful, models are best used to ask further questions, not a representations of reality.

Next, the basic types of models are not those stated on page 5-44. In the AI literature, a contrast is made between *similarity-based* systems and *explanation-based* systems (Lebowitz, 1990). A traditional physical model, for example, which will incorporate each relationship in the real world into a relationship between objects in the computer program, is an explanation-based system. It attempts to reconstruct the cause and effect evolution of the real-world system within the computer system and it will account for the observed data by explaining its causes. Statistical and strictly mechanistic models are both explanation based models. Similarity-based systems stand in contrast to these systems. Similarity-based systems attempt to analyze the data on its own terms, without preconceptions about explanations. Generally similarity-based systems attempt to discover abstractions or generalizations that can reduce the complexity of the data.

Similarity-based systems excel in discovering patterns and relationships within the data that were unknown to human experts, and have in fact been used with great success to diagnose soybean diseases, discover new classes of stars, and design aircraft subsystems (Michalski and Chilausky, 1980; Cheeseman et al., 1988; Domeshek et al., 1994). The periodic table is an example of a similarity based model. Nonmetric clustering and association analysis is another example of a similarity based models used in the analysis of ecological datasets (Matthews et al 1990, 1991, in press and Landis et al 1993a, 1993b, in press). The third type of model is a physical model. In the case of ecological toxicology an example would be the numerous multispecies toxicity tests, although even single species toxicity tests fit the bill. The models described in sections 5.1 to 5.5 all fit the explanation-based modeling scheme.

I also noticed that experimental methods of modeling the response of ecological systems to stressors was barely mentioned although it has an extensive literature. As an example of the extensive literature, a recent review by Gearing [1989] listed eleven freshwater artificial stream methods, 22 laboratory freshwater microcosms ranging from .1 to 8,400 liters, 18 outdoor freshwater microcosms ranging from 8 to 18,000,000 liters, and even larger numbers of marine systems. The methods range from completely synthetic systems to those that rely upon colonization by natural inocula. In addition to toxicological studies they have also been used to investigate the assembly of communities and the rules of landscape ecology (Drake 1991, Drake et al 1993). Microcosms have also been used to develop and test hypotheses such as Pollution Induced Community Tolerance (Mollander and Blank 1992). Unlike explanation based models, these systems allow the discovery and testing of hypothesis that deal with complex biological systems. The major difficulty with these systems has been the problem of extrapolation. The same problem applies to all models as Oreskes et al (1994) have illuminated. Experimental physical models certainly have an important role to play.

Likewise, field studies as models are not addressed yet they serve the same role as multispecies toxicity tests. The variability of real world may preclude the same types of repeatability that is expected from laboratory tests. However, the real world is historical and not a repeatable entity. There are rules but they are fundamentally different from those of simple single species systems. Perhaps we should learn to play by the rules of the real world instead of forcing our views to the point of abandoning the system of interest.

The role of modeling is best illustrated in section 5.2.2 in the work of Vanni. A model was developed for a specific case, predictions made, and the results tested against a historical dataset. Questions as to the specificity of the model and calibration always exist. However, the role of models in generating testable hypothesis is certainly valid and is seen as the primary role modeling by Oreskes et al (1994).

References and Selected Readings

Andrews, R. M. 1991. The population stability of a tropical lizard. *Ecology* 72:1204-1217.

Clements, F. E. 1916. Plant succession: An analysis of the development of vegetation. Carnegie Inst. Washington Pub. No. 242.

Drake, J. A. 1991. Community-assembly mechanics and the structure of an experimental species ensemble. *Amer. Nat.* 137:1-26.

Drake, J. A., T. E. Flum, G. J. Witteman, T. Voskuil, A. M. Hoffman, C. Creson, D. A. Kenny, G. R. Huxel, C. S. Larue, and J. R. Duncan. 1993. The construction and assembly of an ecological landscape. *J. Animal Ecology*, 62:117-130.

Good, I.J. 1982. An index of separateness of clusters and a permutation test for its significance. *J. Statist. Comp. Simul.* 15, 81-84.

Goodman, L.A. and W.H. Kruskal. 1954. Measures of association for cross classifications. *Journal of the American Statistical Association* 49:732.

Hutchinson, G. E. 1961. The paradox of the plankton. *Amer. Nat.* 95:137-143.

Hassell, M.P.H., Comins, N. and May, R.M. 1991. Spatial structure and chaos in insect population dynamics. *Nature* 353:255-258.

Hastings, A., C. L. Horn, S. Ellner, P. Turchin, H. C. Godfray. 1993. Chaos in ecology: Is mother nature a strange attractor? *Annu. Rev. Ecol. Syst.* 24:1-33.

Jain, A.K. and R.C. Dubes. 1988. Algorithms for Clustering Data. Prentice Hall, Englewood Cliffs, NJ.

Jorgensen. S. W. 1990. Ecosystem theory, ecological buffer capacity, uncertainty and complexity. *Ecological Modeling*. 52:125-133.

Kauffman, S.A. and S.D. Johnsen. 1991. Coevolution to the edge of chaos; coupled fitness landscapes, poised states and coevolutionary avalanches. *J. theor. Biol.* 149:467-505.

Kauffman, S.A. 1993. *The Origins of Order, Self-Organization and Selection in Evolution.* Oxford University Press Inc., New York, New York. pp 709

Johnson, A.R. 1988. Evaluating ecosystem response to toxicant stress: a state space approach. In *Aquatic Toxicology and Hazard Assessment: 10th Volume, ASTM STP* 971 (Adams, W.J., Chapman, G.A. and Landis, W.G., eds) American Society for Testing and Materials, Philadelphia, pp. 275-285.

Johnson, A.R. 1988. Diagnostic variables as predictors of ecological risk. *Environmental Management* 12, 515-523.

Katz, T.K., Frost, T.M. and Magnuson, J.J. 1987. Inferences from spatial and temporal variability in ecosystems: Long-term zooplankton data from lakes. *Amer. Nat.* 129, 830-846.

Kersting, K. 1988. Normalized ecosystem strain in micro-ecosystems using different sets of state variables. *Verh. Internat. Verein. Limnol.* 23, 1641-1646.

Kauffman, S.A. and S.D. Johnsen. 1991. Coevolution to the edge of chaos; coupled fitness landscapes, poised states and coevolutionary avalanches. *J. theor. Biol.* 149:467-505.

Kauffman, S.A. 1993. *The Origins of Order, Self-Organization and Selection in Evolution.* Oxford University Press Inc., New York, New York.

Landis, W. G. 1986. Resource competition modeling of the impacts of xenobiotics on biological communities. *Aquatic Toxicology and Environmental Fate: Ninth Volume ASTM STP 921*. J. M. Poston and R. Purdy Eds., American Society for Testing and Materials. Philadelphia, pp 55-72.

Landis, W.G., R.A. Matthews, A.J. Markiewicz, N.A. Shough and G.B. Matthews. 1993a. Multivariate Analyses of the Impacts of the Turbine Fuel Jet-A Using a Microcosm Toxicity Test. *J. Environ. Sci.* Vol 2:113-130.

Landis, W.G., R.A. Matthews, A.J. Markiewicz and G.B. Matthews. 1993b. Multivariate Analysis of the Impacts of the Turbine Fuel JP-4 in a Microcosm Toxicity Test with Implications for the Evaluation of Ecosystem Dynamics and Risk Assessment. *Ecotoxicology* 2:271-300.

Landis, W.G., R.A. Matthews and G.B. Matthews. 1993d. Complexity, irreversibility and multispecies systems. *SETAC News* 13:5 pp 8-9.

Landis, W.G., G.B. Matthews, R.A. Matthews and A. Sergeant. *In press 1994.* Application of multivariate techniques to endpoint determination, selection and evaluation in ecological risk assessment. *Environ. Toxicol. Chem.*

Lebowitz, M. 1990. The utility of similarity-based learning in a world needing explanation. In Kodratoff, Y. and Michalski, R. S., editors, Machine Learning, An Artificial Intelligence Approach, Volume III, pages 399-422. Morgan Kaufmann, Los Altos, California.

Lorenz, E. N. 1993. *The Essence of Chaos.* University of Washington Press, Seattle.

Matthews, G. and J. Hearne. 1991. Clustering without a metric. *IEEE Transactions on Pattern Analysis and Machine Intelligence,* 13(2):175-184.

Matthews, G. and R. Matthews. 1990a. A model for describing community change. In Pesticides in Natural Systems: How Can Their Effects Be Monitored? Proceedings of the Conference, Environmental Research Laboratory/ORD, Corvallis Oregon. EPA 9109/9-91-011.

Matthews, R.A., G.B. Matthews and B. Hachmoller. 1990b. Ordination of benthic macroinvertebrates along a longitudinal stream gradient. In Annual Conference, North American Benthological Society, Blacksburg, Virginia.

Matthews, G.B., R.A. Matthews and B. Hachmoller. 1991a. Mathematical analysis of temporal and spatial trends in the benthic macroinvertebrate communities of a small stream. *Canadian Journal of Fisheries and Aquatic Sciences.* 48, 2184-2190.

Matthews, R.A., G.B. Matthews and W.J. Ehinger. 1991b. Classification and ordination of limnological data: a comparison of analytical tools. *Ecological Modeling.* 53, 167-187.

May, R.M. and Oster, G.F. 1978. Bifurcations and dynamical complexity in simple ecological models. *Amer. Nat.* 110:573-599.

Michalski, R.S. and R.L. Chilausky. 1980. Learning by being told and learning from examples: an experimental comparison of the two methods of knowledge acquisition in the context of developing an expert system for soybean diseases. *Policy Analysis and Information Systems, 4.*

Molander, S. and H. Blank. (1992). Detection of pollution-induced community tolerance (PICT) in marine periphyton communities established under diuron exposure. *Aquatic Toxicology* 22:129-144.

Murdock, M. H. and P. D. N. Herbert. 1994. Mitochondrial DNA diverstiy of brown bullhead from contaminated and relatively pristine sites in the Great Lakes. *Environ. Toxicol. Chem.* 13:1281-1289.

Nicolis, G. and I. Prigogine. 1989. *Exploring Complexity.* W.H. Freeman and Co. New York.

Noreen, E.W. 1989. *Computer Intensive Methods for Testing Hypotheses.* New York, N.Y., Wiley-Interscience.

Oreskes, N., K. Shrader-Frechette, and K. Belitz. 1994. Verification, validation and confirmation of numerical models in the earth sciences. *Science* 263: 641-646

Pimm, S. L. and A. Redfearn. 1988. The variability of population densities. *Nature* 334:613-614.

Schaffer, W. M. 1985. Can nonlinear dynamics elucidate mechanisms in ecology and epidemiology? *IMA Journal of Mathematics Applied in Medicine and Biology*. 2:221-252.

Schaffer, W. M. and M. Kot. 1985. Do strange attractors govern ecological systems? *Bioscience* 35: 342-350.

Strong, D. R. 1992. Non-equilibrium themes for ecological theory: Implications for fungal communities. In G. C. Carroll and D. T. Wicklow Eds, *The Fungal Community*. Marcal Dekkar, Inc. New York, New York. pp 1-15.

Suter, G. W. II. 1993. A critique of ecosystem health concepts and indexes. *Environ. Toxicol. Chem.* 12:1533-1539.

Tilman, D. and D. Weldin. 1991. *Oscillations and chaos in the dynamics of a perennial grass. Nature* 353:653-655.

Tilman, D. 1988. Plant Strategies and the Dynamics and Structure of Plant Communities. Princeton University Press, Princeton. pp 360.

Tilman, D. 1989. Chapter 6, Discussion: Population dynamics and species interactions. In Roughgarden, May and Levin Eds., Perspectives in Ecological Theory. Princeton University Press, Princeton, New Jersey. pp 89-100.

Wiegart, R. G. and J. Kozlowski. 1984. Indirect causality in ecosystems. *Am. Nat.* 124: 293-298.

Wu, J. and J.L. Vankat. 1991. A system dynamics model of island biogeography. *Bulletin of Mathematical Biology* 53:911-940.

Yodzis, P. 1988. The indeterminacy of ecological interactions as perceifed through perturbation experiments. Ecology 69:508-515.

Biological Stressors

Workgroup Leader:	Dr. James A. Drake University of Tennessee
General Reviewer:	Dr. Richard Orr U.S. Dept. of Agriculture
General Reviewer:	Dr. James H. Thorp, III University of Louisville

Pre-Meeting Comments - Biological Stressors - James A. Drake

1.0 General Areas

G-1: Clarity of purpose and scope

One conceptual question. Is the issue paper restricted to invading species whose source is outside the continental US (e.g, pigs in Hawaii, or movements within the country)? Should we be concerned about a species native to the Pacific Northwest which invades the Southeastern United States, when Atlantic and Pacific salmon are transported cross-continent, or when Rainbow trout precipitate a decline in native Brook trout?

I very much appreciate the author's fairness in presenting both viewpoints over what effect invaders have. Clearly, many species pose no risk whatsoever. At the same time the occasional successful invader proves to be a spectacular problem. This is good balance, but I do have one probabilistic concern. The author's mention two "camps" of thought, one purporting that "... the average introduced species will be very unlikely to create an environmental stress." While this is true it also seems to me that we are not concerned with the average species, rather the impact of the outlier. Hence, I think that this is a case where statistics are not terribly insightful and perhaps misleading. Detrimental invasions will occur. That they occur with a frequency of 0.0001, does little to ease my concerns when that 0.0001 could represent many species per year given the onslaught of invaders we are experiencing. Even though this is a Poisson skewed distribution, that the tail is present (at significant cost) causes me concern.

This introduction serves the intended purpose. The author's might consider citing a few of the recent invasion papers.

G-2: Completeness of coverage

Overall there seems to be a disproportionate emphasis placed on the introduction of genetically modified organisms. While this is clearly a valid area of concern, and I like these comments for personal reasons, is this too much? I agree that GEO's should be treated like any other introduced species. Along these lines we all realize that plasmids may be unstable, leaking elements into the environment raises an important caveat. The authors state that ""If such "lateral transfer" occurs, the same probabilities of survival, multiplication, dispersal, and harmful effects must be applied to the organism receiving the genetic information"". This can be read to mean that the expression of the plasmid in the recipient will not differ from the effect seen in the source (e.g., your words "... must be applied"). I assume you mean we must treat such a hybrid organism in the same fashion, or to reassess, not the same exact way-- there could be very significant differences.

I wonder if it is worth adding a section describing emergent properties, their relationship to the community at hand, and what happens when an invasion occurs. This would fit well with indirect effects material.

The last thing which could be included, would be an example of a biological stressor risk assessment (e.g., Richard Orr's Chilean Log Assessment). This could even be a figure.

G-3: Clarity and consistency of terminology

I am uncomfortable with the "Framework for Ecological Risk Assessment" definition of the *community*. This is more than just a definition problem, because our conception of the system, what ever it is, colors our interpretation of how the system functions. I'm sure this will be a point of argument among workshop participants and a discussion would be most helpful. This is vitally important because, a functional definition is critical to all the issue papers, and may improve success of the program when it is implemented. The definition provided in the Framework is:

"**community**--An assemblage of populations of different species within a specified location in space and time".

Given this definition many different species ensembles could be accorded community levels status whether or not those ensembles even possess community levels properties. So conceived, it clearly possible to arrive at entirely incompatible assessments on the same system and using the same variables. As presently defined, it would be easy to show that an assemblage of Chironomids--the "community", is actually enhanced by a toxicant (via. competitive release ...).

G-4: Current capabilities vs. future needs

I feel this area is problematic with respect to invaders. As the author's rightly point out invasion success is a function of the invader *and* the system being invaded. While we have made considerable strides in understanding the community, it remains an elusive entity. Hence, current capabilities are less than adequate for much more than plausible hunches. It would seem to me that a detailed analysis of several assessments which approached community-level issues, might be useful in pointing to improvements in the implementation of an assessment.

G-5: Relationship to EPA's "Framework for Ecological Risk Assessment"

See section G-3 comment 1. I do have an additional comment about a concept defined in the EPA document. "Stressor" is stated to "...induce an adverse response". What of those stressors which have some positive effect by one or more measures, an effect which could induce a negative effect far removed from the scale of analyses?

G-6: Examples

These are all very solid examples. Perhaps a graphic which categorizes invaders via generic effects (in some systematic fashion) might be useful for the manager/risk assessor. For example, one could list a few invaders which (a) induce changes in nutrient cycles, (b) hydrologic pathways (e.g., Vitousek), (c) cause a decline in biodiversity, etc.

2.0 Questions relevant to particular issue papers (issues raised by VERSAR and EPA)

2.1 See G-2 above. At the same time this is a critical area because at least with microbes we do have some post-release control, and a fighting chance. Such control is absent elsewhere.

2.2 I agree largely with the position of the author's. Our ability to make predictions is exceedingly limited, but not as hopeless as one would think at first glance. For example, USDA's risk assessment on the import of Chilean logs to the US shows that when we have a source and target a constructive and useful assessment can be conducted. Richard Orr could comment on this further.

Non-specific invasions, on the other hand, present additional problems. Section 6-2 of "Review Topics" suggests that despite this fact we need to conduct risk assessments anyway. Without salient information such an assessment seems to me like a bit of science and a bit on magic. I do not wish to be overly critical here, but we have limited abilities with respect to understanding communities and their structure in real time. It is no simple task to understand differentials in community vulnerability to invasion and species-specific invasion success. Now consider the added complexities which arise when one embraces communities in both time and space--as the dynamic entities they are (e.g., metacommunities, succession and assembly dynamics)! I believe the best course of action may be to focus on transport vectors, assuming that the systems are vulnerable. This is the case with current legislation forcing intercontinental ships to purge freshwater ballast before entering the Great Lakes.

3.0 Cross-cutting issues

There are endless issues which run throughout most of the issue papers which cross-cut with the biological stressor paper. I'll need help here because I have had a hard time coming up with a way to summarize all this complexity.

Cross-cutting issues I see in most papers include at least the following:

(1) The nature of the system
(2) The process of characterizing the stressor
(3) System response to the stressor

(4) Directing the system to a specific endpoint, or at least away from it's current state. This does bring up the issue of endpoint, because I don't believe we really ever have endpoints. Perhaps relatively persistent transitional states--given our scale of observation..

4.0 Additional comments

I think we need to keep in mind that we are often dealing with spatially extended systems. We can envision situations where a stressor will be large enough to span more than one community types, as well as disjunctions in ecosystem processes such as the cycling of an important nutrient.

DATE : 28-July-1994

TO : David P. Bottimore
VERSAR Inc.
6850 Versar Center
P.O. Box 1549
Springfield, Virginia 22151

FROM : Richard L. Orr RLO
USDA APHIS PPD
6505 Belcrest Rd. Rm. 810
Hyattsville, MD 20782

SUBJECT: EPA's Risk Assessment Forum's Ecological Risk Assessment Workshop -- Comments on the Biological Stressors Paper

I appreciate the opportunity to review the Biological Stressors paper. I found it easy to read, thorough in its scientific coverage, and sound in its ecological assumptions.

The Biological Stressors paper, along with OTA's 1993 extensive publication on Harmful Non-Indigenous Species in the United States, and a number of other pertinent scientific papers on nonindigenous species provides EPA with the present state-of-the-art overview of the problems involved with biological stressors. This is a necessary step in order to proceed with development of a Biological Stressor Risk Paradigm.

I believe that, with a few minor changes, the scientific content of the Biological Stressors paper need not be changed. James Drake's research will be helpful in clarifying some of the issues in the paper; but of course Dr. Drake will himself address these points. The weakness in the Biological Stressors paper in not in the science, but in the next step -- how do we use this information to make decisions about biological stressors.

The ending statement in the paper "At present a Delphic process remains the most reasonable starting point, once the uncertainties involved are clearly stated" is not all that helpful since EPA already knew (long before the paper) that scientific input and correct identification of areas of uncertainty were important.

One of the main functions of a good risk assessment is to take scientific information and put it into a format that can be understood and used by a policy maker in making a decision. The Biological Stressors paper does not do this.

Government policy makers are still going to have to make decisions about biological organisms no matter how little is known about them or no matter how complex and chaotic the environment/organism interaction is. The Biological Stressors paper is full of what can go wrong in evaluating biological stressors but does little to help scientists organize what information they do have into a usable format for the policy maker that:

- communicates what is known about a specific biological stressor and how it interacts with the new environment;
- communicates the degree of uncertainty about the biological stressor and how it interacts with the environment;
- is transparent as to why a specific policy decision about a specific biological stressor is necessary;
- is defensible;
- is open to evaluation, and
- is flexible enough to incorporate new data or information.

The overall impression I received from the Biological Stressors paper was that the state of scientific knowledge about biological stressors and environmental interactions is so limited that any attempt to base a prediction on what will happen to a specific nonindigenous introduction is impossible, or at best a wild guess. I only partly agree with this philosophy.

I will grant that the ability of an introduced species to establish involves a mixture of the characteristics of the organism and the environment in which it is being introduced. The level of complexity between the organism and the new environment is such that the failure or success of a species in a new environment will be based on minute idiosyncrasies of that interaction. I agree that at the present time one cannot predict in advance what idiosyncrasy is going to trigger a successful or unsuccessful establishment.

I also believe that ecological dynamics are so turbulent and chaotic that future ecological events cannot easily be predicted. James Drake has convincingly demonstrated that several alternative states of ecological equilibrium are possible in a community due to a species invasion **despite identical initial conditions.**

In summary, one cannot easily make a predication of the impact of a biological stressor in a new environment based on a linear mechanistic micro-level examination of biological characteristics of the organism (e.g. number of eggs it lays, mating behavior, etc.) and/or the environment (e.g. identification of the various components). The reason is that the fundamental fabric of ecosystems is probably not linear or mechanistic but non-linear and chaotic in nature.

However there are, on a more macro-level, certain characteristics that have been shown to be useful in making predictions about invasive species. One of the most important is that if an organism has been shown to be invasive in other environments (successfully establishing and spreading in other regions) there is an increased probability that it will be invasive in a new similar, environment (e.g. rats & man). Another example is, if an organism is closely associated to its host and that organism occurs throughout its host's historical range; then if you move the host to a new location, the establishment of the organism is likely to occur if it is introduced (e.g., crop pests & livestock diseases).

Note that when you approach the evaluation of biological stressors from the macro-level you are not identifying why they are better invaders, but just that they are.

This macro approach is admittedly filled with flaws. If used there will be numerous mistakes and many incorrect predictions will be made. But it does provide a more usable tool than the micro-evaluation approach does.

The proof, as they say, is in the pudding. The Forest Service conducted an extensive risk assessment on the biological stressors associated with the importation of larch logs from Siberia in 1991. The number of nonindigenous organisms identified that could move on raw logs into the United States numbered more than 175. Using a combination of a macro-level/micro-level approach (see Orr et, al, 1993 for the process) the scientists identified 36 of the 175+ organisms to be of enough concern to warrant detailed evaluations.

Since the assessment was completed, 3 of the 36 organisms have entered the United States and established. None of the remaining 139 nonindigenous organisms assigned lower evaluation importance by the scientists have entered the United States and established. This indicates that the scientists were able to predict to a certain degree which organisms would establish.

One of the three organisms identified by the scientists, was the Asian Gypsy moth which was eradicated from the Pacific Northwest. According to the Forest Service, having the assessment completed on the Asian Gypsy moth, and therefore having all the involved parties (federal, state, environmental groups) already aware of the potential for damage from this organism saved an estimated minimum of 30 million dollars in eradication costs.

I am looking forward to the Ecological Risk Assessment Workshop.

References:

FS, 1991. Pest Risk Assessment of the Importation of Larch from Siberia and the Soviet Far East. USDA, Forest Service, Miscellaneous Publication No. 1495.

Orr, R., Cohen, S. and Griffin, R. 1993. Generic Non-Indigenous Pest Risk Assessment Process -- For Estimating Pest Risk Associated with the Introduction of Non-Indigenous Organisms. Draft USDA APHIS document.

OTA, 1993. Harmful Non-Indigenous Species in the United States. U.S. Congress, Office of Technology Assessment. September 1993

Review of Issue Paper on: **Biological Stressors**
Issue Paper Authors: Drs. Daniel Simberloff and Martin Alexander
Reviewed by: Dr. James H. Thorp

I found this 52-page issue paper on biostressors to be quite informative and interesting to read. I congratulate Drs. Simberloff and Alexander for their thorough contribution. While I do not wish to suggest that I could have written a better paper, I will fulfill my responsibilities as a general reviewer by offering some suggestions for revisions in organization and content. At the end of this review, I will also explicitly respond to reviewer questions 6-1 and 6-2 and to the general areas for consideration (G-1 through G-6), as posed in the pre-meeting notebook.

The authors are highly successful in illustrating the complexity of risk assessment for biostressors and provide a wealth of biological examples (except for aquatic species, as discussed later). This is not surprising given their credentials in this area of science.

Unfortunately, the authors' presentation has pessimistic overtone. Notice that I did not say "overly pessimistic", because their tone, in fact, may be realistic and reasonable. Nonetheless, it is not especially useful except to convince assessors that the job will not be easy. In reality, to answer the fundamental questions of risk assessment, one must have some idea of what controls the distribution and abundance of organisms -- this is a phenomenally huge topic which currently engages the activity of most ecologists! The authors conclude that the heavy use of examples and an emphasis on kinds of effects are the best that risk assessment for biostressors can do (p. 6-38). they also conclude that until significantly more ecological information is available, risk assessment will remain speculative (p. 6-41).

My conclusion is that this paper is an excellent review of the problem, but it is not as successful as a guide for resolving the problems of risk assessment. Its organization and emphases do not lend themselves to identifying future research needs nor is it complete as a guide to risk assessment. This could be resolved in part by the better statement of relevant ecological principles and the identification of testable hypotheses.

The following comments, occurred to me while reviewing various sections of the paper. I apologize in advance for the relatively poor organization of these comments.

Section 2. This is a good section that should help environmental managers better appreciate the differences between biotic and abiotic stressors. I believe, however, that this section fails to list two important differences that are emphasized later; these are: (1) jump-dispersal characteristics of some biostressors (essentially absent in abiotic stressors) (p. 6-22); and (2) the great difficulty eliminating biostressors once a successful invasion has occurred (p. 6-43), in other words, one cannot just turn off a pipeline for the original stressor and expect the problem to be resolved.

Section 3.1. Here again the authors state that only a few generalizations are possible (p. 6-13). I would argue that we need to generalize in the form of testable hypotheses as a means for identifying future research needs. One might also analyze the relative importance of factors that often limit survival and dominance.

Section 3.2. This section contains some important ideas that could be more clearly emphasized and used as areas for research. For example, what are the relationships between survival and proliferation in terms of: (a) prior habitat disturbance (p. 6-15); (b) intrinsic rate of increase (p. 6-16); (c) prior community complexity and resistance to invasion (p. 6-16); and (d) primary versus secondary invaders (p. 6-17).

Section 3.3. An important point is made here between the good applicability of simple diffusion models for abiotic stressors and their poor applicability to biostressors. In part this is due to jump dispersal. Aerial dispersal is also apparently better modeled than aquatic dispersal. Discussions of dispersal corridors (and blockage by environmental managers seeking to stop an invader) and barriers to dispersal would be useful.

Section 4. The authors point out that empty niches probably never occur, but this assessment is more applicable at the ecosystem process level . They correctly emphasize that we have failed to adequately identify how one should select species or processes for assessment (p. 6-24).

Section 4.1. We need more research on the relationship between the complexity of the community and the severity of the subsequent invasion.

Section 4.2. Dose-response curves do not seem useful for risk assessment of biostressors, as they point out.

Section 6. The authors present an interesting challenge to the concept that the effects of genetically-engineered organisms are more easy to predict (p 6-39). This challenge could be very important and is worth further consideration.

Section 6.1. The early classification of potential or new invaders by survival, reproductive, and dispersal characteristics and potential harm might be useful.

Section 7. Authors make interesting point that recovery judged by ecosystem properties (e.g., carbon flow) might be much easier than determinations made for each population. However, this generalization is not adequately discussed or supported in this issue paper.

Response to "General Areas for Consideration"

G-1. Clarity of Purpose and Scope:

Sorry -- I found the "introduction" to be essentially useless as a "roadmap" to the organization and major emphasis of the paper.

G-2. Completeness of Coverage:

Some ecosystem impacts of biostressors are mentioned (e.g., in the introduction) but the coverage at this level of complexity is minimal; however, this may reflect the intensity of scientific studies rather than the biases of the authors of this issue paper. Both spatial and temporal scales (e.g., evolutionary scale) are adequately addressed.

G-3. Clarity and Consistency of Terminology:

The use of jargon was not excessive, and the number of necessary contributions to a glossary of scientific terms would not be great. If a glossary is available, an explanation of the relatively new concept of a "metapopulation" might be useful. Actually, readers are probably more likely to stumble over some of the literary terms than the scientific terms in this issue paper!

G-4. Current Capabilities vs. Future Needs:

I believe the paper's list of examples could be trimmed without significantly damaging the thrust of the paper. On the other and, the paper is markedly weak in explicitly identifying future research needs. Suggestions for research needs are not clearly separated in the text, making it difficult for the reader to recognize, evaluate, and act upon recommendations.

G-5. Relationship to EPA's Framework for Ecological Risk Assessment:

This requires an analysis of all issue papers in order to give an informed response. As I have not yet read all the other papers, I must refrain from a direct response to this question at this time.

G-6. Examples:

The paper was strong on terrestrial examples (especially metazoa) but decidedly weak on aquatic examples. For example, the Asiatic clam, *Corbicula fluminea*, has been extensively studied, and it is an excellent example of jump-dispersal. Human vectors of dispersal were not classified. One current example is the exceedingly rapid movement of zebra mussels on barges throughout much of the Mississippi River drainage. There was very little mention of introduced fishes. Furthermore, the authors never mention the introduction of supposedly-sterile exotic species, such as the grass carp, which occasionally causes significant damage when they suddenly develop the ability to reproduce! Some mention of the reproductive habits of the introduced fish *Tilapia* in relation to density would also be potentially useful.

Questions Specifically Relevant to "Biostressors"

6-1. Balance

This issue paper was adequately balanced in coverage of exotic species macrobes and genetically-engineered microbes, with one exception. The response of genetically-engineered species was assumed to be essentially equivalent to introduction of "natural" species, except for lateral transfer of genes. Unfortunately, the authors have not provided adequate examples of either the introduction of genetically-engineered organisms or the process and likelihood of lateral gene transfer.

6-2. The Next Step

As I have identified in my general discussion, the authors have not adequately identified future research needs nor have they mapped a strategy for risk assessment, other than the Delphic process. This probably relates to the complexity of the problem. If the August workshop cannot develop a plan for identifying research needs and an assessment strategy, then I recommend that EPA and Versar commission additional issue papers and another workshop.

Ecological Recovery

Workgroup Leader: Dr. James R. Karr
University of Washington

General Reviewer: Dr. Patrick L. Brezonik
University of Minnesota

General Reviewer: Dr. Randall Wentsel
U.S. Senate Committee on Environment and Public Works

Review by James Karr

COMMENTS: Fisher and Woodmansee - Ecological Recovery

My comments here are largely in the form of questions. My goal is to stimulate the group to focus on conceptual issues that must be clearly defined before we can advocate their use in formulating societal policy. I also must admit some skepticism about the applicability of a number of ecological theories and the constructs derived from them. The highway travelled by ecology as a discipline is littered with cast-off theory. How can we use but not be controlled by current theory? How can we use the obvious signals from the world around us to develop more informed societal policy whether grounded in current theory, observation, or both?

Page 7-6, paragraph 3, lines 1-3 (7-6,3,1-3) - The sentence specifically cites a laundry list of issues and refers to a figure that contains two major sections (a and b). I do not see the explanatory nature of the figure. Further, the meaning of the components in a and b are essentally identical, suggesting that the spatial and temporal considerations are not different except that "spatial" and "temporal" substitute. Does the figure really simplify and make the issues more transparent? I am not so sure.

7-6, 3, Last few lines - The use of succession here and elsewhere is a bit confusing. Is every systematic change succession? For example, is the seasonal shift in herbs in the undergrowth a succession? Same for phytoplankton in a lake or benthic invertebrates in a stream? How about the migration of birds from place to place during the annual cycle? Or is the seasonal replacement of birds in a single forest a succession? How do we place clear bounds on the use of concepts like succession? Is that essential if we are to cast risk assessment in a broader ecological context?

General comment: The use of ecological concepts, theories, and principles is not consistent among these papers. If ecologists don't use these words consistently when communicating among themselves, how can we expect others to use them in ways that will inform risk assessment and communication?

7-9, 1, 2 - The phrase "current state" here is vague. How do we decide what ecological or biologically relevant attributes are to be measured to reflect state? We have the obligation to measure those things that we know might be influenced by a human action. Should we also think more broadly about unknown or unexpected effects? Should we be collecting information that will help in recognition of broader effects than those currently envisioned? For decades we have focussed on acute and chronic (especially cancer-causing effects) but new evidence suggests that the developmental, immunological, and other effects may be far more ominous. Widespread recognition of many other aspects of degradation are emerging? How do we do the best job to anticipate the unexpected?

7-10, 1, last 4 lines - Excellent points here. How do we avoid conceptual approaches that are constrained by current theoretical framework of ecology or risk frameworks developed to deal with other issues and problems? I see problems with both in this and other papers in this series. How can we focus on overcoming that problem as opposed to finding a convenient set of bureaucratic rules that suggest but do not produce a solid risk assessment approach that will in fact protect society's interests over the long term?

7-11, 2, bullet 3 (second set of bullets) - The switch from ecological context to ecosystem context within and among the papers in this set is a bit disconcerting. In some cases, population issues are identified as important while in others, authors suggest that species loss is not of consequence if "function" is maintained. That kind of conclusion flies in the face of major societal energy to protect species such as bald eagle, salmon, and spotted owls now and wood duck early in this century. I find the varying signals within this paper and among the papers in this series confusing. How do we resolve that?

7-14, 4, 4 - What is meant by the "viability" of ecosystems?

7-5, 2, 1 - Biological integrity is introduced here as a concept without definition and without relating it to the other concepts mentioned throughout this text. Should an agreement be reached on what all these mean and how they relate to each other before they can be used in a formal risk assessment context?

7-15, 4, 1 - Are there other kinds of organisms than "biological organisms?"

7-16, 1, 7 - Is it your intent to equate biodiversity with diversity of genetic stock? Is the text question here serious? How do we go about answering it?

7-17, 2, 6 - To what extent are there or should we explore the possibility of non-economic values of ecosystems? How do we incorporate our lack of knowledge of values that are nonetheless important to society?

7-20, 2, 1 - Is this a widely understood and accepted definition of stability? What is the range of "ecosystem response" that is relevant to this definition? Shrader-Frechette and McCoy (*Method in Ecology*) have extensive discussion of the concept of stability and its use in ecology. I think that universe of concepts is broader than what is reflected in this brief discussion.

7-21 - Much discussion of what disturbance is and what it means here. They do not all agree or even seem to focus on the same thing. How do we move toward consensus?

7-21, 3, 3 - What is the "cycle of an ecosystem?"

7-22, 4 - Resistance - Has resistance ever been measured? How would we express it and define a divergence from expected to infer a significant impact by human society? The same question seems appropriate for resilience and other similar concepts. How do we translate those difficult ecological concepts into something that can be used in formulating societal policy? In effect, how do we measure it and use it in the policy process as opposed to thinking aloud about it as theoretical ecologists?

7-24, 2, 4-8 - If all risk assessment is based in prior definition of human-assigned values, how can risk assessment protect us from the unknown consequences of our actions. I have some thoughts on this issue that can come out in our discussion. At the core, we have the current range of environmental "train wrecks" because we did not do a very effective job of anticipation of threats to human welfare as opposed to operating as if human interests are not threatened by societal actions.

7-25, 1, 1-5 - I am not so sure that resistance and resilience are rigorously negatively correlated in ecosystems.

7-25, 2, 1 - Not clear to me how resistance is the only factor establishing initial conditions in the recovery process.

7-26, 3, last line - Not clear to me how a recently burned forest is immune to disturbance (all kinds)? Is this meant broadly or just immunity to another round of fire? Is that true? Is it idiosyncratic of fire or would the same be true of all kinds of disturbance?

7-27, 2, 8 - What is a "benthic half-cycle?"

7-28, 3 - Good paragraph. The kinds of issues raised here should come up earlier and more forcefully. They are the core of what we should be considering and evaluating as oppoed to the more esoteric ecological concepts that may be impossible to measure such as resilience and resistance.

7-29, 2, 1 - stability - Has this been defined yet? How can the concept be used in the sense of someeone going out and measuring something in a biological systems and using that information to make a decision based on that measurement?

7-30 - What are the emergent principles from the kinds of examples that are listed in this set of paragraphs and those that follow?

7-30, 4, 1 - "Fire is a catastrophe" - What is meant by this? How is catastophe defined? From whose perspective? It is essential to many species of plants and animals (as is noted in the next sentence) and, thus, the lack of fire would be a catasrophe. Is fire always a catastrophe?

7-32, 2, 1 - It seems to me that many fish in North America show considerable resistance to drought. What they don't show resistance to is the kinds of late summer dewatering that is characteristic of streams after human-alteration of landscapes, stream channels, and water tables.

7-35, 2, 3 - Phenology is used here. For some earlier usages of succession in this text, it seemed more appropriate to use phenology to me. How do we sort out those things in text that is designed to inform and be used by policy makers?

7-35, 2 - The die-off of *Diadema* in the Caribbean some years ago is an excellent example of this kind of thing. Should be cited here.

7-36, 2 - Good points about scale here. Perhaps they should be expanded.

7-37, bullets - Seems an odd list to me. Tendency to focus on (plant?) biomass is a bit narrow. This reflects an ecosystem level perspective rather than a broader ecological perspective. What is the intent of this risk assessment process with respect to that issue? Is ecossytem, ecological, or biological the driving interest?

7-37, 2, 1-2 - I am not so sure terrestrial systems subjected to airborne agents will begin recovery immediately.

7-38, 1, 1-2 - Is shift to more autotrophic endpoint recovery? Or is recovery to the original condition? Change to anything is recovery if the former. How and when do we decide which should apply?

7-39, 4, 1 - What is an "ecosystem population?"

7-39, 4, 4-5 - What is the lesson and emerging principle of the Chapin and Chapin example? Later "successful recovery is a function of physiology." What does that tell us. It is also a function of the evolutionary experience with that disturbance? The context of other disturbances then and as antecedent conditions. How do we use all this to make decisions and to anticipate the future needs of society and what risk assessment should be designed to protect us from?

7-40, 3, 8 - How do you and Connell and Slayter define the four concepts listed here? How do they relate to the subject at hand? They seem to hang here with no purpose.

7-41, 3, 2 - Odum citation and leakiness. How do we define an appropriate level of leakiness? It surely is not the same for all biological systems?

7-42, 2, 3 - What are the 8 processes of Vitousek et al? How do they relate to the subject at hand?

7-42, 4, last sentence - What is the lesson of this? Does that distiguish it from other levels? Does that make measurement at ecosystem level less useful? Not useful?

7-43, 1, last couple lines - Is it only collective properties that we are interested in? Why? Is that reflected in the current movements in society to protect ecological integrity or ecological health (they are not the same in my view)?

7-43, 2, 2, 5 - "state variable" - I suggest that this is much too narrow a perspective for ecological risk evaluations.

General comment - I think we should explore the following question: How dependent is risk assessment with the constructs used in this and other texts on the current round of ecological thoery? Should the risk assessment process be driven by that theory alone? Should that theory be abandoned in favor of more general, perhaps even simple, observations of the changing biology of a site influenced by humams? Can any good biologist detect most of the most serious forms of degradation that result from human actions without resorting to resilience or resistence, ecosystem theory or population demographic models? Should we use both and try to establish when each kind of approach is most relevant or important?

7-44, section 5.2.1 - I have serious reservations about this section. They are grounded in ecology and in the kinds of values that many in society express independent of the functional equivalence arguments of some kinds of ecology.

Many other comments are noted in the margin of this manuscript. These thoughts raise some general issues that apply here but also apply to other papers as well. Rather than separate them into two sets of comments I have hinted at the broader, cross-cutting issues in these notes.

James R. Karr
University of Washington

Review of Chapter 7, Issue Paper on Ecological Recovery

for
Risk Assessment Forum's
Ecological Risk Assessment Workshop
August 16-17, 1994

by

Patrick L. Brezonik
University of Minnesota

Overview

This chapter contains many good ideas and worthwhile suggestions regarding the analysis of ecosystem recoverability in the context of ecological risk assessment. However, the text also is encumbered with jargon, undefined terms, and unhelpful generalities. The authors have attempted to lay a comprehensive framework for the analysis of ecosystem recovery; perhaps in so doing they have sacrificed specifics and detail for broad and often vague or abstract statements. The paper provides a useful discussion of concepts that should be considered in conducting the recovery analysis phase of a risk assessment, but it does not (in most cases) describe *how* these concepts should be considered or used in the assessment. Consequently, the agency or person doing the risk assessment is left with no concrete guidelines. Overall, there is too much emphasis on natural agents of disturbance and the recovery of ecosystems from such disturbances as flooding) and insufficient focus on anthropogenic agents of disturbance and the responses/recovery of ecosystems from such agents. The authors are to be commended for the broad framework they provide, particularly in including the socio-economic dimensions of the analysis.

General Areas for Comment

G-1. The introduction is nicely written, particularly the first couple of pages. However, I don't think it provides much of a roadmap to inform the reader as to the organization of the for the rest of the paper. The roadmap, such as it exists, is embedded in the first full paragraph on p. 7-8. I think this could be expanded somewhat and made more specific.

G-2. As stated above, I think the authors have attempted to be comprehensive, but their coverage of different types of stressors and different types of ecosystems is not well organized; the paper is organized along other lines, and inclusion of various kinds of stressors and ecosystems is mostly by way of example (and consequently somewhat haphazard). I would like to see more emphasis placed on describing recovery processes for different categories of ecosystems from various classes of stressors.

G-3. I make specific comments on undefined and inconsistent terminology in the detailed comments that follow. There are problems with both issues in the paper. A glossary may be useful, but where possible I think it would be better to: (1) avoid the use of jargon and terms that are used only by specialized scientific groups, and (2) define terms as needed in the text.

G-4, G-5. I have not had time to analyze the paper sufficiently to respond to these items.

G-6. There are no case studies given in the paper. The use of examples or illustrations is limited to hypothetical or abstract situations/systems or to amplify a specific issue. For example, in discussing physical factors affecting resistance to change and resilience to recovery in streams, the authors briefly discuss differences among cobble-rock bottom, sand bottom, and clay-rich streambeds. In discussing organismal adaptations, jack pine is mentioned as an example of an organism that has a mechanism of resistance that operates at the level of genomes. Many other such "examples" are scattered throughout the text. However, no ecosystem recovery studies are cited or discussed. The paper could profit by inclusion of some specific case studies where recovery happened as predicted or didn't happen (and why it didn't).

Questions Relevant to Issue Paper 7.

7-1. As noted in G-6, the paper does not have specific examples of recovery (i.e. case studies) or much detail about specific recovery processes in any ecosystem types. Within the framework in which the paper uses examples (see response G-6), the paper is short in providing examples related to lakes and wetlands.

7-2. There is very little discussion about recovery of ecosystems from chemical stressors. There is no discussion about recovery of lakes from eutrophication or acidification. There is little or no discussion about natural recovery (once a stressor is removed) versus manipulations to accelerate recovery. In the context of lake acidification, addition of powdered limestone is an example of the latter approach.

Obviously, many examples could be provided with regard to recovery from anthropogenic stressors. This would make the paper rather different from the present version. Given EPA's mandates regarding anthropogenic impacts, I think the paper should include a lot more examples on this topic.

7-3. Paleolimnological methods are not mentioned as a technique to infer past conditions in lakes (hence determine what the target should be for recovery and whether the lake has recovered).

7-4. The paper does a fairly good job of addressing socio-economic factors that affect the likelihood of recovery. The sections on cultural influences (3.2.3, p. 7-18) and politics, policy, laws and regulation (3.2.5, p. 7-19) are vague and very brief. The section on economics could use additional references and perhaps additional text.

7-5. No comment at this time.

Specific Comments and Questions on Chapter 7

p. 5-6 This is a nice introduction.

p. 7 The ideas espoused in the first full paragraph are interesting and in an ideal world they make sense. Realistically, however, they imply that we know a lot more about the "typical ecosystem" requiring restoration than is likely to be the case and more about the range of states available for "endpoint selection" than we do, and that we can exert finer control over which of these states is reached than is the case with our current (crude) tools. In the real world, we are likely to have only general information about the nature of the ecosystem before stress and damage occurred. At least in the case of aquatic ecosystems, much of the information on the nature of the endpoint state (the restoration goal) is likely to be from analogous ecosystems rather than from the system to be restored. Overall, I think this paragraph implies that we have more detailed understanding about ecosystems responses to stress and a finer degree of control over ecosystem restoration than is actually the case.

p. 7 It is perhaps a minor and subjective point, but I do not care much for the term "risk assessor", first used in line 6. (Perhaps it reminds me of tax assessor!) Are we going to develop a new profession or category of government employees called risk assessors (with grades I to IV); I hope not.

p. 8 In my opinion, the final steps in the protocol (second last paragraph) not only are beyond the scope of the paper but beyond the ability of ecosystem managers and restorers to achieve at present. Again, this seems not to be a realistic recommendation (cf. first comment on p. 7).

p. 12 The first sentence does not make a lot of sense to me. I am puzzled by the statement "Since recovery from that stress can easily take on prominence." What point are the authors trying to make here?

p. 12 Second paragraph line 4. The word "sector" is rather vague and is used elsewhere in the chapter to mean other things (e.g. see p. 8, line 5). I think the authors should find a more descriptive term for the ten factors or sets of issues they say need to be included in the analysis.

p. 14 The first sentence could be improved by rewording or re-ordering the ideas it includes.

p. 14-15 The sections on water and soil properties are very vague and general. There is little useful information here, particularly with regard to implications for assessing/predicting recovery. It would be better if the authors provided some examples for different categories of ecosystems (e.g. aquatic [lakes, streams], semi-aquatic [wetlands], terrestrial [forests, arid lands, etc.]).

p. 15-16 The section on assemblages of organisms is better than the two previous sections, but it too could be enhanced by more examples for different categories of ecosystems.

p. 17 The second paragraph implies that recreation has only a nonmonetary value with regard to ecosystems. This is true only in part. Economists have spent a lot of time and effort developing monetary-based values for recreational use of aquatic ecosystems, and there are many studies that demonstrate high monetary values associated with recreational use of rivers, lakes, reservoirs, etc.

p. 18 The first paragraph (on cultural influences) is very vague. To start, the authors need to define what they mean by cultural communities, cultural viability, and cultural trends.

p. 18 Second paragraph, line 4: Change "Thus..." to "For example, ..."

p. 19 The paragraph on politics, policies, law and regulation is so vague as to be useless. The first sentence is a true but general statement. The second statement is unclear. The third and last sentence is meaningless.

p. 20 I do not think it is useful to repeat definitions from the 1970s literature that are no longer accepted. The authors state that there is some confusion about the definition of stability, but they may unwittingly contribute to that confusion in some readers' minds by repeating Holling's definition.

p. 20 Section 4.1.2: The section is not just about disturbance and stress; perturbation is introduced as a comparable term (on p. 21, third paragraph). It would be better simply to label this section "Disturbance" or "Disturbance and Related Terms (or Concepts)".

p. 20 Section 4.1.2, line 1: Define punctuated and differentiate it from discrete.

p. 20 Last line of page: define spate; most readers are familiar with this term in the sense of "a large number or amount of" or "a sudden rush or outburst"; the primary definition in Webster's Unabridged Dictionary (i.e. a flood or freshet) seems less common in use, except perhaps among stream ecologists. Why not use the word flood here?

p. 22 The third paragraph (Thus the first step...) needs some work. The authors say that the disturbance must be described fully and must include consideration of disturbance attributes that formerly were dealt with in an arbitrary and conflicting manner. How do they propose to consider these attributes in a non-arbitrary and non-conflicting manner?

p. 23 Second paragraph of Section 4.1.4: The seasonal examples provided are trivial. Would any ecologist or resource manager expect to restore a system to a perpetual spring-time condition?

p. 23 Last paragraph, line 3: Why add to the confusion; delete reference to Holling's definition. See first comment for p. 20 above.

p. 24 I am not convinced that the Odum concept of ecosystem development presupposes a cybernetic function for ecosystems. I also am a little amused by the author's critical language with regard to Odum's term (e.g. "dubious value", "uncertain origin") and generally positive statements about Margalef's similar views ("uniquely ecosystem-oriented", and "concept is useful"). What gives here?

Rather than criticizing the ecosystem-level trends of Odum as non-universal or inapplicable, perhaps it would be better to describe the concept of succession differently for autotrophic and heterotrophic ecosystems.

p. 25 Line 1: I think the authors mean to say that resistance <u>and</u> resilience are negatively correlated in ecosystems. The third sentence of the first paragraph is a non sequitur.

p. 25 Second paragraph: Resistance to stress or disturbance defines the initial conditions of the recovery process only in part; the amount or severity and longevity of the stress also play a defining role in the nature of the disturbed or degraded ecosystem. In the third sentence of this paragraph, the authors say that the most important variable for predicting recovery capacity is the system's state once the stress has been removed. A state is not a variable (except in the context of models -- "state variables"); a different word would be better. The last sentence of this paragraph is not clear, especially the point about "weighting terms".

p. 25 Section 4.2.1.1: The streambed examples provided in the paragraph dealing with physical factors seem to contradict the earlier statement on p. 25 that resistance and resilience or negatively correlated. A boulder-cobble bottom would provide high resistance and high resilience; a sandy bottom would have lower resistance and lower resilience; but a clay bottom would have high resistance and low resilience.

p. 26 The paragraph about physical factors affecting resistance of lake ecosystems is simplistic. It ignores all chemical factors and seriously understates the physical complexities of lake ecosystems. I suspect that the brief paragraph on terrestrial ecosystems also oversimplifies physical factors. It does not include any consideration of geochemical conditions.

p. 27 **First paragraph:** The second and third sentences may be clear to terrestrial ecologists; I don't think they are clear to others.

p. 27 **Second paragraph:** I don't understand what the authors mean (line 11) by "floods remove the benthic half-cycle in such ecosystems."

p. 28 **Line 6-7:** This sentence is unclear and needs further explanation/description.

p. 31 The section on disturbance type is too long for the amount of relevant information. It focuses too much on natural disturbances and stresses, almost to the complete exclusion of anthropogenic disturbances; the latter, I presume, are of the greatest interest to the EPA. I frankly do not understand the focus on flooding and other natural disturbances. Many of the examples in this section appear to describe responses or recovery of ecosystems from seasonal events like spring flooding. I don't see much relevance of this material to the subject of ecological risk assessment or to ecosystem recovery from anthropogenic stress.

p. 31 **Section on animal-caused disturbance:** The first clause of the first sentence in this section is unclear to me. Beavers are an important example of natural biological agents whose resurgence is causing significant disturbance in aquatic ecosystems of the upper Midwest.

p. 33 **Section 4.2.2.2:** This section is too brief and only discusses some differences between natural and anthropogenic stresses. It should provide a more in-depth discussion of the types of anthropogenic stresses and how they differ among themselves in ecological impacts.

p. 34 **First paragraph:** No mention is made of excessive nutrient additions to aquatic systems and acid loading to forest and aquatic ecosystems from atmospheric deposition. These are two of the most widespread anthropogenic stresses, and ecosystem responses to these stresses are fairly well understood. Aside from physical (habitat) disturbances, these are probably the most common anthropogenic causes of aquatic ecosystem degradation leading to restoration actions in the U.S.

p. 34 **Line 9:** There are many reasons to believe that a flood-damaged stream and a stream damaged by a petrochemical spill will <u>not</u> recover in the same way. For example, the flood-damaged stream may suffer considerable habitat loss or change. A petrochemical spill may or may not involve any habitat damage, depending on the nature of the spill; in any case, the type of habitat damage is likely to be rather different in the two types of disturbance.

p. 35 The examples provided in the first paragraph are largely irrelevant to the needs and interests of EPA with regard to ecosystem disturbances. I don't think that time scales on the order of time-of-day or even season are particularly relevant to what should be the focus of this paper -- even though such scales of course are of considerable interest to ecologists in understanding the detailed behavior of ecosystems.

p. 36 Line 13 from bottom: I disagree strongly with the contention that transparency is not an issue in the cited example. If macrophytes have been lost from the system for some reason, there is a good possibility that nutrient concentrations will have increased in the water column and algal growths also will have increased. Transparency thus will have changed from the predisturbance condition. The example is at best a simplistic application of the statistical findings of Duarte (1991).

p. 37 Section 4.2.5: The first sentence strikes me as a non sequitur; remove the word "Although" and rephrase the sentence as two independent clauses.

The four bullets are not discussed adequately in the subsequent paragraph and need more explanation and/or examples. It is not clear how the first sentence of the paragraph following the bullets acts as an example; the phrase "For example," should be removed. Also, I don't think the idea expressed in this sentence can be justified. If the airborne agent is a toxic substance that has accumulated in the soil or biota, it may take many years for it to be flushed from the ecosystem, just as the authors say is the case for lakes.

p. 38 Line 7 from bottom: Define "vagile".

p. 38 Line 2 from bottom: Another flood example. Can the authors provide an example involving an anthropogenic stress?

p. 39 Lines 13-15: This sentence is a bit unclear and could be improved by rephrasing.

p. 40 Section 4.2.7.2: It would help the reader understand this section if the authors would provide some examples of the assembly rules to which they refer throughout the section.

p. 41 Section 4.2.7.3: Most of the available energy in the aphotic zone of lakes (middle of first paragraph) is autochthonous in the sense of being produced within the lake (in the euphotic zone). Limnologists distinguish between autochthonous and allochthonous on the basis of whether the material is formed in the watershed or in the lake. A material is considered to be autochthonous regardless of where in the lake it is actually produced.

p. 45 First paragraph: The idea that introduction of exotic species supports the contention that some species are more important than others is not well developed and needs further explanation.

p. 45 Third paragraph: Use of the word "reservoir" in line 2 is unclear until one reads the rest of the paragraph. I think it could be deleted from the parenthetical phrase.

p. 47 Line 4 from bottom: The phrase "Relay filtration" is unclear and should be replaced.

p. 47 Last line: Change "short-cut measures such as redox" to "simple measurements such as redox potential [or redox status]".

ISSUE PAPER ON ECOLOGICAL RECOVERY

Review by Randall Wentsel

The paper on ecological recovery is well written and provides a very good overview of questions, issues, and terminology in ecological risk assessment (ERA) and risk management of damaged ecosystems. The authors also show how the Framework for ERA can structure the complex issues concerning damaged ecosystem recovery.

One issue that should be stressed is that scientists are not the only stakeholders in deciding what the best endpoints are and deciding what the best ways to get the ecosystem "back on track." Non-science issues and values have an important role in risk management. The authors stress this in the Problem Definition section with the 10 basic sectors. These sectors are inclusive of many of the stakeholder issues in environmental management.

The issue of organizational viability (NOT a biological indicator) recognizes the long term economic, social, and political stability required to maintain an ecosystem recovery program. Policy issues and regulations can be used to support remediation efforts.

While an ecosystem will undergo a natural succession, I think further discussion of the uncertainty of managed or remediated ecosystem recovery would be beneficial. Methods to aid the recovery of an ecosystem could produced unexpected and undesired results. The point the authors made that - ecosystems with a high capacity to resist stress tend to have a limited ability to recover from the disturbance events and vice versa - is important to remember.

The section on natural versus anthropogenic stresses discussed how anthropogenic stress can be superimposed on stress systems and alter ecosystems in dramatic and unpredictable ways. It emphasizes the impacts from toxic chemicals and exotic organisms.

The authors discuss the important issue of monitoring an ecosystem for recovery. They recognize that there are no standard methods to assess recovery and that managers and scientists must be involved in designing the monitoring program.

Discussions on recovery and its theoretical basis were well done. The role of corridors and size of habitats was not emphasized. However, natural succession was well presented. More discussion of keystone species, "hot spots," and critical habitat could be included. Judging the effectiveness of the recovery needs to include a broad group of stakeholders.

Overall the authors presented a complex subject in a readable manner. The Framework assisted, not hindered, the presentation of the information.

Uncertainty in Ecological Risk Assessment

Workgroup Leader:	Dr. A. Frederick Holland South Carolina Marine Resources Institute
General Reviewer:	Dr. Lev R. Ginzburg Applied Biomathematics
General Reviewer:	Dr. Kenneth A. Rose Oak Ridge National Laboratory

Paper #8: Uncertainty propagation methods

Although the papers are not intended to be comprehensive, I think the paper should review the variety of uncertainty propagation methods. These techniques should at least be mentioned.

DELTA METHOD (Seber 1973; Kirchner 1992) is an approximate method based on a Taylor expansion for finding approximate means, variances and covariances of functions of random variables.

DEMPSTER-SHAFER THEORY (Shafer 1976) is a calculus for weighing evidence that is widely used in computer science. It has fewer assumptions than probability theory and is therefore a weaker, but more general, theory. I know of no examples of the use of Dempster-Shafer theory in a risk analysis problem, although the theory is likely to have substantial utility there.

DEPENDENCY BOUNDS ANALYSIS (Glaz and Johnson 1984; Frank *et al.* 1987; Williamson and Downs 1990; Ferson and Long 1994; Ferson and Burgman 1994; Ferson 1994) is a numerical method by which bounds on probabilities can be computed when joint distributions are unknown and only marginal distributions are specified.

FUZZY ARITHMETIC (Kaufmann and Gupta 1985; Ferson and Kuhn 1992; 1994; Kuhn and Ferson 1994) is a generalization of interval analysis based on possibility theory (Zadeh 1978; Dubois and Prade 1988). It is analogous to probability theory but applies to non-statistical uncertainty such as measurement error.

INTERVAL ANALYSIS (Moore 1966; Alefeld and Herzberger 1983) is a generalization of range arithmetic. This is probably the simplest comprehensive method for uncertainty projection through mathematical expressions.

LAPLACE AND MELLIN TRANSFORMS (Springer 1979) are standard methods for probability distributions by which additive and multiplicative convolutions can be computed by simple addition. This approach doesn't work with arbitrary distributions.

MONTE CARLO METHODS, including simple and structured sampling strategies such as Latin hypercube sampling, (Iman and Conover 1980; 1982; Iman *et al.* 1981a; 1981b; Iman and Shortencarier 1985) are approximate but robust simulation techniques for convolving probability distributions of specified shape and (rank) correlation structure. Iman and Helton (1985) describe the use of these methods.

RANGE ARITHMETIC (Dwyer 1951) is a simple method often used in physics to propagate uncertainty expressed as ± ranges through the basic arithmetic operations (plus, minus, times, divide).

References

Alefeld, G.; Herzberger, J. (1983). Introduction to Interval Computations. Academic Press, New York.

Dubois, D.; Prade, H. (1988). Possibility Theory: An Approach to Computerized Processing of Uncertainty, Plenum Press, New York

Dwyer, P. (1951). Linear Computations. John Wiley, New York.

Ferson, S. (1994). Naive Monte Carlo methods yield dangerous underestimates of tail probabilities. Proceedings of the High Consequence Safety Symposium. Sandia National Laboratories.

Ferson, S.; Burgman, M. (1994). Correlations, dependency bounds and extinction risks. Biological Conservation [in press].

Ferson, S.; Kuhn, R. (1992). Propagating uncertainty in ecological risk analysis using interval and fuzzy arithmetic. Computer Techniques in Environmental Studies IV, P. Zannetti (ed.), Elsevier Applied Science, London, pp. 387-401.

Ferson, S.; Kuhn, R. (1994). Interactive microcomputer software for fuzzy arithmetic. Proceedings of the High Consequence Safety Symposium. Sandia National Laboratories [in press].

Ferson, S.; Long, T.F. (1994). Conservative uncertainty propagation in environmental risk assessments, Environmental Toxicology and Risk Assessment, Vol 3, ASTM STP 1218, J.S. Hughes, G.R. Biddinger, and E. Mones (eds.), American Society for Testing and Materials, Philadelphia, [in press].

Frank, M.J.; Nelson. R.B.; Schweizer, B. (1987). Best-possible bounds for the distribution of a sum—a problem of Kolmogorov. Probability Theory and Related Fields 74:199-211.

Glaz, J.; Johnson, B.M.K. (1984). Probability inequalities for multivariate distributions with dependence structures. Journal of the American Statistical Association 79:436-440.

Iman, R.L.; Conover, W.J. (1980). Small sample sensitivity analysis techniques for computer models, with an application to risk assessment. Communications in Statistics A9:1749-1842.

Iman, R.L.; Conover, W.J. (1982). A distribution-free approach to inducing rank correlation among input variables. Communications in Statistics B11:311-334.

Iman, R.L.; Helton, J.C. (1985). A Comparison of Uncertainty and Sensitivity Analysis Techniques for Computer Models. (NUREG/CR-3904, SAND84-1461), Sandia National Laboratories, Albuquerque, New Mexico.

Iman, R.L.; Helton, J.C.; Campbell, J.E. (1981). An approach to sensitivity analysis of computer models, Part 1. Introduction, input variable selection and preliminary variable assessment. Journal of Quality Technology 13:174-183.

Iman, R.L.; Helton, J.C.; Campbell, J.E. (1981b). An approach to sensitivity analysis of computer models, Part 2. Ranking of input variables, response surface validation, distribution effect and technique synopsis. Journal of Quality Technology 13:232-240.

Iman, R.L; Shortencarier, M.J. (1984). A Fortran 77 Program and User's Guide for the Generation of Latin Hypercube and Random Samples for Use with Computer Models (NUREG/CR-3624, SAND83-2365), Sandia National Laboratories, Albuquerque, New Mexico.

Kaufmann, A.; Gupta, M.M. (1985). Introduction to Fuzzy Arithmetic: Theory and Applications. Van Nostrand Reinhold, New York.

Kirchner, T.B. (1992). QS-CALC: An Interpreter for Uncertainty Propagation. Quaternary Software, Fort Collins, Colorado.

Kuhn, R.; Ferson, S. (1994). Risk Calc: Uncertainty Analysis with Fuzzy Arithmetic. Applied Biomathematics, Setauket, New York.

Moore, R.E. (1966). Interval Analysis, Prentice-Hall, Englewood Cliffs, New Jersey.

Seber, G.A.F. (1973). The Estimation of Animal Abundance. Griffin, London.

Shafer, G. (1976). A Mathematical Theory of Evidence. Princeton University Press.

Springer, M.D. (1979). The Algebra of Random Variables. Wiley, New York.

Williamson, R.C.; Downs, T. (1990). Probabilistic arithmetic I: numerical methods for calculating convolutions and dependency bounds, International Journal of Approximate Reasoning 4:89-158.

Zadeh, L. (1978). Fuzzy sets as a basis for a theory of possibility. Fuzzy Sets Systems 1:3-28.

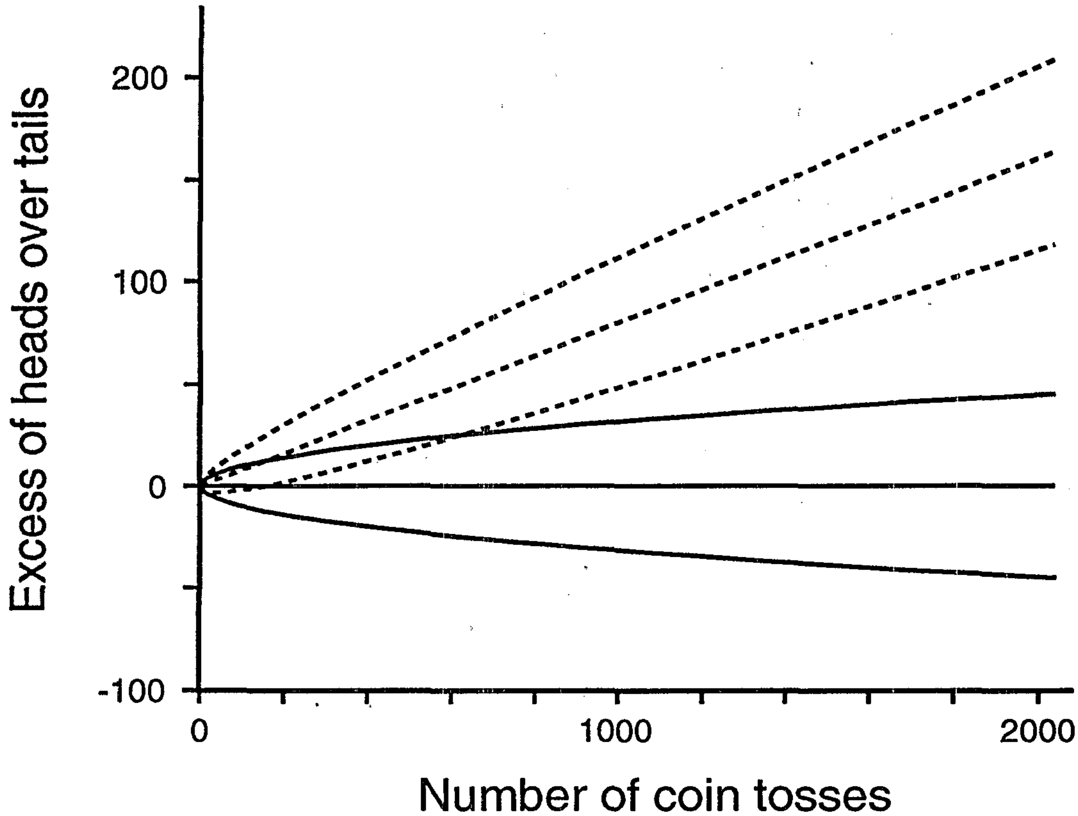
Paper #8: Kinds of uncertainty

While there have been many comprehensive taxonomies of the varieties of uncertainty published (*e.g.*, Faber *et al.* 1992), the main subdivisions are basically of two kinds: variability and ignorance. Variability includes stochasticity arising from temporal and spatial heterogeneity in environmental factors and among exposed individuals. Ignorance includes measurement error, indecision about the form of the mathematical model or appropriate level of abstraction. It's clear that variability and ignorance are fundamentally different since the latter but not the former can be reduced simply by additional empirical study. Variability can be translated into *risk* (i.e., probability) by the application of a probabilistic model. Ignorance per se cannot be strictly translated into probability in the same way. It can be used, however, to generate *error bounds* on the risk statements. The two kinds of uncertainty have to be handled separately, and differently, in an ecological risk assessment.

Most analyses of population viability estimate the risk of extinction by estimating the probability of extinction under random environmental variability. This approach is sufficient only if the demographic rates, and the magnitude of their year-to-year fluctuations, are known reasonably precisely. However, such knowledge is rarely available in empirical situations: even in fairly unchanging environments there can be considerable uncertainty associated with the estimate of each demographic rate. Indeed, it is not uncommon that the variance in some variable due to measurement error is an order of magnitude greater than that due to year-to-year fluctuations. The effect of such uncertainty is to blur any projected population trajectory, even when the environmental variability is known completely. This blurring increases with time, rendering long-term projections particularly susceptible to uncertainties in the original estimates. More precise estimates of the demographic rates would result in narrower bundles of trajectories, and a longer horizon for making meaningful population projections.

The distinction between measurement error and natural variability can be described as the difference between uncertainty about the current value of the parameter and uncertainty about future changes in a parameter. If a parameter contains random variation, uncertainty about future variation is inevitable and may often be significant. For instance, a population that, on average, maintains itself adequately can be driven extinct by a series of bad years, and one job of risk assessment is to estimate the likelihood and probable impact of such a series. However, inaccuracy in the current estimates of vital rates can give projections that inevitably diverge from the actual course of the population, whatever the extent of environmental variability. Measurement error of the temporal variability of the vital rates also exists and may be fairly large. Considering it, however, would require a second-order approximation which we do not address here.

Tossing a coin provides a good illustration of the effect of measurement error on risk analysis. If the probability of tossing heads is known to be p and the probability of tossing tails ($1-p$), well known statistical results concerning the binomial distribution give both the expected number heads after n tosses and the probability that the number of heads will exceed the number of tails by some quantity. We are able to perform a perfect risk analysis for any criterion of risk that we set for ourselves. The particular sequence of outcomes in n tosses is analogous to natural year-to-year variability in the environment. The solid curves in the figure show that the uncertainty about the result increases as the square root of the number of tosses.



Comparison of the uncertainties in coin tossing due to measurement error and due to natural variability. Solid lines are for p=0.50, dashed lines for p=0.54. Each set shows the calculated probabilities of the expected excess of heads over tails and the ranges within which the excess is likely to lie 95% of the time. The ranges expand as the square root of the number of tosses, while the expected means diverge linearly. An initial error of 4% in the estimate of p (0.50 instead of 0.54), yields an excess that, on average, is no longer within the 95% probability range after about 200 tosses; after 700 tosses, the 95% ranges no longer overlap at all.

Now suppose that the initial estimate of p was slightly inaccurate. At first, the difference between the actual and the expected tosses is negligible. Their divergence is linear, however, so that the eventual excess of heads over tails lies well outside the predicted range. Although the analogy between coin tossing and population dynamics is only heuristic, it suggests that measurement error can play a dominant role in limiting our ability to project population trajectories into the future. In general, for long periods of time measurement error may be a dominant cause of our uncertainty about the future, while in the short run natural variability may dominate.

Our analysis of the population dynamics of the spotted owl shows that measurement error dominates in 100-year abundance projections. Crudely speaking, the risk of extinction in 100 years is somewhere between 0% and 100% (not a very informative statement!) because the best available estimates of the mean survival values have significant measurement errors. We can be much more informative on a time scale of 20 to 30 years.

Whether or not ecological risk assessments are expressed in terms of probability statements, all conclusions must be stated with clear reference to their reliability (*cf.* Finkel 1990; Roberts 1990). Any conclusion lacking this reliability statement should be regarded as nonsensical since we have no way to judge its meaning. Uncertainty analysis of measurement error should be used to put error bars on our probabilistic risk estimates.

References

Faber *et al.* (c1992). Toward an open future: ignorance, novelty and evolution. Ecosystem Health: New Goals for Environmental Management, Costanza, R.; Norton, B.G.; Haskell, B.D. (eds.), Island Press, Washington, D.C.

Finkel, A. (1990). Confronting Uncertainty in Risk Management. Center for Risk Management, Resources for the Future, Washington, D.C.

Ginzburg, L.R.; Goldwasser, L.; Ferson, S. (1994). Ecological risk assessment for the northern spotted owl on the Olympic Peninsula. [in preparation].

Roberts, L. (1990). Risk assessors taken to task. Science 248:1173.

Peer Review of Issue Paper on "Uncertainty in Ecological Risk Assessment" by E.P.Smith and H.H. Shugart

Kenneth A. Rose
Oak Ridge National Laboratory

Overall.-- I think the paper contains most of the relevant information but requires significant editing, better choice of examples, and more synthesis. There are also some technical aspects I would like to see addressed. The authors have done a good job of assembling the ingredients for a good issue paper, but more work is required. I think the Framework is very well written and I did not get much more insight into uncertainty in ecological risk assessment from the Issue Paper than I had gotten from the Framework. The case studies are important to bridge the gap between generality (in the Framework and Issue Papers) and specificity (needed for someone faced with performing or reviewing an ecological risk assessment). For the Issue Papers to be useful, they must be very closely linked with the case studies.

8. Editing.--The paper needs a thorough rewrite. Topic sentences do not always match the major contents of paragraphs; some sentences should be clarified or deleted. For example, the second paragraph on page 8-8 begins with "For example, a typical model for demographic analyses would be in the form of ordinary differential equations for each population's numbers." and ends with the sentence "Biology and ecology involve the relationship between geometrical structures of living things and attendant processes.". Terminology is also a little confusing. The paper tries to parallel the Framework and does successfully in the beginning, but then deviates until by the last section on Risk Characterization I had difficulty overlaying the Framework on the Issue Paper. The paper reads as if the two authors wrote separate sections which were then just put together. For example, in Section 2.4 Conceptual Model Formulation we see a list; why a list formatted this way here and only here?

G-6. Examples.--The examples selected by the authors are not always good examples. It appears the authors relied heavily (perhaps too heavily) on their own work for examples, rather than using other more relevant examples from the literature. Also, the use of examples is uneven in the different sections of the paper. Some issues in some sections get several examples while other issues get no illustrative examples. I would have rather seen more even use of examples to illustrate the issues. The approach of Barnthouse and Brown in Issue Paper 3 "Conceptual Model Development" of using two examples throughout the paper is much preferred. Enough details about the examples can be provided so that reader obtains more than 1-2 sentence understanding of the example. Of course, carried too far, this begins to sound like the case studies. Many mentions of different examples, as used by Smith and Shugart, could be effective if better examples were selected and more evenly used throughout the paper.

8. Synthesis.--A major criticism I have of the paper is the lack of synthesis. What are the issues? The paper reads more like a somewhat ad-hoc listing of topics with arbitrary use of examples. I think the paper contains most of the relevant information on the topic. But the information is simply listed without much attempt to synthesize the information. I would the use the criterion of how much more is gained by me reading the Issue Paper versus the 5-10 major papers cited in the Issue Paper. My conclusion with this version of the Issue Paper is that I do not gain much. If this were a review paper submitted to a journal, I would request the authors to synthesize the information. Also, there is too much "see so and so" in the Issue Paper. This is especially unproductive because quite a few of these "see so and so" are references to entire books. The authors should summarize the important information within the Issue Paper. After I finished reading the Issue Paper, I could not succinctly list the major issues associated with uncertainty in ecological risk assessments without careful rereading of the paper. For example, the entire 3 paragraphs in the important section of "Ecosystem Characterization" is devoted to the original definition of ecosystem by Tansely in 1935. What are the issues with uncertainty in Ecosystem Characterization? No mention of uncertainty in feedback loops or indirect effects affecting the predictions of risk, to name just two of the important topics.

8. Technical.--

(a) I am confused by the authors treatment of stochasticity. They define stochasticity as the natural variation in a system (page 8-5). In the following paragraph they imply that stochasticity is "bad" in that it can mask some effects. The critical issue is how should natural stochasticity in the system be included in an ecological risk assessment. If the system of interest exhibits ±5% fluctuations then a 10% effect is significant. If the system exhibits ±100% fluctuations, then is a 5% effect significant? Models are increasingly including stochasticity. Deterministic model predictions will without doubt show an effect; it is the magnitude of the effect relative to the natural variability of the system that is important. There is much confusion in the modelling literature about using Monte Carlo techniques to simulate stochasticity versus the very same Monte Carlo techniques to examine parameter uncertainty. The details of how these two are implemented using Monte Carlo techniques can have major implications on the predicted results. The authors only mention Twari and Hobbie's stochastic differential equations; much has been done since then with most effort devoted to including stochasticity in difference equation population and community models.

(b) The authors contrast simple and complex models by correctly pointing out the increased information demands of complex models (e.g., page 8-18). Just reading the Issue Paper would imply that simple models are better. The authors fail to emphasize that simple models have a history of being grossly in error when used outside the domain of the information upon which they were estimated. Complex models, if configured reasonably with appropriate feedbacks, etc., can perform better outside the domain of observations better than simple models. As many risk assessments involve predictions outside the domain of what has been observed, this feature of complex models should be discussed.

(c) The authors fail to mention some important references. For example, on the topic of model selection, EPA has published a series of Guidance documents for different types of models. These are not mentioned in the Issue Paper.

(d) There are other technical issues I would like to see addressed, but these would be better dealt with in a subsequent version of the Issue Paper.

G-. Case studies.--For this Issue Paper, and the other Issue Papers, to be useful, they need to be very tightly coordinated with the case studies. I personally believe that the case studies will be more informative than the Issue Papers. If closely coordinated, the combination of Issue Papers and case studies could be extremely useful. Without close coordination, the reader will be faced with the almost impossible task of cross-referencing between the case studies and the Issue Papers.

Review by A. Frederick Holland

Comments Paper No. 8: Uncertainty in Ecological Risk Assessment

8-1 Clarity of Purpose and Scope

The Introduction to Issue Paper 8 does not clearly and succinctly define its goals or how these goals are connected to the development of guidelines for ecological risk assessments. This is critical information if EPA scientist will use the paper for development of policy (i.e., guidelines for conduct of ecological risk assessments). The authors should reorganize the Introduction to ensure it accomplishes at least the following: (1) defines what an uncertainty analysis is [the next to last paragraph on page 8-6 is a good start on this], (2) discusses the relationship between an uncertainty analysis and the determination of ecological significance discussed in Issue Paper 2 - Ecological Significance [this topic also deserves a section in this paper], (3) identifies sources of uncertainty (i.e., lack of knowledge, stochasticity, methods error/mistakes -- the first paragraph of the Introduction is a start on this but needs to be expanded - see discussions in Faber et al. 1992 and Suter et al. 1993 for additional details), and (4) relates the evaluation of uncertainty to the steps in the ecological risk assessment process including a discussion of the organization of the issue paper.

8-2 Completeness of Coverage

As will be noted in the discussions below, I think the current objectives of Issue Paper 8 (listed in last paragraph of page 8-7) represent a major problem. This is because these objectives do not lead to a synthesis of what we currently know about the assessment of uncertainty in ecological risk assessments. The current objectives also do not lead to recommendations of future research activities that EPA should pursue related to assessment of uncertainty in ecological risk assessments. The last two sentences of the Introduction are particularly troubling -- "Our purpose is not to present an exhaustive review of all sources of uncertainty and methods for its assessment. Rather, we have attempted to present some of the important aspects of uncertainty as they relate to ecological risk assessment and the Framework, while offering suggestions for dealing with the lack of knowledge". Indeed, the authors did not provide comprehensive coverage of the subject matter. More importantly, however, they did not provide a summary of what is know about assessing uncertainty in ecological risk assessment or which approaches, in their opinion, are most applicable for which kinds (e.g., single species, population, community, ecosystem) of assessments.

I think the major objective of Issue Paper 8 should be to integrate and synthesize what is currently know about evaluation of uncertainty in ecological risk assessments and to use this synthesis to: (1) define a generic process [or at least the steps in a process] for determining the magnitude (relative or quantitative) of uncertainty, (2) develop criteria for evaluating when an uncertainty analysis is adequate or at least determine when an analysis represents the best that can be done using existing technology, and (3) makes recommendations for development of future technology and research. In short, I think Issue Paper 8 should answer the following questions:

- What do we know about assessment of uncertainty ecological risk assessments (i.e., development of a synthesis about the topic - a review paper)?
- What types of uncertainty analyses have others accomplished and when where the results from these uncertainty analyses useful and reliable and when were they unacceptable (i.e., a evaluation of existing methods and approaches - part of the synthesis)?
- What types of research and specific research topics are needed to resolve deficiency in uncertainty analyses?

The completeness of coverage for Section 2 (Problem Formation) is particularly weak. It provides information for only one type of problem (i.e., ecosystem level impacts and risks) and one type of modeling approach (i.e., ecosystem level). As discussed in Issue Paper 2 (Section 3.2), ecological changes occur at all levels of ecological organization (individual, population, community, and ecosystem). In addition, single species population level assessments are, in my opinion, the only ones for which we presently have the empirical and theoretical basis on which to base reliable risk assessments. Ecologists just do not understand trophic dynamics and ecological processes well enough for many ecosystems to predict and understand the consequences of anthropogenic impacts except in very general terms. Ecologists can not even agree on the appropriate endpoints to measure for risk assessments at the community and ecosystem levels. Therefore, assessment of uncertainty for single species population level assessments probably deserves more consideration than it is given in Issue Paper 8. Section 2-6 (Summary) should in my opinion be the introduction or starting point for Section 2 rather than the conclusion.

Additionally, the discussions in Sections 2.1 - 2.5 do not adequately discuss the impacts of model structure, formulation, system characterization, or implementation on the uncertainty of predictions. All these sections do is point out that decisions/choices made during these phases of a risk assessment affect outcomes. It is critical that the discussions in Sections 2-1 to 2-5 provide examples of the effects different model structures, formulations, and implementation have on uncertainty for different types of risk assessments. Such examples would provide the EPA scientists who will be responsible for development of risk assessment guidelines with an understanding of the consequences that decisions made during the problem formulation phase have on assessment of risk and the associated uncertainty. See 8-6 below for a discussion of how the range of models used to evaluate the risks of power plant operations on fisheries may represent an excellent case study for Issue Paper 8.

8-3 Clarity and Consistency of Terminology

If the audience for the series of issues papers is the EPA scientists who will be responsible for development of Guidelines of Ecological Risk Assessment then a glossary is probably not needed. In general, the authors of Issue Paper 8 used accepted terminology. There are, however, a few instances where jargon (e.g., the use of the word "sizing" in the last paragraph on page 8-30 or "input mapping" in the first paragraph on page 8-32) needs to be removed during the editing process or better explained.

8-3 Current Capabilities vs. Future Needs

The discussions in Sections 3 (Analysis-phase Uncertainty) and 4 (Risk Characterization) not only do not provide complete coverage of their subject areas (i.e., a synthesis in the context discussed above), they also do not provide recommendations of future needs. For example, no context for the manner in which the severity of impact, reversibility of effects, duration and timing of exposure, etc affect uncertainty in ecological risk assessments is provided. A series of figures similar to Figure 1 below would provide agency scientists responsible for developing risk assessment guidelines with a set of heuristic tools for identifying the classes of risk assessments when reliable estimates of uncertainty are critical.

Figure 1. Degree of Reliability Required by Uncertainty Analysis

Case 1: Relationship to Severity of Impact

		Uncertainty	
		High	Low
Severity of Impact	High	Quantitative uncertainty estimates desired	Semi-quantitative uncertainty estimates acceptable
	Low	Semi-quantitative uncertainty estimates acceptable	Qualitative uncertainty estimates acceptable

Case 2: Reversibility of Impact

		Uncertainty	
		High	Low
Reversibility of Impact	High	Semi-quantitative uncertainty estimates acceptable	Qualitative uncertainty estimates acceptable
	Low	Quantitative uncertainty estimates desired	Semi-quantitative uncertainty estimates acceptable

8-3 Current Capabilities vs. Future Needs

Any assessment of the uncertainty in models used for a risk assessment must answer the question "How reliable and credible are analysis results?" (e.g., see Oreskes et al 1994, Reckhow and Chapra 1983, Suter et al. 1987, Levins 1966 - I am sure there are probably other relevant literature of which I am unaware on this topic). Models are black boxes to many risk managers including some of the EPA scientists who will be responsible for developing the guidelines document. As a result, a discussion of importance of knowing the assumptions and limitations of models and examples of the effects model assumptions have on the risk characterization and estimates of uncertainty is critical to understanding limitations and strengths of analysis results. In addition, as Suter et al. (1993), and many others, have suggested application of multiple models with different assumptions and endpoints is a reasonable approach for identifying and evaluating uncertainties associated with various model structures and modeling approaches. In Sections 3 and 4 the authors need to expand discussions of the processes that can be used to verify, validate, and calibrate models.

Section 3.1 provides a very general description of the literature on experimental design and the power of the test to reject the null hypothesis. Unfortunately, this discussion is not sufficiently detailed for developing national policy (i.e., guidelines) for risk assessments. For example, it does not include a discussion or criteria for deciding when high power is needed (e.g., when the potential for ecological significance is high), and when it may be acceptable to use less powerful sampling designs (see Figure 2 below). The discussion in Section 3 also needs to elaborate on the association between power and ecological significance. In addition, the discussion in Section 3.1 does not provide any guidance for increasing the power of the test (e.g., it does not include an evaluation of the degree to which a covariate would improve the power or the change in power that would be associated with use of a different test metric).

Figure 2. Decision matrix for evaluating the relationship between severity of impact, ecological significance and the power of the test.

		Ecological Significance	
		High	Low
Severity of Impact	High	High power required	Low power acceptable
	Low	Very high power required	Low power acceptable

A important issue the authors need to address in Sections 3 and 4 is to define the steps in a process that can be used for reducing uncertainty in the design of risk assessments. The process that is developed must be compatible with and build upon EPA's existing Data Quality Objectives Process (e.g., see Boesch et al. 1990 for a discussion of how to design a monitoring program to reduce uncertainty and increase power or Downing 1979 for some of the problems associated with sampling invertebrate populations as it relates to increased power). In addition, the authors should develop criteria that can be used for assessing when the power of an assessment is inadequate since high power and high costs are positively correlated. Ultimately, the "real" question risk assessors must address is "How much power is adequate given the available dollars?" Some simple discussions about how cumulative frequency distributions and cumulative probability functions such as those on pages 45-46 of Suter et al. 1993 may help with these discussion.

The conclusion/guidance on page 8-23, end of 1st paragraph, that "safe level from simple studies must be viewed with some suspicion" needs a better explanation and additional details including a review of the literature. For example in a classic review, Levin et al. (1984) describe the broad range of sensitivity of biota to toxicants that characterize natural ecosystems and suggest that assessments of risk based on acute bioassays of relatively few species are likely to provide inadequate assessments of risk. The question, however, is how many tests are required, of what type and for what species. I am unfamiliar with the toxicology literature, but I am sure that this question has been addressed. This discussion must be expanded.

The treatment of the uncertainties associated with extrapolations in Section 3 would greatly benefit from use of examples such as that presented in Suter et al. 1993 (pages 239-246). Such examples, could also be derived for extrapolations from one population to another (e.g., Barnthouse et al. 1990) on one ecosystem to another (Sloof et al. 1986). In my opinion, it would be sufficient to summarize/synthesize what these other authors have accomplished as part of Issue Paper 8.

8-5 Relationship to EPA's Framework for Ecological Risk Assessment

I found the discussion of uncertainty in the Framework document so general that it provided little insight into how to estimate the magnitude of uncertainty or determine if it was in acceptable ranges. The Framework document is so general that it is no more valuable to the risk assessor than "common sense". Issue Paper 8 expands upon the categories of uncertainty defined in the Framework document; however, Issue Paper 8 does not elaborate upon the relationship between the weight of the evidence discussions in the Framework document and the uncertainty analysis process. It also does not tell a risk assessor when an assessment of uncertainty is critical to interpretation of assessment results, how to estimate uncertainty, and what criteria should be used for determining if uncertainty is concordant with conclusions.

8-6 Examples

The authors of Issue Paper 8 reference some of the relevant literature as examples. Unfortunately, the examples they reference are biased toward ecosystem-level assessments of terrestrial systems and do not represent a cross section of system or assessment types. The authors also do not use examples/case studies to demonstrate the value of uncertainty analysis to the environmental decision making process. Issue Paper 8 would benefit from inclusion of examples of estimating uncertainty in ecological risk assessments for aquatic ecosystems (e.g., Cirone and Pastorak 1993) as well as organism and population level assessments (e.g., Barnthouse et al 1988). Suter et al. (1993) provide many additional examples that could be summarized and presented as part of Issue Paper 8.

In addition, the many different types of models that have been used to assess the risks of power plant operations on fisheries. This problem may provide a good case study for describing the effects decisions made during problem formulation phase have on results and reliability of results. Using available data from the many 316 Demonstrations that have been conducted for power plants, it should be possible to construct a table that contrasts estimates of entrainment losses and uncertainty in those estimates for several fish populations each with different life histories. Model structures in the case study would range from the simple formulations of Horst (1975) and Goodyear (1978) to the more complex formulations of Boreman et al. (1981) to the very complex formulations of Hackney et al (1980) and Christensen et al. (1977) to the system level formulations of Rago (1984). Swartzman et al. (1978) provides a partial review of these models. Power plant 316 Demonstrations have been conducted for many different aquatic environments (river, lake, estuary, coastal ocean).

Other examples that should be included in Issue Paper 8 include: the impact of life history/space/time interactions on model predictions (e.g., Hastings and Higgins 1994) and the impact of life history on population assessments (e.g., May 1974). For example Section 4.2.1 would benefit from additional details and examples from Rose et al. (1991).

Cross-cutting Issues

C-1 Terminology

There appears to be a problem with the use and interpretation of the term "Ecological Risk Assessment". Some of the issue papers appear to focus much of their discussion on ecosystem level impacts/risks where other papers discuss risks at multiple levels of organization. I think the term ecological risk assessment needs to be clearly defined in a forward/introduction to document containing the series of issue papers and clearly applied throughout the papers. Page 2 of the Framework document provides a reasonable definition of "Ecological Risk Assessment".

Of particular importance is the definition of how ecological risk assessment differs from ecological impact assessment as defined under NEPA. Suter et al. (1993) state "The most important feature distinguishing risk assessment, as discussed in this book, from impact assessment is the emphasis in risk assessment on characterizing and quantifying uncertainty." This quote requires some discussion. More importantly, if this quote is valid/true, Issue Paper 8: Uncertainty in Risk Assessment becomes a particularly important paper that may require substantial revision to address all the relevant issues raised by this quote (e.g., the existing general discussion of uncertainty associated with extrapolation may need to be expanded to include examples of the consequences of extrapolations).

C-2 Population Level Risk Assessments

As Lev Ginzburg has discussed in his comments, single species population level risk assessments probably represent the highest level of organization at which predictive assessments can be conducted with in degree of reliability and creditability. The basic problem at higher levels of organizations ecosystems are very complex and ecological theory has not even develop generally accepted endpoints.

C-3 Need for Baseline Information on the Status and Trends of Ecological Systems

A conclusion that can be inferred from many of the Issue Papers is that baseline information on the status and trends of natural ecosystems is critical information for assessment of ecological risks. Status and trends information would be especially useful for determinations of ecological significance (Issue Paper 1) and estimation of uncertainty (Issue Paper 8). None of the issue papers, however, recommend: (1) the spatial scale at which baseline information should be collected (e.g., watershed, regional, national) and what approaches should be used to insure the data that are collected by monitoring programs like EMAP are "representative" and not biased by sampling at sites where data are easy to collect, (2) what parameters, or type of parameters, should be measured by status and trends monitoring programs (e.g., should status and trends information be collected for all levels of organization or just some, should exposure measurements be included), or (3) the most appropriate temporal scale for collecting status and trends information for it to useful for ecological risk assessments (e.g., are samples collected once per year during a critical period adequate or are more frequent collections required). All of the Issue Papers need to address the above questions in their text. This is particularly important since the National Monitoring Act has recently been passed and EPA and NOAA has been charged with answering these questions as part of this act.

References

Barnthouse, L.W.; Suter, G. W.; Rosen, A.E. 1988. Analysis of impingement impacts on Hudson River fish populations. American Fisheries Society Monograph 4:182-190.

Barnthouse, L.W.; Suter, G. W.; Rosen, A.E. 1990. Risks of toxic contaminants to exploited fish populations; Influence of life history, data uncertainty, and exploitation intensity. Environmental Toxicology and Chemistry 9: 297-311.

Boesch, D.F.; Schubel, J.R.; Berstein, B.B.; Eichbaum, W.M.; Barber, W.; Hirsh, A.; Holland, A.F.; Johnson, K.S.; O'Connor, D.J.; Speer, L.; Wiersma, G.B. 1990. Managing Troubled Waters: The Role of Marine Environmental Monitoring, National Academy Press, Washington, DC.

Boreman, J.C.; Goodyear, C.P.; Christensen, S.W. (1981). An empirical methodology for estimating for estimating entrainment losses at power plants sited on estuaries. Trans. Am. Fish. Soc. 110: 253-260.

Christensen, S.W.; Matthews, C.P.; Clark, A.G. 1977. Development of a stock-progeny model for assessing power plant effects on fish populations. pgs 196-226. In: Assessing the Impacts of Power-plant-induced Mortality on Fish Populations, W. Van Winkle (ed). Pergamon, NY.

Cirone, P.A.; Pastorak, R.A. (1993). Ecological risk assessment case study: Commence Bay tidelands assessment. In: A Review of Ecological Assessment Case Studies, EPA/630/R-92/005.

Downing, J.A. 1979. Aggregation, transformation, and the design of benthic monitoring programs. J. Fish. Res. Bd. Can. 36: 1454-1463.

Goodyear, C.P. 1978. Entrainment impact estimates using the equivalent adult formulation. U.S. Fish and Wildlife Service, Biological Services Program, Washington DC, Report No. FWS/OBS-78/65.

Hackney, P.A.; McDonaugh, D. L.; De Angelis, D.L.; Cochran, M.E. 1980. A partial differential equation model of fish population dynamics and its application in impingement impact analysis. EPA/600/780-068 and TVA EDT-101, March 1980, 52 p.

Hastings, A.; Higgins, K. 1994. Persistence of transients in spatially structured ecological models. Science 263: 1133-1136.

Horst,T.J. 1975. The assessment of impact due to entrainment of ichthyoplankton. pgs 107-118. In: Fisheries and Energy

Production: A Symposium, S.B. Salia (ed), D.C. Heath, Lexington, MA.

Levin, S.A. et al. 1984. Perspectives in ecotoxicology. Environmental Management 8: 375-442.

May, R.M. 1974. Biological populations and nonoverlapping generations: stable points, stable cycles, and chaos. Science 186: 645-647.

Oreskes, N; Shrader-Frechette, K; Belitz, K. 1994. Verification, validation, and confirmation of numerical models in the earth sciences. Science 263: 641-646.

Rago, P.J. 1984. Production foregone: an alternative method for assessing the consequences of fish entrainment and impingement losses at power plants and other water intakes. Ecol. Model. 24:79-111.

Reckhow K. H.; Chapra, S.C. 1983. Confirmation of water quality models. Ecological Modeling 20: 113-133.

Sloof, W.; van Oers, J.A.M.; de Zwart, D. 1986. Margin of uncertainty in ecotoxicological hazard assessment. Environmental Toxicology and Chemistry 5:841-852.

Suter, G.W.; Barnthouse, L.W.; O'Neill, R.V. 1987. Treatment of risk in environmental impact assessment. Environmental Management 11: 295-303.

Suter, G.W.; Barnthouse, L.W.; Bartell, S.M.; Mill, T.; Mackay, D.; Paterson, S. 1993. Ecological Risk Assessment. Lewis Publishers, London.

Swartzman, G.L.; Deriso, R.B.; C. Cowan. 1978. Comparison of simulation models used in assessing the effects of power- plant-induced mortality on fish populations. NUREG/CR-0474/UW-NRC-10/RE. College of Fisheries, University of Washington, Seattle, WA.

Risk Integration Methods

Workgroup Leader:	Dr. John Bascietto Dept. of Energy
General Reviewer:	Dr. Peter Van Voris Battelle-Pacific Northwest Laboratories
General Reviewer:	Dr. John P. Giesy Michigan State University

Pre-Meeting Comments Submitted to Versar, Inc. On Behalf of U.S. EPA Risk Assessment Forum - July 29, 1994.

RISK INTEGRATION ISSUE PAPER

PEER REVIEWER: John Bascietto
U.S. Department of Energy
Washington, D.C.

1. p. 9-5, 1: The definition of risk characterization referenced to AIHC, 1992 states that it is a process which renders the relevant information "comprehensible to a diversity of users." While it certainly should do this, the use of risk integration, as the term is used in the Framework (i.e., as the first step in risk estimation, is clearly focused on the risk assessors and risk managers. While this is not contradictory to the AIHC definition, it is perhaps a point for clarification in the issue paper.

2. p. 9-5, 1: The first paragraph of the Introduction discusses the intent of this paper, but flows directly to issues discussed not in this paper, but in the Framework (i.e., the exposure profile and stressor-response profile). A more crisp break between the issues discussed in each document would help to set the stage in a less confusing way.

3. p. 9-8, 3: The review of the initial stages of risk assessment described by the Framework, fell a little flat. I did not get a sense that this review was performed for the purpose of introducing risk integration. Consider providing more commentary on the salient risk integration issues posed by these initial Framework sections, which the authors feel warrant particular attention by the readers (e.g., see next Comment Nos. 4, 5, and 6 below). I would rather see a discussion of how the risk integration approach will flow from the initial stages of the risk assessment. Is there a systematic thought process one uses to proceed from Analysis to Risk Estimation, for example?

4. P 9-8, 3.1: the discussion focuses narrowly on the science issues. The authors should consider that the Problem Formulation must also provide a absolutely essential link to the regulatory and policy context of the risk assessment. The resolution of certain regulatory and policy issues may provide valuable direction later, as to the acceptability of some the potential risk integration methods. These issues may be touched upon in Program Office guidance documents.

5. P 9-8, 3.1: Consider providing an example of how "scale, level of resolution, and available information" assist in selecting risk integration tools.

6. P. 9-9. 3.1: Two of the important activities of the Problem Formulation phase (according to the Framework) are: 1) development of a conceptual model; and 2) selection of endpoints. Although these activities occur prior to risk integration, what are the salient integration-related issues to be considered by the risk assessor at these initial stages in the process?

7. P 9-9, 3.2: Would it be more appropriate to state that "the risk integration technique must be compatible with the data for effects and exposure" instead of the current construction: "effects and exposure data need to be compatible with the risk integration"); and if not, what are the important issues and circumstances which make the current construction appropriate?

8. P 9-10, 4.1.1: In the discussion of Single-Value Comparisons the term "application factor" is used to describe an adjustment that is made to the toxicity benchmark. There may be some confusion result from this term, as it is variously called "safety factor" and "uncertainty factor" by various EPA Program Offices, and other risk assessment guidelines. The Workshop participants could provide guidance to the authors on this and the other issue papers on the use of the term.

9. P 9-10, 4.1.1: It is not always true that assessments employing the quotient method (QM) "assume that exposure concentrations are invariant in space or time." While this is a certainly a limitation of the QM and a common criticism, most assessments I been involved with readily acknowledge the limitation, and do not assume invariance. Nevertheless, the substance of the authors' point is well taken and obviously must be acknowledged.

10. P 9-10 and 9-11, 4.1.1: A very brief explanation of the demonstration by Breck et al (1988) would help clarify the point on implications of spatial-temporal variability in exposure toxic effects for fish populations exposed to aluminum.

11. p 9-11, 4.1.1: Again, I disagree that quotient method assessments routinely assume that effects data are suitable for extrapolating directly to the field (see above comment No. 9 on use of concentration data in QM). EPA QM assessments I've been involved in routinely acknowledge the weaknesses associated with this procedure. Nevertheless, the substantive point is well taken.

12. p. 9-12, 4.1.2: The authors state that in joint distributions calculations, the risk is the probability that the exposure concentrations and the concentrations correlated with measurable effects represent the same underlying statistical distribution, and that risk is the probability that the two distributions overlap perfectly. It would be very useful to the reader to have this graphically illustrated; also consider providing any examples possible imperfect overlaps, their interpretation and implications for risk estimation, and the associated graphics. The same comment pertains to the discussion of the risk as the degree of overlap of a distribution of exposure concentrations with a benchmark point estimate.

13. p. 9-13, 9-14 1and 9-15 4.1.3 and 4.1.4: Consider providing graphic illustrations/ examples of Regression analysis and Fuzzy Sets. Also consider providing a brief discussion of the implications of use for regression models (when? where?) and their limitations in ecological risk assessments; N.B.- there is a specific discussion in the special model discussions, but the authors should provide some generalized guidance on regression model analysis at point.

14. p 9-15, 4.1.4: The discussion of Fuzzy Sets and Fuzzy Arithmetic could benefit by a brief discussion of how the authors believe this approach would be communicated to decision-makers an the public.

15. p 9-18, 4.1.6: The authors suggest that the parameters and coefficients in the models of Individuals may have little or no meaningful interpretative value that could help assessors and risk managers understand relationships or develop and evaluate mitigation or remediation alternatives. This is no small point, since in programs like Superfund and RCRA (which have driven much of the efforts on ecological risk assessment guideline development), project and risk managers are likely not to focus on (or even perform) studies which do not tell them anything about remediation. Therefore, this line of discussion needs to more fully fleshed out, particularly in the guidelines development process.

16. p. 9-19, 4.2: There is a very interesting commentary on the traditional biological level-of-organization terminology, which the authors state has become "ecological shorthand", which can act to suppress "conceptually powerful alternative approaches to description, study, and understanding of Nature." The reader would certainly have appreciated more insight into what the authors' feel are "Nature's essentials", i.e., that which is being glossed-over by the use of "ecological shorthand."

17. p.9-20 and 9-21, 4.2.2: provide definition or explanation of the term "ecologically relevant population", and provide consistency with the term "ecologically important population". It would also help if the authors could provide some preliminary thoughts, specifically as how assessors should go about "rigorously and meaningfully" defining the populations which are the subjects of risk assessments.

18. p 9-21, 4.2.2: The authors make a very good point regarding the limitation on effective application of population modelling in ecological risk assessment, due to difficulties in deriving disturbance-response functions for use in altering model parameter values in relation to the degree of disturbance. A discussion and perhaps graphic illustrating how such models are nevertheless used would be particularly beneficial here.

19. p 9-41, 4.6: The endpoint selection criteria discussion seemed more appropriate for the Problem Formulation review section up front (see comments Nos. 3 & 4 above). Discussion in Section 4.6 could focus more on how natural variability is handled in specific risk integration methodology.

20. p 9-43, 4.8: After the resistance and resilience have been evaluated, how should they be handled in specific risk integration methodology?

21. p 9-45, 9-46 and 9-47, 4.10: As a general comment, there needs to be a clearer differentiation between the discussions of recovery to pre-disturbance baseline state, as opposed to recovery between "healthy", post-disturbance state.

22. p 9-53, 5.3: The authors have associated the term "Weight- of- evidence" with the balancing of risks with the other dynamic factors such as worker health and safety, cost-benefit analysis, social and political considerations) which is essentially a risk management, not risk assessment function. EPA has used what it has called the "weight-of-evidence" approach to characterizing (i.e., risk integration in this context) ecological risks, particularly risks to non-target organisms resulting from applications of pesticides, which could be termed a semi-quantitative risk assessment methodology. What, if anything, should be presented, in terms of this apparent risk integration methodology?

Risk Assessment Forum
Ecological Risk Assessment
Issue Paper
Peer Review Workshop

Pre-Meeting Comments
Risk Integration Methods
by
Peter Van Voris

1.0 Introduction: - Page 9-5

The Introduction addresses those items which the Framework document covers as well as those issues addressed in this particular issue paper. It states that the Framework Report identifies several approaches that can be used to characterize ecological risk and then goes on to list three critical elements. However, it does not state if the following factors are addressed or considered: (1) whether or not comparisons can be made between cumulative effects of single or multiple stressors, (2) it does not state whether or not the system conditions prior to or during the stress event are important factors, (3) whether or not spatial/temporal factors important to the system at risk are considered in the integration of risk, (4) whether or not system susceptibility or adaptation or sequestration of a stressor are accounted for in the process of integration of risk, and (5) whether or not the current trajectory of the system and its components are considered within the framework.

3.1 Problem Formulation Page 9-8

The authors state that the scope of the risk to be characterized and the level of biological organization population, community, landscape, and larger must be identified but do not provide an example of how one can effectively limit the assessment to a given level of ecological organization. Additionally, the status or condition of the system (system state variables) are not mentioned as important to defining the problem; only the type of ecological stressors are provided as examples.

Reviewed by PVV

The last paragraph of 9-8 allude to "evaluation of the decision-makers requirements to (1) discuss how these requirements further constrain the studies" - This makes it sound as if a complete and full assessment of the risks can be sublimated by the decision-maker. This reviewer takes this to mean that the decision maker can control the out come of (1) risk characterization; (2) risk assessment and (3) risk management in an a prior way.

4.0 Risk Characterization page 9-10

The authors have provided a good assessment of the Single-Value Comparison quotient methods and its limitations. They have clearly identified the assumptions made and they have assess the validity of making comparisons of ratio of exposure concentration to a toxicity benchmark that is based on toxic chemicals. They have also identified the issue of suitability of extrapolating the tox data derived on single species or populations to field conditions. - This reviewer would find it useful if further discuss could be provided on the reliability of the values referenced in table 3 and the Suter (1992) "empirical validity" reference. This reviewer finds it valuable that this paper places in prospective the value of the single quotient method - i.e., for "screening purposes or assessing comparative effects of natural or human caused disturbances". Additionally, the authors do an excellent job of reminding the reader that the quotient method is difficult if not impossible to integrate with any assessment endpoint because the quotient does not share the same distribution as probabilities.

4.1.2 Joint Distribution - page 9-11

The discussion of joint distributions is well done and uses an excellent example to drive home a point in paragraph two; however, it again shows the limits of this approach in that in joint distributions the limits are placed on determining the probability that the exposure concentrations distribution overlap with the measurable effects distribution. This discussion points out that this method allows one to address the spatial and temporal patterns of the stressor but it does not address how the spatial and temporal patterns of the target organism, population, community, system, or landscape play in the risk characterization processes.

Reviewed by PVV

4.1.4 Fuzzy Sets and Fuzzy Arithmetics

It is not clear to this reviewer where this section is leading - it needs a practical example of the use of this approach to risk characterization.

4.1.5 Extreme Events Analysis

This section starts off well but needs an example to carry the relevance of EEA for empirical methods of risk characterization. An example of the value of an extreme event such as the risk of nuclear mishaps or comet/Jupiter collision and its effects would be worth while.

4.1.6. Advantages and Disadvantages

Is this section a compilation of the value and limitation discussions that have been previously provided. I was not expecting this section after the discussion of the pros and cons of each methods.

In paragraph one of Advantages and Disadvantages the discussion seems to be limited to single chemical events that rely on the standard factors such as bioaccumulation or organics - and ignore factors such as metabolism or such compounds as well as sequestration of a stressor to avoid exposure. Compensatory mechanisms are not a factor or are they.

Finally, this reviewer believes that a more effective way of showing the Advantages and Disadvantages would be to take the same set of examples through each model approach and finish with a table showing how each approach characterized the risk

4.2 Process Models - page 9-18

The general presentation of the Process Models section is much stronger and is very well written. The authors do a good job of identifying the fact that these types of models represent "a priori sets of hypotheses about causal mechanisms operating in the system" - This reviewer thinks that the authors should expand on this point - identifying the limitation with examples of modeling the process based on one hypothesis versus another.

Reviewed by PVV

The authors predict that process models will see increasing use in risk characterization based on the shear number of assessments that will need to be performed. They state that in some instances using process models will allow the analyst to avoid the experimental evaluation of the disturbance and models are the "only" alternative. This reviewer agrees but - other model systems can be used to test a subset of the disturbance and the use of "only" might be a little strong.

The discussion of the levels of ecological organization is important and the reader should be advised that this issue paper will use this approach to segregate the various models that have been used for risk assessments.

4.2.1 Models of Individuals

This issue paper reviews IBMs and this reviewer believes the authors have wrongfully included the FORET model in this class of models. The gap models are clearly based on individual dynamics but the output parameters are for individuals, populations and community properties. Should this type of model be considered to be a bridging type model.

4.2.2 Population Models

The authors have done an excellent job of reviewing population type models; however, should this section be subdivided to separate the population type models from the bioenergetics approach. Additionally, if there are examples of each that have been used for "ecological risk characterization" this reviewer would like to see how they have been used.

4.2.3. Community Models

The authors have provided a good general review of the community concept and the associated models and suggest that these models offer some potential for assessment of food web impacts. More examples of the potential applications of community models are needed in this section.

4.2.4 Ecosystem Models

This reviewer is pleased that the authors choose to address up front the issue of "ecosystems" and the value of feedback mechanisms in determining system functional integrity as well as system recovery. However, they almost

Reviewed by PVV

casually suggest that "advances in ecosystem understanding should be considered carefully in the development of ecosystem-level endpoints for risk analysis" - It seems as if we have moved from risk characterization to risk analysis without a true transition. Additionally, the authors could expand the types of citations such that they cover the various types of ecosystems - lakes vs. streams vs. rivers and other types of examples for terrestrial ecosystems.

4.2.5 Landscape and Regional Models

The authors have done a reasonable job of reviewing the ecological models that have been used in landscape and regional risk assessment; however, they have overlooked several recent articles that have been published in the Int. J. Geographical Information Systems.

A copy of Van Voris et al., 1993 is attached to this review for the authors consideration. This article is entitled "**TERRA-Vision** - the integration of scientific analysis into the decision-making process" - Here TERRA stands for Terrestrial Environmental Recourse Risk Assessment - Visioning System - and it uses a FORET forest growth gap model over large geographic areas (one latitude by one longitude) using a Cray computer as the processor coupling the data output to a GIS. This system was used to address concerns with global climate change over a variety of geographical areas and support decision makers with a way to embed scientific analysis into the decision-making process.

4.2.6 Aggregation and Disaggregation

The authors might better address this issue by attacking the problem from the angle of scaling modeling output - articles written by Ken Perez from EPA Narragansett should be sought to support this area.

4.2.7. Implementation

I'm not sure why this section is needed - if we had parallel structure then we would have Advantages and Disadvantages of Process Models and the implementation issues could be address under this section.

Reviewed by PVV

4.3 Physical and Experimental Models - 9-34

I would have hoped for a more balanced presentation by the authors for the reader. After having spent approximately 30 pages on mathematical and statistical models and how to apply these to risk assessment, I would have hoped for something more than a short paragraphs dealing with "Cosms" and approximately a page dealing with Field-Scale Experiments. Additionally, the citations are limited and for the most part are quite dated. Strongly suggest that this section be expanded to address the application of both physical and experimental models and how to couple these systems with mathematical models as well as the advantages and disadvantages of Cosms and Field-Scale Experiments.

4.4 Example Application

The chapter headings don't appear to be logical - 4.4.1 Phosphorous-Loading Models - 4.4.2 Toxicity Risk Models in Ecosystem Context - then 4.5 jumps to Uncertainties. The authors might want to reconsider the structure of the issue paper and its organization.

4.5 Uncertainties

Again the structure and organization of the issue paper seems to have broken down - I would have organized the paper to have this section in the process model section.

4.5.3 Model Validation

I would have included "Cosm" validation in this section - see Van Voris, P., D. A. Tolle, M. F. Arthur and J. Chesson. 1983. Terrestrial Microcosms: Validation, Applications, and Cost-Benefit Analysis. In: Multispecies Toxicity Tests, ed. J. Cairus, Jr.

4.6 through 4.10

Reviewed by PVV

These sections seem to be a compilation of a variety items that could be reorganized into other sections. Also, more examples and demonstrations are needed throughout the sections.

5.0 Risk Summary

As stated previously, the organization of the issue paper needs to be reconsidered - some of the early sections could be moved into this section.

Reviewed by PVV

Risk Assessment Forum

Ecological Risk Assessment Issue Paper
Peer Review Workshop

Pre-meeting comments
Risk Integration Methods

By

John P. Giesy

August 10, 1994

General Areas for Consideration:

G-1. Clarity of purpose and scope.

The paper is well organized and clearly written.

G-2. Completeness of coverage.

The paper is very comprehensive.

G-3. Clarity and consistency of terminology.

The terminology is clear and consistent

G-4. Current capabilities vs. future needs.

There is little information on what additional technologies are needed or how they would be used. There is some coverage of how current technologies would be used.

G-5. Relationship to EPA's framework for ecological risk assessment.

The document is not organized to address particular sections of the framework for risk assessment directly.

G-6. Examples

There are a few examples but there could be more concrete examples. Also, tables or figures would be good to illustrate concepts.

Questions Relevant to Risk Integration Methods Chapter:

9-1. Physical and experimental models are included as risk integration tools. Is this correct, or should these models be considered as analysis phase methods?

Yes. I feel that this is correct. Both types of models need to be presented and discussed

9-2. What examples can be provided regarding the application of fuzzy set theory to ecological risk assessments?

Here some numerical examples would be helpful. I suggest that some figures would also be helpful.

9-3. How (if at all) should the paper be changed to better differentiate current capabilities from future research needs?

See specific comments on each section.

9-5. What changes, if any, should be made in the balance between the various sections of the report.

See specific comments on specific sections of the paper.

Comments on specific sections of the discussion chapter.

General:

1) The chapter, as currently written, focuses on aquatic systems. Additional information and examples could be presented on terrestrial systems.

2) I suggest that more information on scaling of the various models be added to the discussion.

1. Introduction:

1) The introduction should include as discussion of the ecological uncertainty principle, in the context that the framework will be improved incrementally by better and better simulation models or improved quantity and quality of information on the parameters used in simulation models.

4. Risk Characterization

4.1 Empirical models

1) All conceptualizations of ecosystems are simplifications of the "real world" and their responses to stressors are simplifications. Even if these simplifications are made in such a manner to explain most of the variation in an ecosystem, it is unlikely that accurate predictions can be made in a generalized manner. This must be recognized as a basic limitation of models. Since there are multiple parameters that have incremental effects on the responses of systems to stressors it will remain impossible to predict, a priori, effects that have not been observed previously with any certainty.

2) The models used in the risk assessment process should be structured in such a way that they are protective of ecosystem

function, but need not be predictive. The only way to do this is to disaggregate the system into constituent elements. I suggest that these elements are, in fact species. If one uses a range of species of known general sensitivities to stressors it is likely possible to protect ecosystem functions with a high degree of certainty, but will be impossible to predict the actual trajectory that a stressed ecosystem will take.

3) I suggest that probableistic models be used in this context. I suggest that simulation models will be more useful for the exposure portion of the risk function than the hazard portion.

4) The approach suggested by the EPA Framework will work with individual chemical stressors, but currently does not have the sophistication to deal with multiple chemical stressors or physical stressors.

5) The structure of neither the EPA framework nor the method suggested in the position paper will effectively deal with community-, ecosystem- or landscape-scale perturbations. An example of the use of the framework with incremental habitat loss would be useful. Estimation of the duration and intensity of exposure can be effectively estimated by some simulation models. This information can be compared to a probability distribution of effects on individual species. A great deal about ecosystem function can be predicted by an expert system from the probability of effects on different species without the use of integrating statistical or simulation models at the community or landscape-levels of organization. This may allow one to predict most probable safe concentrations in the ecosystem, but will not allow for effective prediction of effects.

6) Effects on top predators will be most difficult to predict from the current framework.

7) Multi-generational studies of effects of chronic exposure to chemical stressors under ecologically relevant conditions should be included in the risk assessment process.

8) The recommendations of the Aquatic Effects Dialogue Group on the risk integration methodologies should be included in the current document.

9) This section needs a discussion of the theoretical limits of uncertainties of models.

4.1.1 Single-value Comparisons

1) Do not use arbitrary safety factors in the risk assessment process. These should be added in the risk integration section of the process.

2) P. 9-11 Para. 2: The authors state that the empirically derived application factors given in Table 3 were empirically

derived. More discussion of these factors and how they were derived is needed.

3) P.9-11 Para 3: I agree that these types of quotients should not be considered to be quantitative risk assessments. Do not use any single value quotient methods in ecological risk assessments without considering the types and extents of adverse effects to be incurred.

4) I agree that most models are empirical. For this reason, most risk assessments of chemical stressors will need to rely, at least in part, on historical information on similar compounds or with similar chemical and physical properties.

5) Section 4.1.1 need more examples. These should include uncertainties introduced by pulsed exposures, multiple stressors and transformation products of stressors.

6) Section 4.1.1 needs more discussion of uncertainty factors and how they will be integrated into the risk integration methodologies. A discussion of error analysis and how it could be used in the risk assessment process would augment this section.

4.1.2 Joint Distributions

1) Better models of toxic modes of action will be needed if the predictive power for multiple chemical stressors is to be develop.

2) I suggest that probableistic models be used in this context. I suggest that simulation models will be more useful for the exposure portion of the risk function than the hazard portion.

3) P. 9-11 Para 4. I endorse the suggestion that there is a need for more realistic assessments by the use of probability distributions (see AEDG document, US EPA).

4) P. 9-12 Par. 4 L. 2 I disagree. The information can not and should not be random, but rather directed based on previous knowledge of the system or stressor of interest. It should be endeavored to include a range of uncertainties, such as critical species or life stage. Caution should be taken so that the complete range of possibilities is included in the analysis such that the probabilities derived are not a function of the values chosen as starting values in the analysis.

NOTE: Furthermore, when these probabilities are calculated the endpoints chosen must be consistent and duration and intensity of exposure to the stressor included.

NOTE: These types of probableistic models will need to specify the appropriate target receptor (organism of sub-organismal or even a function) and be coupled to simple factors that will affect the receptor and thus it's response to the stressor. This should be done in a tiered approach (see AEDG report from EPA).

4.1.3 Regression Analyses:

1) Regression models were noted, but what about the use of quantitative Structure Activity (QSAR) effect models? More on this topic, including a state of the science should be added to the chapter.

2) P. 9-13, Para 3: Add that this can include compounds (see reference by Giesy and Graney, 1989).

Giesy, J. P. and R. L. Graney. 1989. Recent developments in and intercomparisons of acute and chronic bioassays. Hydrobiologia 188/189:21-60.

4.1.4 Fuzzy Sets and Fuzzy Arithmetic

1) The section on Fuzzy logic is good, but could be expanded. Add a section on how an expert system could be built into the risk assessment process, especially in conjunction with fuzzy logic.

2) P. 9-15: Need to add an example of how fuzzy logic could be incorporated into the ecological risk assessment process.

3) Need to add a section on the allowable or most probable ranges to bound regressions of the fuzzy logic so that fuzzy but not "crazy" predictions are made.

4) Some figures would make this section more demonstrative.

4.1.5 Extreme event analysis:

1) This section is excellent. I agree with everything stated in the section.

4.2 Process (Mechanistic) models:

1) I would add a table to this section in which are listed a number of possible mechanistic process models with an indication of when they should be used and the degree of confidence for each model.

4.2.1 Models of Individuals

1) A limitation of mechanistic models of individuals is the existence of alternative pathways and pathway switching that goes on in organisms as an adaptive response to environmental stressors. Need to have better models for scope for growth and other

relationships that can be either continuous or discontinuous.

2) P. 9-24 suggest that any models used in integrating ecological risk assessments will be combinations of both energetics and population models.

3) It will be more likely that models will allow prediction of population-level effects for effects on individuals or populations. The most sensitive endpoints should be specified. These are probably growth and reproduction. Sensitive species should be used in screening tests conducted for the minimum data set. An example of how this can be done is given by Foran et al (1991).

Foran, J. A., L. L. Holst and J. P. Giesy. 1991. Effects of photoenhanced toxicity of anthracene on ecological and genetic fitness of Daphnia magna: A Reappraisal. Environ. Toxicol. Chem. 10:425-427.

4) Since it is yet to be demonstrated that simple population of effects on individuals or populations are possible at the current time how will more complex models be used in the RA process?

4.2.3

1) This section is well done. Very insightful.

4.2.4 Ecosystem Models:

1) I suggest aggregation at lower levels of organization at greater levels of organization.1 This would result in models of the greatest complexity of intermediate levels of organization. These would be those that would be affected by effects of stressors at greater and lesser levels of organization. Thus, the models would be targeted at those processes that would be most likely to be observed in a moderate period of time and also most amenable to be tested in various cosums.

4.2.5 Landscape and Regional Models:

1) Use an environmental checklist of factors expected to change for non-chemical effects to develop a combinatorial screening system for chemicals with suggestions of the greatest probability of effects such as where and when not to use.

1) P. 9-26 Para 3, L. 1 Delete "all too"

4.2.7 Implementation:

1) More discussion is needed on how modeling efforts in the ecological risk assessments will be implemented. The SAB requests a simplification of the risk assessment process, which should result in a concomitant decrease in the data required in the process. However, the proposals made in the chapter seem to

indicate that more complex models will be used more frequently in the RA process. How can these tow suggestions be reconciled?

2) A least for newly manufactured chemicals no results of effects studies are required. If the type of modeling effort indicated is to be used, I suggest that we make a recommendation for the use of some minimum data set.

3) Few good models exist for the most simple environmental fate properties of organic compounds such as photolysis, hydrolysis and chemical oxidation. The section should mention a need for better data and understanding of these processes, but especially biological transformation processes.

4.3.1 Cosms

1) There are two primary uses of the various sizes of cosms. These are to gain more realistic exposure regimes. An example of this is the toxicity of Polycyclic aromatic hydrocarbons (PAH) which are photo-toxic and thus much more toxic in full sunlight than under laboratory conditions. alternatively, metals for instance can be much less toxic in more complex systems where the available for is less due to a reduced activity. The second is that cosms are an efficient way to test a number of species with different sensitivities simultaneously. Cosms should not be used to look for secondary effects of stressors at eh community or ecosystem level of organization.

4.4.2 Toxicity Risk Assessment Models in the Ecosystem Context:

1) P. 9-37, Para 1. Discuss expert systems here in the context of ecological risk assessments. I think that models should be used in an expert system context and as part of a tiered approach.

2) I am concerned that a greater use of models in a regulatory context will lead to greater uncertainty and potentially obfuscation of the assessment process.

4.4.3

4.7 Multiple Stressors

This section need to be strengthened.

1) Need more discussion of the effects of type II errors on the risk assessment process.

2) It is more likely that the effects of chemical stressors will be accurately predicted than the effects of non-chemical stressors such as temperature or habitat loss or fragmentation.

5.1. Qualitative versus Quantitative Assessment:

1) P. 9-48 Para 4. More discussion of these concepts is needed,

both by the review group and in the chapter. Discuss embodied information in the context of qualitative vs quantitative risk assessments.

Cross-Cutting Comments

William J. Adams

Robert A. Bachman

Lev R. Ginzburg (Addresses Issue Papers #3, 5, 7, and 9)

Kent W. Thornton

Frederic H. Wagner

Review by William J. Adams

Cross-Cutting Issues

C-1. Exposure Terminology: This subject needs to be discussed in detail and cannot be resolved by myself with a few quick comments. Discussion and standardization of the terms exposure characterization, stressor characterization, stress regime, disturbance, and exposure should be discussed at the workshop.

EPA's Framework for Ecological Risk Assessment

C-2. Overall Process (figure 1): I agree with the recommendation that the data acquisition, verification, and monitoring box be moved inside the risk assessment box. This will tie the processes closer together, which is the way they work. Whether or not the box with the dotted line is moved into the problem formulation box is of little concern since the concept portrayed is the same either way.

Problem Formulation (figure 2): I probably agree with this recommendation for the following reason. When you are performing a risk analysis you need to select the important eco-components and exposure components to formulate a conceptual model for how the agent and the appropriate ecological components interface or co-occur. Assessment endpoints are not needed at this point in time.

I see no reason to differentiate between ecosystem and ecological system.

Analysis (figure 3): I agree that the boxes for exposure and stressor-response profiles can be eliminated as long as the concepts are embodies in the boxes above. I would also add that the parallel boxes for ecological response analysis and exposure analysis could be eliminated for the same reasons (i.e., the stressor characterization and evaluation of relevant effects data boxes embody the concepts of analyzing and profiling the data). This would simplify the problem formulation box considerably.

Risk Characterization(figure 4): I tend to agree with this recommendation. I would go a little further and not only eliminate the interpretation of ecological significance box, I would simply this risk description section into one box entitled Ecological Risk Summary.

C-4. I think the terms prospective, retrospective, effects-driven, and source-driven are adequately differentiated. I had difficulty with the concept that an effects-driven assessment is only for the purpose of determining the causative agent, or for determining the magnitude and extent of the observed effects. Perhaps this should be discussed at the workshop with a view towards modifying this slightly.

C-5. The dimensions of exposure are adequate from the viewpoint of chemical exposures. There is room for additional discussion relative to non chemical stressors.

C-6. No comment.

C-7. I thought the authors of the Characterization of Exposure paper did a good job of bringing into the paper at several points the concept of anthropogenic disturbances as related to characterization of exposure. While the concept has been given a much higher profile than in past documents, there is a need to demonstrate how exposure data are analyzed and exposure profiles are developed for these types of data.

Review by Robert A. Bachman

Cross-cutting Issues

C-7. As the process of risk assessment moves more and more from the physico-chemical arena into the socio-biological arena, it may be necessary to establish clear overall guidelines or sideboards for the framework for ecological assessment. It is unclear to me how or where the uncertainties regarding the predictability of natural systems are to be dealt with or how concepts such as the recovery of ecosystems are to be defined. For example, is it possible to define at all what is meant by the "recovery" of an ecosystem? Is it necessary or desirable? Questions such as to what extent can the direction or progression of ecosystems be predicted and how the distinctions between "natural" and "anthropogenic" effects are to be made, need to be addressed. It might be helpful to explicitly define or specify the assumptions that have implicitly been made in the formulation of the risk assessment framework in order that resource managers and decision makers can understand the robustness of the risk assessment product.

Review by Lev R. Ginzburg

Cross-cutting issue: Software

The spread of ('canned') software is threatening to the theoretical priesthood in ecology because it gives away their power (or a reasonable equivalent to it) to every motivated ecologist. Just as nostalgia for slide rules and long division did not prevent the spread of calculators, neither will theoreticians prevent the inevitable increase in availability and application of software for ecological risk assessment. Therefore, available software useful for specific tasks should be referenced and reviewed in this volume. Such reference would not constitute any endorsement, but would be helpful to readers interested in actually applying the approaches discussed. I am somewhat familiar with the software listed below, but this list should be expanded to be reasonably comprehensive.

@RISK (Salmento *et al.* 1989) is a software add-in for Lotus 1-2-3 spreadsheets for doing Monte Carlo propagation of probabilistic uncertainty. Source: Palisade Corporation; 31 Decker Road; Newfield, New York 14867.

CASM (DeAngelis *et al.* 1989) is DOS software implementing a risk assessment simulation of plankton-planktivore-piscivore ecosystem. Source: Environmental Sciences Division; Oak Ridge National Laboratory; P.O. Box 2008; Oak Ridge, Tennessee 37831; EPA Research Laboratory; Duluth, Minnesota.

CRYSTAL BALL (Burmaster and Udell 1990) is software for Excel spreadsheets for doing Monte Carlo propagation of probabilistic uncertainty. Source: Decisioneering; 1380 Lawrence Street, Ste. 610; Denver, Colorado 80204.

EUA (O'Neill *et al.* 1982) is DOS software (isn't it?) that translates toxicity summaries into consequences on biomass production in lake ecosystems. Source: Environmental Sciences Division; Oak Ridge National Laboratory; P.O. Box 2008; Oak Ridge, Tennessee 37831.

MEPAS (Droppo *et al.* 1991) is DOS software for screening environmental and human health impacts from exposure through multiple media (soil, air, *etc.*) to hazardous and radioactive releases. Source: Battelle Pacific Northwest Laboratory; P.O. Box 999; Richland, Washington, 99352.

PC-ILWAS (Chen and Gomez 1993) is Windows software implementing a finite-element simulation of watershed dynamics including several important hydrological, chemical, and biological mechanisms. It is a microcomputer version of the mainframe code ILWAS. Source: Systech Engineering; 3744 Mt. Diablo Blvd., Suite 101; Lafayette, California 94549.

PGSM (Chen *et al.* 1994) is DOS software for integrating impacts of multiple simultaneous stresses on plant physiology to predict consequences for growth, carbon-balance, and other variables. Source: Systech Engineering; 3744 Mt. Diablo Blvd., Suite 101; Lafayette, California 94549.

QS-CALC (Kirchner 1992) is DOS software for analytical and Monte Carlo propagation of probabilistic uncertainty in mathematical operations. Source: Quaternary Software; Box 9521; Fort Collins, Colorado 80525.

RAMAS (Ferson *et al.* 1989; Ferson and Akçakaya 1992) is DOS software for assessing risks of decline or extinction of single-species populations or metapopulations. Source: Applied Biomathematics; 100 North Country Road; Setauket, New York 11733.

RISK CALC (Kuhn and Ferson 1994; Ferson and Kuhn 1992; 1994) is Windows software for propagating uncertainty through mathematical expressions using fuzzy arithmetic. Source: Applied Biomathematics; 100 North Country Road; Setauket, New York 11733.

SWACOM (O'Neill *et al.* 1982; Barnthouse *et al.* 1986; Bartell *et al.* 1989) is DOS software for modeling pelagia of lake ecosystems. Source: Environmental Sciences Division; Oak Ridge National Laboratory; P.O. Box 2008; Oak Ridge, Tennessee 37831.

TREGRO (Weinstein and Yannai 1994) is Macintosh software for integrating impacts of multiple simultaneous stresses on plant physiology to predict consequences for growth, carbon-balance, and other variables. Source: Boyce Thompson Institute; Tower Road; Cornell University; Ithaca, New York 14753.

References

Barnthouse, L.W.; Suter, G.W., II; Bartell, S.M.; Beauchamp, J.J.; Gardner, R.H.; Linder, E.; O'Neill, R.V.; Rosen, A.E. (1986). User's Manual for Ecological Risk Assessment. (ORNL-6251, ESD Pub. No. 2679), Oak Ridge National Laboratory, Oak Ridge, Tennessee.

Burmaster, D.E.; Udell, E.C. (1990). A review of Crystal Ball. Risk Analysis 10:343-345.

Chen, C.W.; Tsai, W.T.; Gomez, L.E. (1994). Modeling responses of ponderosa pine to interacting stresses of ozone and drought. Forest Science [in press].

DeAngelis, D.L.; Bartell, S.M.; Brenkert, A.L. (1989). Effects of nutrient recycling and food-chain length on resilience. The American Naturalist 134:778-805.

Droppo, J.G, Jr.; Strenge, D.L.; Buck, J.W.; Hoopes, B.L.; Brockhaus, R.D.; Walter, M.B.; Whelen, G. (1991). Multimedia Environmental Pollutant Assessment System Application Guidance. (PNWD-1857), Battelle, Richland, Washington.

Ferson, S.; Akçakaya, H.R. (1992). Quantitative software tools for conservation biology. Computer Techniques in Environmental Studies IV, P. Zannetti (ed.), Elsevier Applied Science, London, pp. 371-386.

Ferson, S.; Kuhn, R. (1992). Propagating uncertainty in ecological risk analysis using interval and fuzzy arithmetic. Computer Techniques in Environmental Studies IV, P. Zannetti (ed.), Elsevier Applied Science, London, pp. 387-401.

Ferson, S.; Kuhn, R. (1994). Interactive microcomputer software for fuzzy arithmetic. Proceedings of the High Consequence Safety Symposium, Sandia National Laboratories [in press].

Ferson, S.; Ginzburg, L.R.; Silvers, A. (1989). Extreme event risk analysis for age-structured populations. Ecological Modelling 47:175-187.

Kirchner, T.B. (1992). QS-CALC: An Interpreter for Uncertainty Propagation. Quaternary Software, Fort Collins, Colorado.

Kuhn, R.; Ferson, S. (1994). Risk Calc: Uncertainty Analysis with Fuzzy Arithmetic. Applied Biomathematics, Setauket, New York.

O'Neill, R.V.; Gardner, R.H.; Barnthouse, L.W.; Suter, G.W.; Hildebrand; Gehrs, C.W. (1982). Ecosystem risk analysis: a new methodology. Environmental Toxicology and Chemistry 2:167-177.

Salmento, J.S.; Rubin, E.S.; Finkel, A.M. (1989). A review of @Risk. Risk Analysis 9:255-257.

Weinstein, D.A.; Yannai, R.D. (1994). Integrating the effects of simultaneous multiple stresses on plants using the simulation model TREGRO. Journal of Environmental Quality 23:418-428.

Papers #5 and #7: Extrapolation of toxicity bioassays to population-level

I argued elsewhere that it is impractical to conduct ecological risk assessments above the level of the species. Here I would like to argue that these assessments be conducted no lower than the level of the species.

Ecological risk assessment is sometimes characterized as a superset of human health risk assessment, for the obvious reason that humans are one of the species in ecosystems. I believe this prospective is misleading. Although they do share many areas of interest and technical methods, the two fields have an essential difference. In human health risk assessment, analysts are concerned about every incidence of death or disease: individuals are themselves the focus of interest. In ecological risk analysis, we are primarily concerned with detectable impacts at the level of entire populations or whole systems. We study individuals mostly to learn about consequences to their assemblages. (A possible exception arises in regard to the Endangered Species Act, where concern has been specifically targeted on 'take' of even a single individual. Endangered species, therefore, may enjoy the same analytical attention shown to humans, but the focus of the law is clearly on species.)

Standard toxicity bioassays report results in terms of several endpoints focused at the level of the individual. These may include individual fecundity, growth rate, life span, and other variables. However, the *meaning* of such endpoints in terms of consequences at the level of the population is not always evident or simple. Are decreases of similar magnitude of similar import at the population level? What if some endpoints exhibit increases and some exhibit decreases? It is well known that the complexities of population dynamics, including age- or stage-structure, density dependence, and time delays, can magnify (or mask) impacts that are evident at the individual level so that they become very serious (or negligible) at the population level. Recent research has applied standard population models to interpreting toxicity bioassays (*e.g.*, Pesch *et al.* 1987; 1991; Ferson *et al.* 1993; Caswell and Martin 1993; Bridges *et al.* 1993; 1994). This research shows that it is naive to attempt to simplistically rephrase toxicity results to the level of the population. Extrapolation of the impacts to population-level consequences *requires* a carefully formulated population dynamics model.

References

Bridges, T.S.; Wright, R.B.; Gray, B.R.; Gamble, V.E.; Gibson, A.B.; Dillon, T.M. (1994). Effects of suspended Great Lakes sediments on *Daphnia magna* survival, reproduction, and population growth. [manuscript].

Bridges, T.S.; Dillon, T.M.; Moore, D.W. (1994). The use of demographic modeling to assess sediment toxicity with the polychaete *Neanthes arenaceodentata*. Presented at the 14th annual meeting of the Society of Environmental Toxicology and Chemistry.

Caswell, H.; Martin, L.V. (1993). Life table response experiments with quantitative treatments: a new method for decomposing effects on population growth rate. Bulletin of the Ecological Society 74(supplement, no.2):188

Ferson, S.; Akçakaya, H.R.; Silva, P. (1993). Stage-structured modeling techniques and software for risk assessment of the effects of dredged material on the population dynamics of aquatic animals. Report to Waterways Experiment Station, U.S. Army Corps of Engineers, Applied Biomathematics, Setauket, New York.

Pesch, C.E.; Zajac, R.N.; Whitlach, R.B.; Balboni, M.A. (1987). Effect of intraspecific density on life history traits and population growth rate of *Neanthes arenaceodentata* (Polychaeta: Nereidae) in the laboratory. Marine Biology 96:545-554.

Pesch, C.E.; Munns, W.R.; Gutjahr-Gobell, R. (1991). Effects of a contaminated sediment on life history traits and population growth rate of *Neanthes arenaceodentata* (Polychaeta: Nereidae) in the laboratory. Environmental Toxicology 10:805-815.

Papers #5 and #7: Single-species vs. ecosystem-level risk assessment

I believe that in the foreseeable future, single-species assessment (including all the spatial complexity as needed) will remain the only practical way for ecological risk assessment.

The difficulties of extrapolating from single species and laboratory conditions to a general ecological assessment have been much discussed. There is general agreement on the need to extend ecotoxicological assessments to higher levels of biological organization (populations, communities and ecosystems), but no agreement on how to accomplish this task. The most significant limitation prohibiting the development of risk assessment protocols at higher levels is the state of ecological theory. In order to make assessments at the community or ecosystem levels, ecologists need to know the processes and interactions among species and trophic levels, in addition to interactions between the biotic and abiotic components of natural systems. Despite recent advances in theory of trophic interactions, there are no generally accepted models that can be used as basis of ecosystem-level impact assessment.

Inadequacy of the current state of ecological theory for community-level and ecosystem-level risk assessments is exemplified by the recent controversy in the ecological literature involving the dynamics of trophic interactions. Most studies on food web theory and the dynamics of trophic interactions are based on the Lotka-Volterra predation model developed in the 1920's. Recently, a number of studies have challenged the basic assumptions of the traditional approach (Arditi and Ginzburg 1989; Matson and Berryman 1992; Ginzburg and Akçakaya 1992; Arditi and Saïah 1992; see review by Hanski 1991). These studies are currently being criticized and defended (Abrams 1994; Sarnelle 1994; Diehl *et al.* 1994; Akçakaya *et al.* 1994; McCarthy *et al.* 1994). Since ecologists cannot even agree on the very basic assumptions of food web and food chain models, any risk assessment protocol developed at the community-level would be on shaky ground.

The advantages of the single-species level are that (1) it is better understood than higher levels, (2) it requires less data to treat comprehensively, and (3) it has well-defined endpoints such as risk of decline or extinction. The Endangered Species Act is a perfect example of a reasonable legal compromise between what needs to be done (conserve habitats and ecosystems) and what can be done (risk assessment at the single-species level). The implementation of the act has reduced the restrictive aspects of the singe-species approach by focusing on species considered to be 'indicators' of ecosystem stress (as a result of their threatened status), and as 'umbrella' species (as a result of their large habitat requirements). As much as we would like to be able to evaluate ecological risks at the ecosystem level, we will be practically constrained to the single-species level for the foreseeable future.

References

Abrams, P.A. (1994). The fallacies of 'ratio-dependent' predation. Ecology (in press).

Akçakaya, H.R.; Arditi, R.; Ginzburg, L.R. (1994). Ratio-dependent predation: an abstraction that works. Ecology (submitted).

Arditi, R.; Ginzburg, L. R. (1989). Coupling in predator-prey dynamics: ratio-dependence. Journal of Theoretical Biology 139:311-326.
Arditi, R.; Saïah, H. (1992). Emprical evidence and the theory of ratio-dependent consumption. Ecology 73:1544-1551
Diehl, S.; Lundberg, P.A.; Gardfjell, H.; Oksanen, L.; Persson, L. (1994). *Daphnia*-phytoplankton interactions in lakes: is there a need for pragmatic consumer-resource models? American Naturalist (in press).
Ginzburg, L.R.; Akçakaya, H.R. (1992). Consequences of ratio-dependent predation for steady state properties of ecosystems. Ecology 73:1536-1543
Hanski, I. (1991). The functional response of predators: worries about scale. Trends in Ecology and Evolution 6:141-142.
Matson, P.; Berryman, A. (1992). Ratio-dependent predator-prey theory. Ecology 73:1529.
McCarthy, M.A.; Ginzburg, L.R.; Akçakaya, H.R. Predator interference across trophic chains. Ecology (submitted).
Sarnelle, O. (1994). Inferring process from pattern. Ecology (in press)

Paper #9: Fuzzy sets and fuzzy arithmetic

I was pleased to see fuzzy set theory mentioned. Fuzzy set theory and its derivative, fuzzy arithmetic, is useful for uncertainty propagation in two circumstances: (1) when empirical information is very spotty, and (2) when uncertainty is non-statistical in nature. I know of three significant examples of the application of fuzzy set theory to environmental risk assessment.

Although fuzzy set theory has occasionally been used in ecology (*e.g.*, Bosserman and Ragade 1982), the application of fuzzy set theory to ecological risk assessment will likely focus on *fuzzy arithmetic* (Kaufmann and Gupta 1985). Fuzzy arithmetic is a refinement of interval analysis that permits propagation of uncertainty through mathematical expressions or complex models. Fuzzy arithmetic is part of *possibility* theory which was introduced by Zadeh (1978; Dubois and Prade 1988). Possibility theory is analogous to probability theory but can be used successfully even when only very poor empirical information is available. Duckstein *et al.* (1990) and Bardossy *et al.* (1991) reviewed the potential use of fuzzy sets in environmental human health assessments. Ferson (1994) applied fuzzy arithmetic to a probabilistic ecological risk assessment of a fishery. Ferson and Kuhn (1992; 1994) describe software implementing fuzzy arithmetic.

When a full probabilistic analysis is not possible because of a lack of empirical understanding about the distributions of the variables involved, it is still possible to use fuzzy arithmetic to get a reasonable, albeit crude, estimate of the uncertainty about a projection. In other cases, when the nature of uncertainty is not statistical in the first place (such as when it is generated by systematic mensuration bias or measurement error), fuzzy arithmetic may be more appropriate than probability theory to project uncertainty.

References

Bardossy, A.; Bogardi, I.; Duckstein, L. (1991). Fuzzy set and probabilistic techniques for health-risk analysis. Applied Mathematics and Computation 45:241-268.

Bosserman, R.W.; Ragade, R.K. (1982). Ecosystem analysis using fuzzy set theory. Ecological Modelling 16:191-208.

Dubois, D.; Prade, H. (1988). Possibility Theory: An Approach to Computerized Processing of Uncertainty, Plenum Press, New York

Duckstein, L.; Bardossy, A.; Barry, T.; Bogardi, I. (1990). Health risk assessment under uncertainty: a fuzzy-risk methodology. Risk-Based Decision Making in Water Resources, Y.Y. Haimes and E.Z. Stakhiv (eds.), American Society of Engineers, New York.

Ferson, S. (1994). Using fuzzy arithmetic in Monte Carlo simulation of fishery populations. Management of Exploited Fish, T. Quinn (ed.), proceedings of the International Symposium on Management Strategies for Exploited Fish Populations, Anchorage, 1992, Alaska Sea Grant College Program, AK-SG-93-02 [in press].

Ferson, S.; Kuhn, R. (1992). Propagating uncertainty in ecological risk analysis using interval and fuzzy arithmetic. Computer Techniques in Environmental Studies IV, P. Zannetti (ed.), Elsevier Applied Science, London, pp. 387-401.

Ferson, S.; Kuhn, R. (1994). Interactive microcomputer software for fuzzy arithmetic. Proceedings of the High Consequence Safety Symposium, Sandia National Laboratories [in press].

Kuhn, R.; Ferson, S. (1994). Risk Calc: Uncertainty Analysis with Fuzzy Arithmetic. Applied Biomathematics, Setauket, New York.

Zadeh, L. (1978). Fuzzy sets as a basis for a theory of possibility. Fuzzy Sets Systems 1:3-28.

Papers #3 and #9: Single-population vs. metapopulation

While ecological risk analysis at or above the level of the community is not supported by current ecological theory, current methods can comprehensively model several population of one species. In the Issue Papers, ecological risk assessments are discussed at the population-level and the landscape-level, but these two levels are mostly discussed independently of each other. Metapopulation dynamics offers a way to integrate the assessments at these two levels, as well as to make assessment methods at each of these levels more realistic and applicable to natural populations and landscapes.

Habitat fragmentation as a result of human impact and natural spatial heterogeneity cause most endangered species to exist in a small number of relatively isolated populations that may occasionally exchange individuals (a *metapopulation*). The need to evaluate management options (such as reserve design, translocations and reintroductions) and to assess human impact (such as increased fragmentation and isolation) at the metapopulation level have made the metapopulation concept one of the most important paradigms in conservation biology (Gilpin and Hanski 1991; Burgman *et al.* 1993).

Factors operating at the metapopulation level, such as correlations (Gilpin 1988; Harrison and Quinn 1989; Akçakaya and Ginzburg 1991) and dispersal (Burgman *et al.* 1993), make it impossible to extrapolate the risk assessment at the population-level to an assessment at the species-level, unless metapopulation dynamics are explicitly incorporated into the assessment. The metapopulation approach has been integrated with landscape-level data, using geographic information systems (Akçakaya 1994), and using spatially-explicit metapopulation models (*e.g.*, see LaHaye *et al.* 1994 and Lamberson *et al.* 1992, for examples of risk analysis for two different spotted owl metapopulations). Spatial distribution of single species should be and can be taken into account in ecological risk assessments.

References

Akçakaya, H.R. (1994). RAMAS/GIS: Linking Landscape Data With Population Viability Analysis (version 1.0). Applied Biomathematics, Setauket, New York.

Akçakaya, H.R.; Ginzburg, L.R. (1991). Ecological risk analysis for single and multiple populations. Pages 73-87 in: Species Conservation: A Population-Biological Approach. A. Seitz and V. Loeschcke (eds.) Birkhaeuser Verlag, Basel.

Burgman, M.A.; Ferson, S.; Akçakaya, H.R. (1993). Risk Assessment in Conservation Biology. Chapman and Hall, Population and Community Biology Series.

Gilpin, M.E. (1988). A comment on Quinn and Hastings: extinction in subdivided habitats. Conservation Biology 2:290-292.

Gilpin, M.; Hanski, I. (1991). Metapopulation dynamics. Biological Journal of the Linnean Society 42:nos 1 & 2.

Harrison, S.; Quinn, J.F. (1989). Correlated environments and the persistence of metapopulations. Oikos 56:293-298.

LaHaye, W.S.; Gutiérrez, R.J.; Akçakaya, H.R. (1994). Spotted owl metapopulation dynamics in southern California. Journal of Animal Ecology (in press).

Lamberson, R.; McKelvey, R.; Noon, B.R.; Voss, C. (1992). A dynamic analysis of northern spotted owl viability in a fragmented landscape. Conservation Biology 6:505-512.

Paper #5

(Page 5-48, Section 5.1.4). The last sentence may be very misleading. After all, probabilistic modeling is only possible after a considerable amount of information on a species or system has been amassed.

(Page 5-51). ROPIS is not a model; it was a research program (Goldstein and Ferson 1994). However, it produced two models of direct interest here: TREGRO (Weinstein and Yannai 1994) and PGSM (Chen *et al.* 1994). Both can be used to estimate the population- or community-level consequences of physiological impacts on plants from one or multiple interacting environmental stresses.

References

Chen, C.W.; Tsai, W.T.; Gomez, L.E. (1994). Modeling responses of ponderosa pine to interacting stresses of ozone and drought. Forest Science [in press].

Goldstein, R.; Ferson, S. (1994). Response of Plants to Interacting Stresses (ROPIS): program rationale, design, and implications. Journal of Environmental Quality 23:407-411.

Weinstein, D.A.; Yannai, R.D. (1994). Integrating the effects of simultaneous multiple stresses on plants using the simulation model TREGRO. Journal of Environmental Quality 23:418-428.

CROSS-CUTTING ISSUES

C-1 Exposure Terminology

I would suggest using the terms defined in Issue Paper 4: Characterization of Exposure because the terms are developed in both the text and in the Glossary. These individuals have reviewed the literature, published many of the seminal papers on the topic, and have thought about the importance of incorporating physical and biological agents, in addition to chemicals, in the exposure terminology. Exposure terminology represents only one of several sets of terms and definitions that are used somewhat differently among the Issue Papers, e.g., ecological versus assessment endpoint. A very careful review and reconciliation of terminology should occur among all the Issue Papers.

C-2 Framework or Issue Paper Changes

(For the Workshop)

C-3 Biological Stressors

(For the Workshop)

C-4 Prospective, Retrospective, Effects-Driven and Source-Driven Assessments

The Issue Paper on Characterization of Exposure was the only paper I recall that distinguished among these assessment types. I think that the primary assessment type discussed in most issue papers was a prospective, source-driven assessment. I think it is important that retrospective and effects-driven assessments be addressed, but it is critical that these assessments be addressed as complementary, not mutually-exclusive. There is a whole arsenal of techniques, approaches and procedures available for conducting assessments and it would be foolish not to use as many of the appropriate tools as time and funding permits. Additional discussion on these different assessment focuses could be forthcoming in second round issue papers or provided in supporting documents developed specifically for guideline development.

C-5 Dimensions of Exposure

(For the Workshop)

C-6 Bioavailability and Environmentally-Realistic Exposure in Toxicity Tests

(For the Workshop)

C-7 Increased Emphasis on Anthropogenic Disturbances

To my knowledge, the Issue Papers focused principally on anthropogenic disturbances and each paper emphasized we know more about assessing effects from chemicals than other forms of stressors at local scales. Increased emphasis on other anthropogenic stressors than chemicals at larger scales, I think, was acknowledged by each of the Issue Paper authors.

Review by Frederic H. Wagner

C - 1

I now reconsider my comments above on terminology. I prefer the text-box definitions in 4-1 for Source, Stress Regime, and Exposure. And I prefer it for Stressor if "physical, chemical, or biological entity" is deleted and replaced with the word "agent." I prefer the Characterization of Exposure glossary definitions of Agent and Disturbance. The reason the latter and Exposure get confused is that "Co-occurrence" are included in both in the 4-1 text box. It seems to me that Disturbance is the environmental phenomenon (fire, plowing) per se. Exposure is the process of the ecological component coming into contact with that phenomenon.

C - 2

<u>Overall Process</u>. I agree with these suggestions.

<u>Problem Formulation</u>.

- I guess it's OK to emphasize conceptual model development, but I don't agree with making Endpoint its <u>output</u>. The latter should be part of the model.
- Yes, use "ecological system."
- I don't understand the arrow comment.

<u>Analysis</u>.

- I don't understand the reason for eliminating the boxes. I don't think they are outputs.
- OK with feedback arrow.

<u>Risk Characterization</u>. OK as long as summary includes interpretation.

C - 3

This whole issue is an extremely complex one that can't be detailed here. I hope that we have time to discuss it at the Workshop. In part they should be discussed in Effects Characterization.

C - 4

See my comments above.

C - 7

I think anthropogenic disturbances need much more elaboration, probably in Characterization of Exposure. I have a few comments on this above.

Miscellaneous Comments

P. 4-12, section 1.2.3. I think this paragraph needs considerable elaboration.

P. 4-15, section 2.2. The heading needs some words. "Defining the Spatial and Temporal Extent" of what? The risk? The exposure? The following paragraph talks about the spatial and temporal extent of the assessment. Is that what's intended? If so, I don't understand. Same question re 2.2.1 and 2.2.2.

3.2.2.2. Should this be a much more extensive section that discusses the characteristics of ecological systems and how a first-order effect can have manifold ramifications through the system? Will the assessor have a sense of all this if there has not been some elaboration of it? And these considerations should be carefully coordinated with the Effects Characterization section. This means getting into the complexities of community and ecosystem structure and function.

General. I think each Issue Paper should have an executive summary.

APPENDIX F

DETAILED RECOMMENDATIONS FOR REVISION OF ISSUE PAPERS

APPENDIX F
DETAILED RECOMMENDATIONS FOR REVISION OF ISSUE PAPERS

1. INTRODUCTION

Brief summaries of the recommendations for revisions of the issue papers were presented in section 3. This appendix presents the detailed recommendations to the authors for revisions to the papers that were developed during the individual Work Group sessions.

2. ECOLOGICAL SIGNIFICANCE

Authors: M. Harwell, B. Norton, W. Cooper, J. Gentile
Reviewers: K. Thornton, R. Bachman, T. O'Connor

Six recommendations were made to the authors of the Ecological Significance paper as follows:

1. Define ecological significance;
2. Reorganize the issue paper;
3. Incorporate the Public Values appendix into a separate issue paper entitled "Public Values Affecting Ecological Significance";
4. Expand discussions of attributes and criteria;
5. Incorporate additional examples; and
6. Incorporate specific pre-meeting comments, where appropriate.

2.1. Define Ecological Significance

A working definition of ecological significance was developed by the Work Group, which defines ecological significance as:

- A change detected or projected in the ecological system or its individual components that exceeds a variance estimate; and

- A change in the ecological system or its components that is of sufficient type, intensity, extent, or duration to be important to society.

2.2. Reorganize the Issue Paper

The following reorganization of the paper was recommended:

Section 1. Introduction, with Road Map to Contents of the Issue Paper
Section 2. Ecological Significance - Definition and Societal Values
Section 3. Attributes and Criteria Determining Ecological Significance
Section 4. Current Capabilities and Examples
Section 5. Relation to Framework - Future Needs

2.3. Incorporate the Public Values Appendix Into a Separate Issue Paper

Because societal values are a critical part of defining ecological significance, this topic should not be relegated to an appendix. Identification of societal values initiates the problem formulation phase of ecological risk assessment as part of assessment endpoint identification, and it concludes the risk characterization phase by contributing to the determination of ecological significance. Therefore, it was recommended that societal values be discussed in a separate issue paper ("Public Values Affecting Ecological Significance") referenced by both the issue papers on Conceptual Model Development and Ecological Significance.

2.4. Expand Discussions of Attributes and Criteria

The attributes of ecological significance should be expanded to include:

- Temporal scale (duration of change, time to recovery, life history, etc.);
- Spatial scale (extent, refugia); and
- Magnitude of effect change.

These attributes relate to the change in the assessment or measurement endpoint and not the stressor or exposure regime unless the endpoint represents these regimes. The focus is primarily on effects. It also was recommended that a decision tree/flow diagram be used to illustrate how attributes and criteria are applied. Finally, it was recommended that the Environmental Risk Decision Square presented in section 2 of the issue paper, but developed in the appendix, be further discussed in this section as another approach for describing how ecological significance can be presented.

2.5. Incorporate Additional Examples

It was recommended that the approaches for applying the attributes and criteria and assessing ecological significance be illustrated through the use of three or four examples, such as:

- Assessing significance of risk at a Superfund site—local-scale, potential long-term exposure;
- Assessing significance of risk from deforestation or different forest management practices—landscape impacts;
- Assessing the significance of risk from the cumulative use of hot water vs. chlorine for zebra mussel control in Lake Erie or a large river system—large-scale impacts; and
- Assessing the significance of risk from an oil spill—contrast a no action alternative vs. a dispersant alternative.

3. CONCEPTUAL MODEL DEVELOPMENT

Authors: L. Barnthouse, J. Brown
Reviewers: G. Biddinger, R. Kendall, R. O'Neill

Ten recommendations were made to the authors of the Conceptual Model Development paper as follows:

1. Provide basic information for a broader audience on the scientific method and the use of science to make management decisions;
2. Clearly state how conceptual model development focuses the study;
3. Include references identified by reviewers;
4. Include a third case study on a waste site;
5. Reduce the level of detail on characterization of stress;
6. Add statements of scope and purpose;
7. Discuss the importance of documentation and transparency;
8. Consider including a dictionary as an alternative to a glossary;
9. Include a process flow diagram; and
10. Ensure consistency with other issue papers.

3.1. Provide Basic Information on the Scientific Method

A broader audience for the guidelines should be assumed. It was recommended that the authors focus beyond the regulatory context and provide guidance on the use of the best scientific methods within a good decision matrix as driven by a regulatory need. The paper should define the basic steps in the scientific method and discuss the use of science to make management decisions. The guidance should support the multitiered aspect of risk assessment, which should be illustrated by a process flow diagram.

3.2. Clearly State How Conceptual Model Development Focuses the Study

The paper should clearly state that conceptual modeling development can help focus the study and target the decision. The document should support building conceptual models for both prospective and retrospective assessments.

3.3. Include References Identified by Reviewers

Additional references were identified by reviewers in pre-meeting comments and should be included in the paper.

3.4. Include a Third Case Study on a Waste Site

An additional case study on a waste site should be included.

3.5. Reduce the Level of Detail on Characterization of Stress

3.6. Add Statements of Scope and Purpose

Statements of scope and purpose of the paper will help focus the text.

3.7. Discuss the Importance of Documentation and Transparency

A paragraph should be developed on the importance of documenting and communicating what was left out and why. This is necessary to ensure transparency of the assessment and to gain credibility.

3.8. Consider Including a Dictionary as an Alternative to a Glossary

In the area of terminology, the group was mixed on need for a glossary. An alternative solution could be a dictionary. Terms to be defined in the text were identified, and it was suggested that undefined terms not be used if an explanation within the text would suffice.

3.9. Include a Process Flow Diagram

A process flow diagram helps elucidate the process, especially for novices. The work group developed a diagram, which is included as figure 4.

3.10. Ensure Consistency With Other Issue Papers

Consistency with other issue papers, especially in the use of terminology, is essential.

4. CHARACTERIZATION OF EXPOSURE

Authors: G. Suter II, J. Gillett, S. Norton
Reviewers: W. Adams, L. Kapustka, F. Wagner

Five recommendations were made to the authors of the Characterization of Exposure paper as follows:

1. Follow the exposure characterization descriptions in the Framework Report;
2. Modify some terminology;
3. Revise the figures;
4. Restructure the issue paper; and
5. Provide recommendations on performing exposure characterization for chemical and nonchemical agents.

4.1. Follow the Exposure Characterization Descriptions in the Framework Report

The issue paper should be tied more closely to the Framework Report so that the major components of exposure characterization as presented in the Framework Report also are presented and/or summarized in the issue paper.

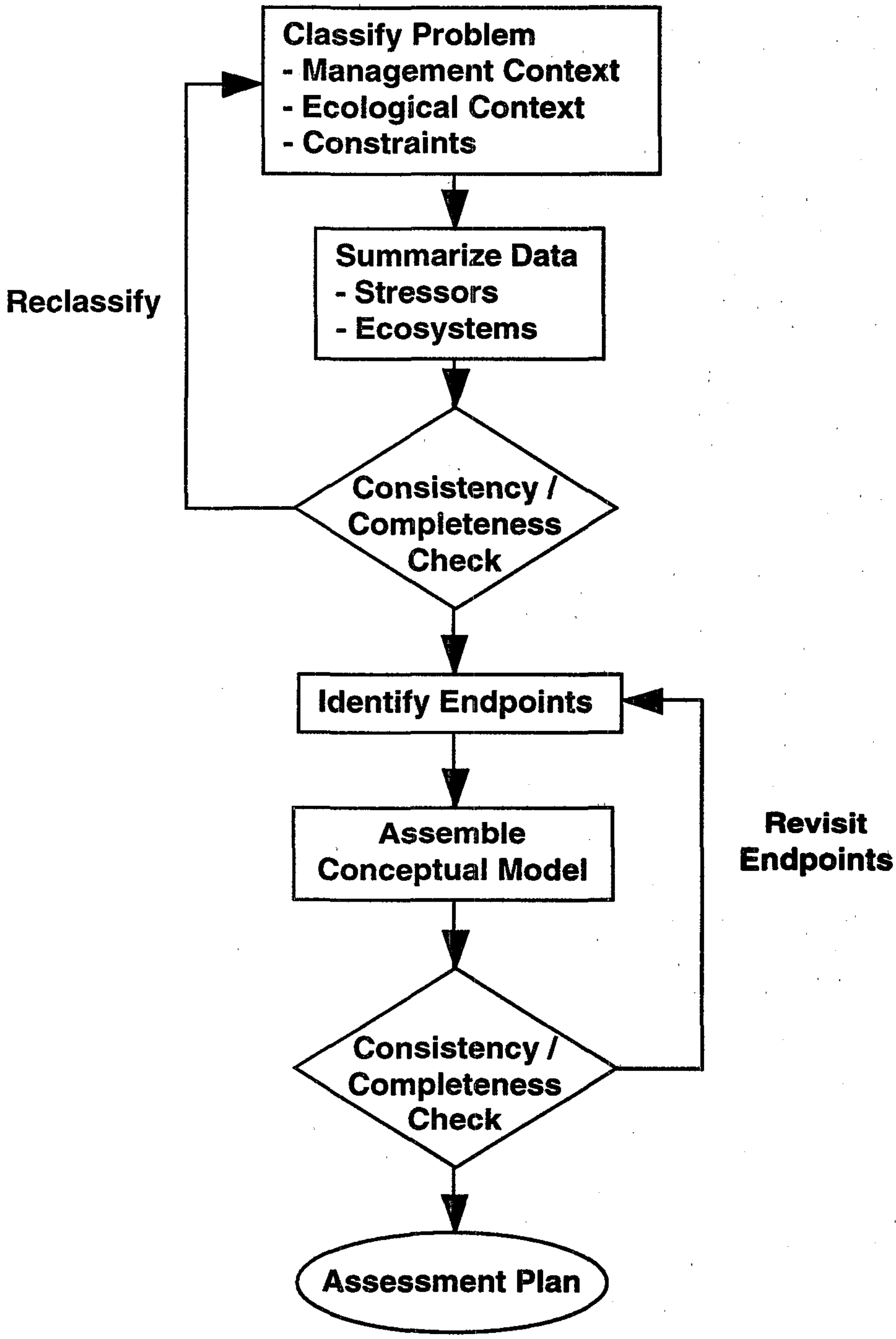


Figure 4. The Process Flow Diagram Developed by the Conceptual Model Development Work Group

4.2. Modify Some Terminology

Several terms were discussed, and modifications were suggested to provide either a more concise or a more accurate definition. The terms include: agent, stressor, stress regime, disturbance, co-occurrence, agent, and bioavailability. Work Group members noted that stress regime can have two different meanings depending on the context, and it was recommended that both definitions be included.

4.3. Revise the Figures

The figures in the issue paper were redrawn by the Work Group to be more descriptive of the processes and entities being represented. An effort was made to follow modeling notation where entities are in boxes and process and rates are reflected by arrows. The authors were encouraged to modify the figures in the spirit of what was discussed.

4.4. Restructure the Issue Paper

Restructure the issue paper specifically to:

- Ensure that the connection between the Framework Report and the issue paper is clear (possibly add a paragraph in the introduction that provides links to the Framework Report);
- Shorten the introduction;
- Move the discussion on exposure profile from the introduction to section 3; and
- Include a section early in the paper that focuses exclusively on the major components of exposure.

4.5. Provide Recommendations on Performing Exposure Characterization for Chemical and Nonchemical Agents

Recommendations on performing certain aspects of exposure characterization for chemical and nonchemical agents should be included either as part of the issue paper or (more likely) in the ecological risk assessment guidelines.

Specifics for chemicals are as follows:

- Guidance is needed on how to deal with significant figures throughout the exposure characterization process.
- How does one deal appropriately with data below the analytical detection limit?
- How does one construct an exposure profile?
- How does one deal with exposure data on a probabilistic basis?
- How should background exposure data be integrated with source exposure data?
- How should uncertainty be expressed as part of the exposure characterization process?
- How can exposure pathways be collapsed or deleted, when appropriate, to facilitate the exposure characterization?
- How does one use sensitivity analysis to streamline the exposure characterization?

Specifics for nonchemicals are as follows:

- How does one calculate exposure for nonchemical agents? What units and what timeframe are used?
- How are nonchemical and chemical exposure data integrated and used to construct an exposure profile?
- How is succession incorporated into exposure characterization?

5. EFFECTS CHARACTERIZATION

Authors: P. Sheehan, O. Loucks
Reviewers: J. Giddings, N. Beyer, W. Landis

Five recommendations were made to the authors of the Effects Characterization paper as follows:

1. Retain the emphasis in the introductory section on important general concepts;
2. Clearly state that risk assessments should not be based on simplistic "indices";
3. Include additional types of effects in the sections on individual- and population-level effects;
4. State that many ecosystem structure/function endpoints need more research and development before they can be routinely used in risk assessment; and
5. Discuss additional research and development needs.

In other respects, the reviewers stated that the paper is comprehensive and adequate without major revision; however, some minor editing is needed to increase clarity and to bring out the organization of topics.

5.1. Retain Emphasis in the Introductory Section on Important General Concepts

Emphasis (in the introductory section) should be retained on the following important general concepts:

- Indirect effects can be as important as direct effects.
- Natural variability can obscure effects of stressors.
- The threshold concept is useful in describing stressor-response relationships.
- Spatial, temporal, and ecological scale must be defined in problem formulation.

5.2. Clearly State That Risk Assessments Should Not Be Based on Simplistic "Indices"

The paper should stress that risk assessments should not be based on simplistic "indices" at the expense of detailed information. As examples: data on species abundance ranking are more useful than a single diversity index, and the entire dose-response curve is more useful than the LC_{50}.

5.3. Include Additional Types of Effects in the Sections on Individual- and Population-Level Effects

Certain additional types of effects should be included in the sections on individual- and population-level effects, specifically:

- Histology;
- Pathology;
- Molecular markers; and
- Estrogens (and other hormonal effects).

Also, some measurements that are chiefly used as indicators of exposure, e.g., biomarkers and tissue residue concentrations, can be used to help characterize potential effects, if they can be linked to effects. For example, DDT residues in birds have been linked to eggshell thinning.

5.4. State That Many Ecosystem Structure/Function Endpoints Need More Research and Development Before They Can Be Routinely Used in Risk Assessment

The authors should emphasize that many of the ecosystem structure and function endpoints need more research and development before they can be used routinely in risk assessments. These ecosystem-level research and development needs include:

- Stability;
- Nonlinear ecosystem and population dynamics;

- Nutrient cycling;
- Disease resistance;
- Diversity; and
- Biotic integrity.

5.5. Additional Research and Development Needs Should Be Discussed

Other research and development needs that should be discussed are:

- Effects of fluctuating exposure regimes; and
- Combined effects of physical and chemical stressors.

6. BIOLOGICAL STRESSORS

Authors: D. Simberloff, M. Alexander
Reviewers: J. Drake, R. Orr, J. Thorp III

The reviewers stated that only a few changes were recommended to the authors because this is a well-written document. The changes include:

1. Clarify the community/ecosystem concepts; and
2. Include additional thoughts and guidance on practical applications.

6.1. Clarify the Community/Ecosystem Concepts

These ideas have been incorporated into a new version of the introduction that the authors provided during the meetings. The reviewers stated that the new introduction is exactly what they had in mind, providing balance between a continuum of thought in this area.

6.2. Include Additional Thoughts and Guidance on Practical Applications

Including suggestions on practical applications ("how to" information) was not a charge to the authors of the issue papers. However, the reviewers did suggest that vectors and dispersal corridors could be discussed in more depth. It was recommended that the authors discuss modes of dispersal other than diffusion (which may act in a fashion similar to chemical stressors). The reviewers noted that the authors did discuss other dispersal modes such as "jump-dispersal," species dispersing in large geographic steps, which is similar in some sense to airborne pollutants.

7. ECOLOGICAL RECOVERY

Authors: S. Fisher, R. Woodmansee
Reviewers: J. Karr, P. Brezonik, R. Wentsel

Eight recommendations were made to the authors of the Ecological Recovery paper as follows:

1. Consider the written pre-meeting comments of the reviewers;
2. Emphasize anthropogenic disturbance and the kind of variation it produces;
3. Stress the importance of monitoring to determine the success of recovery;
4 Stress the uncertainties that exist in recovery;
5. Include case studies to illustrate key concepts;
6. Remove the unnecessary references to ecological theory;
7. Expand coverage of different kinds of stressors; and
8. Include the proper range of disciplines in the discussion of risk assessors.

7.1. Consider the Written Pre-Meeting Comments of the Reviewers

The authors should consider the pre-meeting comments of the reviewers and incorporate them as appropriate.

7.2. Emphasize Anthropogenic Disturbance and the Kind of Variation It Produces

The emphasis in the paper should be shifted from a discussion of natural disturbance as a driver of variability to anthropogenic disturbance and the kind of variation it produces. It is important to identify the ecosystem parameters that will provide the data needed to conduct the ecological risk assessment.

7.3. Stress the Importance of Monitoring to Determine the Success of Recovery

It is important to stress that merely establishing a protocol for recovery will not assure success. A program of post-action monitoring should be established to determine if the desired recovery has occurred.

7.4. Stress the Uncertainties That Exist in Recovery

Uncertainty is involved in ecological recovery at many levels. The authors should consider incorporating a discussion of uncertainty into the text.

7.5. Include Case Studies to Illustrate Key Concepts

Case studies should be included to illustrate key concepts and points made in the paper. Even if this is done only briefly, it is valuable to include the full citation and the key points of those studies to lead the reader to these other sources.

7.6. Remove the Unnecessary References to Ecological Theory

Certain references to ecological theory, a constantly evolving science, are not necessary to present the important points that the paper contains.

7.7. Expand Coverage of Different Kinds of Stressors

The coverage of the different kinds of stressors should be expanded. In addition, the examples could include different types of ecosystems.

7.8. Include the Proper Range of Disciplines in the Discussion of Risk Assessors

The phrase "risk assessor" suggests a single person will be doing the work; it is important to acknowledge that a range of disciplines and expertise is involved in the risk assessment process.

8. UNCERTAINTY IN ECOLOGICAL RISK ASSESSMENT

Authors: E. Smith, H. Shugart
Reviewers: A.F. Holland, L. Ginzburg, K. Rose

This issue paper defined most of the scientific issues associated with characterizing uncertainty in ecological risk assessment. It did not, however, bridge the gap between the general treatment of uncertainty provided by the Framework Report and the specific information required to develop Agencywide guidance for ecological risk assessments. Reviewers made the following recommendations to the authors of the Uncertainty in Ecological Risk Assessment paper:

1. Provide more synthesis of the science of characterizing uncertainty;
2. Use a broader variety of examples;
3. Integrate discussions and recommendations with those in other issue papers;
4. Reorganize the introduction section;
5. Refocus the problem definition section;
6. Refocus the analysis-phase uncertainty section;
7. Expand and generalize the discussions in the risk characterization section;

8. Incorporate pre-meeting comments as appropriate;
9. Define terminology used; and
10. Reorganize the describing uncertainty section.

8.1. Provide More Synthesis of the Science of Characterizing Uncertainty

Within the page constraints imposed for issue papers, it would be impossible to do a comprehensive review of the scientific literature relevant to measuring and characterizing uncertainty in ecological assessments. The authors should therefore focus on synthesizing what is known about the topical area and presenting it in a form that can be understood by technical and nontechnical audiences.

8.2. Use a Broader Variety of Examples

Examples presented in this issue paper are not balanced and focus on identifying issues for characterizing uncertainty for terrestrial ecosystem-level and statistical models. The reviewers recommend that a broader range of organizational levels (e.g., organism, population, community, and ecosystem), ecosystem types (e.g., freshwater, marine, wetlands, and terrestrial), and model types (statistical, structural, and process) be represented. It is particularly important that the authors present an example for characterizing the uncertainty associated with the application of single-species population models.

8.3. Integrate Discussions and Recommendations With Those in Other Issue Papers

Discussions about uncertainty occur in several other issue papers including the paper on Conceptual Model Development, Characterization of Exposure, Effects Characterization, and Risk Integration Methods. To the degree possible, discussions and recommendations in this issue paper should be integrated with findings of other issue papers to reduce the amount of redundancy and prevent conflicts.

8.4. Reorganize the Introduction Section

The introduction should be reorganized to include the following:

- Clearly identify the audience for uncertainty analysis;
- Describe the critical nature of uncertainty information to the decision making process;
- Define the difference between impact assessment and risk assessment;
- Include a definition of uncertainty analysis that is consistent with that in other issue papers;
- Identify and describe the various types of uncertainty that occur in ecological risk assessment;
- List the objectives of this issue paper and identify where in the text each objective is addressed; and
- Simplify table 1 by making it three tables structured on the major types of uncertainty (model structure, parameter, and natural variability).

8.5. Refocus the Problem Definition Section

The problem definition section should be refocused around the existing summary for this section to include the following:

- Identify the uncertainty associated with the lack of knowledge and choice of endpoints, scale, and modeling approach;
- Discuss and provide an example of the need to constrain the time scale for model applications;
- Integrate the discussion of types of models and criteria for model selection with discussions in the Conceptual Model Development Issue Paper;
- Integrate the existing discussion on structural uncertainty, ecosystem characterization, and stressor characterization; and

- Provide examples of the effects of different model structures, formulations, and/or implementation approaches and how they influence the reliability (i.e., uncertainty) analysis results. A contrast of results based on integral-type analysis approaches and central tendency analysis approaches would be a particularly useful addition.

8.6. Refocus the Analysis-Phase Uncertainty Section

The Analysis-Phase Uncertainty section should be refocused to include the following:

- Make the introductory paragraphs more general;
- Emphasize the simple vs. complex model discussion on the bottom of pages 8 to 19;
- Include the process described in Boesch et al. (1990) and Holling (1978) on reducing the uncertainty that results from an inadequate experimental design;
- Include reference to and discussion of how the discussion on development of an experimental design is linked to EPA's Data Quality Objectives process or to another strategy that answers the question "How much power is enough?"
- Include examples such as those on pages 239 to 246 of Suter et al. (1993) into the discussion on extrapolations;
- Develop a general scheme for the types of extrapolations;
- Include an example of how knowledge of magnitude of natural spatial and temporal variation can be used to reduce uncertainty in ecological risk assessment (e.g., see comment in section 8.7 on the power of an ANOVA vs. ANCOVA);
- Link the discussion of computer simulation models and model credibility (validation) and make it more general. The question that this discussion must address is how credible and reliable are results and under what conditions do predictions apply; and
- Include a discussion on the advantages of using multiple models that have different assumptions and endpoints as an approach for characterizing uncertainty in ecological risk assessments.

8.7. Expand and Generalize the Discussions in the Risk Characterization Section

The discussion of risk characterization should be generalized and expanded to include a discussion of error propagation following the detailed written comments provided by Ginzburg. Other specific recommendations for this section include:

- Include figures such as those on pages 45 to 46 of Suter et al. (1993) in the introductory paragraph of this section as an example of the uncertainty that results from integration of exposure and effects data;
- Provide an overview discussion of the effects of the independence assumption on the characterization of uncertainty for statistical models;
- Expand the discussion on input mapping (Rose et al., 1991) to provide more details and explain how this approach differs from a weight-of-the-evidence argument;
- Expand the discussion on power analyses to show how increased knowledge can increase power (e.g., compare the power of an ANOVA and ANCOVA for the same data set); and
- Revise the reducing uncertainties section to be a list that summarizes the contents of this section.

8.8. Incorporate Pre-Meeting Comments as Appropriate

The authors should consider the written pre-meeting comments of reviewers and incorporate them as appropriate.

8.9. Define Terminology Used

The following terminology used in this issue paper needs to defined:

- Space and time scale;
- Disturbance regime;
- Stiff system model;
- Liebig's Law;

- Scaling-up;
- Physiological model;
- Conceptual model;
- Qualitative and quantitative models; and
- Sizing and screening tools.

8.9. Reorganize the Describing Uncertainties Section

The describing uncertainty section should be reorganized to conclude the paper more effectively by:

- Including a summary of the material presented in this section; and
- Emphasizing the value of uncertainty information to decision makers.

9. RISK INTEGRATION METHODS

Authors: R. Wiegert, S. Bartell
Reviewers: J. Bascietto, J. Giesy, P. Van Voris

Four recommendations were made to the authors of the Risk Integration Methods paper as follows:

1. Revise section formatting;
2. Provide more balance in the discussion of different model groups;
3. Include a discussion of alternative model approaches; and
4. Include examples of each model approach.

9.1. Revise Section Formatting

The paper should provide consistent section formatting with regard to the discussion of the various integration models. The model description should be followed by a discussion of advantages and disadvantages of the model. The one section on implementation issues should not be a "stand-alone," rather it should be included in the advantages and disadvantages for each model type.

9.2. Provide More Balance in the Discussion of Different Model Groups

More balance should be provided in the discussions of the different model groups. In particular, the authors should expand the discussion of cosms by utilizing the considerable literature on micro- and mesocosms available through EPA sources, such as the Office of Pesticide Programs and the Office of Water.

9.3. Include a Discussion of Alternative Model Approaches

The paper would benefit from the inclusion of a discussion of the results of alternative model approaches, illustrated by a case study of an ecological risk assessment, which could be done using hypothetical data sets if necessary or like the RAF's ecological assessment case studies (U.S. EPA, 1993a; U.S. EPA, 1994). The exercise should array the results comparing alternative risk integration approaches as to stressors, endpoints (reflecting differing risk management objectives), and relative risk ranking. This may need to be a separate EPA exercise due to the increase in scope.

9.4. Include Examples of Each Model Approach

At least one example of each model approach should be included, using graphs, charts, and tables, where necessary, to illustrate the model and any model principles highlighted by the authors.

*U.S. Government Printing Office: 1995 — 651-776