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Peer Review Workshop Report on Draft Proposed Guidelines for Ecological Risk Assessment

RISK ASSESSMENT FORUM

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PEER REVIEW WORKSHOP REPORT ON DRAFT PROPOSED GUIDELINES FOR ECOLOGICAL RISK ASSESSMENT

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NOTICE

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Foreword

EPA's work to develop a set of Agencywide guidelines for ecological risk assessment started in 1989, when the Agency's Risk Assessment Forum began holding a series of colloquia to identify and discuss significant issues in ecological risk assessment. Based on these discussions and on consultation with EPA's Science Advisory Board (SAB), the Risk Assessment Forum decided to pursue a stepwise process for developing ecological risk assessment guidelines. This process has involved development of:

- *Framework for Ecological Risk Assessment*, a widely used report that proposed principles and terminology for the ecological risk assessment process.
- Case studies illustrating ecological risk assessment approaches.
- Issue papers highlighting important principles and approaches that EPA scientists should consider in preparing ecological risk assessment guidelines.
- The Draft Proposed Guidelines for Ecological Risk Assessment currently being reviewed.

The guidelines development process has emphasized peer review and consensus-building. Indeed, many experts from academia, industry, consulting firms, all EPA program offices and regions, and state and other federal agencies have participated in the development and review of the Draft Guidelines and its predecessor documents.

To continue this emphasis on peer review and consensus-building, EPA convened a 2-day workshop to discuss and peer review the Draft Proposed Guidelines for Ecological Risk Assessment. The workshop, held December 6 to December 7, 1995, in Washington, DC, brought together 25 peer reviewers and more than 50 observers from academia, industry, state agencies, EPA, and other U.S. and Canadian agencies. Workshop participants discussed the main topics in the Draft Guidelines in three series of introductory plenary sessions, work group sessions, and summary plenary sessions. Dr. William Smith of Yale University chaired the workshop, while Dr. Dwayne Moore of Environment Canada and Dr. Richard Kimerle of the Monsanto Company led the work group sessions.

This report highlights the main comments and recommendations arising from workshop discussions. Based on the highly constructive and useful suggestions outlined in this report, EPA will give serious consideration to workshop participants' opinions and revise the Draft Guidelines accordingly. EPA will then seek both internal and interagency review of the Guidelines and revise the document again. After submitting the revised document as proposed guidelines to the *Federal Register* for public review and comment and to the SAB for review, EPA will publish final guidelines. As the report that follows indicates, the workshop was a very productive effort that will help EPA move forward in this ambitious development process.

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

EXECUTIVE SUMMARY

William Smith, Ph.D.
Workshop Chairperson
Professor of Forest Biology
Greeley Laboratory, Yale University

The EPA Workshop on the Draft Proposed Guidelines for Ecological Risk Assessment, held December 6 to December 7, 1995, in Washington, DC, brought together 25 experts charged with generating a clear set of comments and recommendations for EPA to use in revising the Draft Guidelines. The workshop also attracted more than 50 observers, who offered their perspectives on the Draft Guidelines as well. Workshop participants generally agreed that the Draft Guidelines represent an appropriate evolution toward a uniform strategy for conducting ecological risk assessments—one that can be used not only by EPA personnel, but also by a broader array of natural resource and environmental managers. Thus, the Draft Guidelines represent an important step toward improving the scientific soundness, consistency, comparability, and completeness of ecological risk assessments conducted in the United States and elsewhere.

Workshop participants also agreed that the overall framework for and main elements of ecological risk assessment proposed in the Draft Guidelines are sound. In their current form, the Draft Guidelines are not (and should not be) a comprehensive technical manual. Rather, the document promotes and guides selection of appropriate risk assessment techniques for specific situations—including situations involving biological or physical stressors rather than chemical stressors. Considering information on biological and physical stressors is appropriate given increasing recognition of the relevance of these stressor types to ecological risk assessment. In fact, reviewers recommend expanding the treatment of nonchemical stressors.

Opportunities to improve the Draft Guidelines include:

- Expanding the treatment of nonchemical stressors (as noted above).
- Emphasizing the importance of multiple stressors.

- Adding more material on the utility of a tiered approach to risk assessment.
- Presenting hypothetical or actual case studies that run through the entire document (i.e., to illustrate important points in each section of the document).

The Draft Guidelines reviewers encourage EPA to move forward with the document as quickly as is reasonable after considering the specific recommendations highlighted in sections 2 and 3 of this report.

SECTION ONE

INTRODUCTION

WELCOME

Dr. William Wood, Executive Director of EPA's Risk Assessment Forum, opened the workshop by welcoming the guideline reviewers and workshop observers. He then introduced Dr. Robert Huggett, Assistant Administrator (AA) of EPA's Office of Research and Development (ORD), noting that Dr. Huggett is a longtime supporter of the Forum's efforts to develop guidelines on ecological risk assessment.

INTRODUCTORY REMARKS BY AA/ORD ROBERT HUGGETT

Dr. Huggett began his remarks by noting the importance of the workshop to review EPA's Draft Proposed Guidelines for Ecological Risk Assessment. In the past, he said, EPA has spent most of its labor and financial resources on human health research and human health risk assessment; the ecological risk assessment guidelines development effort is an important part of EPA's move toward improving the balance between human health work and ecological work. In addition, several pending regulatory reform bills would require the federal government to conduct a risk assessment and a cost-benefit analysis for any mandate or action generating costs of more than $100 million. Given that EPA will likely have to rely increasingly on risk assessments to fulfill legislative requirements such as these, this review of the Draft Guidelines is important to advancing EPA's ability to conduct sound ecological risk assessments. Dr. Huggett emphasized that EPA will take reviewers' comments very seriously in revising the Draft Guidelines.

Dr. Huggett went on to state that the ecological risk assessment guidelines development effort also fits in with ORD's new strategic planning process, which is organized around the risk assessment paradigm to ensure that EPA focuses its research on areas that will most reduce uncertainties in risk assessments. Noting that ORD's strategic plan is available to the public, he invited workshop participants to comment on the document. A sound strategic planning process is especially important now, he said, because EPA's fiscal year (FY) 1997 budget will be considerably less than the FY 1996 budget. ORD will use the new planning process to prioritize EPA research efforts. Despite budget cuts, EPA hopes to increase resources devoted to the extramural grants program—from $44 million in FY 1995 to $85 million in FY 1996 to $100 million in FY 1997. So far, the response to EPA's advertisements for new fellowships has been tremendous.

In concluding his remarks, Dr. Huggett thanked the guideline reviewers and workshop observers for their participation in an effort that is very important to EPA. Reiterating that EPA will consider comments on the Draft Guidelines very seriously, he urged the reviewers and observers to be as candid as possible.

WORKSHOP OBJECTIVES AND FORMAT

Workshop chairperson William Smith thanked Dr. Huggett for his remarks and the energy that Dr. Huggett has brought to the Agency. He then introduced the reviewers of the Draft Guidelines (see appendix A), described the charge to reviewers (see appendix B), and reviewed the workshop agenda (see appendix C). Dr. Smith explained that the primary objective of the workshop was to generate a clear set of comments and recommendations that EPA can use to revise the Draft Guidelines. The three main topics in the Draft Guidelines (problem formulation, analysis, risk characterization) would be discussed separately, he said, in a series of plenary sessions and work group sessions on each topic:

- An introductory plenary session with presentations summarizing key issues from the perspective of the authors of the Draft Guidelines and common themes seen in the reviewers' premeeting comments (reproduced in appendix D).
- Concurrent work group sessions in which reviewers, divided into two groups (see appendix E), would discuss their comments and recommendations.
- A followup plenary session in which the work group leaders, facilitated by the workshop chairperson, would summarize the comments and recommendations of their groups.

Dr. Smith told observers (listed in appendix F) that they could offer comments during the work group sessions at the discretion of the work group leaders and that they also would have an opportunity to speak during plenary sessions at the end of each workshop day.

As a prelude to the plenary and work group sessions on individual Draft Guidelines sections, Dr. Smith offered his own perspective on the document as a whole. He said that the Draft Guidelines have the potential to advance the goal of a single strategy for ecological risk assessment, and that such a strategy would in turn enhance the consistency, comparability, and completeness of these assessments. To achieve these ends, the Draft Guidelines do not necessarily need to address all types of stressors in detail; rather, he suggested, they must provide a coherent framework and clear guidance for at least some major stressors. In addition, the Draft Guidelines should clearly state the importance of being very explicit about the nature and scope of individual ecological risk assessments (e.g., their boundedness over time and space, the ecological level that they address, the societal values that they reflect). Moreover, because ecological risk assessments and stressor/ecological resource monitoring are intimately linked, the Draft Guidelines should emphasize the importance of effective monitoring.

Dr. Smith's remarks sparked a lively discussion of issues that were subsequently explored in greater detail in the work group sessions. The next section of this report summarizes overarching comments and recommendations that arose from these sessions, while section 3 summarizes comments and recommendations related to specific Draft Guidelines sections and section 4 highlights the comments of workshop observers. Section 5 of this report discusses how EPA plans to follow up on this workshop.

SECTION TWO

CHAIRPERSON'S SUMMARY OF THE WORKSHOP

William Smith, Ph.D.
Professor of Forest Biology
Greeley Laboratory, Yale University

Throughout the 2-day Workshop on the Draft Proposed Guidelines for Ecological Risk Assessment, guideline reviewers and workshop observers representing many different disciplines exhibited tremendous interest in the Draft Guidelines and commended EPA for its efforts in developing the document. Indeed, although reviewers offered numerous suggestions for improvement, workshop participants overall viewed the Draft Guidelines as a very useful extension of the *Framework Report* and an appropriate next step in the evolution of specific recommendations for conducting ecological risk assessments. The development of standard guidelines represents an opportunity to achieve greater scientific soundness, consistency, comparability, and completeness in ecological risk assessments. Directing resources to "technology transfer" of the Guidelines would represent a wise investment by the Agency.

Overarching themes and recommendations that emerged from workshop discussions and an informal opinion survey conducted at the end of the workshop (see appendix G) include the following:

- The Draft Guidelines should not be a comprehensive technical manual. They should, however, express preferences and/or provide criteria for choosing among alternative techniques.

  RECOMMENDATION 1. Place greater emphasis on selection criteria in the next draft of the Guidelines by referencing seminal primary literature references, by referencing conclusions of previously developed Issue Papers, and by using case studies to highlight selection criteria for specific situations.

- Recognition of the importance of biological and physical stressors is increasing. As a result, it is appropriate to use the Draft Guidelines as an opportunity to present information about biological and physical as well as chemical stressors.

- The present practice of risk assessment follows a phased approach that begins with broad initial screening and continues with more refined analyses. As a result, it is appropriate to expand the discussion of the tiered approach to risk assessment in the Draft Guidelines. Such a discussion could provide guidance on deciding when data are sufficient to move to a next step, describe how the costs of Type II errors are used in tier decisions, and provide illustrative case studies.

  RECOMMENDATION 2. Expand the discussion of the tiered strategy in the next draft of the Guidelines by outlining the logic for progressing from one step to the next and by illustrating this logic with case studies.

- Ecological resource exposures to stress typically involve concurrent or sequential exposure to more than one stress factor. As a result, single-stress risk assessments rarely reflect actual exposure conditions. This topic is sufficiently important to justify a more detailed evaluation.

  RECOMMENDATION 3. Develop an Issue Paper on multiple stressor interactions. Rather than delaying publication of the Guidelines while the Issue Paper is being developed, add information from the Issue Paper at a later time.

- Hypothetical case studies that are consistently continued through all sections of the Draft Guidelines would represent a very effective training and technology transfer tool.

  RECOMMENDATION 4. Consider developing one or more case studies that are carried through the Problem Formulation, Analysis, and Risk Characterization sections of the document.

Reviewers found *no* major fault with the general organization of the Draft Guidelines, nor with the main themes in the sections on the principal elements of the risk assessment process. Specific recommendations for improving the Problem Formulation, Analysis, and Risk Characterization sections of the Draft Guidelines are summarized in the next section of this report.

SECTION THREE

WORK GROUP SESSIONS

During the workshop, reviewers divided into two work groups, which separately reviewed the three major sections of the Draft Guidelines. During plenary sessions, the work group leaders presented the major comments and recommendations of their work groups. Following the workshop, the workshop chair and work group leaders integrated the comments and recommendations of the two work groups into a single summary on each major section reviewed. These summaries are presented below.

PROBLEM FORMULATION

William Smith, Ph.D.
Professor of Forest Biology
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Problem formulation represents the first major element of the ecological risk assessment process. More important, it is the foundation that supports and bounds the entire process. Deficiencies at this stage will permeate the entire assessment and compromise the full process and final product. The most critical steps of this phase include:

- Clear articulation of the question that initiates the risk assessment
- Identification and engagement of relevant parties to the assessment
- Identification of source/stressor characteristics
- Identification of ecological resource(s) at risk
- Identification of ecological effects
- Identification of assessment endpoints
- Development of a conceptual diagram
- Development of an analysis plan

Clarity of Original Question

The clarity of the original question leading to the risk assessment process is critical. Recognition of the importance of the initial question led the reviewers to make the following recommendation:

> *RECOMMENDATION 5. For site-specific assessments, the initial question should provide temporal, spatial, biological hierarchy, and human value boundaries for the assessment.*

Identification and Engagement of Relevant Parties

Identifying parties relevant to the risk assessment, and involving these parties at the beginning of and throughout the assessment, is extremely important. Social science techniques for "extracting societal values" and identifying relevant stakeholders are well established. Legal statutes, political considerations, historical knowledge, and self-identification (e.g., via the *Federal Register*) are additional techniques for identifying relevant parties. Stakeholder "maps" should be carefully developed. Including too many parties can slow and complicate the process, while excluding relevant parties can undermine chances for acceptance of the assessment strategy.

> *RECOMMENDATION 6. Through examples, the Draft Guidelines should identify methods for identifying stakeholders as well as the advantages and disadvantages of a smaller or larger stakeholder map.*

In most cases, it will be appropriate to think of the risk assessors and risk managers in EPA's framework diagram as teams rather than individuals.

> *RECOMMENDATION 7. At the outset, the Draft Guidelines should very clearly articulate the roles of assessors, managers, reviewers, and other relevant parties.*

Identification of Assessment Type/Purpose

Labeling risk assessments as stressor-, ecological effects-, or societal value-initiated is of limited usefulness. This classification contributes little of substance to the assessment and adds to the proliferation of noncritical technical distinctions. Organizing assessments by stressor type (e.g., chemical, biological, physical) or as prospective or retrospective assessments appears to have greater merit.

RECOMMENDATION 8. Eliminate or de-emphasize the origination designations in the next draft of the Guidelines. Consider relying more heavily on case studies to illustrate the differences between different types of assessments.

Risk assessments can be useful tools for hypothesis testing, but not all assessments involve hypothesis testing.

RECOMMENDATION 9. Clarify the distinction between risk assessments for science (hypothesis testing) and those for environmental management (decision-making). To avoid confusion about what is meant by "hypothesis testing," consider adding a text box on the difference between "risk hypotheses" in risk assessment conceptual models and statistical mill hypothesis testing.

Data Decisions

Development of a conceptual diagram should include a formalized procedure to guide determination of how much data are required, elucidation and application of data "decision rules," and data selection. This procedure should provide the opportunity for risk assessors, risk managers, and other relevant parties to achieve consensus on data quality objectives (DQOs).

RECOMMENDATION 10. Through examples in the Problem Formulation section of the Draft Guidelines, illustrate processes for defining DQOs.

More formal adoption of a tiered approach to risk assessment also will facilitate decision-making on the quality and quantity of data needed in particular assessments.

Introductory Material on Cross-Cutting Issues

Uncertainty is a cross-cutting issue that is fundamentally important to every step in the risk assessment process. As a result, EPA should introduce this topic early in the Draft Guidelines, covering the main types of uncertainty that are relevant throughout the risk assessment process and providing an expanded treatment of uncertainty specifically associated with laboratory and field studies.

> *RECOMMENDATION 11. Add an expanded introduction to uncertainty in the Problem Formulation section of the Draft Guidelines.*

Other cross-cutting topics that pervade the entire risk assessment process also should be introduced early in the Draft Guidelines.

> *RECOMMENDATION 12. Consider adding specific introductory material on multiple stressors, interactive and cumulative effects, and selection criteria for surrogates to the Problem Formulation section of the Draft Guidelines.*

Written material in the reviewers' premeeting comments might provide a useful starting point for addressing some of these issues.

ANALYSIS

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The Analysis section of the Draft Guidelines is impressive in covering a wide range of stressor types and in raising key issues that affect the analysis of each. Covering such a broad range of topics compromises the section's effectiveness, however, when it prevents in-depth discussion of complex issues. This occurs in the subsections on physical, biological, and multiple stressors. The subsection on chemical stressors is more complete, presumably because of EPA's experience in this area.

On the whole, the Analysis section is well organized, although some reviewers questioned the need to discuss uncertainty throughout the document and several reviewers suggested adding or deleting various text boxes and figures.

The most fundamental criticism of the Analysis section is that it provides "precious few guidelines" (see, e.g., John Bascietto's written comments). Although the document does an admirable job of raising complex issues (e.g., uncertainty, secondary effects, multiple stressors), many of which have been ignored by other jurisdictions, it rarely provides guidelines or recommendations on preferred approaches and methods—or even criteria for choosing among available approaches and methods. Unless EPA takes this further (if difficult) step, program-specific guidelines developed in the future will not be consistent with each other, nor will they reflect the state of the art. Specific suggestions are provided below.

Organization

The Analysis section would be more useful if it were organized around the components of ecological risk assessment rather than around the various types of stressors. With the new organization, the section could explain how analysis fits into each component of ecological risk assessment and provide examples, while still noting how analysis differs depending on the types of stressors (biological, physical, chemical) involved.

RECOMMENDATION 13. Start the Analysis section by describing the aim and intent of the analysis phase, focusing on the components of the risk assessment process rather than on stressors. Include a figure and perhaps a table showing types of exposure and effects relevant to increasing levels of biological organization. Also include a hypothetical deterministic example that at some point in the section includes the issue of uncertainty; the example could be carried through subsequent sections of the document. Later in the Analysis section, using illustrative examples where possible, note aspects of the analysis phase that are unique to each major type of stressor.

Guidance

The Analysis section of the Draft Guidelines rarely provides specific guidance on complex issues.

RECOMMENDATION 14. Provide criteria for choosing between methods and approaches and, where possible, note preferred methods and approaches and conditions for their use. Also note that preferences sometimes depend on the level of sophistication (tier) of the ecological risk assessment.

Hierarchies

Multispecies testing is insufficient to analyze community- or ecosystem-level effects. Considering a large area or scale does not necessarily mean that ecosystem or landscape issues are being addressed.

RECOMMENDATION 15. Discuss more fully what is meant by "community-level" and describe attributes applicable at the ecosystem and landscape levels of organization.

Dose-Response Relationships

In contrast to the Draft Guidelines as a whole, which assume an elementary level of expertise, the level of treatment of dose-response relationships varies from one subsection to another in the Analysis section; information is elementary in some places and much more detailed in others. If the document is intended to be a guidelines document rather than a "Framework II" document, EPA should provide more information on dose-response relationships related to nonchemical stressors (e.g., the introduction of exotic species or removal of a disturbance to which a system is adapted) to raise these subsections to the level of other sections.

RECOMMENDATION 16. Improve the consistency with which dose-response relationships (and other topics) are addressed in the various subsections of the Analysis section of the Draft Guidelines.

Natural Disturbances

Ecological risk assessments encompass both anthropogenic and "natural" disturbances, but the Analysis section does not address both with equal clarity. Background disturbance regimes and the effects of physical stressors relative to these regimes need to be discussed much more clearly and explicitly. The intensity, frequency, and magnitude of disturbances need to be clearly delineated as factors to consider in an ecological risk assessment. A short separate section—possibly written with the help of experts outside the Agency—would be useful.

RECOMMENDATION 17. Provide a clear, explicit treatment of background disturbance regimes, noting the effects of physical stressors. Discuss the intensity, frequency, and magnitude of natural (and possibly chemical) disturbances against which to measure human effects. Explicitly comment on whether disturbances smaller than background are of concern.

Biological and Physical Stressors

The sections on biological and physical stressors are somewhat superficial compared to the section on chemical stressors.

RECOMMENDATION 18. Expand the discussion of biological and physical stressors, relying in part on the Issue Papers by Simberloff and Alexander and by Sheehan and Loucks.

RECOMMENDATION 19. Focus on biological and physical stressors over which EPA has jurisdiction (i.e., those with which EPA has experience).

Multiple Stressors

A fuller discussion of multiple stressors would be useful.

RECOMMENDATION 20. Divide the section on multiple stressors into subsections on chemical mixtures, habitat alteration, mixed types of stressors (biological, physical, chemical), and receptor-driven assessments. Note the different approaches and methods used for each.

RECOMMENDATION 21. Develop an Issue Paper on receptor-driven assessments. Review existing case studies (e.g., striped bass in the Hudson River) to garner common themes and lessons learned.

Biological Indices

Guidelines on biological indices are inadequate and written in a tone suggesting a negative bias against these indices. EPA appears to have dismissed biological indices without adequately exploring the available literature.

RECOMMENDATION 22. Review appropriate literature and revise the discussion of biological indices accordingly, noting the utility as well as potential problems of these indices.

Indicator Species

To be useful, indicator species must have relevant characteristics that are relatively closely congruent with those of the species they are believed to indicate.

RECOMMENDATION 23. State that indicator species should be used as a response measure only after the characteristics believed to be indicated are clearly stated, documented, and fully justified.

DQOs and Terminology

The Draft Guidelines appear to confuse the terms "DQO" and "quality assurance/quality control (QA/QC)," which are not synonymous. Data quality concerns more than the procedures by which data are collected. In this light, should line 6 on page 58 refer to DQOs or QA/QC? The Draft Guidelines also appear to confuse the terms "data" and "information." In line 5 on page 56, for example, "data" should be replaced with "information," since model outputs are not really data.

In addition to addressing these terminology questions, the discussion of DQOs should emphasize the need for flexibility to avoid exclusion of data that might be useful for decision-making. For example, data obtained through Good Laboratory Practices (GLP) might not be useful for decision-making; these data should not be used at the expense of other, more useful data. To sort out this issue, EPA should provide criteria for selecting and using data/information.

RECOMMENDATION 24. Clarify the real differences between DQOs and QA/QC and check the use of these terms throughout the Draft Guidelines. Provide criteria for including data/information in a risk assessment; in so doing, note that useful data/information should not be excluded and that GLP might be too rigorous in some cases.

Meta-Analysis

Although meta-analysis is a developing field, this method of analysis should be addressed in the Guidelines, particularly given EPA's goal of producing a "living document" that is sufficiently broad to avoid becoming obsolete quickly.

RECOMMENDATION 25. Consider discussing meta-analysis and other emerging methods of analysis; indicate areas of science that need further development.

Modifiers of Exposure

The figure on page 69 fails to mention modifiers of exposure, as does the text. A clear discussion of how exposure can be modified is required.

RECOMMENDATION 26. Add a short discussion of exposure modifiers, explaining the relationship between dose levels, toxicokinetics, bioaccumulation, and factors that affect these exposure parameters relative to food chain issues (where modifying factors are particularly important). Clarify how the environmental chemistry and fate of chemicals can modify the exposure potential of some chemicals.

Monte Carlo and Uncertainty Factors

The Analysis section would benefit from more guidance on the use of Monte Carlo (which is already commonly used), more guidance on the use of safety factors, and more contextual information about uncertainty factors. Uncertainty factors, which actually are extrapolation factors (also called application factors), are considered by many to be arbitrary. Since uncertainty factors have not been revisited since their inception, the Agency should do so by retrospectively analyzing existing data bases (e.g., to examine the relationship between acute-chronic ratios and valued ecosystem components). Potential resources for this effort include Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) data bases, work performed by the Europeans, and the pyrethroid data sets.

RECOMMENDATION 27. Improve the discussion of uncertainty factors by including references, rationales for their use, advantages and disadvantages of their use, criteria for when and when not to use them, appropriate terminology, and so on. Provide resources to revisit, update, and improve the case for uncertainty factors.

Statistical Expressions

Rather than trying to definitively establish cause-and-effect relationships, confidence limits around point estimates might be more appropriate than other statistical expressions. Use of confidence limits would minimize or eliminate inappropriate statistical inferences.

RECOMMENDATION 28. Explain the potential for misuse and misrepresentation of statistical analyses. Encourage readers of the Draft Guidelines to express statistical inferences as point estimates with measures of precision when possible.

Uncertainty

The Draft Guidelines provide a great deal of useful discussion on sources of uncertainty, but they provide little guidance on how to incorporate uncertainty in stressor-response profiles (e.g., EC_{20} ± 95% confidence limits) and exposure profiles (e.g., confidence limits, skewness, kurtosis, underlying distribution, importance of considering sampling design).

RECOMMENDATION 29. Provide guidance on how to incorporate uncertainty in stressor-response and exposure profiles.

Monitoring and Validation

When possible, risk assessments should include and be followed by "reality checks." Reality checks could take the form of monitoring and/or appropriate and realistic validation.

RECOMMENDATION 30. Emphasize the importance of monitoring as a tool for estimating exposure and existing impacts, for evaluating predictions, and for monitoring recovery.

Roles of Decision-Makers and Interested Parties

The Draft Guidelines effectively explain the roles of decision-makers and interested parties in the problem formulation and risk management phases of ecological risk assessments. These groups should also be involved in—or at least consulted during—the analysis phase.

RECOMMENDATION 31. Emphasize the continuing interaction between risk assessors and interested parties, decision-makers, and scientific experts. Consider developing terms of reference for each of these groups.

Window to the Literature

Although the Draft Guidelines document is not (and should not be) a textbook, citing key references (e.g., seminal papers, review papers) to provide a window to the literature for readers who need to understand issues in greater depth would substantially improve the Analysis section of the document.

RECOMMENDATION 32. For all major issues in the Analysis section of the Draft Guidelines, cite review articles (not just Issue Papers), seminal papers, and existing guideline documents from other jurisdictions.

Training and Certification

This issue was discussed in the context of the inadequacy of many present-day ecological risk assessments. Because many groups will be using the Guidelines, some training would be very useful. EPA also might wish to consider establishing certification procedures to ensure adequate training of those involved in ecological risk assessment.

RISK CHARACTERIZATION

Richard Kimerle, Ph.D.
Senior Fellow
Monsanto Company

If goals addressing all interested parties' concerns are clearly articulated at the beginning of an ecological risk assessment, and if all aspects of the plan generated by the problem formulation step are carefully considered, the overall assessment is likely to be successful. Linking all components of the assessment—problem formulation, analysis, and risk characterization—is critically important to ensuring that the assessment fulfills the established goals. As the final step in the technical and scientific portion of ecological risk assessment, risk characterization serves this purpose. All data outputs on exposure and stressor responses from the analysis phase—as well as considerations such as elements of uncertainty, assumptions, limitations, scientific judgment, ecological relevance, and the concerns of all interested parties—are integrated into a judgment about the probability of an impact (adverse or beneficial) occurring in some component of an ecosystem or in an entire ecosystem. During workshop discussions, reviewers recognized the importance of risk characterization and offered the following suggestions for improving this section of the Draft Guidelines.

Congruence with Analysis Phase

The Analysis and Risk Characterization sections of the Draft Guidelines should follow a similar organization to provide a logical flow from analysis to risk characterization. Indeed, the Risk Characterization section should be, but is not yet, a powerful section that builds on the Analysis section. Improving the connectivity between analysis and risk characterization, especially with regard to exposure and response profiles, would be useful. Similarly, although the Risk Characterization section presents many of the "tools" to be used in characterizing risk, it does not provide sufficient detail on the use of specific tools. Carrying examples through all sections of the Draft Guidelines to illustrate the pros and cons and the utility and non-utility of various tools under various circumstances would be useful.

RECOMMENDATION 33. Through an example carried through the Problem Formulation, Analysis, and Risk Characterization sections of the Draft Guidelines, elaborate on how "tools" or methods of integrating assessment results can be used in characterizing risk and formulating risk decisions.

Ecological Significance

The Draft Guidelines' discussion of ecological significance appears to confuse ecological consequences and human values. These two factors should be distinguished, and their roles in determining ecological significance explained. Moreover, EPA's interpretation of ecological significance (i.e., whether the magnitude and probability of observed effects are ecologically relevant) is unclear. EPA needs to clarify its interpretation of ecological significance and note that it is appropriate to consider an effect's magnitude in evaluating ecological significance.

The discussion of ecological significance belongs in the Problem Formulation section rather than the Risk Characterization section. The Problem Formulation section should clearly define the ecological relevance of various types of effects relative to their magnitude. It should also address the question of whether assessment and measurement endpoints are important to determining ecological significance and emphasize the importance of knowing "where one is going." For example, establishing the level of change that can be detected (i.e., determining the power of the test) is important to ensure that a significant effect can be determined. If such decision criteria are not established at the beginning of an assessment, interpreting results will be difficult. As with other aspects of problem formulation, stakeholders should be involved in setting these types of decision criteria.

RECOMMENDATION 34. Clarify the meaning of ecological significance, distinguishing between ecological consequences and human values and their roles in determining ecological significance. When discussing ecological significance, stress the likelihood and consequences of effects.

RECOMMENDATION 35. State that all parties should agree on ecological significance issues (i.e., "if this is found, it means this and this should be done...") a priori during problem formulation rather than setting these issues aside until risk characterization.

Analysis Versus Risk Characterization Methods

The discussion of simulations as methods of analysis beginning on page 118 belongs in the Analysis section, since risk characterization should not involve selecting methods of analysis. The use, possible misuse, advantages, and disadvantages of various risk characterization methods (e.g., from quotients to probabilistic methods), on the other hand, should be discussed in more detail. For example, the discussion of uncertainty analysis for the risk estimate (section 4.2.4) should be expanded to discuss in more detail the advantages and limitations of and best practices for various techniques for estimating uncertainty (see also related recommendation to develop guidance on communicating uncertainty under the heading "Risk Communication" below).

Similarly, at least part of section 4.2.3.4 (Causality) might be more appropriate in the Risk Problem Formulation and/or Analysis sections. The Risk Characterization section cannot and should not review all methods of determining causality, but should focus on (and explain more clearly) the principles involved in determining causality, stressing the difficulty of establishing causality and the advantages of multiple lines of evidence. Case studies (e.g., herring gulls and organochlorines, acid rain examples) might be useful to illustrate these principles.

RECOMMENDATION 36. Move methods of analysis to the Analysis section so that the Risk Characterization section focuses on risk characterization methods and issues. Provide more detailed guidance on the use, possible misuse, advantages, and disadvantages of various risk characterization methods.

RECOMMENDATION 37. Discuss and expand on the advantages and limitations of and best practices for various techniques for estimating uncertainty (from quotients to probabilistic methods).

RECOMMENDATION 38. Consider moving part of the discussion of causality to earlier sections of the Draft Guidelines. In the Risk Characterization section, focus on principles involved in determining causality, stressing the difficulty of establishing causality and the advantages of multiple lines of evidence; if possible, use case studies to illustrate these points.

Multiple Stressors and Total Risk

Like the Analysis section, the Risk Characterization section provides little guidance on how to address multiple stressors and estimate the total risk associated with these stressors. Endpoints for total or aggregate risk do exist, and EPA should review the literature in this area to provide more guidance in the document.

RECOMMENDATION 39. Discuss available population models, community simulation models, and other state-of-the-art techniques for estimating total risk. Describe the advantages and disadvantages of these techniques (including their utility in describing ecological consequences and estimating total risk) and provide a window into the literature on these techniques.

RECOMMENDATION 40. Stress the importance of identifying and addressing all key stressors and identify diagnostic tools for doing so.

Recovery

Determination of recovery time, currently discussed only briefly, needs to be clearly articulated in both the Analysis and the Risk Characterization sections. Recovery, like risk, is best addressed in a probabilistic framework. Discussions of recovery should note that one cannot return a system to exactly pre-perturbation conditions, that recovery from one impact might be followed by another impact (thus, consideration must be given to sustainability through and beyond the end of anthropogenic insults), that restoration is part of recovery, and that "something" of value must be retained. EPA might be able to draw from National Trustee language on ecological services provided by resources and on situations when substitution of resources is acceptable.

RECOMMENDATION 41. Clearly articulate issues related to recovery time, including the issue of whether a return to pre-perturbation conditions is possible and the relationship between multiple insults over time, persistence, and recovery. Consider combining the discussion of restoration with that of recovery in section 5.3.2.3.

Natural Variability

Reviewers questioned whether anthropogenic impacts should be discussed in the section on natural variability, but decided that this is unnecessary given previous discussions (assuming EPA implements the reviewers' other recommendations).

Weight of Evidence

EPA should expand the section on weight of evidence (page 121), and perhaps add hypothetical examples, to elucidate what "weight of evidence" means and how to use weight of evidence. A document on this topic prepared by a volunteer work group in Massachusetts (details available from Nancy Bettinger) might be a useful resource.

Weight of evidence can involve determining how well endpoints are characterized in an assessment and how useful they are for final problem-solving; this, in turn, sometimes points to new measurement endpoints for an assessment endpoint. Similarly, weight of evidence can be used to compensate for deficiencies and to estimate risk in the face of conflicting information (a topic that should receive more attention in the Risk Characterization section). Thus, weight of evidence can be defined as a systematic, rigorous method of developing a risk assessment through logical interim decision points to achieve a final decision. Evaluating the weight of the evidence results in either a decision on the magnitude of the risk (which in turn results in a management decision) or a decision to iterate to the next tier.

RECOMMENDATION 42. Expand section 5.3.1 to explain the meaning, reasoning involved in, and use of weight of evidence. If possible, provide examples (cf. previous recommendation for an example, possibly hypothetical, carried through all major sections of the Draft Guidelines).

RECOMMENDATION 43. In this or a separate subsection, provide more guidance on how to deal with conflicting lines of evidence.

Optimum Use of Information

Interplay between risk analysis and data acquisition (e.g., via tiers) helps ensure optimum use of available assessment data in characterizing risk and in determining what is needed if a decision is made to proceed to the next tier.

RECOMMENDATION 44. In part through text and in part through an example carried through all sections of the Draft Guidelines, provide guidance on how to exploit all of the data generated by the analysis phase; describe both effective use of data in risk characterization and in determining data needs for a subsequent assessment iteration/tier.

Roles of Interested Parties in Risk Characterization

The Draft Guidelines appear to suggest that interested parties should be involved mainly in the problem formulation phase of ecological risk assessment. Interested parties play a key role in risk characterization as well. Their involvement in risk characterization helps ensure that assessment results are expressed in a way that will be meaningful at the management phase.

RECOMMENDATION 45. Discuss the roles of risk assessors, experts, decision-makers, and interested parties in risk characterization. Note that this step should be appropriately inclusive to ensure that assessment results are expressed in a way that is useful for decision-making; the appropriate level of inclusivity depends on the type and goal of the assessment (being too inclusive might be unnecessary to meet the Agency's needs or might stall the process).

Monitoring

Monitoring, especially as it relates to recovery, should be discussed in a separate section.

RECOMMENDATION 46. In a separate subsection in the Risk Characterization section, provide more guidance on monitoring, paying special attention to the need to develop data over time and the use of monitoring to determine the effectiveness or impact of ecological risk management decisions.

Risk Communication

Audiences of risk communication include nontechnical individuals and groups. Reaching these audiences should include communication and education during problem formulation, not just preparation of readable documents after completion of the assessment. Communicating uncertainty during and after the assessment is particularly challenging and should be a topic of additional guidance.

RECOMMENDATION 47. Note that risk communication is an integral part of problem formulation, include this topic in the text box on planning, and emphasize this topic more in the Risk Characterization section. Spelling out objectives and elements of good communication, addressing risk perception, and providing a window to the available literature would be useful.

RECOMMENDATION 48. Develop guidance on how to communicate uncertainty to a variety of audiences. Cover such issues as putting uncertainty into context, explaining quantifiable as well as qualitative uncertainty, and discussing sources of high uncertainty.

End of Section

Currently, section 5 ends "flat." This could be corrected by adding a summary that addresses the following topics: use of the Draft Guidelines to simplify what is often perceived as a hopelessly complex challenge, the role of scientific judgment, integration of uncertainty issues discussed throughout the document, and preparation of the overall ecological risk assessment report (providing a generic framework or outline would be useful). Scientific judgment and values especially need to be highlighted, and a separate section on reporting might be useful. The bullets on pages 127-128 should be integrated and presented earlier in the text or in a text box earlier in the document.

RECOMMENDATION 49. Develop a new section (section 5.4) to provide closure for the Risk Characterization section and a logical lead-in to section 6. Address at least the following topics (and perhaps others): simplifying ecological uncertainty, scientific judgment and values, and the final assessment report.

SECTION FOUR

OBSERVER COMMENTS

At the end of each workshop day, time was allotted for workshop observers to comment on the guidelines and workshop deliberations. These comments are summarized below.

DAY 1 OBSERVER COMMENTS

Elizabeth Kelly, Los Alamos National Laboratory

This observer commented on the definition of ecological risk assessment in the Draft Guidelines. Noting that some workshop reviewers and observers had struggled with whether an effects-initiated assessment is truly a risk assessment and if so how it differs from a stressor-initiated assessment, the observer suggested that a deficiency in the definition might account for the confusion. Illustrating her point mathematically, the observer compared what she considered a traditional definition of risk to the Draft Guidelines' definition of ecological risk:

Traditional definition of risk:

$R = P(\text{Hazard} \cap \text{Consequence})$

Risk equals the probability of a hazard and the consequence of the hazard. In the case of ecological risk, this translates to:

$R = P(S \cap E \cap AE)$

Risk equals the probability of the stressor and the exposure causing the effect (i.e., the hazard) and the adverse effect (i.e., the consequence) associated with the stressor and exposure.

Draft Guidelines definition of ecological risk:

$ER = P(AE/S \cap E)$

Ecological risk equals the probability of an adverse effect given an exposure resulting from a stressor. (The slash in the equation means "given" or "conditioned on".)

Given these equations, traditionally defined risk (R) equals EPA's ecological (ER) risk times the probability of exposure given the stressor, times the probability of the stressor:

$$
\begin{aligned}
R &= P(S \cap E \cap AE) \\
&= P(AE/S \cap E) \times P(S \cap E) \\
&= ER \times P(S \cap E) \\
&= ER \times P(E/S) \times P(S)
\end{aligned}
$$

Thus, traditionally defined risk and ecological risk are the same (R = ER) only when the probability of the stressor is one and the probability of exposure given the stressor is one. In an ecological risk assessment, the former might be true (i.e., the existence of the stressor might be known), but the latter might not be true. The observer contended that EPA's definition of ecological risk ignores the dependence of exposure on the stressor—the probability of observing a particular exposure given the stressor—and that this might cause problems in assessments involving comparisons.

To illustrate, the observer discussed the implications of the absence of the probability of exposure term for an assessment in which it is known that there is an effect, that multiple sources of exposure exist, and that each source is (or could be) associated with a different level of risk. Mathematically, the risk associated with source i is the probability of source i and the exposure given the observed adverse effect, times the probability of the adverse effect:

$$
\begin{aligned}
R_i &= P(S_i \cap E \cap AE) \\
&= P(S_i \cap E/AE) \times P(AE)
\end{aligned}
$$

Since the effect is known to exist, the probability of the effect is one, and that term can be dropped:

$$
\begin{aligned}
R_i &= P(S_i \cap E/AE) \times P(AE) \\
&= P(S_i \cap E/AE) \times 1 \\
&= P(S_i \cap E/AE)
\end{aligned}
$$

Equating this to EPA's definition of ecological risk as shown above produces the following:

$$R_i = P(S_i \cap E/AE)$$
$$= ER_i \times P(E/S_i) \times P(S_i)$$

Assuming that the assessment examines stressors that have been observed, the probability of the stressors is one; but the probability of the exposure given the stressor remains unknown. As a result, traditionally defined risk and ecological risk are not the same—they differ by the probability of exposure given the stressor. It is unlikely that exposure will be the same for different stressors. Thus, using the more limited definition of ecological risk in the guidelines could lead risk assessors to miss an important component of risk. The observer suggested that EPA reconsider the definition of ecological risk, or at least point out how and why it differs from the traditional definition of risk.

The observer's comments sparked a number of questions. To help clarify the discussion, one reviewer suggested that the observer's comments reflect differences in how ecological risk assessment and "traditional" or engineering risk assessment have evolved. He suggested that analysts in both fields do the same things, but that this has not necessarily been captured in the definition of ecological risk. In ecological risk assessment, he said, risk assessors focus on the probability of an adverse event and assess the consequences of the event in a separate step. Thus, the observer's concern is not addressed in the ecological risk definition, but it is addressed in the risk assessment process as a whole. The observer and reviewer agreed that risk assessors probably address the issue in practice, if not in equations or definitions.

Michael Harrass, Amoco Corporation

This observer recommended that EPA:

- *Examine products developed by other organizations to supply details on methods and approaches mentioned in EPA's Draft Guidelines.* In particular, several American Society for Testing and Materials (ASTM) groups have developed or are developing consensus technical documents on identifying assessment endpoints, identifying potentially impacted sites, performing risk-based corrective actions, and so on. It might be productive to consider using these documents to support EPA's Draft Guidelines—and to promote harmonization of methods and approaches.

- *Consider what sites should be assessed and what conditions make a site suitable for ecological risk assessment.* Should an ecological risk assessment be conducted for every site? Can meaningful ecological risk assessments be conducted for service stations? For operating wellheads? What are the minimum conditions needed to conduct a sound, meaningful assessment? How should assessment activities be scaled in different situations?

- *Require that risk managers take the time to participate in the problem formulation step if EPA decides that this step is important.* The Draft Guidelines should reflect the reality that risk managers' time is often very limited.

- *Note the need to train people who conduct ecological risk assessments,* since these individuals are usually engineers or human health risk assessors rather than ecologists.

- *Distinguish between ecological risk assessment activities and other types of activities.* For example, investigating a site known to be impacted might be a diagnostic activity rather than an ecological risk assessment. Similarly, verifying the presence of a stressor at levels sufficient to produce the observed consequences might not be a risk activity.

DAY 2 OBSERVER COMMENTS

Alan Rubin, Water Environmental Foundation

This observer urged EPA to produce a practical product that:

- *Provides (or aids in generating) numerical standards, management practices, or mechanisms* that can be written into regulations to reduce the impact of regulated materials on the environment.

- *Recognizes the beneficial as well as damaging impacts of regulated materials*—and notes that the resulting overall picture should be compared to that associated with alternative materials. This information is important to risk managers in crafting regulations.

- *Addresses the issue of ecological significance.* For example, putting biosolids on degraded arid range land produces an impact: greater crop growth and replacement of animal populations adapted to sparse conditions with populations that do well in lush soil. Is this a positive impact, negative impact, or no impact?

- *Addresses terrestrial and marine systems.*

- *Reflects the real-world data needs of different programs.* The sewage program, for example, needs actual field information rather than laboratory or experimental data. This should be reflected in a discussion of hierarchy of data and weight of evidence.

Daniel Michael, Neptune and Company

This observer noted that workshop reviewers and observers commented on the lack of specific guidance in the Draft Guidelines, the need to reorganize the document, and the need to expand on the discussion of the DQO approach. He suggested that these perceived deficiencies result from an effort to address all levels of decision-making at once. Thus, a reader consulting the document from a particular point of view (e.g., that of needing to support a particular level of decision-making) would not know how to proceed. This problem could be resolved, he suggested, by dividing the Draft Guidelines into sections based on the three levels of decision-making:

- Site-specific decisions (e.g., whether to remediate a site, what limits to set for a specific discharge at the site).

- Programmatic decisions (e.g., at what level to set a threshold, whether to register a pesticide, how to deal with sewage sludge).

- Policy decisions (e.g., whether to regulate a new chemical or industry, whether to introduce a new species).

The observer suggested starting with the site-specific level, providing relatively specific guidance at this level. Subsequent sections on higher-level decisions would provide broader and broader guidance. Each section could include guidance on how to implement the ecological risk assessment process *and* how to present the results of the process, both of which depend on the level of decision-making being supported.

The observer commented that dividing the Draft Guidelines in this manner also would facilitate resolution of other issues raised during the workshop. The question of tiering, for example, becomes straightforward in the context of a specific decision level. Tiering has been well described at the site-specific level, where each tier is intended to reduce the level of uncertainty and the level of conservatism used in estimates to avoid wasting public dollars. Tiering takes on different meanings at the programmatic level and at the policy level.

One reviewer suggested that some ecological risk assessments might not fall easily into any of the three decision levels. He asked, for example, how the observer would categorize a watershed assessment. The observer replied that he would ask what kind of decision is to be made. Most likely, the assessment would be aimed at supporting a site-specific decision—whether to remediate various sources affecting the watershed. He went on to state that, having worked with nearly every EPA program, it is his experience that every EPA decision can be categorized into one of the three levels listed. A reviewer added that the approach suggested would have the additional benefit of underscoring the concept of risk assessment as a decision-making tool.

The observer concluded by suggesting that the expanded discussion of DQOs recommended by some reviewers during the workshop might not be warranted because the document specifically excludes data collection from the ecological risk assessment process. He contended that the DQO issue would be clearer if the document's discussion of drawing people into the process distinguished between who needs to be involved in assessments supporting different decision levels.

Unidentified Observer

This observer agreed with Daniel Michael that distinguishing between assessments for different decision levels may have some utility. He noted that when the U.S. Food and Drug Administration, for example, reviews food and drug product applications, it is being called upon to make what are clearly nationwide, programwide decisions. A watershed assessment, he suggested, would be a site-specific assessment because the watershed has a specific "address." Distinguishing between these two types of assessments (nationwide versus site-specific) is useful because they involve different approaches to assessment and decision-making.

Suzanne Marcy, National Center for Environmental Assessment, ORD, EPA

Suzanne Marcy concurred that there may be some utility in presenting the information this way, but that reorganizing the document accordingly might be difficult. Anne Fairbrother, a reviewer, said that she favors the current organization because it reflects the fact that the core of ecological risk assessment lies in defining the question being asked and that the rest of the assessment process is driven by that question. The observer responded that he is not recommending that the three phases of risk assessment (problem formulation, analysis, risk characterization) be removed; rather, he recommends that issues related to each of the three decision levels be defined and explained in each phase.

SECTION FIVE

NEXT STEPS

Prior to the work group sessions, William Wood, Director of EPA's Risk Assessment Forum, addressed a series of questions that might influence how reviewers and observers view the Draft Guidelines and this workshop. His remarks, and reactions to them, are summarized below.

WHERE DOES EPA GO FROM HERE?

EPA is following a very deliberate course in developing the Draft Guidelines. Having concluded early on that no one document can cover all aspects of ecological risk assessment, EPA is developing a series of guidance documents. The process of developing these guidance documents began with the development and publication of a number of reports: *Framework for Ecological Risk Assessment*, several case studies, and several issue papers. The Guidelines expand upon and will replace the *Framework Report*. EPA expects that the Guidelines will in turn form the basis for a series of followup activities and documents on areas needing additional guidance development. This workshop is intended to produce recommendations on what guidance can be provided now and what must be addressed later.

Following this workshop, the Risk Assessment Forum (RAF) will consider all recommendations offered and revise the Guidelines accordingly. The RAF will then seek both internal and interagency review of the Guidelines. The RAF will revise the document again and submit the revised document as proposed guidelines to the *Federal Register* for public review and comment. At the same time (probably in the late Spring), the RAF will submit the proposed guidelines to the SAB for review. The RAF will then work with the public's and SAB's comments to revise the document. EPA hopes to publish final guidelines by the end of calendar year 1996 or early in calendar year 1997.

WHO IS THE AUDIENCE FOR THE GUIDELINES?

In general, EPA guidelines contain two types of guidance:

- *State-of-the-science guidance*, consisting of information with which most risk assessors would agree. The goals of this guidance are to document the Agency's position on the topics addressed and to make the information understandable to people inside and outside the Agency.
- *Science policy guidance*, consisting of EPA's policy positions on key issues, especially where methodology or data gaps exist. These positions are not necessarily positions that other agencies or private groups would take. Thus, science policy guidance in EPA guidelines are primarily aimed at Agency risk assessors. EPA hopes that this guidance is reasonable enough that others might adopt it, but the Agency does not presume to impose it on others.

The Draft Guidelines being reviewed at this workshop are intended to provide these two types of guidance.

WHAT ARE EPA'S GOALS IN TERMS OF GUIDANCE?

In providing state-of-the-science guidance and science policy guidance, EPA aims to use a range of guidance language based on EPA's "guidance pyramid" (see figure 1) in which the majority of guidance language pertains to the use of judgment; somewhat less language describes case-by-case issues, guideposts, and preferences; and relatively little sets forth specific rules.

In their premeeting comments, many reviewers indicated that the Draft Guidelines should provide more "guidance," meaning preferences and rules. EPA recognizes that the document might rely too heavily on guidance language pertaining to the use of judgment rather than preferences, and the Agency hopes that the workshop yields suggestions for improving the balance between the various types of guidance. At the same time, EPA recognizes that the guideline must be a living document—one that is not overly prescriptive and, thereby, becomes dated.

Risk Assessment Guideline Content

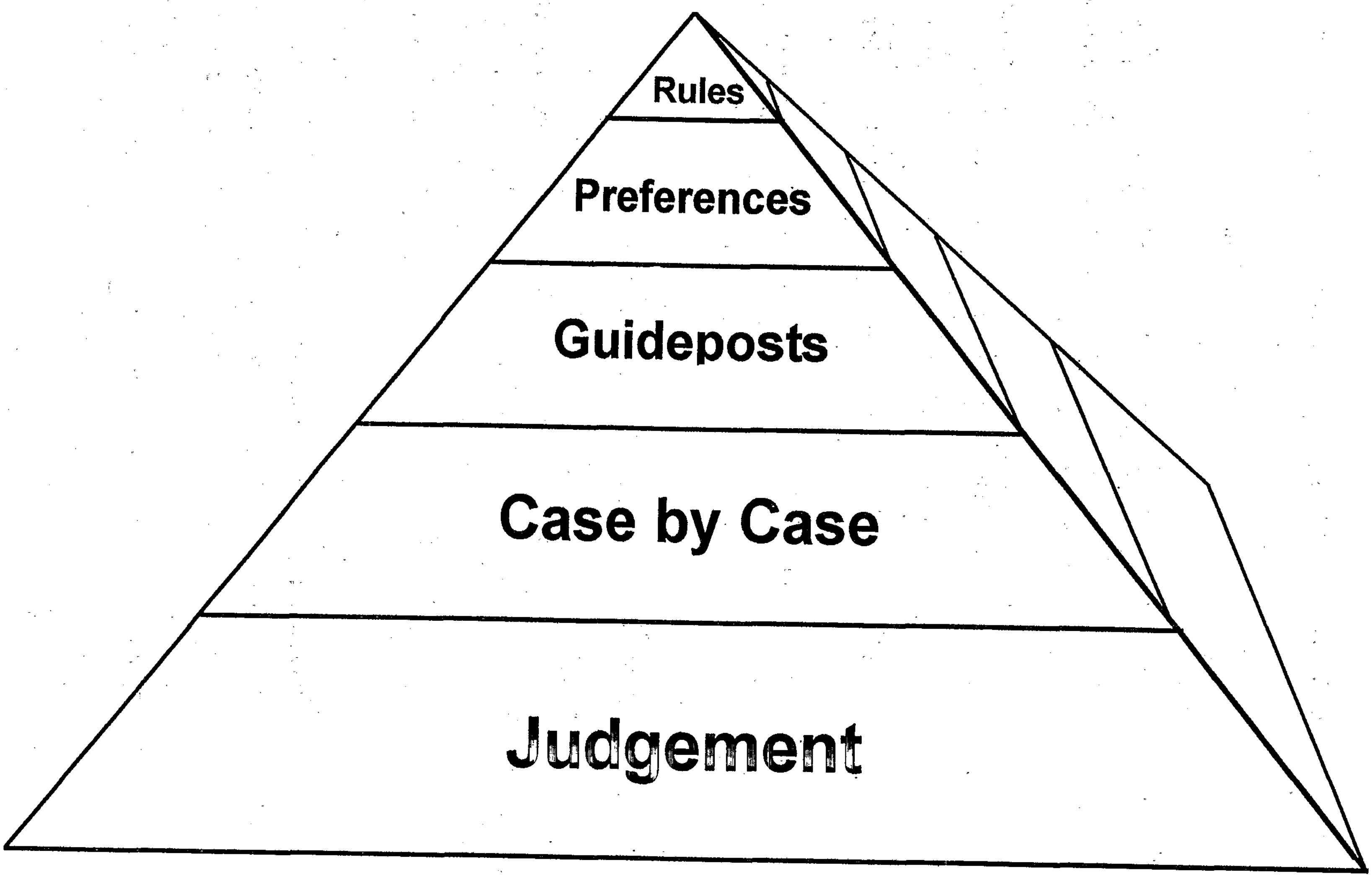

Figure 1. EPA's "guidance pyramid."

WHAT IS THE RELATIONSHIP BETWEEN THESE GUIDELINES AND EXISTING PROGRAM GUIDANCE OR PROGRAM GUIDANCE THAT MIGHT BE DEVELOPED IN THE FUTURE?

Publication of the guidelines for ecological risk assessment is expected to spur development of program-specific guidance materials. Compared to Agencywide guidelines, program-specific guidance generally places greater emphasis on preferences and rules. This is appropriate because programs have particular applications in mind, and they know what types of data are typically available. In addition, programs can update program-specific guidance materials more frequently than can the Agency as a whole.

DISCUSSION

Observing that the premeeting comments were quite lengthy, one reviewer remarked that addressing the comments would be a monumental task and wondered how EPA plans to accomplish the task. William Wood agreed that the task is monumental, but said that EPA hopes that the workshop produces consensus recommendations to guide the revision process. He also noted that EPA will seek further input from within and outside the Agency. A reviewer asked if this will ensure some consistency between program offices. William Wood responded that the programs have reviewed predecessor documents and that, although debate continues, the Agency is moving toward concordance. Another reviewer asked whether EPA would seek input from the European Union, commenting that international harmonization is a worthy goal. William Wood replied that EPA has shared drafts of the documents and will continue to do so.

During the course of the workshop, reviewers offered additional suggestions related to EPA's planned next steps:

- The reviewers encourage EPA to move forward with the guidelines as quickly as is reasonable.
- Developing issue papers on complex or poorly understood topics (e.g., multiple stressor interactions) would be useful, but should not delay revision and publication of the Guidelines.

- Similarly, providing resources to revisit, update, and improve the case for uncertainty factors would be useful, but should not delay work on the Guidelines.

- Funding technology transfer of the Guidelines would represent a wise investment of Agency resources.

APPENDIX A

REVIEWER LIST

United States
Environmental Protection Agency
Risk Assessment Forum

Workshop on the Draft Ecological Risk Assessment Guidelines

Holiday Inn - Georgetown
Washington, DC
December 6-7, 1995

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APPENDIX B

CHARGE TO REVIEWERS

CHARGE TO REVIEWERS

FOR EPA'S ECOLOGICAL RISK ASSESSMENT GUIDELINES

EPA's Risk Assessment Forum first published Agency-wide guidelines for human health risk assessment in 1986 and has been working to develop ecological risk assessment guidelines since 1989. As discussed in the Foreword and Introduction to the guidelines, EPA has approached guidelines development in a step-wise fashion, with each subsequent step drawing upon prior products and experience. Consistent with the recommendations of previous peer reviewers and the Science Advisory Board, the guidelines are organized by the major phases of the ecological risk assessment process: problem formulation, analysis, and risk characterization. The goal of the guidelines is to improve the quality and consistency of EPA's ecological risk assessments.

This charge is divided into two parts. The first part asks for your assistance in identifying and highlighting important guidance principles in the document. The second part asks specific questions concerning particular portions of the guidelines. Please focus on those Part II questions that you feel are most important and that best suit your expertise, and feel free to comment on other issues that may not be addressed by the questions. Your comments, along with those of other reviewers and recommendations from the workshop, will be considered in revising the guidelines.

EPA's Risk Assessment Guidelines

Guidelines are developed by the Risk Assessment Forum, with oversight from EPA's Science Policy Council. The guidelines are intended to describe the scientific principles and approaches for risk assessment and establish EPA's science policy on new or controversial issues. They are a product of consensus-building and peer review processes.

Guidelines **are** intended to:

- improve the quality of EPA's risk assessments;
- promote Agency-wide consistency; and
- inform the scientific community and the public.

Guidelines **are not**:

- rule books. Guidelines are intended primarily for use within EPA.
- cook books. Guidelines do not provide detailed "how tos". Rather, they address major issues of concern.
- text books. Guidelines do not contain extensive background material for novice readers.
- program-specific guidance. It is left to each EPA program (e.g., Superfund, pesticides) to adapt Agency-wide guidelines to their own needs.

PART I. GENERAL PRINCIPLES

For each phase of the ecological risk assessment process, the ecological risk assessment guidelines discuss the general options available and the various considerations, strengths, and limitations that the risk assessor should keep in mind when evaluating these options. The National Research Council has recommended that EPA's human health risk assessment guidelines indicate the basic assumptions underlying risk assessment approaches, the default positions for these approaches, and the circumstances under which deviations from the default positions are permissible. Please answer the following questions, and keep them in mind as you review the Part II questions.

- Specifically, how can the ecological risk assessment guidelines be improved to more clearly indicate underlying assumptions and default positions?
- What changes would you recommend in each section of the document?

PART II. SPECIFIC QUESTIONS

Guidelines Balance

These questions concern crosscutting issues that involve all parts of the ecological risk assessment guidelines.

1. Considering both the present state of the science and present and future Agency needs, how well are the guidelines balanced regarding the range of stressors, levels of biological organization, ecosystem types, and spatial/temporal scales? Specifically, what would you emphasize or de-emphasize?

2. What would you suggest to improve the use of case illustrations in the guidelines? How useful is Appendix A in illustrating a range of applications of the risk assessment process?

3. Some Agency reviewers of the guidelines have suggested that more examples of terrestrial assessments and field approaches (e.g., bioassessment techniques) should be used. Specifically, what, if anything, should be added?

4. Areas of uncertainty are summarized in the problem formulation (section 1.5), analysis (section 3.7), and risk characterization (section 5.2.4). How useful is this approach in providing guidance on uncertainty issues?

Introduction and Scope

The introductory portion of the guidelines (section 1) describes background, scope, and the intended audience for the guidelines. Section 1 also discusses the importance of ecological risk assessment for environmental decision-making, contrasts these guidelines with the previously published Framework Report, and clarifies terminology issues.

5. How could the Introduction be modified to more clearly communicate the scope and content of the guideline?

6. Terminology, especially related to endpoints and exposure, has always been controversial. What changes, if any, would you recommend in guidelines terminology?

7. The overall framework figure for the ecological risk process has been retained, although some changes have been made to the diagrams for problem formulation, analysis, and risk characterization. What further modifications, if any, are required?

Risk Manager Interactions

Although the primary focus of these guidelines is risk assessment, not risk management, appropriate risk assessor-risk manager interactions are critical to the success of ecological risk assessments. Sections 2 and 6 of the guidelines highlight these interactions at the beginning and end of the ecological risk assessment process.

8. Please comment on the description of the risk manager's role at the initiation of an ecological risk assessment and on the principles for selecting management goals.

9. What additional points, if any, should be covered about relating ecological information to risk management decisions after the completion of an ecological risk assessment?

Problem Formulation

During problem formulation (section 3), the purpose for the assessment is articulated, the scope and boundaries are defined, the assessment endpoints and conceptual model are developed, and the plan for analyzing and characterizing risk is developed.

10. How useful is the categorization of assessments as either stressor- or source-initiated, effects-initiated and ecological value-initiated?

11. Please comment on the discussion of assessment endpoints and their relationship to management goals and "measures."

12. What, if anything, would you add to the discussion of risk hypotheses and conceptual models to give the reader a clearer understanding of their nature and content?

Analysis

The analysis phase (section 4) includes technical evaluation of data on potential effects of and exposure to stressor(s) identified during problem formulation. Primary activities include exposure and ecological response analysis. The outputs of the analysis phase are summarized in exposure and stressor-response profiles. Section 4 is organized by stressor type: chemical, physical, biological, and multiple stressors.

13. How would you change this section, if at all, to improve the balance in the discussion of the different stressor types?

14. Are there additional points or principles that should be emphasized for either chemical, physical, or biological stressors?

15. What additional principles would you suggest, if any, for the analysis of multiple stressors?

Risk Characterization

Within risk characterization (section 5), key elements include estimating risk, evaluating ecological significance, and determining the weight of evidence. Major uncertainties, assumptions, and limitations of the assessment are summarized.

16. What additional principles should be highlighted in the discussion of risk estimation techniques?

17. The guidelines propose four criteria for ecological significance. How should this list of criteria be modified, if at all? What additional guidance, if any, might be added to the discussion of these criteria?

APPENDIX C

WORKSHOP AGENDA

EPA United States
Environmental Protection Agency
Risk Assessment Forum

Workshop on the Draft Ecological Risk Assessment Guidelines

Holiday Inn - Georgetown
Washington, DC
December 6-7, 1995

Agenda

Workshop Chair	William Smith Yale University New Haven, CT

WEDNESDAY, DECEMBER 6, 1995

7:30AM	Registration/Check-In
	PLENARY SESSION
8:30AM	Welcome *William Wood, U.S. Environmental Protection Agency (EPA), Office of Research and Development (ORD)*
8:35AM	Introductory Remarks *Robert Huggett, EPA, ORD*
8:45AM	Workshop Background, Objectives and Format, and Overview of Guidelines Issues *Workshop Chair: William Smith* *William Wood, EPA, ORD*
9:05AM	Discussion
9:35AM	B R E A K
9:50AM	Problem Formulation Highlights *Suzanne Marcy, EPA, Office of Water*
10:00AM	Problem Formulation Issues *William Smith*

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WEDNESDAY, DECEMBER 6, 1995 (continued)

	CONCURRENT WORK GROUP SESSIONS (2)
10:15AM	Problem Formulation Discussion
11:35AM	L U N C H
12:45PM	Problem Formulation Discussion (continued)
2:45PM	B R E A K
	PLENARY SESSION
3:00PM	Problem Formulation Discussion: Comments and Recommendations to EPA *Richard Kimerle, Monsanto Company; Dwayne Moore, Environment Canada; and William Smith*
4:00PM	Analysis Highlights *Susan Norton, EPA, Office of Research and Development*
4:15PM	Analysis Issues *Dwayne Moore*
4:30PM	Observer Comments
5:00PM	A D J O U R N

THURSDAY, DECEMBER 7, 1995

	CONCURRENT WORK GROUP SESSIONS (2)
8:00AM	Analysis Discussion
10:30AM	B R E A K
	PLENARY SESSION
10:45AM	Analysis Discussion: Comments and Recommendations to EPA *Richard Kimerle, Dwayne Moore, and William Smith*
11:45AM	L U N C H
12:45PM	Risk Characterization Highlights *Patricia Cirone, EPA, Region 10*
1:00PM	Risk Characterization Issues *Richard Kimerle*
	CONCURRENT WORK GROUP SESSIONS (2)
1:15PM	Risk Characterization Discussion
2:45PM	B R E A K
3:00PM	Risk Characterization Discussion (continued)

THURSDAY, DECEMBER 7, 1995 (continued)

PLENARY SESSION

4:00PM	Risk Characterization Discussion: Comments and Recommendations to EPA *Richard Kimerle, Dwayne Moore, and William Smith*
5:00PM	Observer Comments
5:30PM	Workshop Chair's Closing Remarks
5:45PM	A D J O U R N

APPENDIX D

PREMEETING COMMENTS

Workshop on the Draft Ecological Risk Assessment Guidelines

PREMEETING COMMENTS

December 1995

EPA

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

TABLE OF CONTENTS

Lawrence Barnthouse

Comments on Ecological Risk Assessment Guidelines

General Principles

For the most part, this document is simply an incremental elaboration of the Framework for Ecological Risk Assessment According to the Charge to Reviewers, guidelines are intended to "promote Agency-wide consistency and to "inform the scientific community and the public." In their present form, the guidelines are much too vague to perform either function effectively. To be effective, the guidelines should:

- provide explicit, detailed guidance on issues expected to be common to most or all agency programs. Examples of such issues might include the use of phased or tiered assessments; the use of formal scoping procedures such as the Data Quality Objectives Process; a preference for populations/ecosystems as assessment endpoints (except when protected species are involved); establishment of a hierarchy of preferred data types (QSAR to life- cycle chronic tests); a preference for using weight-of-evidence procedures rather than the most conservative line of evidence;...

- clearly identify issues that differ among programs and for which the program offices should develop their own. One easy distinction is between predictive (PMNs, pesticide registration, NPDES permit), retrospective (RCRA, CERCLA, FIFRA special review) and nonregulatory (watershed management) programs.

Ecological risk assessment guidelines should strive for the same level of specificity the agency's health risk assessment guidelines. Otherwise, almost any assessment that can be massaged into the format of the Framework can qualify as a valid ecological risk assessment.

Specific Questions

Guidelines balance

I'm not overly concerned with whether this document provides a complete listing of the stressors, levels of organization, etc. that are or may be relevant to ecological risk assessments. I think it's more important to identify the types of stressors, endpoints, and scales associated with the different types of assessments of interest to EPA. Clearly, assessments that involve persistent, bioaccumulative chemicals require a longer time-scale and more complex endpoints than do assessments of acutely toxic but nonpersistent chemicals. Watershed-level assessments almost by definition require large spatial scales and consideration of nonchemical stressors. A thoughtful discussion of the types of scientific information needed for different types of assessments would add a great deal of value to the guidelines.

Unfortunately, almost all of the case studies predate the Framework, and for this reason they can do little to illuminate the current guidelines. Adding additional examples of the same type won't help much. What *would* be useful would be a discussion of how the case study assessments could have been *improved* by adherence to risk assessment practices that are defined in the guidelines.

The taxonomy of uncertainty described in section 1.5 is very useful. I would, however, recommend either revising or eliminating the column of "examples" included in the tables. Some of these are quite confusing. Definitions of the various sources are already provided (they could be highlighted in a table or sidebar); eliminating that column would leave space for more details concerning the strategy for dealing for each source - some of these are pretty perfunctory.

Introduction and scope

The discussion of scope and content should be more specific. As noted above, the current scope and content differ only marginally from the Framework document and don't provide much, if any, concrete guidance. Interminable arguments over terminology have been a pathological affliction in the ecological risk assessment community and have significantly impeded progress. I choose not to add to this problem. The Framework modifications are minor; any additional changes would be irrelevant. Breaking out the assessment plan from the conceptual model is a good idea. This material has to go somewhere; shoehorning it into the conceptual model (as was done in the Conceptual Model Issue Paper) is clumsy.

Risk Manager interactions

The guidelines would benefit from a much more thorough discussion of just who/what is a" risk manager" and about the whole topic of the role of managers and the public in risk assessment. This needs more than a sidebar. There aren't many situations where the "risk manager" is a single person, even within the agency. The Data Quality Objectives Process (EPA QA/G-4) suggests that representatives of the risk manager should be directly involved in the development of assessment endpoints and decision criteria. I'll admit that the health risk assessment guidance is also very weak on this point. The only attempt I know of to determine how EPA makes decisions concerning ecological risk is the 1994 report on "Managing Ecological Risks at EPA" (EPA/600R-94/183). This report, which isn't even cited in the guidelines; provides a number of concrete recommendations concerning risk manager/risk assessor

Problem formulation

The categorization of assessment types is useful. It could be more aggressively exploited by identifying specific agency decisions that fall into each category and describing any associated issues that should be addressed in program-specific guidance for those decisions. There's nothing new to say about assessment endpoints and associated measures. It's time to stop splitting terminological hairs. More explicit examples of risk hypotheses (as in the conceptual model issue paper) should be provided; the focus again should be on distinguishing between issues common to all agency assessments and issues that are program-specific.

Analysis

The section on chemical stressors is much too lengthy. Subsections 4.2.2.3 (*Estimating Chemical Exposure*), 4.2.3.1 (*Estimating Primary Effects*), 4.2.3.2 (*Extrapolations*) and 4.2.3.4 (*Secondary Effects*) could be reduced to a couple of paragraphs each. These subsections simply survey available methods and provide no judgements about which should be used in a given circumstance. Since the program-specific guidance-writers will have to consult the original literature (which will have changed substantially by the time guidance is written), it seems pointless to include an overview of methods in these guidelines. Physical disturbances, on the other hand, are treated in a highly perfunctory manner. The primary and secondary effect dichotomy is ill-defined and confusing. More often than not, many ecosystem characteristics are affected virtually simultaneously by physical disturbances. The only example discussed is the

FORFLO modeling case study. The scientific literature on ecological effects of physical disturbance is large and diverse; a thorough review is needed to support the preparation of guidelines. The section on biological introductions is somewhat more thorough, but still provides relatively little material for prospective guidance-writers. The Simberloff/Alexander issue paper the USDA reports are much more comprehensive. For both physical disturbances and biological introductions, the main emphasis in these guidelines appears to have been to show how these stressors fit into the Framework. This is not sufficient. Again (am I repeating myself?), the guidelines should clearly identify the scientific issues that should be addressed in program-specific guidance for each of the agency's major program areas.

All of my comments on physical disturbances and biological introductions are equally applicable to multiple stressors. In the case of multiple stressors, however, the scientific literature is scattered, confusing, and not always reliable. My opinion is that the term should be reserved for combinations of qualitatively different stressors (e.g., chemicals + habitat disturbance) and should not be applied to chemical mixtures. Multiple stressors are routinely encountered in retrospective risk assessments and are the rule rather than the exception for all watershed-level assessments. In hindsight, this should have been an issue-paper topic. An expert review such as the ongoing ILSI/EPA effort would be extremely helpful; without such a review the agency can provide little or no substantive guidance.

Risk characterization

This section identifies most of the key issues, but in some respects lags behind the current state-of-the-science. Uses of the "quotient method" and "physical models and field surveys" are often substantially more sophisticated than is implied in the guidelines. This is certainly true in many CERCLA-driven ecological risk assessments. The theoretical limitations discussed in the issue papers and in the guidelines are recognized by practitioners. Procedures for screening-level assessments and for weight-of-evidence-based risk characterization intended to account for these limitations are now widely applied. As with the rest of the document, it is essential in the risk characterization section that the scientific issues associated with each type of assessment problem be identified. Simulation models, for example, are (or could be) an extremely useful risk characterization method in predictive assessments. They could also be used in some retrospective pesticide risk assessments (e.g., projecting changes in raptor population characteristics due to changes in pesticide use patterns). Such models are much less commonly used in retrospective assessments of contaminated soil or water. On the other hand, criteria for inferring causation are critical for retrospective assessments but rarely applicable to predictive assessments.

The discussion of recovery in section 5.3.2.3 is somewhat vague and confused. A wide variety of factors influence the recovery of ecosystems from disturbance; there is no point in attempting to list or discuss them here. This section should clearly identify two critical aspects of recovery: the *potential* for recovery (i.e., the reversibility of the predicted or observed change) and the *rate* of recovery. Nothing further is needed. Otherwise, the four significance criteria discussed in section 5.3.2 provides a reasonable foundation for guidance development.

Overall, I would say that the draft guidelines report is a good start but is still much more a revision of the Framework report than a bridge between the Framework and program-specific guidance.

Steven Bartell

PART I. GENERAL PRINCIPLES

The draft guidelines represent an important first step towards developing the necessary Agency guidance towards promoting scientifically credible and consistent ecological risk assessments. The authors should be congratulated concerning their efforts, yet much work remains to provide the final document. The following comments are offered towards that end.

There are several issues and general principles emphasized in the draft document. The draft rightly emphasizes the importance of discussions between the risk manager and the risk assessors *prior to* the formulation and design of the overall assessment. The draft also emphasizes the importance of the problem formulation phase in determining the final quality and effectiveness of the risk assessment. Flexibility in addressing chemical, physical, and biological stressors is a major theme in the draft guidelines. Importantly, risk assessment is presented as an iterative process that provide information for decision making. Finally, the issue of uncertainty, in all its forms, is addressed repeatedly in the draft as a central component of the risk assessment process.

UNDERLYING ASSUMPTIONS AND DEFAULT POSITIONS

The draft does not really specify the assumptions underlying various methods and approaches for assessing ecological risk. The document, in its attempt to provide for flexibility for specific Agency programs, is quite general in its guidance. In order to become more specific to the point of identifying key assumptions and default positions, the guidelines would have to assume more of the character of a "how to" manual. Specific tables of stressors, endpoints, data sources, methods for exposure and effects assessment, and methods for characterizing ecological risk would have to be described in sufficient detail (including example calculations) to facilitate their use in specific assessments. The result would be an immense document that would necessarily remove some of flexibility advocated as necessary in the current draft.

RECOMMENDED CHANGES

Specific comments will be provided in Section II. However, some general remarks may prove useful. One, there should be better balance among the sections - the document as it stands is unnecessarily long. Many issues (e.g., uncertainty) are repeated across sections. The few pages devoted to risk characterization provide minimal guidance at best. Two, references to the issues documents for important detail to support contentions made in the various sections does little to serve the reader, who might not have ready access to these documents. (Also, it's not quite clear what is meant by changing or modifying the issues paper's contents to meet the Agency's needs. Three, each of the sections would benefit from a clear statement of the purpose of the material presented. In attempting to be general and flexible in guiding ecological risk assessments, much of the writing come across as unsuitably vague. A general approach to guidance will prove only generally useful. Unfortunately, nothing happens in general. Four, the material presented as case studies in Appendix A should be reviewed carefully to make sure the presentations are (1) consistent with the overall ecological risk assessment framework, and (2) fairly even in their detail of presentation for each of the sections in each case study.

PART II. SPECIFIC QUESTIONS

Guidelines Balance

1. It's difficult to anticipate future Agency needs. However, considering the present state of the science, the draft guidelines attempt to provide fair treatment of physical, chemical, and biological stressors. As reflected in the years of work preceding the guideline draft, much emphasis is placed on chemical stressors. The sophistication in treatment of the various stressor categories is certainly biased towards toxic chemicals. Given the effort in developing "the cube" by Harwell, Gentile, et al., the minimal presentation and discussion of different levels of organization and ecosystem types in the draft is somewhat perplexing. Perhaps "the cube" might be incorporated into the guidelines to demonstrate the comprehensive nature of previous discussions of organization, scale, ecosystem type, and ecological complexity.
2. The use of case illustrations would be improved by replacing the general discussion in the text boxes with some actual example calculations, i.e., do some risk assessment, at least as examples. Don't be afraid to show some methods and applications in relation to the case studies. As suggested previously, the case studies developed in Appendix A would benefit from better balanced, more detailed, and quantitative presentations.
3. Perhaps examples of risks posed by insect pest outbreaks (e.g., spruce budworm, gypsy moths), habitat loss and alteration resulting from changes in land use, or risk and recovery from fire (forests vs. prairies) might serve as useful terrestrial examples.
4. Put all the discussion of uncertainty in a single section, perhaps the risk characterization section. This would remove much of the redundancy regarding uncertainty from the current draft.

Introduction and Scope

5. It's not clear that the history and background discussions are particularly helpful to the reader. The treatments are too brief to accurately reflect the years of effort represented by the draft. The discussion of risk and decision making does not make the connection between the quantitative nature of risk assessment and its potential for integration with quantitative methods for decision analysis. Such a combination might provide a powerful decision support tool for decision making. More attention could be given to brief description of each component of the process, e.g., what the reader will encounter in the sections to follow.
6. The terminology issue has not been resolved. As much jargon as possible should be removed from the document. It only lends a pseudo-intellectual air to the process and serves no real purpose other than to confuse and obfuscate. The entire process distills into identifying what is at risk, what are the odds, and what are the consequences. In the least, the terminology selected for presentation here should be removed to the glossary.
7. The modifications to the figure appear reasonable and useful. Perhaps remove "relevant" from the data boxes? Also, I'd argue for including the Planning box inside the Problem Formulation box. I'd also drop the iteration figure.

Risk Manager Interactions

8. The description is suitably general and makes difficult any real criticism or review. The collections of questions in box 2-2 seems rather arbitrary. It's also not clear why the text box concerning sustainability is presented; there are certainly other management goals (e.g., complying with environmental laws). Why is the planning outcome not a plan, instead of a summary of decision (p. 23)? Perhaps the focus should be on the nature of risk manager - risk assessor interaction in designing the assessment, rather than on the manager and principles for selecting management goals. Either get much more specific and comprehensive (maybe identify actual positions of decision making power and the kinds of decisions entrusted to their care) or greatly abbreviate this section.
9. It might prove useful to mention that one strength of quantitative risk assessment lies in being able to exploit (i.e., analyze) the various uncertainties associated with the assessment to identify the critically needed information for refining the assessment in successive iterations until a decision can be made and justified.

Problem Formulation

10. The categorization is not particularly useful. What is the value added to problem formulation by recognizing such categories? They are sometimes confusing, for example, is an effects-initiated assessment really a source-initiated assessment, one step removed? Isn't is merely a matter of focus? The value-drive assessment is also vexing - i.e., whose values?
11. The discussion of assessment endpoints follows fairly straight from the supporting documents (e.g., the Framework). However, the endpoint definitions (e.g., p. 35: "explicit expressions..." and "... the valued attributes..") are too vague to be of real use to the reader - maybe omit them and get right to the "focus of a risk assessment should be..."
12. "Risk hypotheses" should be removed from the discussion of the conceptual model. The reader might confuse risk assessment with statistical hypothesis testing. Risk assessment might involve hypothesis testing, but does not require it. The "hypotheses" stated in text box 3-22 are not hypotheses in the strict sense. These statements are really sequences of deduction, inference, or speculation. The discussion of the conceptual models is, otherwise, pretty consistent with previous deliberations (e.g., the framework and supporting technical papers). Figures 3-2 and 3-3 are not good examples of conceptual models (i.e., they are ecosystem model flow charts); figure 3-4 is much better (it relates stressor to exposure and possible effects).

Analysis

13. Before discussing stressor types, consider removing the section on uncertainty from the analysis phase and constructing a single section on uncertainty regarding all phases of the assessment. Similarly, the discussion of sensitivity analysis should be moved to the risk characterization section. To balance the discussion of the different stressors, it might be useful to begin with the necessary components of the exposure profile - then develop separate examples using the chemical, physical, and biological stressors. Shorten the discussion of what exposure is and the dimensions of exposure. Note the contradiction regarding the use of biomarkers on p. 69 and p. 70. Also, simply introduce more examples of physical and biological stressors to balance the section.
14. Perhaps even more emphasis should be placed on determining the relevant spatial-temporal scale for the stressor (physical, chemical, or biological), as well as for the ecological effect of interest (e.g., different levels of organization). The juxtaposition of these scales should assist in developing meaningful assessment endpoints, conceptual models, and corresponding scales in assessing exposure. In essence, such considerations should lead to appropriately scaled (e.g., minimize variance) stress-response functions for use in risk characterization.

More comprehensive coverage of different levels of ecological effects could be provided. Additional tables of the kinds of effects that have been used as endpoints in assessments would be helpful in guiding the reader. Perhaps the multispecies assays and field experiments sections could be moved to risk characterization. The section on causality also needs to be developed in more detail or removed.

15. No comment.

Risk Characterization

The risk characterization section seems not to reflect the effort that entered into previous discussions and workshops on this topic. Given the important integrating role of this phase of the overall assessment process, more attention should be given to quantitative concepts and measures of risk (i.e., the quotient does not characterize risk), risk estimation, and addressing uncertainty - with perhaps less attention on weight-of-evidence discussion.

16. Evaluation of risk principles in the draft guidelines depends in part on the interpretation of risk assessment and risk estimation. The draft is a suitable start if one adopts a broad definition of risk to include qualitative risk assessment. If one insists on reserving *risk assessment* to refer specifically to quantitative assessments that explicitly address uncertainty (e.g., a probabilistic framework), then much of the section on risk characterization, particularly risk estimation, needs considerable revision. The first of the principles offered on p. 114 is an unsubstantiated generalization (e.g., "... a simple approach ... is more credible than a complex assessment..."). If the approach is simple, yet insufficient (i.e., quotients), the accuracy of the data is a moot point. The second and third principles don't really seem to be principles of risk characterization, as much as they are advice and cautions regarding problem solving in general. Given the importance of risk estimation in this phase of the assessment, perhaps more of the information included in Wiegert and Bartell (1994) should be included directly (e.g., maybe in text-boxes or tables), rather than by reference. Note that the first bullet under the quotient discussion seems to contradict the advantages outlined in the preceding paragraph. On p. 118, what is meant by the sentence, "Simulations can be applied to regression analysis to determine cause and effect relations." On p. 119, replace the term "risk hypotheses" with assessment endpoints? Also, why would exclusions in the assessment be addressed in the characterization phase instead of the problem formulation phase?
17. The current draft identifies the following criteria for ecological significance: nature and intensity; scale; recovery; and natural variability and disturbance. It might be worthwhile to

note that an ecological response can also be scaled in relation to the overall life history characteristics for species (population) level impacts. The dynamic nature of systems, mentioned under the recovery section, also refers of course to natural variability and disturbance. It is important to emphasize that recovery is best assessed in probabilistic terms; recovery complements risk in ecological risk assessment.

Miscellaneous Comments

Time and resource constraints preclude a detailed, point-by-point review of the draft document. Nonetheless, several observations and comments might assist in revising the draft guidelines document:

1. The guidelines should be written under the assumption that the reader will not be intimately familiar with the history and development of ERA process that led to these draft guidelines. Therefore, ecological, toxicological, and regulatory jargon should be kept to an absolute minimum (i.e., see the first bullet under *clarity*, p. 127).
2. The guidelines should provide a clear picture of the *process* of ecological risk assessment - emphasizing the purpose and product(s) of each phase. The current draft loses the train of thought as the result of introducing a plethora of issues, considerations, caveats, strengths, and limitations, etc. Diverse ecological and toxicological phenomena, observations, and generalizations seem selected and interspersed throughout the sections without any common thread or theme. The net result does not engender so much a feeling of generality and flexibility, as it does confusion and bewilderment! It might be more effective to select one or two very different assessment problems (i.e., case studies) and "walk them through" the assessment process. The same set of important issues can be raised, but with a constant frame of reference for those who might not be so broadly trained and experienced as those who have participated in the long evolution leading to the draft.
3. Replace most of the general text boxes with more specific examples and calculations based on a small set of case studies (see above). This information should provide more detail for the interested and technical reader instead of being merely additional text that could have just as well been incorporated into the main body of each section.
4. Some of the discussion is so general as to be essentially truisms that provide minimal guidance, either in concept or method, to potential risk assessors and managers (e.g., p. 42: " The assessment of multiple stressors..." and p. 43: "the best assessment endpoints...").
5. Is the conceptual model really a "verbal description" (p. 44)? Documentation is offered elsewhere as an important aspect of the overall risk assessment process - why *verbal* here?

Also, the statement, "hypotheses are assumptions..." (p. 44) poses real confusion to risk assessors and is a good reason to omit the use of "risk hypotheses" throughout (see also text-box 3-12). Hypotheses are not assumptions!

6. The modifications made to the original risk assessment diagram appear beneficial. Yet I fail to understand the need to point out the modifications to those who might have never seen the original.
7. Put the uncertainty table (e.g., Table 3-1, et seq.) in one place, one time. The examples are not particularly compelling or enlightening. Just focus on the nature and source of uncertainties and provide some clear-cut examples (maybe even some basic statistics) in relation to a few well developed case studies, as mentioned above.
8. Remove Figure 4-4. Omit lines 13-22 on p. 69.
9. Remove text-box 4-5.
10. Remove first sentence on line 13, p. 74.
11. What is the difference between adjunct material and examples? (lines 18-23, p. 75).
12. Leslie models do not extrapolate effects from individuals to populations (text-box 4-7).
13. The secondary effects section needs more basic conceptual development (p. 84). Much of the following section seems more appropriate to risk characterization than analysis of secondary effects.
14. The stressor-response profile should be discussed in greater detail, particularly from the viewpoint of biology, ecology, and endpoint selection (p. 86).
15. Why are only "clean" sediments a physical stressor (p. 88)?
16. In Table 4-3, why use "extirpation"? Do you really mean local extinction?
17. On p. 90, lines 21-26 would make a good lead-in to section 4.3.2.
18. Why put the bottomland hardwood information in text-box 4-9 if it is better presented in the Appendix?
19. Delete lines 1-2 on p. 93; they are redundant.
20. The "delphic" approach is mentioned several times (e.g., p. 97), but is not well described. It's also not in the Appendix B glossary. Maybe provide a text-box description and example?
21. The selection of key terms seems rather arbitrary. Several of the definitions (e.g., for *community, ecosystem, ecological component*) are too superficial to be helpful.

John Bascietto

REVIEW OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S DRAFT PROPOSED GUIDELINES FOR ECOLOGICAL RISK ASSESSMENT, EXTERNAL REVIEW DRAFT; OCTOBER, 1995.

REVIEWER: JOHN J. BASCIETTO
U.S. DEPARTMENT OF ENERGY
WASHINGTON, D.C.

The U.S. EPA's Risk Assessment Forum staff should be commended on drafting this next phase of EPA's effort to produce ecological risk assessment guidelines. While the guidelines development effort has spanned many years (1987-present), it has been carried out under sometimes difficult circumstances, and always with insufficient budgetary and manpower resources.

The following comments are offered in the spirit of constructive criticism, with the best intentions. I hope these comments help to make the ecological risk assessment guidelines successful, and useful to a wide variety of stakeholders.

PART 1. General Comments

EPA has provided several disclaimers concerning the scope and intended use of the guidelines: that they are intended "primarily" for use by EPA staff and EPA programs; that they are not a rule book, nor a cook book or a textbook; that they address only general principles, and do not contain extensive background materials for novice readers. EPA should realize, however, that like it or not, these guidelines will instantly become the *de facto* standard for ecological risk assessments performed in this country, and perhaps abroad. This should have been evident from the enormously positive reaction to EPA's 1992 report "A Framework for Ecological Risk Assessment," and its almost universal adoption.

It is clear that these guidelines do not constitute a manual on "how to do" ecological risk assessment. An experienced risk assessor will see that the results of approximately twenty years of negotiated ecological risk assessment science policy is reflected in the equivocal tone of much the current draft. The discussions on the underlying science of ecotoxicology, the vast array of science policy choices and the discussions on how to handle uncertainty, all with a special emphasis on the interface between risk assessor and risk manager, do indeed reflect the lessons learned from twenty years of operating without the benefit of the guidelines.

The EPA has characterized these draft guidelines as "not a textbook." I'm not sure I agree. The document is certainly pedantic enough, and in this reviewer's opinion, could indeed serve as manual for an advanced undergraduate or graduate student taking a beginning course in ecological risk assessment. The current draft does a good job of describing the underlaying principles used by many ecological risk assessors, particularly if they are working in a regulatory context (I was struck with the comprehensive nature of the discussions), but it also disappoints, in the sense that the document barely lives up to its title - it presents precious few guidelines, *per se*. The draft serves to expand on the 1992 "Framework" document in great detail. The authors' stated intention to do just that was indeed fulfilled.

Nonetheless, with a few welcome exceptions, I found little in the way of ecological risk assessment "guidelines" that could be of immediate use to experienced assessors who are engaged, with EPA regional and state counterparts, in the difficult questions of assessment design, endpoint selection, sampling and analysis, and hypothesis testing. Ecological risk assessors in the U.S. Department of Energy could certainly benefit from these proposed guidelines, but of more immediate use, DOE would like to see much more concrete, consistent and specific information from EPA about what is expected, what is required, what is acceptable, and what is not acceptable in risk assessment documentation. This is where the guidelines are most needed, and they need to apply equally to the regulators as well as the regulated community.

I should probably state my own bias, preferences and expectations for the current manuscript. In this reviewer's opinion, a "guideline" clearly spells out limits or boundary conditions. I expected that these guidelines would integrate and synthesize information from the two earlier volumes of published cases studies of ecological risk assessments, and the 1994 report, "Ecological Risk Assessment Issue Papers."

A guideline should not be an inflexible rule, but should provide a discrete method and context for moving through a systematic process (such as risk assessment), even as new data and hypotheses regarding the process are being formulated. Speaking as one who has developed EPA ecological risk assessments without the benefit of guidelines, this reviewer is concerned that the lack of even qualitative ecological risk assessment guidelines could be (and has been) used as an excuse to dismiss significant and serious investments of time and effort, out of hand, as mere speculation.

At this point in time, given the enormous resources at stake in many environmental compliance programs and with pressures from legislators for more reliance on risk-based decision making, there is clearly a need for EPA to issue unambiguous statements of what is acceptable and what is not, in a risk assessment. Default positions are needed to help risk assessors move through controversial areas of science policy. Such policy statements should be clearly labeled as such. Default positions should be rebuttable by proponents of an alternative hypothesis, provided that they offer new, problem-specific, or stressor-specific data.

Particular risk assessment problems could be addressed in specific guidelines (e.g., a population risk assessment for acute toxicity of pesticides to birds; or a community risk assessment for a freshwater stream receiving releases of uncontrolled hazardous wastes, taking into account acute, subacute and chronic effects). I suggest that specific guidelines could be prepared for or by EPA Program and Regional scientists, and reviewed and finalized by the Risk Assessment Forum.

As a follow up to the Framework, EPA published two volumes of case studies of specific ecological risk assessments. This presented an opportunity to write the guidelines for the types of risk assessment problems illustrated by the case studies. EPA instead chose to use the case studies to see if the Framework was appropriate for these types of exercises. Some parties suggested that the case studies could also be used as interim guidelines until the "real" guidelines could be produced.

It is not my intention to discourage further use of this draft report. It is a very good catalogue of potential issues that one will run across in the course of one's employment as an ecological risk assessor. EPA has now certainly done more than enough on the "process." Perhaps EPA could consider the current draft as a preamble for the next iteration, which should be supplemented with some specific guidelines, as I've indicated. For example, the conceptual model section of the current draft was very helpful, but should have been integrated more closely with the risk hypothesis formulation section, which itself needed further development. The detailed discussion integrating these two sections could have been the subject of a guideline, and focused on a particular type of ecological risk assessment.

EPA should consider providing more detailed information on default positions when appropriate, and should address three specific questions in any guideline: what is in bounds?, what is out of bounds?, and when is it permissible to step outside the bounds of a presumptive (default) approach? EPA should integrate the Agency's science policy decisions (based on the issues raised by the "Issue Papers" report) into the next interation of the draft guidelines. Initial efforts could center on dose-response methodologies and modeling, risk hypothesis formulation, endpoint selection, hypothesis testing, use of computer codes, risk estimation methodologies, and uncertainty analysis.

PART II. Specific Questions and Comments on Sections

Guidelines Balance

This draft attempts to cover too many bases, in this reviewer's opinion. Considering the present state of the science and the needs of the Agency and its regulated community, EPA should consider postponing development of the biological stressor guidelines at this time. EPA should instead focus on population, community and ecosystem effects from chemical and physical stressors.

There appeared to be a uneasy balance in the treatment of levels of biological organization. There is not enough specific discussion of individuals, populations and the community level issues. EPA should, and has begun to explore the ecosystem level issues (to the extent that they are really ecosystem issues and not really community level issues).

The temporal/spatial scaling issues had better balance than the biological organization issues. This is acceptable, since the latter are usually much more important to actually performing an the assessment, once the endpoints have been selected.

(I've covered the remaining questions for "Guidelines Balance" in the body of my Section-by-Section comments).

Section 1 - Introduction.

The purpose of this discussion was not at all clear to me. In addition to needing an editor, the ideas should flow like a good story, from beginning, to middle to end. It is confusing for EPA to cite specific definitions for terms from previous EPA documents, implying that they are obsolete, without also stating or referencing the current, official EPA definition of that term. For example, I could not tell what the current, official EPA definition of an ecological risk assessment is!

It is particularly confusing to split the perfectly good term "measurement endpoint" into three new terms, each with an only a marginally different definition from the original, given the inclusive context of the term "measurement endpoint" in the Framework report. It seems to me that very little value was added by the splitting the term into "measures of exposure", "measures of effect" and "measures of ecosystem characteristics." The point is that you either can measure this thing, or you cannot! I took this as a warning sign that EPA may be getting too focused on the "process" of risk assessment, and perhaps not focused enough on the substance.

Section 2 - Planning ....Assessor and Risk Manager.

The stated purpose for the assessment is too narrow. It not only includes bringing assessors and managers together, but also some very important stakeholders, and the public in general. Recognize that "planning" is not a step in the assesment, *per se*. It is only distinct from the risk assessment process on the Framework report's diagram for purposes of clarity of communication. In reality, the process and the players should form a team, and continually "plan" for contingencies (see my comments on data quality objectives below). Recognize also, that it is very difficult to overcome stakeholders' perceptions that "government policy" and risk "managers" bias the scientific analysis. Such perceptions can only be overcome by constant, conscientious efforts to involve the stakeholder in a meaningful way, clear communication of "the rules of the road" (i.e., the guidelines), combined with a rigorous adherence to good laboratory and field practices, plus a thorough independent review process.

I recommend adding a clear and rigorous process of Data Quality Objectives (DQO) development to the process guidelines. Both the risk assessor and the risk manager need to participate in setting DQOs, as well as the other stakeholders. The planning section tries to get at this notion, but seemed to develop only a cursory discussion of DQOs. The guidelines should spell out a formal DQO process.

DQO's are designed to answer the following questions:

- o What is the problem we are trying to solve? - (management goal)
- o What decision are we going to make ? (action alternatives?)
- o What data is needed ? (assessment and measurement endpoints)
- o What are the study boudaries (conceptual model, spatial and temporal considerations)
- o What rules will be used to make the decision ? (risk hypothesis, statistical limits design)
- o What are limits on the decision error? (probability of Type I and Type II errors)
- o What is optimum study design? (trade off between precision of the decision v. cost of the sampling and assessment design)

Ideally, the guidelines would specify DQO's for each type of risk assessment. However, for certain ecological risks, DQOs development may be very difficult. For example, it may not be possible to quantify decision error limits if EPA is unwilling to specify which endpoints should be used when multiple endpoints could be used; or if acceptable reductions could not be specified for a population risk assessment.

Risk assessors should not allow risk managers and political officials to unfairly put the burden of a developing a "magic bullet," (also known as "risk-based decision making") on the assessor. Government agencies and responsible public officials need to know that if they are unwilling, or unable to pay for needed systematic and defensible data collection and risk analysis efforts, they should not expect their decision-making to be "risk-based." The DQO process is a very effective way to establish a systematic approach to risk assessment and risk management, and prevents the "raising of expectations" of public officials and the public, beyond our ability to deliver defensible results.

Section 3. Problem Formulation Phase.

While I very much enjoyed the discussions on the initiation of risk assessments (i.e., source-, effects- and values-initiated), I was left wondering how this information helps me to develop an ecological risk assessment, and why EPA spent so much time describing it. It seems to me that one ends up in the same place, regardless of how one got there: conceptual models and risk hypotheses need to be developed, endpoints selected, assessment methods agreed upon, data collected, massaged and described.

Based on the text box and other written descriptions of the case studies, I could think of several ways in which a so-called "effects-initiated" assessment of granular carbofuran could have been construed to be a "stressor-initiated" or "values-initiated" assessment. Likewise, the Spotted Owl assessment (ostensibly an "effects-initiated" assessment) could be construed as a "values-initiated" assessment. In fact, regardless of what the case study says, the actual Special Review of granular Carbofuran was supported by a "stressor-initiated assessment"[1], not an "effects-initiated" assessment. The time taken to split intellectual hairs would have been better spent developing formal DQOs.

I very much appreciated the discussions on Management Goals and the cascading of goals to objectives, assessment endpoints and measurement endpoints. These are real-life risk assessment issues which deserve this kind of detailed reflection. Please continue to refine and expand this aspect of the guidelines. These issues should be clearly hashed out by risk managers in planning sessions with risk assessors, but are not necessarily obvious to everyone involved, including the risk managers. They are prerequisites to DQO planning.

I'm not sure whether there is a great deal of value-added information in the continuing efforts to refine the Framework report's process diagram. The diagram (and the process) probably does not need expanding and refining. This does not actually help risk assessors do their job. Again, spend more time developing ecological DQOs.

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[1]The granular Carbofuran case study published by EPA and cited in these draft proposed guidelines has apparently been rewritten at least three times subsequent to the original risk assessment used by the OPP staff to initiate the Special Review. The original was a stressor-initiated risk assessment, which met the toxicity-based regulatory criteria to initiate a Special Review of a pesticide, at the time the review was initiated (1985).

I very much enjoyed the discussions on "Ecosystem Potentially at Risk." This and related sections need considerable refinement and editorializing (there is an inappropriate emphasis on geographic location, rather than ecosystems as "systems." One point however: the current revision of the Framework process diagram, Problem Formulation Phase (Fig. 3-1) makes it appear that every assessment should have an ecosystem component. That interpretation of the figure is probably not what EPA intended, nevertheless, its confusing.

I was quite surprised to find (in Sec. 3.4.1.3, "Susceptibility to the Stressor") a familiar discussion of the appropriateness of using particular species as assessment endpoints. An example is used in which turkey and deer could be selected as assessment endpoints because they are good surrogates for other species in terms of sensitivity to a particular contaminant. This scenario very closely parallels an actual assessment endpoint issue at a DOE site in the Southeastern U.S. The dispute unfortunately reached an disproportionate level in my opinion, with both sides taking strong opposing positions. This is why I find it rather disturbing to read about the issue here. I hope EPA is not trying to make a point in these guidelines. This is not the place to win an argument.

Furthermore, I did not see that the 'turkey and deer' example well illustrates the point being made - i.e., 'should deer and turkey be included as assessment endpoints because they well represent the sensitivity of ungulates and birds to a chemical contaminant?' The example, which indicates that deer and turkey may not be good assessment endpoints because they may not live at the site, fails to consider the very real possibility of off-site exposures to these critters, which clearly would have been a concern for DOE and the other Trustees. In the DOE case, sensitive endpoints of relevance to both the Trustees and EPA's programmatic goals should have been allowed to be pursued.

Section 4. Analysis Phase

There are many good issues raised in this section, and much good information that will be of use to assessors. This discussion clearly comes the closest to providing "guidelines."

Rather than hash out each opportunity in the section when EPA should have gone the extra mile to a guideline, I suggest that the reviewers and Agency personnel may want to discuss this effort at the workshop. Generally, the discussions here were well thought out, clearly presented and well supported. There is ample bulleted and tabulated information here, and also available in the literature, for EPA to begin to make the tough science policy choices that will be needed for the guidelines. EPA should make these choices in the next iteration.

I refer the authors to a new (1995) book, by Dr. Michael C. Newman, Savannah River Ecology Laboratory, U. of Georgia, entitled Quantitative Methods in Aquatic Ecotoxicology (Lewis Publishers), which contains an excellent discussion of the calculation, use and interpretation of biological indices, particularly useful for community level assessments. These measures deserve another look by EPA.

Section 5. Risk Characterization

Although I agree that the discussion of the hazard quotient has to be presented in this section, EPA may want to consider more clearly defining the hazard quotient in terms how it differences from other measures of risk, *per se*. Ideally, one should estimate the magnitude of the effect and the probability of that magnitude materializing in order to assert "risk." Since the hazard quotient does not do this, EPA may to reconsider such statements as "the higher the quotient the higher the risk."

In the uncertainty analysis section (5.2.4), EPA should include an explicit guideline for the risk manager to indicate precisely how the uncertainty was interpreted and how the interpretation effected the decision.

Some of the bulleted information requested to be discussed in the Risk Description (Sec. 5.3), especially with respect to data sources and conceptual models, would have already been discussed in the previous phases of the risk assessment, and therefore may not need to be repeated here.

Does EPA really think it is necessary to discuss "Human Error" (Table 5-1), or that it will be a significant contributor to the uncertainty? Can't a good editor mitigate some of the human error?

Section 5..3.2.1, Nature and Intensity - What are we going to do with this information?

In the discussion of ecological significance, it should be pointed out (but not in a guideline) that "change" in nature is constant and not necessarily "bad." There is change in the Darwinian sense, and then there is the kind of change that we notice. Even rapid change might not be "bad" if we all agree that we like the results. However, even "good" change may not be acceptable from certain stakeholders' point of view.

The elimination (or reduction in numbers) of one or more species opens niches to other, perhaps exotic species. Exotics are probably not desirable as a general proposition. I suppose it depends on your management goal. In any case, the real the trick will be carrying these types of issues and predictions through the risk assessment. Maintenance of suitable, preferably native habitats, and a reservoir for reintroductions are likely to be more important than avoiding certain population reductions.

The EPA suggests that "the evaluation of recovery is made more difficult because ecosystems are dynamic and will not return exactly to a preexisting state." While this may be true, I'm not sure that we need to worry about it. To the extent that this concern reflects a Management Goal (i.e., restoration of preexisting state) it's probably doomed to failure anyway. The more significant ecological value should focus on restoration of ecological services and the their implications for biological resources. This is the concept ("restoration of natural resource services") used by natural resource trustees to restore (not necessarily replicate) important structures and basic functions to a system, in lieu returning a resource, *per se* to its pristine state.

Nancy Bettinger

The *Draft Proposed Guidelines for Ecological Risk Assessment* (subsequently referred to as the Draft Guidelines) are a major step forward in expanding upon and clarifying the principles outlined in EPA's Framework for Ecological Risk Assessment. This guidance will be a valuable reference for risk assessors and risk managers, both inside and outside of EPA. The comments that follow recommend additional discussion of assessment questions that have been, in DEP's experience, common sources of confusion or controversy.

Guidelines and Balance

Question 4. The proposed categorization of different types of uncertainty is helpful because different types of uncertainty have different implications for risk assessment and risk management. However, the tables that describe different types of uncertainty and the text in Section 4.1.2 should be revised.

Differences in species sensitivity within an aquatic community is given as an example of variability in the table, but in many risk assessments, these differences are not necessarily variations that result in uncertainty. In risk assessments that evaluate community structure, the metrics themselves should account for interspecies variability. In risk assessments that evaluate effects on a single species, interspecies differences would fall into the category of extrapolation error. The Guidelines should present a clearer example of variability, such as intake rates or body weights within a species.

The chemical concentration of a soil sample is given as an example of measurement error. This is a good example to the extent that it refers to the accuracy, precision and sensitivity of the sampling and analysis techniques, which may be affected by soil matrix effects and/or technology limitations. However, the text states that measurement error arises from variation in the characteristic of interest. Further, the table suggests constructing probability distributions as a strategy for addressing measurement error. This presentation confuses measurement error with variability in soil concentrations.

The Guidelines should provide a more extensive discussion of the implications of different types of uncertainty. For example, risk assessors and risk managers should recognize that, in many cases, risk assessment is done *because* of lack of knowledge, not just in spite of it. Thus, tempering risk estimates with descriptions of uncertainty due to lack of knowledge may be circular logic. The risk managers should be given a full appraisal of all types of uncertainty associated with the assessment, but different types of uncertainty may have very different meanings for risk management decisions.

Problem Formulation

Question 10. The categorization of assessments appears to be very useful. It is an improvement on the predictive/retrospective categorization scheme because it emphasizes consideration of the available information. It provides a basis for applying general principles consistently to a variety of assessment problems, while encouraging the risk assessor to apply a process that best fits the type of assessment in question.

Question 11. The discussion of assessment endpoints and their relation to management goals is clear, but an expansion of the guidance on applying the endpoint selection criteria would be helpful. Specifically, the Guidelines should indicate whether any of the three assessment endpoint criteria should be used to compare the utility of potential endpoints when choosing endpoints for the risk assessment. The Draft Guidelines seem to imply all of the criteria should simply be considered pass/fail criteria. If EPA intends to use the criteria to compare the utility of potential assessment endpoints, the Guidelines should indicate which criteria should be given more weight when selecting assessment endpoints.

The discussion of relationships between assessment endpoints and measures of effect should be expanded to include guidance on comparing the utility of various measures of effects for evaluating an assessment endpoint. The strength of association between the measurement result and the assessment endpoint, anticipated data quality, and study design issues such as spatial representativeness should be addressed in detail.

The Massachusetts Weight of Evidence Workgroup has identified measurement endpoint attributes that determine how well the measurement estimates or predicts the effect defined by the assessment endpoint (Draft Report - A Weight-of-Evidence Approach for Evaluating Ecological Risks). Although the attributes were initially developed to evaluate weight of evidence in risk characterization, the Workgroup also concluded that the same attributes were equally valuable for selecting measurement endpoints (or measures of effects) in problem formulation. These attributes may be useful as a basis for EPA guidance on developing criteria for selecting measurements of effect.

<u>Question 12.</u> The guidelines should describe in more detail the relationship between hypotheses and assessment endpoints and measures of effects. They are discussed separately in the text, even though they are closely linked.

Analysis

<u>Question 14.</u> In Section 4.3.2.1 under Chemical Stressors - Estimating Primary Effects, the texts states that in hazardous waste sites, field studies are often an integral part of ecological risk assessments. The Draft goes on list a number of reasons for using field studies in risk assessments, but only briefly mentions the

importance of appropriate reference sites and statistical power. In our brief experience, the lack of availability of appropriate reference sites and study design deficiencies associated with low statistical power (small sample size, for example) often lead to field study results that are less than compelling. These drawbacks, however, seldom seem to discourage investigators from conducting field studies and placing relatively high weight on the results. Guidance on deciding when a field study may not be appropriate would be helpful, as would examples to illustrate the effect of high variation and low sample size on statistical power.

Risk Characterization

Question 16. In the section on *Weight of Evidence*, the *relevance of the evidence to the assessment endpoint* is mentioned very briefly. This discussion should be expanded substantially. The Massachusetts Weight of Evidence Workgroup has recently produced a draft report on the results of the workgroup's efforts, which may be useful as a starting point for expanding EPA's weight of evidence guidelines (See response to question 11).

Question 17. The criteria that are discussed are relevant and important. Nevertheless, the Guidelines would be strengthened by expanding this section to address some frequently raised issues related to ecological relevance.

In the section on *Scale*, the Draft Guidelines indicate that localized contamination may be significant if the impacts translate into landscape or ecosystem-level effects. In several other places, the Draft Guidelines indicates in several places (Section 3.3.2 title and first paragraph) that ecosystem effects should be the focus of most ecological risk assessments. The implication is that assessment endpoints should represent ecosystem level effects, or that the results of any assessment should be extrapolated to the ecosystem level. However, risk assessments are often conducted for stressors that are likely to affect only a small area and are unlikely to affect an ecosystem. It seems a waste of resources to focus an assessment of localized effects and then temper any positive results by a judgement that those effects are unlikely to translate to ecosystem level effects. If the agency considers effects significant only at the ecosystem level, the Guidelines should clearly state that, and perhaps should suggest that some small-scale stressors (some waste sites, for example), which are unlikely to have ecosystem wide effects, may not warrant risk assessment or remediation to address ecological risk alone. If, on the other hand, the agency considers effects on local subpopulations and communities potentially significant, the Guidelines should say that explicitly, and it should discuss the importance of matching the spatial scale of the assessment to the spatial scale of the stressor.

The section on *Nature and Intensity* introduces the concept of intensity in broad terms, but does not explain how evaluate whether nature and intensity of a certain effect make it ecologically significant. The Guidelines should discuss the problem of determining what magnitude of change is ecologically significant.

In the section on *Natural Variability and Disturbances*, the text states that "it is important for the risk assessor to ask whether changes in assessment endpoints are distinguishable from the natural variability of the response being measured". The Draft Guidelines do not state, however, whether predicted or estimated changes in an assessment endpoint that are smaller than the magnitude of natural variability may nevertheless be ecologically significant. If EPA believes that smaller changes may be significant, perhaps the Guidelines should discourage risk assessors away from using field studies to measure changes in endpoints when the natural variability in the response is expected to be high.

Joanna Burger

JOANNABURGER

GENERAL PRINCIPLES

GUIDELINES BALANCE

1. The guidelines are generally well-balanced. However, I feels that there is still an overemphasis on chemical stressors, and on individual and population parameters rather than community or ecosystem-level interactions. I would add (rather than delete) these aspects.

2. My copy did not have Appendix A, nor did it have the discussion papers. My other concern is that most of the references are to the discussion papers, rather than to the original papers. This leads to too many chemical examples, rather than a balance. It might be useful to have the committee come up with some other references that use more biological and physical stressors.

3. I agree, the document as it now stands relies too heavily on aquatic systems, which in the past, have largely taken a single-species approach. Thus ecosystem approaches are given less time, as are terrestrial ones.

4. It is useful to have the uncertainly issues outlined in each section. However, it might also be useful to pull them together in an Appendix so the assessor could get a complete picture of the problem.

INTRODUCTION AND SCOPE

5. More emphasis should be placed on the importance of examining ecological risks to ecosystems and ecosystem **function** and to mixtures. Managers and the public will be interested in this aspect. Quality assurance considerations should be listed up front. The importance of evaluating whether the risk assessments were accurate should be included. We cannot get to a predictive stage if we do not evaluate our

past risk assessments.

6. I feel that assessment and measurement endpoints should be clearly defined up front, in this section. They should both be defined, and have clear examples. This is especially important for managers and for the public. Although you refer to sources for definition, these are very important points, and the reader will find it easier if they are here.

To the definition of disturbance, Page 15, you might add processes. Processes are important endpoints for ecological disturbance. To the first sentence in section 2.3: I think that ecological value should be defined, perhaps in a box with some examples.

7. None

Other additions and suggestions to introduction and scope

a. page 2; sometimes new data might be required, and this should be incorporated in the process.

b. page 3, under 1.4: it might be useful to add "evaluating competing risks" to the initial sentence.

page 3, last sentence: it might be useful to refer to dose-response here, since many risk assessors will want to see just how this fits in even though a decision was made not to use it. We still must deal with the real world, and should be able to talk to human risk assessors

Page 3-4: in the bullets, I feel we should add a phase for evaluating the efficacy of the risk assessments (after Burger 1994)

Page 8: figure should be enlarged slightly for readability.

Page 9 (top): it might be useful to have a box that delineates some of the landscape-level effects you are talking about since this may be the phase most unfamiliar to risk assessors.

Page 12: Need to add something about data quality assurance.

Page 13: first bullet: may need to give an example or two.

RISK MANAGER INTERACTIONS

8. The most important thing that is missing from the discussion is **stakeholder participation.** Although it is implied that the manager will have this in mind, and there are several references to the public, I think this needs more inclusion.

In this same vain, stakeholders should be clearly defined and enumerated. For example, stakeholders other than those living in the immediate vicinity should be considered. For example, when considering logging in the northwest, the American public outside of the immediate area was very interested in the outcome, and had a stake since these were public lands (in many cases). This might well need a box.

9. Environmental justice considerations should receive more attention.

Additional comments on this section:

Page 17: I would consider adding stakeholder to box 2-1. Stakeholder is absent from most of this section; and this will become increasingly important over the years.

Page 19: Top sentence; I might add commercial uses to the public perspective.

Page 19: In addition to risk managers and risk assessors coming to agreement on goals and scope, they should also agree on the timing of the process.

Page 20: to box 2-2, the question: How soon will recovery occur should be added.

Page 21: Box 2-3: I am still uncomfortable with sustainability and its definition.

Page 21: to the first sentence under 2.4, I might add endangered species as an example of implementation of management decisions. It would be good to have a non-chemical stressor here.

Page 25: To the data acquisition phase on the right of the diagram I would add quality assurance instead of verification because it includes more factors.

PROBLEM FORMULATION

10. Overall I think these terms are confusing as presented, or at least will be to managers when presented with them. The distinctions are excellent, they just need more examples.

I do not agree that value-initiated assessments are conducted at the landscape scale. Many of our value ones are based on endangered species, or appealing ones that people are concerned about.

11. In discussing assessment endpoints, it would be useful to distinguish between "indicator species" and assessment endpoints - perhaps a box would do nicely.

12. I would add a couple of more models that show conceptual models for real systems. Burger 1995; A risk assessment for lead in birds (J. Toxicol. and Environ. Health) has one for lead that might help for some risk assessors. Another one or two of different types would be good.

Specific comments

Page 27: It might be a good idea to give some physical or biological examples in addition to the chemical (middle of page)

Page 27: Box 3-2 is less clear than some of the others.

Page 28: May need to expand the bullet to give some examples

It might be useful to have a box for both physical and biological stressors.

Page 28: 3.2.3 It might be helpful to add endangered or appealing species to the values.

Page 30: Need to expand here on the stakeholder participation, since this is critical to value-initiated goals.

Page 31: I might also include a species level box (such as for Spotted Owl, one managers will relate to).

Page 33: Add half life of chemicals to box 3.5

Page 34: Might want to add endangered species or those of special concern to box 3-6.

Page 37: Need to mention indicator species, since this seems like what you are discussing in many ways.

Page 38: the first sentence is confusing.

The last sentence of line 20 is not a complete sentence.

Page 39: ecological entity needs to be defined.

Page 40: Assessment endpoints are not management goals: this needs a bit more expansion. It is an important point.

Page 42: Box 3-10 makes little sense as it stands. It needs to be more readable on its own.

Page 44: Risk hypotheses need more boxes;the one given is good. More would help

Page 44: add "ecological relationships " to the list of bullets at the bottom

Page 46: Need to have a box to show relationships of more conceptual models. Burger 1995 for a "Risk assessment for Lead in Birds" (J.of Toxicol and Environ. Health) has one that applies to the real world that might be good.

ANALYSIS

13. I think the balance is fine, might have more biological stressors since this aspect has been largely ignored by ecological risk assessors.

14. I think there needs to be a discussion about dose-response information from the laboratory, what kinds of dose-response data there are from the field, and how to interpret them. Also, how to deal with the lack of such data.

I also think it would be good to get some examples from the main ecological literature, instead of only using Barnthouse and Bartell examples. This will vary the interest, and make it more relevant for other readers. I can provide some if you wish.

Multispecies approaches (page 79) are NOT measuring community level effects. They may indicate problems at different trophic levels, but community level effects can only be measured by doing so.

15. None, it is fine.

Additional comments for this section

Page 58, middle of page: I would add quality assurance to the carrots.

Page 59: I think you need further definition of secondary effects (line 18). For many risk assessors, this will be a new thought

- line 26-8: Might need to add life stages. That is, some organisms (such as frogs) live their life in very different habitats (aquatic vs terrestrial) and these should be included.

Page 61: (line 22). I wonder if error in selection of appropriate endpoints should be mentioned.

Page 62: Table 4-1: Under Variability: I would add life stages and allometry.

Page 63: Considerations of power should be done before any new field data are collected.

Page 67. line 1: might add or stressors that interact.

Line 5: not only concentration, but species or form of contaminant.

I did not find Box 4-4 useful on its own.

Page 68: line 1-3. Might be useful here to give an example. For example, the presence of selenium decreases the uptake of mercury.

Line 19: Might need a box to define "reference" environment. This is a term that is not equally used in all communities. Yet it will be used more in the future.

Page 70: line 4: may need to be compared across systems as well.

line 10-12: May need a further explanation of the relationship between dose and bioassays. In my experience, there are not enough studies to examine these relationships.

Page 71: Need to add some discussion concerning toxicodynamics, and the difficulty of determining dose from tissue levels in different tissues over time.

Line 16: Need to add life stages and life history information

Line 20-22: Need to add secondary behavioral effects.

Page 72: Box 4-5 is less useful than it might be.

Page 73: top: Might need to discuss thresholds here briefly; and have a box explaining how they relate to risk assessment. DDT and eggshell thinning might be a good example.

Line 24: Might want to summarize the usual ones.

Page 74: line 11-14: May want to include some reference to dose-response data.

Line 29: Might want to add "and how well they represent time, space and life stages variations"

Page 79: Line 21: I disagree that multispecies assays evaluate community level effects. They can be evaluated only by measuring community level effects (there are such measures, such as productivity, nutrient cycling, species composition)

Page 80: TOP: Need to test the assumptions of extrapolations as well.

Page 83: line 14: and in different species, should be added.

Line 27: Can find good studies to reference here (see Burger and Gochfeld 1994, 1995 - call if you wish reference). These studies conducted dosed studies in the field with wild birds.

Page 84: line 10: need references to secondary effects for general reader.

Page 86: line 27: add habitat stages (since some may be in water, others on land).

Page 89: You might add Beach Nourishment as another disturbance to give an oceanic one.

Page 93:line 1:you might add daily variations.

Line 20: You need to define and give a reference for the Habitat Suitability Index work.

Page 94: Analysis of Biological Introduction: I wonder if Extinction should be added here. We might want to do risk assessments for how extinctions would affect particular ecosystems.

Page 96: The secondary effects listed in table 4-4 should be more specific to be meaningful

Page 101: line 12: I wonder if you want to add "what are the effects of natural competitors?"

Page 102: lines 1-8: I wonder if you want to add landscape-scale features?

Page 104: Line 5: The delphic approach may not be known to all readers, perhaps a box is needed.

Page 106: line 29: again, I would add synergism (such as the effect of selenium on mercury uptake).

RISK CHARACTERIZATION

16. I would suggest adding Meta-analysis. It will become increasingly important in risk assessments (both human and ecological).

17. This was not clearly spelled out; and deserves a box of its own. It should be highlighted, not buried in the guidelines.

Additional comments:

Page 114: Line 16-18: Again, quality assurance should be added here.

Page 115: lines 1-15: I wonder if the cost of being wrong with a particular analysis or characterization should be added in some way.

bottom: Sublethal effects should be added more clearly.

Page 116: Another bullet should be added that refers to bioaccumulation and species differences.

Page 119: bottom. Again, I wonder whether the potential ecological costs for being wrong should be added.

Page 121:line 7: Power tests should be added here.

Under weight of evidence: I wonder if a discussion of metanalysis should be added here.

Page 123: Under scale: some other landscape features should be added like corridor, pattern, etc.

Page 125: It might be useful to do a box on recovery

Peter Chapman

ENVIRONMENT
CONSULTANTS

REVIEW COMMENTS:
EPA'S ECOLOGICAL RISK ASSESSMENT GUIDELINES

Prepared (November 1995) by:

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General, then sequential comments are provided. These directly or indirectly address the specific questions asked of reviewers.

General Comments

1 The document is very good, though there are some improvements which could be made as noted below. We commend the authors for their efforts. In particular, past risk assessments have often contained vague and ambiguous assessment endpoints. The document provides a clear explanation of the definition and objectives of assessment endpoints. Text box 3-9 (page 41) is particularly helpful in that it provides examples of correctly worded assessment endpoints. However, we are concerned that this document not replace past guidance documents which actually guide the risk assessor through the process. The present document is a compilation of expert reports which focus on specific considerations and examples and covers such a wide range of topics that only vague statements can be made regarding chemical-based ERAs, which will probably be the major focus (correctly or incorrectly) of users of this document.

2 There is a general avoidance of discussion related to issues which would improve standardization of the risk assessment process. For instance, there is no discussion of the application of uncertainty or species sensitivity factors for extrapolating between taxa used in food web modelling. EPA Region 8 has developed guidance for applying uncertainty factors, which may provide a basis for sound risk assessment decisions and help to ensure that risk assessors are applying these factors in a uniform manner.

3 Selecting the most appropriate toxicity reference values from the literature is critical to accurately estimating risk to ecological receptor species using a food web modelling approach. Basic criteria which should be followed when selecting appropriate values should be outlined in the document. Trophic transfer of contaminants is a significant component of both screening level (predictive) and higher level risk assessments. More information should be provided on a food web modelling approach to exposure and effect assessments,

particularly for terrestrial receptor species. The discussion of field sampling techniques can be tied into the food web model approach so that the appropriate data types can be collected. A discussion of the criteria used to select toxicity reference values and EPA approaches to applying uncertainty factors for interspecies extrapolations could be included.

4 There is a need to hilite more in the report as detailed in the sequential comments below. The document contains many useful concepts and ideas which should receive greater emphasis. As it presently stands, however, the document is somewhat fragemented and lengthy, which makes it difficult to read in one sitting and difficult to use as a reference document.

5 Some of the text boxes are very good, some are not, and some are useless. Under sequential comments below suggestions are made as to which text boxes to remove and what text boxes to add. Ensure all text boxes are refered to in text, are relevant, and appear where they should in the document.

6 A Glossary should be provided at the beginning of the document. Such a Glossary should build upon but not be restricted to Appendix B. For instance, Appendix B does not: (1) clearly indicate changes since the 1992 document; (2) define all key terms (a few examples are "weight of evidence", "delphic"; lots of other terms, noted below, need definition). Both need to be done. Specifically, with regard to (1), in the definition note in italics any changes.

7 To avoid confusion (there will be lots) it is important to provide, up-front, a "Summary of Changes to 1992 Framework Document" with reference to specific sections where details are provided.

8 The case illustrations are all noted to be flawed and, in at least one case, incomplete. Why not provide one or two generic illustrations which are as close as possible to the ideal?

9 Text discussion related to maintaining the status quo (e.g., sustainability) is confused and inappropriate given the reality that one cannot return exactly to pre-disturbance conditions (noted towards end of document).

10 Particular emphasis must be placed on defining "weight of evidence". In particular, what the significance of conflicting lines of evidence is needs to be addressed. In other words, some sort of guidance is required though it is recognized that flexibility must be maintained.

11 The most common form of analysis is by Monte Carlo. While not espousing this method (which is 50 years old in 1996), a good discussion of how to use Monte Carlo analysis in risk

assessment would be most useful. We don't believe such explanation/guidance exists anywhere?

Sequential Comments

1 Page 2, hilite first sentence.

2 Text box 1-1, page 2: The information contained in this text box is more suitable for the text (Section 1.2). Instead, most of the information in the first two text paragraphs should be put into a text box, as this is more important to hilite than case illustrations, particularly when it is noted that these illustrations "all have strengths and limitations that cannot be fully explored in this document." This latter statement detracts from the utility of these illustrations. Why not provide generic illustrations built upon these that are less flawed?

3 Page 3, lines 27-31; page 4, lines 1-9: This information should be hilited in a text box.

4 Page 6, line 3: Weight of evidence, used here and throughout the document, needs to be defined. A text box would be very useful as well as a Glossary definition.

5 Text box 1-2 is good, but should appear on the next page adjacent to Figure 1-3 (it is presently separated by a page). Figure 1-2 is not useful; delete. Specific problems with this figure include the lack of a decision point determining whether one makes a decision or just "rolls along". Instead, provide a text box on the iterative nature of ERA using information beginning on page 6, line 6.

6 Page 9, lines 9-12: Should be hilited by a text box.

7 Page 9, line 16: "survival, growth, and reproduction of individuals" is not much clearer than "healthy populations". How much mortality allowed? How much growth and reproduction needed?

8 Page 11, lines 15-21: Good.

9 Page 11, line 30: The term "measurement endpoint" is widely in use and finally understood. Switching to "measurement of effect" is disruptive and does not improve conceptual understanding.

10 Page 12, line 9: Data acquisition is part of the risk assessment process. Text Box 1-3: The

new terms "measures of exposure" and "measures of ecosystem and receptor characteristics" are awkward and do not improve conceptual understanding. However, if they are to be used, they should be introduced in the main text also to receive the deserved emphasis. At present these terms are not introduced until page 53.

11 Page 13, line 22: A recommendation is required on terminology that is being used synonymously (i.e., either recommend relative risk assessment or comparative risk assessment) to standardize terminology. Line 29: Insert (1992) after Leibowitz et al.

12 Page 14, line 23: The italicized definition of stressor should be included as the word stressor to maintain a consistent format. Ditto for the term exposure on page 15, line 6. Line 31: The term stressor should be used instead of agent (to be consistent with Text Box 1-5).

13 Page 15: Delete this text box and put information in text; this is not worth hiliting. We suggest, under Section 1.6.3, if you insist on using both terms, defining both agent and stressor. Similarly, page 16 delete this text box and simply define and discuss stress regime in text. Remember, you are not trying to have text boxes spread nicely around in the text; you are trying to hilite what is key.

14 Page 17, first sentence: hilite. Line 6, are you really referring to Figure 1-2 or do you mean 1-3? More importantly, all parties in the ERA process should be involved in the planning stage including all regulatory parties. The use of the term "planning" seems rather arbitrary. Planning is just part of the problem formulation process and discussions should occur at frequent intervals during the entire process to keep all parties apprised and involved. Text box 2-1: include a reference to text box 1-4 and/or Section 2.2 re what risk managers do.

15 Page 18, lines 2-6: Hilite. Maybe a text box?

16 Page 19, lines 1-2 and 9-10: Hilite these sentences, they are important. Also hilite sentence on line 25. End of Section 2.2: Clarify whether risk managers and assessors work jointly from the beginning or not. There are pros and cons to both possibilities.

17 Page 20, text box 2-2: Fifth bullet re uncertainty under Risk Managers should also occur under Risk Assessors.

18 Page 21, line 2: The term "place-based" is awkward. Text box 2-3: We do not agree that sustainability (i.e., keeping the status quo) is intuitively the right approach. Lack of sustainability (death of dinosaurs, development of mammals and hominids) is a reality that is

not always negative. This box needs to be rethought, especially in the light that you can never return to pre-disturbance conditions after remediation (mentioned later in the text).

19 Page 21, line 24: Hilite this sentence.

20 Page 22, text box: Good.

21 Page 23, line 2: Hilite. However, re lines 10-11 note that infinite resources do not equal a lack of uncertainty. Section 2.6: This section should discuss the tiered approach in general. For example, screening versus phase I or II type assessments should be discussed with guidance criteria for determining the degree of rigour necessary for an ERA and how best to proceed.

22 Page 24: Hilite first sentence under 3.0 and first sentence under 3.1. Sentence covering lines 7-9 should be a text box. However, line 9: The third shortcoming identified under case studies "failure to identify important risks" seems ambiguous. The problem formulation stage of an ERA involves: (1) compiling all available information about the site (e.g., industrial processes, waste disposal methods, historical reports of environmental effects, ecological communities at risk); (2) determining the extent of contamination using available data; (3) selecting chemicals of potential concern; (4) developing a conceptual site model; (5) selecting ecological receptor species; and, (6) developing assessment and measurement endpoints. Risk identification is addressed in the analysis phase, specifically in the exposure assessment when receptor species exposure point concentrations are presented. Perhaps this third point is to be related to one of the components of the problem formulation identified in Figure 3-1 on page 25? Bullet the three numbered points in Section 3.1 to hilite these. Text box 3-1: Direct links need to be clearly made between measurement and assessment endpoings, and emphasized in the problem formulation. Care should be taken not to separate them too much (i.e., identify measurement endpoints in the analysis plan without stating relevance with respect to assessment endpoints).

23 Page 25, Figure 3-1: Under source and stressor characteristics, list these characteristics instead of repeating the words sources and stressors.

24 Page 26: Second sentence is not a sentence. Lines 10-13 should be a text box, and refer specifically to Section 3.7 at end. Line 13: Actual section numbers should be listed instead of phases like "in the final section". This will facilitate organizational understanding. Hilite sentence on line 21. Section 3.2 is awkward and needs focus.

25 Page 27, line 17: Omit "of". Section 3.2.1: Divide into two sections (i.e., separate stressor- and source-initiated). Text Box 3-2: The example is too general to be specific to aquatic environments. Line 3): The conceptual site model does not show the relationship between the stressor and the assessment endpoint. The model displays the contaminant transport pathways and, therefore, the exposure pathways to the ecological receptor species (e.g., inhalation, ingestion re aquatic species, dermal exposure). To quote the September 28, 1994 review draft: "assessment endpoints are explicit expressions of the actual environmental values that are to be protected". The conceptual site model does not take into account the assessment endpoints (e.g., reproduction and growth of small mammals) identified in the problem formulation, but only the potential for exposure resulting in the assessment endpoint being evaluated.

26 Page 28: line 8 - is constituency the same as stakeholders? Line 10: The sentence "ecological receptors that originally showed the adverse effect are frequently selected as the assessment endpoint" is confusing. Ecological receptors are not selected as assessment endpoints in and of themselves. An assessment endpoint represents a measurable ecological characteristic (e.g., diversity of the benthic community) of the receptor species. Assessment endpoints are developed to direct the evaluation of potential adverse effects of a stressor on the ecological receptors. In most cases receptor species themselves are not the values to be protected. More likely assessment endpoints would, for instance, be: a reduction in the receptor species population (i.e., survival of birds), or community diversity (e.g., reduction in benthic macroinvertebrate community diversity). Lines 16-17: Biomarkers, depending on which and how used, are not always reliable indicators of exposure. Lines 29-30: Hilite this sentence. Line 31: omit "a vista in a national park"; surely this is trivial?

27 Page 30: hilite sentences on lines 23-24 and 27-28. A lot of this text refers to the need for balance; distill this into a text box. A general comment: there is here and elsewhere a lot of implicit emphasis on the negatives of anthropogenic inputs. Be careful with what appears to be an implicit bias; some anthropogenic inputs are beneficial, others are neutral.

28 Page 31, text box 3-4: Good. Second sentence of first bullet: shouldn't that read "could also have been based on", not "can also be based on"?

29 Page 32, line 5: "Actual, inferred, or estimated" data should be defined. Lines 27-28: Hilite sentence. Also, an important point that cannot be overlooked is that one must look beyond artificial or other boundaries to check re outside impacts or influences (past, present or future).

30 Page 33, text box: Define stochastic, chaotic. What non-natural stressor event is lunar? Consider adding: Is there any historical evidence of adverse ecological effects? Examples might include: federal or state agency incident reports of fish kills or waterfowl mortality. Fourth bullet: substitute recruitment for reproduction.

31 Page 34, text box: add sediment after soil otherwise this sounds primarily terrestrial. Delete mention of QSARs relative to ecological effects information. This does not make sense, or are we missing something?

32 Page 35: hilite sentences on line 10 and lines 19-20. Line 12: The statement beginning "Their relevance to assessment..." is circular. Line 14: The statement should read "whether there are measurable characteristics" and not "whether they are measurable characteristics" because it is the measurement endpoints that must be measurable (and linked to the assessment endpoints). Lines 28-31 and lines 1-3 on page 36 should be a text box.

33 Page 36: The text box is too obvious to hilite; put into text. Delete lines 6-14. Begin Section 3.4.1.1 with paragraph starting on line 26. Second paragraph of this section is present second paragraph starting on line 15, but is presently in need of rewording. Line 24: Omit "in national parks" after clean air. We need such everywhere.

34 Page 37: Hilite lines 9-11 (replace "can be very useful" on line 9 with "are vital"). Reword lines 14-16 as follows and hilite: "Ecologically relevant endpoints sustain the natural structue and function of an ecosystem." First paragraph under Section 3.4.1.2 needs more discussion of the keystone concept, which now includes groupings of species and also includes bacteria, i.e., it is not just predators which are really charismatic species in most cases, not keystones. Hilite sentence on lines 26-28.

35 Page 38, line 4: Sensitivity is not a relative characteristic (i.e., all sensitivities are not compared to a standard sensitivity). Lines 16-17: But note that adult bivalves after energetic depletion due to spawning are the most sensitive life-stage for those organisms. Line 20: during what? Lines 26-27: what is "birds require unobstructed views where they roost"? Sounds anthropogenic, though we gather much later on that this may be a requirement of whooping cranes? In any case it is both unclear and confusing.

36 Page 39: Hilite sentences on lines 1-2 and 18-21. Text box is very good. Commas needed on lines 29 and 30. Lines 2-6: This is too simplistic an example; more cogent discussion of laboratory versus field is required. Section 3.4.2 should go first in Section 3.4.

37 Page 40: comma needed on line 3. Hilite sentence on line 6.

38 Page 41: What is meant by the Specific under New Chemical?

39 Page 42: Line 13, second word should be "individual". Text box is too vague early on. For instance, if endpoint is too vague, what should it be? What is the midges example? What is turkey and deer example? In comparison, the last two bullets are clear.

40 Page 43: Hilite lines 7-8.

41 Page 44: Hilite sentence on lines 4-6. Line 4: replace the word "verbal" with "written".

42 Page 44, line 14 and page 45, line 13: Similar statements are repeated. This type of repetition occurs regularly throughout the document. Other examples include: page 44, line 8 and page 46, line 12; page 80, line 13 and page 82, line 22.

43 Page 45: Hilite sentence on lines 11-12.

44 Page 46: Hilite sentence on lines 12-13. Line 19, explain stressor-response curves.

45 Page 47: Quotes which continue on page 50 appear to include material which could not have been verbatim, for instance the figure numbers (lines 7, 19) and Appendix A, Case A-1 (line 23). Also, Odum, 1971 (line 24) is not in the References.

46 Page 50, line 2: Diagrams such as Figure 3-3 are complex and not readily comprehensive; they should not be included in generic guidance. Lines 4-17: Too much exerpted text; more generic guidance is needed. Generalizations (e.g., lines 18-20) should be given before specific examples, so as to orient the reader. Line 21: on, not up.

47 Page 51, Figure 3-4b: Delete one of the arrows pointing from "ingestion of particles by birds" to "death".

48 Page 52: Line 4, into, not on. Hilite sentences on lines 11-14 and 17-18. Line 18: reference the Framework Report. Section 3.6: The inclusion of an analysis plan as defined is a welcome addition to the process.

49 Page 53: Hilite sentence on lines 7-9. Line 11: Assessment endpoints include responses of receptors. Line 17: Assessment endpoint is used interchangeably with ecological receptor

throughout a substantial portion of the document. It would be clearer to distinguish between the two since the assessment endpoint incorporates both the ecological receptor species itself, and the receptor species attribute that is being assessed (page 40, line 4). Statements such as "well defined assessment endpoints reduce uncertainty in a risk assessment" (page 40, line 27) also clearly indicate that the assessment endpoint is more than the ecological receptor species. Line 24: importance, not important.

50 Page 54: line 26: The six main areas should be listed and discussed in the text. The uncertainty section should not be broken into so many different sections throughout the document (Section 1.4, 3.7, 4.1.2, 5.2.4...) Tables 3-1, 4-1, etc. seem repetitious. Hilite sentence on lines 27-29.

51 Page 55: First example is not "as clear as possible" as previously noted. Table 3-1: It appears that two examples are given for variability. This is confusing to the reader since all other categories have just one example.

52 Page 56: Hilite lines 4-7.

53 Page 58: Lines 4-23 should be captured in a text box.

54 Page 59, line 25: Introduction of the section organization comes too late to be useful - instead it confuses the reader at that point who then questions what it is they have been reading. Another example is page 75, line 3.

55 Page 61: Line 5, examples, not samples. Hilite sentence on lines 9-10. Section 4.1.1. should not be a section; it is too short and says too little.

56 Page 63: All periods (end of sentences, between section numbers, in e.g.) are missing from line 12 to the end of the page. Line 25: communicate, not communication.

57 Page 64: Hilite lines 28-30.

58 Page 66, text box 4-2: delete; put this information into the legend for figure 4-3. Also, delete text box 4-3. Text boxes should be hilites that are key to reader comprehension. This is not and adds little to the text. In fact, it is also confusing. Also, neither of these text boxes is refered to in the text. Hilite sentence on lines 16-18.

59 Page 67: Hilite sentence on lines 9-11. Line 10 would be clearer if it read: "...and may include

measurements of the concentrations of contaminants in the air, soil..." This text box is useful.

60 Page 68, line 1: The "speciation" of chemicals has more meaning than the "nature" of chemicals as used in this sentence. Line 19, seventh word should be "from". Hilite sentence on line 27.

61 Page 69, lines 16-21: Should this be in quotes?

62 Page 71, lines 4-8: Agreed, hence previous comments re biomarkers.

63 Page 72, line 11: Sentence is difficult to understand.

64 Page 73, line 10: More guidance is required regarding spatial scales and averaging techniques. Line 24: text should accompany each point. Section 4.3.3.4 was particularly helpful with respect to designing an exposure profile. It prompts the risk assessor to consider both the receptor species' natural history characteristics and abiotic factors that influence exposure. It should be stressed that local or regional receptor characteristics (e.g., home range size) should be considered over general literature information whenever possible.

65 Page 74, line 13: The ecological response analysis, as defined, is far more than simply a number crunching analysis and requires a careful examination of the type and usefulness of toxicity data available.

66 Page 76, line 17: "...such as..."

67 Page 77, first (incomplete) paragraph: Good. Line 12: Discussion should first be on interpreting and using available data rather than skipping to QSAR when chemical-specific data are not available. At the very least the section on Single-Species Assays, "the most common method", should be discussed first.

68 Page 78, line 17: What does "q.v." (used twice on that line) mean? Line 24: Recommendations should be made.

69 Page 79, line 15: An example of data which may not support regression analysis should be provided. Line 28: Laboratory testing with field media should not be defined as a field experiment since the purpose of the field experiment is to assess *in situ* conditions which are disrupted when transferred to a laboratory setting and manipulated. The Triad should be discussed in this section.

70 Page 80: Line 18, toxicants not toxicant. Lines 20-21: Omit "In the previous example". Line 29: This document should make recommendations.

71 Page 81: Text box 4-7 is good. Ensure Leslie Matrix is defined. However, section on Extrapolations Between Respones covers too many topics to be user-friendly.

72 Page 82: Line 15, the 1982 Gentile et al. reference is dated; why not use more recent example(s)? Line 17: data were, not data was (data are the plural of datum).

73 Page 83, line 17: Guidance should be provided on other useful factors to regress.

74 Page 84: Line 5, "...geographic area..." Line 16, insert "to" after close parentheses. Lines 20 and 24: Physical models, ecosystem models and microcosm models should be better defined with examples. Line 22, rewrite: "Costs and time are certainly factors..."

75 Page 85, Section 4.2.3.4: This section does not make sense here. The reader is lost at this point as to the overall organization and point of Section 4.

76 Page 86, line 24: "...contained in..." Line 25: additional information that would be useful should be listed in the text.

77 Page 88, lines 8-9: A verb is needed to mesh with the format of the other bullets. Line 29: If characterization of exposure and effects is discussed somewhere in the document, these sections should be referenced.

78 Page 90: Hilite sentence on lines 9-10. Text box 4-8: Omit first "were"; this box is not very useful. Ditto for text box 4-9 on page 92.

79 Page 91: Can't read the figure; hopefully this will not be the case for the final.

80 Page 93: Text box 4-10 is good but is not referenced in the text. All text boxes need to be referenced in the text so their usefulness is clear.

81 Page 94, Section 4.4: Analysis of Biological Introductions is an awkward title. Introduction of Biological Stressors would be much clearer.

82 Page 95: Text box 4-11 is good. However, line 6: differences are not given in the text box

as stated in the text. Line 22: The use of "for instance" does not make sense here.

83 Page 97, line 18: Define fault trees.

84 Page 99, lines 5-6: Explain more re the Chestnut Blight. What are the lessons? Maybe such were provided earlier, but the reader cannot be expected to remember them. At least provide a reference to where in the text to find this information. Line 19: The risk assessor will not know if a worse case estimate is being made if little information is available. Line 22: This discussion should start more generically and then move to discuss genetically engineered organisms.

85 Page 101: Text box 4-13 is not useful and is not referenced in the text. Omit.

86 Page 102: Text box 4-15 is not useful. Instead, make lines 4-10 into a text box. Line 29: "Primary" effects should be stated for clarity, not "direct" effects.

87 Page 103: Text box 4-16 is useless, delete (note APHIS is not defined). Line 9: is, not in. Line 13: delete "of the". Hilite sentence on lines 23-25. Line 27: Define "qualitative estimates" of what.

88 Page 104: Line 5, define delphic approach. Line 6: "...also by..." Text box 4-17 is useless; delete.

89 Page 106, line 7: Response addition should be discussed in more detail or omitted. Line 21, second in should be is. Lines 24 to 3 on next page should be a text box. But, line 26: it is not clear what is meant by "exposure measurements for mixture components". Is this a reference to the form of the individual chemicals (e.g., arsenate as opposed to arsenite), to determine potential bioavailability of the mixture?

90 Page107: Text box 4-18 is not refered to in text, is not the only way of doing this, suffers from problems not elaborated here, and should not be the subject of a text box. Delete this text box. Instead, make a text box of lines 21-27.

91 Page 108, line 12: This sentence implies that the physical stressors in the Detenbeck study were independent and had additive effects. Line 21: If sediment chemistry and toxicity test results are available, they are more useful than simply comprising part of the problem formulation phase.

92 Page 109: Text box 4-19 is good. Line 26: It is not clear why "indices that include both exposure and effect measures should be avoided."

93 Page 110, line 13: We cannot [yet] generally link biomarkers to effects. Sentence is confusing; rephrase. Section 4.5.4: This section should be combined with the other section on causality.

94 Page 111: Text box 5-1 is good. However, it is not referenced in the text (as many are not) and contains important information which should receive greater attention and inclusion in the main text. The distinction between risk estimation and risk description is not clear. Where does the uncertainty analysis go? Hilite sentence on lines 5-7.

95 Page 113: Hilite sentence on lines 3-4. Line 30: "...exposed to a..." Lines 7-27 and Text Box 5-2 are out of place and seem repetitious - were they discussed elsewhere?

96 Page 114: Lines 1-20 should be a text box. Line 11: Approaches such as population and ecosystem modelling should be described in greater detail to point out the kind of output expected. Line 22: omit "are". Line 31: The HQ equation should be given.

97 Page 115, line 1: Most risk assessors use the NOAEL instead of the LD_{50} in the HQ approach.

98 Page 116: Explain why subtle short term effects may be missed if results are only tabulated on the final day. This is from text box and is presently unclear. The four days should be consecutive unless additional time-response information is available. The 28-d results should also be applied to consecutive exposure. Line 13: The use of distributions does not alleviate all of the pitfalls identified in Section 5.2.2.1. Line 29: Distributions are still useful when evaluating a single species since many times a wide array of toxicological data is available.

99 Page 117: Lines 7-16 should be a text box. Line 27: semicolon, not comma. Section 5.2.2.3: The use of the term physical models for field testing is misleading.

100 Page 118, line 2: Something is missing on this line or else omit "types". Line 23: Delete this sentence. Simulations are commonly used for many reasons.

101 Page 119: The following should be text boxes: lines 7-15, and lines 27 to 6 on page 121. Hilite sentence on lines 18-20. Sections 5.2.4 and 5.3: The proposed format for risk estimation, uncertainty analysis, and risk description is not clear. Line 17 discusses a risk

summary which is assumed to be the risk description.

102 Page 121: Make a text box of lines 15 to 7 on page 122. Section 5.3.1: ASTM is coming out with guidance on ranking weight of evidence. This information, presented at the Second SETAC World Congress in Vancouver this November, should be included in this section.

103 Page 122, line 9: Much more is needed re when different lines of evidence are in apparent disagreement (e.g., see lines 27-28 on page A-19). Line 25: Hilite this sentence.

104 Page 123: Line 7, "...aspects of an..." Also, why the periods at the ends of the headings on lines 12 and 19?

105 Page 124, line 4: Something wrong here. Line 13: The temporal scale should range from seconds to centuries, not minutes to days.

106 Page 125: Hilite sentence on lines 2-3. Make a text box of lines 27 to 2 on page 126.

107 Page 126: Text box 5-4 does not illustrate well the importance of understanding natural disturbances. Such a text box would be useful; this is not it. Also, hilite sentence on lines 20-24.

108 Page 127: Hilite lines 3-4. Line 6: This sentence is not clear and should be shortened, or the information should be presented in two sentences. Make a text box of lines 20 to 14 on page 128.

109 Page 128, line 12: Consistency characteristics should be presented with bullets as well. Last sentence: This is an important point which is also controversial and which needs much more discussion and justification.

110 Section 7, References (pages 129-144) only spot checked.

111 Page A-3, line 3: Connor here, Conner on page A-21.

112 Page A-13, line 16: from a, not froma.

113 Page A-21: Where is rest of Harris et al. (1994) reference?

114 Page A-22: U.S. EPA (1993, 1994) cited in Appendix A?

115 Appendix B: No References but many citations. Page B-2, line 10: omit second (lower case) "a". Page B-3, line 24: needs close parentheses; line 25, needs a comma before "(3)".

James Clark

COMMENTS PERTAINING TO ISSUES THROUGHOUT THE DOCUMENT

1) Document quality and responsiveness to outside input is very high.

This document incorporates many of the discussion points of the May 3 Colloquium held in Washington, DC, to discuss stakeholder perceptions of ecological risk assessment guidance. The authors are commended for being responsive to that input and accommodating many of the suggestions. This document is well-written, the ideas and topics are clearly presented and logically organized. The examples and appendices provide useful insight into the application of the guidelines and concepts important to the agency.

2) Greater detail in guiding principles for conducting risk assessments is needed.

These guidelines must link the need to have flexibility in how ecological risk assessments are conducted and the necessary consistency in ecological risk assessment products. This can be achieved only by providing greater detail in the criteria by which decisions are to be made when in the middle of the risk assessment. An overly prescriptive guidance document will not be useful to resolve the myriad of environmental issues the agency must address. However, this document lacks sufficient detail in the guiding principles of ecological risk assessment to achieve consistency in products developed by following this draft. The reader needs more specific direction on where to go for basic information, how to recognize good data from bad, what to search for when looking for surrogates, or reference sites. The text cites a number of useful references, but does not provide the detailed guidance necessary to achieve consistency in products. Some of these issues are discussed more fully below.

3) References to use of common sense and good judgement require more

elaboration to form a useful guidance document.

In numerous places, the text rightly refers to areas where common sense and good judgement are required to make an assessment regarding the role of some factor or data in the risk assessment process. However, it is the function of a guidance document to lay out the basis to define the application of good judgement or common sense. These areas in the text should be enhanced to set up criteria by which decisions can be made regarding the direction the risk assessment is to take. Instead of limiting the discussion to "use common sense", the document should direct the reader's actions (provide a list of do's and don'ts, such as go with documented or peer reviewed information only, seek direction from government agencies, make a decision on your own and document the rationale, etc). Such an elaboration is necessary in (at least) the following areas: S 4.2.3.2, P 80, L 27; S 4.2.3.2, P 82, L 29-30; S 4.2.3.3, P 85, L 8-11; S 5.2.1, P 114, L 16-19; S 5.3.2, P 123, L 1-10).

4) Data quality/data usability issues need to be addressed in a detailed, cohesive manner.

Throughout the text there are limited references to literature regarding appropriate use of data, but the guidance lacks a focused and comprehensive discussion of the attributes of good data, how to compare old and new data, data generated by different methods, etc. The text includes references to various EPA documents regarding DQOs and quality assurance issues, but appropriate data use in ecological risk assessment is much broader than merely generating quality analytical data. In particular, the guidance document should have a separate section that addresses the issue of how to decide to use or exclude data or data sets based on data quality, data usability, and data relevancy issues. These issues should be discussed in a separate section, then referenced as necessary to pertinent areas in the following sections (S 3.6, P 54, L 12; S 4.1, P 58, L 6-9; S

4.3.2, P 74, L 27-29; S 4.3.2.1, P 76, L 22-27; S 4.2.3.2, P 82, L 3; S 4.2.3.4. P 85, L 25-26; S 5.2.1, P 114, L 2-4; S 5.2.2.2, P 116, L 28).

5) A new section on selection and use of surrogates (species, endpoints, indicators) is needed.

The guidance document lacks an adequate overview and detailed guidance on what attributes are to be considered when selecting surrogates for receptors or assessment endpoints. A detailed discussion regarding a search for surrogates with similar life histories, exposure pathways, toxicological sensitivities, predator-prey interactions, etc., is needed to guide risk assessors in selection of surrogates. This pertains to discussions presented in S 3.4.1.3, P 39, L 1-6; S 4.1.2, P 63, L 9-13).

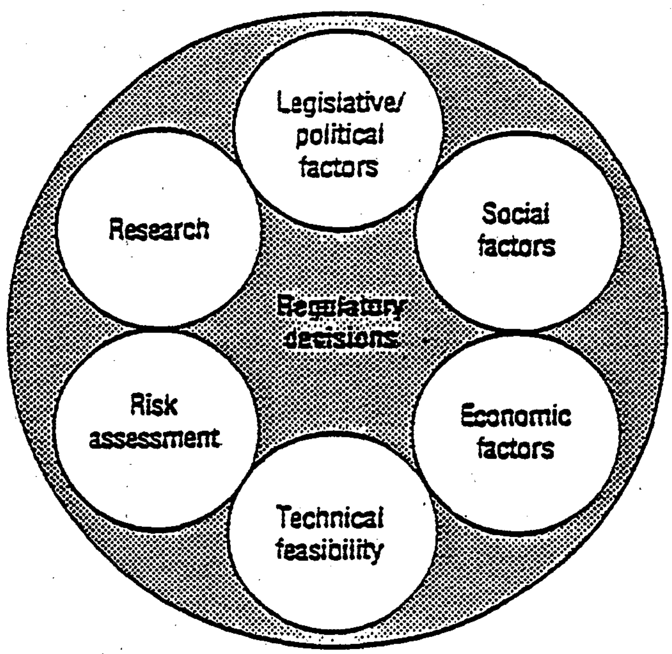
SECTION-SPECIFIC COMMENTS

Section 1.2. The perceived audience for this document should be broadened (P 3, L 1-4).

Although the agency needs a guidance document for its risk assessors, the regulatory aspect of agency functions require that all stakeholders must understand the basis for agency actions. This document will become the cornerstone for regulatory agencies, as well as business, industry, contractors, and landowners. The agency should recognize this responsibility and create a document that targets a much broader audience.

Section 1.4. Risk assessment is only a small part of decision-making.

The text should recognize that there are numerous factors to decision-making, and risk assessment is only one (although important) component. A diagram (enclosed) taken from an OTA document shows five other factors affecting a regulatory decision. This diagram helps risk assessors



Elements in risk management. Modified from the U.S. Congress. Office of Technology Assessment [25].

understand where their contribution may fit into a decision.

Section 1.5. Figure 1-3 and accompanying text are very useful.

This diagram and the text describing the activities in each box are so much more useful than the overall framework diagram. By breaking out inputs, actions and deliverables, the figure offers much greater insight on activities and expectations associated with each step in the risk assessment process.

Section 1.6.1. Need greater consistency in use of "adverse" to describe effects.

The text in this section needs greater consistency in the use of the term adverse, as it relates to the types of ecological effects that a risk assessment will address. If in the final analysis, as indicated in line 14 of page 3, any change (positive or negative) must be assessed, then the definition can focus on ecological changes alone. In my opinion, the guidance should focus on significant adverse effects, not any change. The terminology in this section is not consistent with discussions in Section 1.6.3, where the terms adverse response (P 14, L 25) and disturbance (P 15, L 28) are used.

Section 1.6.2. Don't confuse hazard quotients and risk quotients (P 14, L 6-9).

The discussion in this section may confuse readers as to the value of risk quotients versus hazard quotients, since the reference to the SETAC document includes an exposure and toxicity term. The text here should elaborate on the differences between risk quotients and hazard quotients. Risk quotients are mentioned extensively in Section 5.2.2.

Section 1.5. Address Tiered risk assessment process in more detail.

The iterative nature of a risk assessment is discussed in sufficient detail here, providing examples of how data and analyses become more complicated as necessary. Others have used a tiered approach, designed around data availability or costs. Screening-level tiers might use only available toxicity data, yet may have several iterations as investigators search for more published data.

This document should have a whole section dedicated to tiered approaches in ecological risk assessment. It should address issues such as how to organize a tiered approach to a risk assessment, setting up decision criteria at each level (perhaps with multiple iterations within each tier). Taking the reader through a discussion of how a screening level assessment is organized and executed, a process for formulating a decision on why and how to proceed to the next tier, when and where site-specific risk assessments are useful, how and when to collect more field or lab data, and other aspects of tiered approaches as necessary to demonstrate cost-effective, efficient approaches to risk assessment. The costs in time, data, and effort at each level could be discussed and a rationale for how tiered assessments are used in decision-making would be useful. Currently, this document implies, perhaps implicitly, that a risk assessment is always a full blown, data intensive, lengthy and costly endeavor to be undertaken for every significant environmental decision. Ecological risk assessment is not practiced in that fashion today, nor does it need to evolve to that level for every decision.

Sections 2.0 and 2.1. Broaden the discussions concerning, and the definition of, risk managers.

The discussion on page 17 regarding who is a risk manager (along with Box 2-1) should be broadened to include risk managers in the private sector of business and industry who manufacture products and operate facilities.

Likewise, the discussion of planning objectives should be broadened to include all stakeholders (business, industry, land owners, etc.).

Section 2.2 Quality job on delineating roles.

This section provides a good delineation of the roles for risk assessors and risk managers. These responsibilities hold for those in the private sector involved in risk assessment/risk management as well.

Sections 2.3 and 5.2.2.1. Costs and benefits should be addressed.

These sections should include references to cost/benefit or other economic factors that must be considered in risk assessments and discussion of the goals for risk management. Examples used in these sections omit reference to economic factors, which are drivers in nearly every case. Many management decisions come from Tier I studies which are low cost tools, for low cost issues.

Section 2.3. Sustainability should be considered in a management goal (P 21).

In Box 2-3, the discussion on sustainability is too narrowly focused. Sustaining populations and communities of ecological resources is indeed the goal of an ecological risk assessment. When expressed in this manner, sustainability does meet the criteria for an assessment endpoint.

Section 2 overall. Good job on discussion of planning and interactions between risk managers and risk assessors.

Overall, Section 2 provides a solid explanation of the roles and activities of the risk assessor and risk manager as a risk assessment is initiated. This is a well written chapter, the examples are clear, the roles and expected outcomes of interactions are delineated. There are good examples of government activities, responsibilities, and topics of dialogue.

Section 3.2.2. Beef up text on causality (P 28, L 15-20).

This discussion points out three criteria (bullets) for linking exposure and effects. The text should emphasize that all three conditions must be met in order to confidently assign causality to an observed ecological change.

Section 3.3.1. Effects driven assessments should not be witch hunts (P 32, L 10-18).

When working with generalized conceptual models, any type of change often is linked to suspected chemical stressors, leading to a witch hunt for the offending toxicant. The text here should reflect the conditions for causality outlined on page 28 (L 16-20), or at least refer the reader back to those ideas. In addition, the text in this section needs to reinforce the need for balanced, scientifically-based, problem formulation.

Section 3.3.2. Management should not define ecosystems.

The text implies that issues other than ecology define ecosystems. Perhaps the intent is to say that risk managers define the area/geography/locale of concern, then ecologists can discern the relevant ecological boundaries. Most ecological receptors do not obey risk management directives (the same might be said of risk assessors, too).

Section 3.3.3. Link discussion of effects more closely to exposures (P 34).

Effects to be considered are those resulting from some form of direct or indirect exposure. The discussion should focus the reader only on effects that can be linked to exposures. Text in Box 3-6 does not address exposure pathway analyses, which is crucial in assessing potential for effects. This text should be tied into the discussion of selecting what to protect (Section 3.4.1), focusing on exposed populations that lead to adverse ecological effects.

Section 3.4.1.2 Discussion of ecological relevance is very useful (P 37).

The text in this section provides the reader with valuable guidance on what to take into consideration when selecting endpoints that are ecologically relevant.

Section 4.2 Add section addressing issues regarding background conditions and use of reference sites.

This guidance document should include specific recommendations regarding how to select or define appropriate reference sites and background conditions. Ecosystems which have adapted to baseline or background exposure conditions should be the basis of site-specific risk assessments. This document should explain, in detail, the procedures for obtaining appropriate information regarding background conditions and exposure levels. An expanded text should incorporate areas briefly discussed on pages 67, L 1-6; P 68, L 21-24; P 107, Box 4-18.

Section 4.2.2.3. Use of biomarkers of exposure should be discussed more fully.

The guidance document should provide a list of attributes that make biomarkers reliable and useful. Currently, a number of useful and useless biomarkers are being incorporated into risk assessments (and other ecological activities), which confuses their role and taints their overall utility. The text should lay out the expectations of what makes a useful biomarker, the documentation and validation necessary to support it, and the role it can play in risk assessments.

Sections 4.2.3.2 and 4.2.3.3. Data quality issues with modeling should be emphasized.

In addition to an overall discussion of data quality and usability (my comment #4), the sections discussing applications of models should have a paragraph providing guidance regarding use of quality data in modeling attempts. Use of poor quality input data destroys the credibility and usefulness of an otherwise excellent modeling tool.

Section 4.2.3.4. Reference to use of anecdotal information requires accompanying cautions.

Effects-driven assessments must be based on sound science. Quantitative information must be a priority need when conducting a risk assessment on this basis. The text does not go far enough in providing caution regarding use of anecdotal or incomplete information. The guidance document should emphasize that when confronted with a "wide array of data", scientific evidence should be heavily weighted and decisions to utilize other information should be openly documented and justified.

Section 4.3.2. Spatial scale of disturbance must be considered (P 92, L 15-27).

Discussions regarding loss of habitat and physical disturbance must be put into perspective of the spatial and temporal scale of the disturbance/loss. This concept is captured elsewhere in the document (4.3.4), but should also be introduced here. This text comes across as an absolute statement, and is incorrect without some modification. Discussions of relative risk and incremental risk could be added to this section as well.

Section 4.5. Differentiate multiple stresses and multiple risks.

The presence of multiple stressors is indeed a difficult task to assess, and the guidelines provide useful explanations for how to address these. However, the guidance document should recognize that there may be a difference between the impact of multiple stressors on a single (or limited number of receptors), and the risks posed by the presence of these stressors. Multiple adverse impacts to a receptor may pose a single ecological risk, if the ecological risk hinges on the growth, reproduction and survival of that receptor. Cumulative impacts from multiple stressors can pose a single risk. Summing the effects of multiple chemicals, as discussed on P 106, does not necessarily result in summing the individual ecological risks. The guidance document should elaborate on this concept.

Section 5.2.1. Introduction needs tighter link to subsequent text.

The introduction to this section provides an overly simplistic assessment to a complex problem. The subsequent text (all of section 5.2) provides an acceptable description of how quantitative and qualitative approaches are used, and how they differ. However, this introductory material provides absolute statements (e.g., "Qualitative assessments rely solely on knowledge") which would be more accurate when accompanied by modifying and limiting adjectives and adverbs ("Some qualitative assessments", or "may rely solely on", or "rely heavily on"). This introductory paragraph should more accurately reflect the numerous combinations discussed in subsequent sections.

Section 5.2.2.1. Quotient method is more useful than text implies.

The text provides insight into development and application of single quotients in a very simplistic context. There are opportunities to compute various quotients based on other types of toxicity data, or for other effects measures. The quotient is not a sophisticated risk assessment tool, but it can be a very efficient and cost effective screening level risk assessment for decision-making. The guidelines should provide a broader, and open discussion of the uses, an perhaps misuses, of quotients in risk assessments. This tool has may useful purposes, and is worthy of greater attention.

Section 5.2.3. Distinguish between sensitivity analysis of a model and sensitivity assessment of the ecosystem (P 118, L 24-25).

The text in this section provides a good overview of the role of modeling in ecological risk assessment. However, the reader should be reminded that there may be significant differences between the model of the real world and the real world itself. Therefore, sensitivity analysis and data prioritization based on a model may not necessarily reflect the real world conditions. Important parameters identified through empirical studies should be prioritized over important parameters identified through modeling runs.

Section 5.3.2.3 Is the statement regarding logging impacts on recovery true? (P 125, L 17-18).

Is there some context where the statement proclaiming continuous logging of old-growth forests will eliminate forest ecosystems is true. Harvesting at what rate, using what techniques? With replanting, selective harvesting, or other management techniques, some aspect of a forest ecosystem could be sustained. Physical alterations, as described in subsequent text, could lead to a loss off of forest ecosystems, but this case seems different than the impacts of continuous logging.

Section 6. The focus of the risk communication text is too narrow (P 128, L 16-19).

This short discussion regarding risk communication is a topic worthy of its own section in this document. Risk communication is a very important process throughout the entire process of risk assessment. It begins with discussions between the risk manager and risk assessor. Good risk communication must occur among the multidisciplinary team conducting the risk assessment. Communication is important at the end of the risk assessment, not only when dealing with the public, but with all stakeholders and risk managers.

SIMPLE EDITORIAL COMMENTS

P 43, L 1-6. This text is redundant with P 42, L 9-23.

P 53, L 24. Change "important" to importance.

P 82, L 17. Replace "data was" with data were.

William Cooper

Review of EPA Draft Guidelines for Ecological Risk Assessment

by Bill Cooper

General: The document is well written and covers the subject very well. The distinction between Effects - Initiated and Ecological Value Initiated is one of scale, not one of substance. The selection of assessment points are common to both. If you want to maintain a clear distinction between these two, you need more work on this - pages 28-30.

Specifics:

Page 3, line 2. "risk assessors at EPA" - With the shift of power to the states, this is no longer true (Florida).

line 4. "ecology and ecological risk" - This is not true with many risk assessors in EPA. This is why you needed so many outside consultants.

lines 23-26. These are all chemical insults. Broaden your base.

Page 4, line 20. "preferable alternatives" - One still needs a relative risk analysis to determine "preferable".

Page 6, line 3. "weight of evidence" - The quality of the evidence is more important than the magnitude.

Page 9, line 28. "carefully designed experiment" - How do you carefully design an experiment for something you don't even know exists? How do you define a null hypothesis?

Page 18, line 4. The focus is primarily a management function. The extent and complexity will be dictated by the science for any given level of acceptable uncertainty. You might expand the definition of roles.

Page 22, line 26. "community, court-ordered or legally mandated" - Why would only the knowledge of the origin of request help determine the maximum uncertainty?

Page 28, line 11. "adverse effect - assessment endpoints" - (Page 29, line 24 - early selection of assessment endpoints). These are the same. One is empirical and the other is anticipatory.

line 20. This is presumed guilt by association. Be careful here.

Page 32, lines 12-15. Again, these only differ by observation versus anticipation of endpoints. If one observed effects that were considered not important, one would not initiate a risk assessment.

Page 33, Test Box 3-5. "absence of such influences" - The absence of the stabilization of water levels in the Everglades (stabilization is the stress) is not stochastic or chaotic, but a return to the normal yearly cyclicity in water levels.

Page 38, line 4. "one individual" - I can't think of an ecological situation where one individual response makes a difference. Ecologically, individuals are expendable.

line 14. "small home ranges" - No! Metapopulations are multiple small patches coupled by frequent migration.

line 20. "during" - What comes next?

line 30. "spatial extent" - also location - the contextual component of landscape ecology.

Page 39, lines 1-6. Most test organisms for laboratory dose/response calibrations for sensitivity don't match anywhere near this well - "ungulates to deer".

Page 41, Text Box 3-9. Carbofuran - The assessment endpoint should not be individual bird survival. It should be a population characteristic. See pages 81 and 82 of this report.

Page 43, lines 1-6. This is redundant to the same statement on page 42, line 19+.

Page 44, line 31. "what initiated...known and unknown" - This is not clear. The knowns and unknowns included a lot more than stressor identifications. Stressor and effects are not as difficult to hypothesize as getting all the detailed data on transformations, fates, potency, etc.

lines 5 and 8. "affected ecological entity" and "undesirable changes observed" are the same. The value of this distinction between effects and values is not obvious.

Page 47, Test Box 3-12. "Effects and value" - They both have the same logic, only the scale is different.

Page 59, line 9. "assessment endpoint identifies" - No. It is the other way around. The level of biological organization and the type of effect identifies the assessment endpoints.

Page 63, line 3. "random variation" - Variability is a genetic property of the biological system. Based on the magnitude of this variation, a different sample size is needed to achieve a given level of discrimination. This is not "error". Errors would involved bias sampling (non-random), poor analytical techniques (level of detection), etc.

Page 84, line 16. <u>to</u> large scale.

Page 85, line 18. "other 95 percent" - This is very incorrect. The 0.5 level is the probability of falsely rejecting a true hypothesis. Ho's are always negative statements of causality. The Type II error of incorrectly accepting a false hypothesis still exists. It is not correct to say that 95% of the time the causality is proven.

Page 106, line 24+ Steve Safe's TEQs are obvious by their lack of presence. Why?

Page 114, line 22. remove "are".

Page 115, line 14. "data are limited" - This is where it is most risky to use the single value quotient method. Even the GLI mandates a 28-day chronic.

Page 118, line 2. "of type kinds" - makes no sense.

Page 122, line 8. "greatly increases" - only if the biases and uncertainties are <u>independent</u>.

Page 124, lines 4 & 5. Something is wrong here.

Page 125, line 2. Populations and communities also do not retain the original condition. The new ecosystem constraints prohibit this.

line 17. "eventually eliminate" - Not necessarily. It might select for "weedy" tree species.

Page 128. One should also identify easily observed response characteristics to verify the impact of the risk management.

Peter deFur

Draft Proposed Guidelines for Ecological Risk Assessment

Comments by Dr. Peter deFur, Environmental Defense Fund

General Comments

1. I commend EPA staff for creating the guidance and putting a great deal of information together. The guidance shows that EPA has given a great deal of consideration to incorporating new developments and concepts into the way in which ecological risk assessments are practiced.

2. In no small part because the field of ecological risk assessment is changing and developing, further concepts and practices need to be incorporated into the guidance document. The conceptual basis for risk assessment guidelines needs enrichment and expansion even farther beyond the initial steps of chemical-specific risk assessments. While the present draft does not rely solely on chemical, source and end-point specific assessments, the text needs to more fully develop the issues beyond such narrow foci.

3. The challenge for EPA in preparing such guidelines is in adding the basics of health risk assessment along with the diversity of ecological endpoints and the mathematical modeling that has come to be used in ecological RA. Furthermore, the practice of RA is changing rapidly in all areas, especially in ecological areas. EPA will need to update this guidance in order to keep the readers and users of the guidance up to date. EPA should indicate this developing nature of the guidance in the document, and, if possible, suggest the areas where changes might

and might not be expected.

4. The guidance document would benefit from a more thorough discussion of processes that are not analytical. There is some reference to data collection, but not to other areas in which process is determinative. Numerous other areas in which deliberative and collaborative activities are required or highly desirable should be identified and the process summarized.

5. There is not enough discussion of public participation and participation of interested and affected parties. This guidance should not propose or imply that ecological risk assessment is conducted without full and complete involvement of interested and affected parties. This involvement encompasses much more than public hearings and notices. Substantive and meaningful involvement requires membership on advisory and review committees, participation in planning, and even joint assessment and analysis, in appropriate cases.

6. There are too many indefinite antecedents to the "this's" throughout the document.

7. Section 3 must include describing the context for the risk assessment. The assessment process must begin with a determination of the context -- physical, chemical, ecological, social, political, economic, etc.

8. The scope of ecological risk assessments has to be intentionally determined and set in the beginning. Given EPA's current efforts to use the watershed for more and more activities, ecological risk assessments should have a default assumption that the watershed will be determined for each assessment, unless compelling reasons exist to the contrary.

9. The guidance still needs more language on non-chemical situations.

10. This reviewer disagrees with the premise that risk characterization is

primarily or exclusively risk estimation and a qualitative description of risk. The statements about all the excluded aspects are not in agreement with many commonly accepted and practiced areas of risk characterization. IF EPA is going to maintain the assertion that rick characterization is only the quantitative estimation and the subjective description accompanying the estimate, then EPA will have to defend to position that human health and ecological risk assessment are different procedures.

11. The guidance document needs to provide more explanation of process, particularly deliberation and consultation.

12. There is an underlying assumption that the reader (and the process for which the document is being used) is familiar with computer models applicable to these cases. There is also an assumption that the reader can USE the models. I doubt the accuracy of either assumption.

P.L.deFur

Comments in Response to Reviewers' Charge

General Principals

Assumptions and defaults

The guidance could identify assumptions and defaults in a single separate section or in labelled subsections of the document. In any case, it is probably prudent to indicate the assumptions in explicit and separate statements.

Balance

1. There are a few areas that need more explanation. First, more discussion of non-chemical stressors is needed. The document could and should point out that any change to an ecosystem can be considered a stressor. Next, all stressors come in combinations in the real situations that assessor face. The legal or regulatory conditions may limit the consideration given to some or all of the stressors, or may offer other barriers, but the guidance should acknowledge to the readers that all can be stressors. There is less use of terrestrial than aquatic systems. EPA should consider adding some more terrestrial examples in the text, not necessarily as new case studies.

2. No major recommendations on the use of case studies. EPA may want to consider where additional use could be made of the ones in the Appendix.

3. In adding cases or examples of terrestrial ecosystems, EPA may want to consider those related to land use cases and events. Logging and wetland filling are all too well discussed, so site selection for a facility, or transportation activities would be common and applicable examples.

4. I found the uncertainty approach quite useful, particularly in the manner in which it was carried through the document. I do think the document should refer

the reader to additional reading in key areas, this being one of the more important and significant ones.

Introduction and Scope

5. The scope and content are clearly stated in the Introduction, but as written, all the people who now rely on such guidance are excluded from the intended audience. I suggest EPA explicitly identify the longer list of people who are expected to be using this document. I also believe that EPA wants state agency regulatory staff to use this, and wants consultants and private analysts to at least consult the document. Therefore, EPA should say so explicitly. If some legal barrier prohibits this language, then say that.

6. Terminology changes should be clearly identified up front, and then when used. Too much repetition of terminology changes is not possible.

7. Further modifications to the figure are required in language only. Not all of the figures throughout the document have sufficient legend explanation and could not stand alone as they should. In the framework figures, the language needs to indicate multiple assessors, multiple managers, and interested and affected parties as participants in the process. The risk characterization box needs to be inclusive of more factors, primarily in the Risk Description that could be multiple circles. EPA may consider adding iteration steps along the left side, indicating that there is constant flow of information and refining of analysis as the process goes forward.

Risk Manager interactions

8. My specific comments include more details on this point. To sum here, the risk managers have to be involved to set the decision-making stage and inform the analysis from start to finish. The document is overly ambitious in expecting the goals to all be spelled out, BUT should identify such as a goal. Risk assessments may not be able to wait until management goals have been agreed to be all the

parties (toxic chemical controls for the Chesapeake Bay watershed, or Mississippi River delta).

9. The relating information to the manager should not be expressed as though it were a simply linear one-way flow with a single manager and assessor. The entire process should be recognized as more inclusive and more iterative. Therefore, the step to which this question refers should be a "confirming" step in which the management team and the assessment team agree that a logical stopping point has been reached.

Problem Formulation

10. The approach of the "driver" seems quite pragmatic and usable in its present form. Some specific comments are found in the later comments.

11. It is hard for reviewers who are familiar with the assessment/measurement end point topic to objectively answer this question. I found some places where the distinction was unclear, and others where it was perfectly clear. I have tried to identify these in the detailed comments. I suggest a read from someone who is not so familiar with the issue and make text refinement and improvements.

12. I think the hypothesis component is fine. I suggest using other and more diverse examples for the demonstration of conceptual models. It is later in the analysis where the use of models is more difficult.

Analysis

13. The balance is in the direction of chemicals. EPA could expand the other parts to include some additional discussion of the same type that is found in the chemical section.

14. The chemical section should note combinations with non-chemical stressors.

Guidance on dealing with these is especially needed in state level actions. Multiple chemical stressors and time and space differences can and should be noted specifically here and in the later section on multiple stressors.

15. There is an additional principal in multiple stressors : the unknown and the unexpected should be expected as the norm in these cases. Multiple stressors tend to be usual, but more complicated in the more difficult situations that have less predictability. As with biological stressors, it is the unanticipated outcome that will undo the system at risk.

Risk Characterization

16. The document needs to include reference to risks that are downstream, indirect, delayed or multigenerational. Impacts that are generated in non-adjacent trophic levels, the next generation, or in another medium (air v water v soil) must be explicitly considered. The document should point this fact out and give some guidance on considering such non-immediate and indirect effects.

The document should say that quantitative risk estimation is an extension of quantitative risk analysis.

17. Ecological significance is manifested in two additional areas: predictability and generational/evolutionary nature of the impact. On the first point, the predictability is not the same as uncertainty as used in the present guidance, though it could be added. Predictability refers to whether or not outcomes have been measured or otherwise assessed, if there is a pattern and whether or not the type and nature of actual outcome can be anticipated from the known inputs. Many biological stressors have low predictability.

The evolutionary/generational scale of effects is an important one that must be considered. It is now apparent that some chemicals alter the reproductive capabilities of entire populations over multiple generations. Changing the species composition of ecosystems can and will often provoke much wider and longer change that are evolutionary in nature. These should be included.

Other -- This section should not state that risk characterization excludes social, political, economic, etc considerations, as in the last paragraph. The concept of characterizing risk includes a great range of perspectives and expertise, ranging from the statistical to the cultural. Loss of bald eagles may cause little ecological harm, no economic cost and an undetermined social cost. Yet, the bald eagles will be protected and saved for a great variety of critically important reasons. The risk characterization described here would exclude these areas from the characterization.

SPECIFIC COMMENTS:

[4:7] State specifically, limit with unknown endpoints

[4:ft] But are there any terminology changes that we should note?

[10:29-30] Do not expect human errors can be eliminated entirely, especially as a regular matter of course.

[12:6-18] Paragraph is too fragmented.

[12:20] Typo: Figure noted should be 1-3, NOT 1-2.

[13:15-16] "and help . . . potential." This is too narrow, only one option. Rather CRA is useful in understanding the landscape of issues -- risks, stressors, and existing future concerns.

[13:19] "Relative Risk" category should be separate.

[13:23] Which is recommended?

[13:29] "impact" Is this ecological impact?

[14:21] Ballast water release

[14:28] Or any unknown outcome

[16:box 1-6] "(more clearly described . . ." Clarify.

[17:1] Change to: "2. PLANNING: DISCUSSION BETWEEN RISK

ASSESSORS AND RISK MANAGERS"

[17:6] Typo: Figure noted should be 1-3, NOT 1-2.

[17:22] Inform the analysts and the analytical process

[17:box 2-1] The text needs to conform to usage of term "general public.

[18:2] This seems ambitious. In the context of a requirement, e.g. statutory, setting the management goal at the outset is fine. But in cases of Greenfield, new activities, de novo or one time, the context way does not exist. For example, even now, what is the management goal for land use in the Chesapeake Bay, for toxic chemicals in Terrebone Benataria, or living resources in the Mojave Desert? I suggest rephrasing this to agreeing on the management context, goal, if possible.

[18:9] "Planning is initiated . . ." Not really. How about in urban settings where planning has been ongoing for years?

[18:19] after "local resource managers " insert: "interested and affected parties"

[18:23] add "IN PLANNING" to end of title

[19:1-8] Narrow use of the term risk manager in entire paragraph. The decisions, time frame, severity, and nature of consequences.

[19:11-13] Here too, the public IAP's may have vital information.

[19:23] This place in the process is where values and perceptions initially arise -- that should be the case. Intended use and value of the resource should be clearly articulated as part of planning context.

[20:1-19] These assumptions still need to be articulated e.g. this habitat is to remain intact and undisturbed.

[20:box 2-2] "Questions for Risk ManagMENT" and "Questions for Risk AssessMENT"

[21:27-28] Multiple activities, stressors impacts

[22:3] extent and complexity?

[22:19] Delete "The"

[22:20] Change to plural: "managerS" and "assessorS"

[22:29-30] Delete "the" and change to plural "managerS" and "assessorS"

[23:19] Add here that this is another iterative process and includes multiple intereste, perspectives, expertise.

[24:17] "from human activities" Do not discount the impacts of natural events, mostly disasters.

[24:box 3-1]	"contains several changes" ADD "from the framework"
[27:32]	These assessments are not without value issues, especially on the part of the IAP's that may hold or rank different values.
[28:16-20]	Give other examples in text list: decline in harvested resource -- e.g. crabs, or z. mussels
[29:22]	"present special challenges to . . ." Expand -- different conditions, especially of process and interaction with the IAP's who may wish to be over the shoulder of the "risk assessor"
[29:24]	"early selection of assessment" Not so! It is the point above [see 29:22] and the IAP's.
[30:13,16]	??
[30:27]	Where are the values and importance?
[32:25]	"the ecosystem" [ADD] and components"
[32:32]	Must work out differences between ecological and political boundaries.
[33:box 3-5]	bullet 5: Spatial
[35:6]	text box 3-6: on this page
[36:all]	Less political controversy, especially among the public and IAP's. The RA may be admittedly easier to use with LCV's or commercial SP's, but those are issues of practicality.
[36:8-14]	Reword: Reality should be stated as such without value judgements.
[36:27]	"to them or" INSERT even "find them annoying"
[36:box 3-7]	Final sentence: state as an assumption
[37:9-11]	Public involvement at the earliest stages is necessary. The manner and mode of involvement will be determined by the situation. Representation may be the best method in one case; public hearings may be required by law.
[37:17]	even if only within a limited area.
[37:22-23]	refer to past experience with Eco RA.
[38:8-9]	Toxicity testing for ambient physical and chemical conditions also.
[38:13]	Why Barnthouse?
[38:18]	Include here indirect exposures that are separated by time, space, or severation i.e. downstream sediment accumulation of high k-ow chemicals may kill fish fry later because the chemical is passed to eggs from the female.

[39:25-26]	Change order to: "Two elements are required to operationally define an assessment endpoint."
[40:17-18]	This is where IAP's are needed.
[40:21]	Reword for the positive. Change "can" to "must" and change "inappropriate" to "appropriate."
[40:26]	Suggest a way of fixing this error--reproducing population of indigenous species?
[43:1-6]	Why repeated almost verbatim?
[43:22]	And what guidance for cases unknown, not well studied, etc.?
[43:23-30]	Again, this has to be broadened beyond two folks talking.
[45:2]	"The risk assessor . . ." Comment: but may not be fully characterized.
[46:12]	"are assumptions . . ." Comment: They should not be assumptions. They should be testable statements of relationships and predictions.
[47:box 3-12]	Stressor-initiated: This is a testable hypothesis, not an assumption.
[50:26-28]	Should at least reference and cite an example for information and refer to another source for greater detail and explanation, e.g. Chesapeake Bay nutrient model, Commencement Bay, etc.
[59:11-17]	Are we referring here to interactions and relationships that influence the stressor, the target, the response, etc.? I am not sure of the intent.
[63:15]	ADD comma after "rationale"
[63:21]	ADD comma after "results"
[63:25]	ADD period after "research"
[63:27]	ADD period after "analysis"
[63:29]	ADD period after "communicated"
[63:30-31]	This is a problem! More guidance needed or something! Is Monte Carlo even considered uncertainty analysis? I don't think so.
[64:11]	"much of the. . ." ADD "activities intentionally termed" and REMOVE "activity"
[65:chart]	Not clear: The sequence and flow do not seem right. Put explanatory text in the figure at the bottom next to "Analysis example."
[67:10]	change "may" to "should usually"
[67:11]	ADD "and" after "water"

[67:17] Change "They" to "Measurements(?)"

[67:19] The specifics of sampling designs, procedures, and analysis

[67:28] Hg v. MeHg

[68:9] Typo: "transforming it the"

[68:11] ADD "primary" before "production"

[68:12] ADD "if algal population crashes" after "decomposition"

[68:18] Where? High flow is the concern for some pollutants for erosion, etc.

[69:29] Other techniques may be appropriate or different assumptions may apply. Depending on the source of nature e.g. national as in acid-rain.

[71:14] "exposure . . ."ADD "during the period of anoxia"

[71:17] After "individual" ADD "or species and distribute the exposure among individuals or species."

[72:28-29] Multigenerational exposures must also be considered and critical periods of the exposure, e.g. fetal, lactational

[73:31] Perhaps this is the place to flag life stage specific exposure.

[74:4-7] Pulse, sine, background, mixtures

[74:13] Also dose-response?

[75:16-22] Not clear -- especially how this is number crunching

[75:31] Multi or trans generational e.g. endocrine, immune

[79: 3-4] these lines should refer to other EPA documents that are relevant, i.e. water quality criteria

[79:10] this paragraph should refer to the intrinsic variability in systems, especially biological ones in nature

[80: 26] make some note about data for invertebrates, i.e. shrimp, crabs, worms

[81: 1] this language needs caution as the population genetics of many species is not well known or is poorly understood

[81: 26-30] more explanation is needed for this paragraph to help the reader; provide specific information that is needed to extrapolate or when such is not possible

[83: 8] there is an abundant physiological literature dating back many decades on allometric scaling. One text on the topic has been written by K. Schmidt-Nielsen, and numerous reviews by C. R. Taylor.

[84: 3-4] include reference to climatic and geological factors

[84: 16] "to" is missing

[85: 1] refer to the current model for Chesapeake Bay modeling on the basis of trophic analysis

[86: 15] note that this is equivalent to dose response

[88: 14] include clear cutting forests as example

[88: 20] refer to other agency's reports -- ACOE, FIRC, USDA, etc

[90: 13] what is identifiable outfall?

[93: 15] spell out the measurement and assessment end points here to help the reader

[93: 22] By this point I am convinced that I will have to use computer models to complete any analysis, without knowing why that is so, what good it will do, if I am correct in the assumption and which ones to use.

[93: 28-29] I don't understand the terms

[95: 1] refer to reports by OTA and J. Carlton

[95: 3] add "in contrast to the case of POTW discharges, thermal discharges, etc"

[95:the box]: What about unanticipated outcomes of biological stressors?

[95: 17] The fact is that the "hydrilla" in the Potomac was 5 species of submerged aquatic vegetation; please correct for accuracy

[99: 15-8] expand the explanation here

[99:20] elaborate on the details

[99: 22] Open this paragraph with a more general statement

[100:119-24]. This section mixes topics so that it is confusing. Separate the topics into different paragraphs.

[101: 5] what about temperature here?

[101: 26] I would refer to an authority on species dispersal at this point

[103: 17] make the assessor plural

[105: 2] This section needs discussion of multiple categories of stressors.

[105: 26] the following section is too chemical dependent

[108: 23] see review by R. Diaz on hypoxia in aquatic systems

[109: 2-3] I disagree that this is a problem formulation only consideration

[109: box] -- another error is the exclusion of observational data.

[111] Generally, the Risk Characterization should summarize all the components and processes that have gone into the assessment/analysis. RCh includes consideration of process

as well as substance, the design and plan, the participation and review by interested and affected parties. An analysis that simply crunches the numbers will not be able to adequately characterize risks.

[115: 28] it is not clear what the "toxicity measurement" is.

[126: 129] I suggest referring to the overfishing and the risk assessments that did/did not deal with that going back as far as 20 years.

James Donald

EPA's ECOLOGICAL RISK ASSESSMENT GUIDELINES QUESTIONS

The following comments represent the collective opinions of staff in the Ecotoxicology Unit of the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. These staff are:

James M. Donald, Ph.D. (Senior Toxicologist)
Regina M. Donohoe, Ph.D. (Associate Toxicologist)
Karin E. Ricker, Ph.D. (Senior Environmental Research Scientist)
Julie T. Yamamoto, Ph.D. (Associate Toxicologist)

GENERAL PRINCIPLES

- **Specifically, how can the ecological risk assessment guidelines be improved to more clearly indicate underlying assumptions and default positions?**

These draft guidelines present a good attempt at reviewing the status and general advantages and disadvantages of current methodologies for ecological risk assessment. They are, however, heavily oriented towards descriptions and discussions of general options available to the risk assessor, as is explicitly recognized in the opening discussion of the scope and intended audience of the document. A similar point is made in relation to the importance of scientific judgment in successfully completing an ecological risk assessment. This is all well and good, as far as it goes. The major flaw in the existing draft "guidelines" is that they provide little in the way of actual guidance as to the optimal or preferred methods for conducting or reviewing ecological risk assessments. The discussion provided of the strengths and limitations of alternate ecological risk assessment approaches is useful, but some indication of appropriate criteria for selecting preferred, or at least acceptable, methodologies and approaches under specific types of risk assessment would be of much greater value both to the regulated and regulatory communities, in that it would greatly improve the consistency and appropriateness of ecological risk assessments in general. This is not inconsistent with the stated intent of avoiding a requirement that certain procedures always be followed.

Specific improvements that could be made include:

Explaining rather than just mentioning methods/procedures etc. (e.g., give reference for Habitat Suitability Index; explain how and why multivariate statistical techniques might provide alternative approaches when measuring effects of multiple stressors; explain why the success of a risk assessment depends on the quality of communication early in planning)

Explaining more unusual technical terms/jargon, such as delphic; tree fault, etc. (these could be included in Appendix B).

Avoiding examples that are not well introduced, out of context, or where the point is not immediately clear. Some of the examples used were confusing to the reader. Some style and organizational changes would greatly improve the clarity of the guidelines. Due to the considerable size of the document, efforts to facilitate the reader's ability to focus on summary points is critical. Currently, four basic types of summary information (important principles, checklists, examples and supplementary text) are highlighted in a variety of inconsistent ways (bulleted list, italicized list, italicized headings with text, text boxes and plain text) which distracts the reader and makes it difficult to comprehend the relative importance of the points. Each type of information could be presented in a uniform manner that would represent the hierarchy of their relative importance.

- **What changes would you recommend in each section of the document?**

Most of the comments on individual sections are incorporated into the responses to subsequent questions. A couple of specific suggestions are:

Provide a more lengthy discussion of the analysis plan in the Problem Formulation section. If it is not appropriate to discuss specific methodologies, then provide guidance on limitations/advantages of different types of approaches (e.g., field data versus lab studies versus literature search/model results) for purposes of analysis.

In the Analysis Phase section, provide discussion of monitoring. This is an important mechanism for the iterative process, for verifying predictions (reducing uncertainty), and for evaluating recoverability of ecological values due to mitigating actions.

Guidelines Balance

1. **Considering both the present state of the science and present and future Agency needs, how well are the guidelines balanced regarding the range of stressors, levels of biological organization, ecosystem types, and spatial/temporal scales? Specifically, what would you emphasize or de-emphasize?**

The range of stressors covered by the guidelines is comprehensive, but the treatment of stressors such as physical stressors and biological introductions, which may be relatively unfamiliar to some users of the guidelines, could be expanded and made more detailed. Similarly, dealing with multiple stressors may be the most complex and difficult challenge facing ecological risk assessors. The discussion of current approaches, all of which have obvious limitations, would be greatly improved by inclusion of discussion on potential future improvements. If no improvements are foreseen, this important issue should also be discussed.

With regard to levels of biological organization, individual to community effects were considered, but could be discussed at more length with respect to relationships and extrapolations between levels, and other issues/problems associated with assessing risk at each level. It would also have been useful to have included discussion of sensitive/fragile ecosystems besides wetlands (e.g., desert, prairie).

(See response to question #13 for further discussion of sections on stressor types)

2. **What would you suggest to improve the use of case illustrations in the guidelines: How useful is Appendix A in illustrating a range of applications of the risk assessment process?**

In general, the case illustrations included in the text were helpful and showed that risk assessment can be applied to a wide variety of environmental problems. Additional general information on the risk assessor/risk manager interface would enhance the risk assessor's ability to consider various approaches to this interaction. Specifically, the cases studies do not uniformly address the process and outcomes of the discussions between the risk assessor and managers during the planning and post-assessment phases. While it is stated that details of the cases are intentionally limited to avoid prescriptive use, the potential benefits of providing detailed information to the assessor may outweigh the feared misuse. Ecological risk assessment is an evolving process and consideration of past practices will help assessors develop and refine available methods. As with the USEPA case study review (1993), outlining the general strengths and limitations of the case assessment may assist in preventing widespread adoption of imperfect methods. In some cases where the information is spread and imbedded throughout the main body of text, the example is difficult to "digest". Perhaps for some sections, the case illustration should be presented in a more cohesive and comprehensive way. This would also make the main text easier to read and follow - in some areas the examples seem to cloud the concept that they are meant to clarify.

Appendix A is a good overall summary of the selected case studies and illustrates the common elements as well as the range of risk assessment applications, but would have been more useful overall had it provided more details of the examples provided. It would be useful to have an evaluation of how well these risk assessments fit in with the proposed U.S. EPA guidelines or if the result would be very different if the EPA guidelines had been used to conduct the risk assessment (e.g., a conceptual model was developed only for the Waquoit Bay Estuary risk assessment). A critique of each risk assessment would also be useful.

3. **Some Agency reviewers of the guidelines have suggested that more examples of terrestrial assessments and field approaches (e.g., bioassessment techniques) should be used. Specifically, what, if anything, should be added?**

It is unlikely that any six case studies would encompass the universe of ecological risk assessments. Additional case studies to represent other ecosystems (desert or semi-arid regions), cumulative impacts of multiple stressors (overgrazing or urban/agricultural runoff) and assessment endpoints (survival of endangered species) would be useful.

Addressing exposure in a terrestrial situation is very different and in some ways more complex than in the aquatic situation. Methods/approaches for exposure characterization would therefore be useful, such as discussion of the use of exposure factors, extrapolation from laboratory rodent studies to relevant terrestrial wildlife, and treatment of multiple exposure pathways (oral, inhalation, dermal). Mention of commonly used terrestrial tests may be beyond the scope of the document.

4. Areas of uncertainty are summarized in the problem formulation (section 1.5), analysis (section 3.7), and risk characterization (section 5.2.4). How useful is this approach in providing guidance on uncertainty issues?

Summarizing areas of uncertainty and providing guidance on how to appropriately deal with that uncertainty are not necessarily the same thing. As noted above, actual guidance on appropriate methodologies, or criteria for selecting appropriate methodologies and/or rejecting inappropriate methodologies, would be of great value. Overall these sections are useful, but expression of uncertainty is a critical feature of ecological risk assessment and is worthy of more extensive treatment. These sections would be improved by inclusion of more guidance on what types of uncertainty are qualitatively or quantitatively evaluated and on how to go about this evaluation. Perhaps there should also be a discussion of how to define unacceptable levels of uncertainty.

The list of uncertainty sources for each phase of the assessment is a worthwhile classification scheme. While this is a rapidly developing area, a distillation of developed approaches and required improvements would promote a more consistent and rigorous quantitation of uncertainty in assessments. Approaches towards integrating all the sources of uncertainty to estimate or rank the overall assessment uncertainty should also be discussed. Under Section 1.5., the reader might benefit more from an abbreviated version of the uncertainty issues. The amount of detail provided (bullets) distracts somewhat from the focus of this section, i.e., an overview of the risk assessment process. Just listing the types of uncertainties at this point would be fine. Under Section 3.7. the level of discussion is appropriate, although a link to section 5.2.4 could be provided here.

In Section 5.2.4., it might be helpful to summarize how Table 5-1 and Table 3-1 differ, i.e., what stays the same and where changes/progress have been made during the risk assessment process. (It might also be useful to change Table 5-1 to include information from Table 3-1 with an additional column of the issues that are part of the Risk Characterization Phase Strategies. This way, a side-by side comparison would be easier).

Introduction and Scope

5. How could the Introduction be modified to more clearly communicate the scope and content of the guideline?

The intended audience, scope and content are clearly defined in the introduction. However, it is questionable whether the scope and content fully meet the needs of the risk assessor. It is stated that techniques, methods and models are beyond the scope of the guidelines but this is exactly the type of information the risk assessor needs to conduct the assessment. While the data acquisition, verification and monitoring steps are outlined in the paradigm, they remain a vague, black box. More detailed descriptions of the available data acquisition/analysis methods and general evaluations of their strengths and limitations are strongly suggested. Rather than being prescriptive, these descriptions would instead serve to illustrate that ecological risk assessment methods are continually evolving. Further discussion would be extremely helpful and applicable to many program's needs. This opinion was also voiced in the recent series of public workshops sponsored by Cal/EPA. Workshop participants consistently requested more detailed guidance be developed in the areas of extrapolation factors, uncertainty expression, trophic transfer factors, reference site selection and mixture evaluation. At the very least, annotated bibliographies of available methods should be included as Appendices or Supplements. Since the field of ecological risk assessment is in its infancy, it is probable that any set of guidelines will become outdated and require revision. The focus of the document should be to facilitate information transfer in order to assist in continued improvements in method.

Several terms used and statements made were not entirely clear or understandable, e.g., "In a larger sense, experience with many risk assessments can help verify the usefulness of the overall ecological risk assessment process" (p.12, line 29). Similarly, the definitions and usages of "stressor" and "receptor" were not fully understandable to all readers. Expansion on the statement that "primary effects may become stressors" (page 14, line 29) would be helpful. It would also be helpful to put the use of ecological risk assessments into some regulatory context, in addition to being presented as a general problem-solving approach. Perhaps a table of federal mandates that require ecological risk assessments or for which ecological risk assessments are commonly carried out could be included, as well as examples of the regulatory decisions in which ecological risk assessments play a large role.

6. **Terminology, especially related to endpoints and exposure, has always been controversial. What changes, if any, would you recommend in guidelines terminology?**

While the general definition of exposure (page 15, line 19) fits all stressor types in a literal way, it may be open to misinterpretation. For example, chemicals must contact the receptor not just co-occur. To avoid confusion, two operational definitions for chemical and physical/biological stressors may be helpful.

Addition of the phrase "a process with three phases" to the definition on page 13 (line 8-9) adds needed detail to the definition of ecological risk assessment presented on page 11 (line 6-7).

Additional terms that would benefit from a formal definition include: risk hypotheses, risk management, problem formulation, analysis phase.

7. **The overall framework figure for the ecological risk process has been retained, although some changes have been made to the diagrams for problem formulation, analysis and risk characterization. What further modifications, if any, are required?**

The planning phase could also be considered to have a distinct output or plan (page 23). This could be diagrammed in a separate circle, similar to other phases.

Risk Manager Interactions

8. Please comment on the description of the risk manager's role at the initiation of an ecological risk assessment and on the principles for selecting management goals.

As noted in text box 2-1, the risk manager can be a single person or represent groups of interested parties. This important information on who can be a risk manager should be expanded upon and incorporated into the text; the text box then could serve to provide specific examples or summarize what was said in the text.

The statement on page 19 of the document that the level of certainty needed should be determined by the risk manager was rather confusing. It was not clear whether "certainty" was used quantitatively or qualitatively, or if the ability of the risk assessor to guarantee that level of certainty would determine whether or not the risk assessment was conducted. Also, the apparent predetermination of the required level of certainty by the risk manager seemed questionable - it may be more appropriate to have the risk assessor work with the risk manager in arriving at that determination.

Determining the amount of resources available for a risk assessment in advance of implementing the assessment can certainly help to keep the risk assessment focused and prevent escalation of costs. Also, the risk assessor needs should be involved in determining the amount of resources he or she needs to properly conduct the assessment. Obviously, the amounts of resources allocated may greatly influence the quality of the risk assessment. Determining what resources are needed should be an evolving discussion between the risk manager and risk assessor.

With regard to selection of management goals, the relationship of "management goals" to "legal endpoints", or "protection goals" should be clarified since, in some instances, the law spells out what is to be protected or maintained.

Increasingly, the risk manager is called upon to develop stakeholder involvement to ensure that the decisions arrived at have considered the range of viewpoints. It is recognized that some regulatory programs have greater requirements for developing stakeholder involvement than others, and that it is not appropriate to include in this guidance directions for risk managers to develop stakeholder involvement. Nevertheless, a generalized comment to the risk manager on the need to consider stakeholder involvement would seem to be appropriate.

9. What additional points, if any, should be covered about relating ecological information to risk management decisions after the completion of an ecological risk assessment?

Clarify what is meant by "status of peer review explained" (page 128, line 11). This is the first mention of peer review. If internal/external review is advocated, details of the recommended purpose and extent should be clarified. Perhaps this should be mentioned earlier in the problem formulation phase where it should be noted that a team of experts will be required to design the assessment and review the outcome.

Other discussions that might help to communicate ecological risk to managers include reiteration and further explanations of the ecosystem at risk (e.g., driving forces, functions and foodwebs of interest) and stressor behavior in the ecosystem.

Also, the terms "clear", "transparent", "reasonable", and "consistent" would be better understood with more definition, especially with respect to what each achieves in conveying risk assessment information, and why it is important to the process (e.g., to some, "clear" and "transparent" may have the same or very similar meaning).

10. How useful is the categorization of assessments as either stressor- or source-initiated, effects-initiated and ecological value-initiated?

This is potentially useful in conceptualizing and organizing the information to be obtained in an ecological risk assessment, and may help to point out that the sequence of events in the process is related to the type of information available when the assessment is initiated. However, the bulleted text boxes and use of examples throughout the text do not illustrate the sequence differences for the three classes in a clear, concise manner. Three separate flow diagrams might better serve as examples to illustrate the differences, followed by explanatory text in Section 3.2.

11. Please comment on the discussion of assessment endpoints and their relationship to management goals and "measures."

The link between these three components would be better established by adding a "measures" column to Text box 3-9. It would also be useful to expand on stakeholder involvement (Section 3.4.1.1). The document defines three criteria that need to be considered when selecting endpoints: policy goals and societal values; ecological relevance; susceptibility to stressor. While ecological relevance and susceptibility to stressors are discussed, no guidance on how to determine societal values is provided. We recognize that specific risk management guidance in this area is difficult and beyond the scope of this document. It is briefly mentioned that "public meetings during the initial stages can be useful...", but no further discussion or procedure on how to elicit stakeholder involvement is provided. It would be useful to at least briefly summarize the more commonly used techniques to gather this type of information as well as discuss the importance of stakeholder involvement. At a minimum, appropriate references should be included.

12. What, if anything, would you add to the discussion of risk hypotheses and conceptual models to give the reader a clearer understanding of their nature and content?

The conceptual plan examples do not reflect all the recommended attributes of a conceptual plan. Are there better examples or would addition of a hypothetical conceptual plan serve to illustrate the ideal situation? The section on conceptual models could be better organized. For example, risk hypotheses are described twice; once in the introductory paragraphs of the section and once under the risk hypotheses heading. Also the example of a simple conceptual model (single stressor/receptor situation) is given twice (page 44 and 45). The relationship of the conceptual plan to the analysis plan, and how these processes differ, is not explicit. The role of the manager/management goals in risk hypothesis and conceptual plan formation and evaluation is not clear. While data collection and analysis has been stated to be outside of the scope of this document, these issues perhaps should be addressed at least briefly. For example, describe the general types of data used in conceptual plan development, and how it is collated and assessed in terms of applicability and confidence.

Analysis

13. How would you change this section, if at all, to improve the balance in the discussion of the different stressor types?

The statement that "a detailed treatment of data acquisition and model development is beyond the scope of these guidelines" (page 58) is not explained, and appears to arbitrarily exclude an issue of major importance to the regulated and regulatory communities. This section could be more cohesive if the information on the different stressor types were organized in a uniform fashion. For example, the headings used for the chemical stressor section could become general headings under which all three types of stressors were discussed. This may make analysis of different stressors more uniform and comparable. In particular for physical and biological stressors, some mention of habitat quality evaluation methods would be helpful.

Additional examples for the biological stressor section would be instructive, particularly retrospective assessments. One potential example would be increased disease incidence in fish and wildlife due to pathogen exposure from domestic animals, humans (sewage effluent) or introduced species. The emphasis put on host-pathogen interactions leaves the reader with the impression that the majority of biological stressors are microbes, particularly plant pathogens and genetically engineered organisms. Perhaps expand the section with examples of other biological stressors that have been encountered in the past (e.g., Zebra mussel).

Other examples of primary and secondary effects scenarios in different ecosystems for different physical stressors would be helpful. The section could also benefit from comparison between physical and chemical stressors (some physical stressors could be more similar to chemical stressors than others). Table 4-3 could be expanded to include additional physical stressors such as UV, radioactivity, noise. Some discussion of how the focus of risk assessments for evaluating effects of different physical stressors may vary would be useful (e.g., UV radiation vs. the building of a dam).

For both chemical and physical stressors, summary text or a bibliography of key principles, methods and case studies would be useful. It was also not clear why the discussion on causality (Hill's Factors) and selected points on extrapolation were placed in the chemical stressor section when they have relevance to biological and physical stressors.

In addition to interactions between multiple chemical stressors, it would be helpful to address interactions between different types of stressors (i.e., combinations of chemical, physical, and biological stressors). For example, how would the presence of a physical stressors (e.g., severely fragmented habitat) influence risk from exposure to a toxic chemical?

The statement on page 81 that uncertainty factors are empirically based is unsupported, and the fact that they are presented in multiples of 10 suggests that there is at least a degree of arbitrariness in their selection. References to support this statement should be provided. Also Figure 4-4 on page 69 appears to represent only spatial or temporal intersection, but not both. It is so poorly representative of the concept as to be misleading.

14. Are there additional points or principles that should be emphasized for either chemical, physical, or biological stressors?

Criteria for establishing or evaluating reference or background conditions should be addressed. For chemical stressors, discussion of bioaccumulation and trophic transfer factors would be useful.

15. What additional principles would you suggest, if any, for the analysis of multiple stressors?

In section 4.5.2 the only potential interaction discussed is additivity. For completeness, the potential for synergism and antagonism in chemical mixtures should be mentioned. Further discussion of potential approaches for integrating risk from the three classes of stressors over space and time (cumulative impact assessment) would be beneficial.

Establishment of baseline or reference points for all measures should be discussed. The focus is primarily on multiple *chemical* stressors in this section, or multiple stressors of the same type. More strategies on how to isolate specific stressor effects against a background of many other stressors, and how to combine effects of different types of stressors would be helpful, although difficult to formulate. Also, what about the use of models for assessing complex exposure and effects relationships?

Risk Characterization

16. What additional principles should be highlighted in the discussion of risk estimation techniques?

Text summarizing the strengths and weaknesses of existing methods for risk characterization would be preferred to referencing the reader to numerous citations. Also, the statement on page 114 that any method should be critically evaluated before being applied to a risk assessment is of great importance, but no guidance on how to evaluate such a method is offered. This is particularly important for new methods, the use of which is encouraged when the situation warrants. How is a risk assessor supposed to determine if use of a new technique is warranted?

17. The guidelines propose four criteria for ecological significance. How should this list of criteria be modified, if at all? What additional guidance, if any, might be added to the discussion of these criteria?

It should be emphasized that one's understanding of the ecological relevance of a finding is dependent upon the degree of understanding of an ecosystem. If a given ecosystem has long-term monitoring data available, more refined estimates of ecological significance will be possible, compared to a relatively unstudied ecosystem. This type of uncertainty/bias should be emphasized in the introductory section 5.3.2. Another criterion might be the actual nature of the effect (not addressed although there is a subheading called "Nature and Intensity" in this section), that is, how important the effect is with respect to the ecosystem integrity/function. For example, is the effect directly on a keystone species or on a species that is nonessential to the functional aspects of the system. This topic is also related to that of ecosystem recoverability.

It may also be worth considering whether it is appropriate to expand the definition of recovery to "partial or full return of a population, community, the ecosystem, or services provided by a natural resource". (The incorporation of "services provided by a natural resource" is a definition from NOAA's proposed rule for NRDA under OPA).

Typographical Errors

pg 16, text box 1-6. Item (1) is incomplete, in that the sentence reads "both chemical stressors..." and does not go on to identify the other consideration. Also, parentheses are opened but not closed in the same sentence (text omitted?)
pg 11, line 21; change "ignoring" to "ignore"
pg 12, line 20; should refer to figure 1.3, not 1.2
pg 13, line 4; delete "in"
pg 32, line 24; change "affects" to "effects"
pg 43; text box 3-11 not referenced in section text and lacks explanatory text (missing?)
pg 48; the diagram of contaminant transport processes shows an arrow from zooplankton to piscivorous fish, but no arrow from zooplankton to forage fish. Was this arrow transposed?
pg 50, line 21; change "up" to "upon"
pg 53, line 24; exchange "important" with "importance"
pg 63, line 14; no periods between section numbers
pg 69, line 24; heading has no section number
pg 71, line 26; heading has no section number
pg 75, line 16; insert "for" between "guidance" and "preparing"
pg 84, line 16; insert "to" before "large scale"
pg 103, line 13; delete "of the"
pg 105, line ll; change "give ecosystem" to "given ecosystem"
pg 113, line 30; insert "a" before "variety"
pg 114, line 22; change "are rely on" to "rely on"
pg 118, line 2; change "of type kinds" to "of kinds"
pg 124, line 4; truncated sentence
A-10, line 5; change "Note the these" to "Note that these"
A-13, line 22; change "matts" to "mats"

Charles Eirkson, III

Comments on Draft Proposed Guidelines for Ecological Risk Assessment
October 1995 EPA/630/R-95/002

1. I had trouble tracking all of the questions that were presented in the charge to reviewers. I have simply listed my comments below. Additionally, my comments are biased toward stressor-initiated actions. I hope this will be acceptable and that the comments provide some value.

2. Overall the document is very well written and easy to follow and read. Its concurrent publication with new texts in ecological risk assessment (ERA) is beneficial.

3. There is an underlying assumption that we can accurately predict potential risks to the environment through ecological risk assessment . The document could be improved by providing citations to cases where predictions were made and data exist to show that the prediction was reasonably correct. In the same vain, the document could be improved by expressing the need to do monitoring and compare the monitoring with the predictions. This is only way, I can see to turn the perceived art of ecological assessment into a predictive science.

4. On page 7, there is discussion of the iterative nature of ecological risk assessment. Although an iterative process is academically and scientifically desirable and should be held as the ideal, it presents a concept that may not be acceptable to some. In a regulatory atmosphere, under which much ecological risk assessment is conducted, unrestricted iterative processes imply the potential for unrestricted expenditure of time and resources. This is not usually acceptable to the regulated industry who desires and is somewhat entitled to know some specifics on the rules of the process and what is expected. To accomplish this, it is appropriate to encourage tier testing in at least the earlier (hazard assessment portions of an assessment). Early tiers could be well-defined and specific cutoff criteria (e.g., safety factors, assessment factors) could be suggested. As the tiers progress and the

likelihood of risk increases the process would be less defined in some respects but come to rely more heavily on probabilities of occurrences.

5. The use of the term stressor as defined should be continued.

6. The concept of sustainability should be emphasized more. The assessment endpoints that are important for sustainability should be included. This is important because nearly every system should be able to continue to provide the value it was created or modified to perform, e.g., an agricultural field should be expected to produce crops without decline.
The exception should be that the value is purposefully modified, e.g., change an agricultural valley into a water reservoir, a forest into an agricultural field.

7. The need to educate risk managers and decision makers should be emphasized in the document. One of the primary obstacles to performing ERA is the lack of knowledge of individuals with regard to ecosystem theories. If a decision maker or manager does not understand the ecological and toxicological concepts associated with assessment endpoints, measurement endpoints, and management goals, then the ERA may serve only a cursory role in a decision (see also comment 15 below).

8. On page 39, its is expressed that if a species is unlikely to be exposed it is an inappropriate assessment endpoint. This is true but the results from effects on an unexposed species can still serve as a measure endpoint. This was not clear to me.

9. On page 43, the discussion that if the response of an assessment endpoint cannot be directly measured, or be predicted from a measure of responses by surrogate or similar entities, it cannot be assesses, causes me some bewilderment. How can we ever hope to validate a prediction if we can never measure the affect on an assessment endpoint.. It is very important that we begin to recognize a need to systematically monitor for predicted outcomes. Without some monitoring, ERA will always be perceived as an art form rather than a science.

10. I liked the relatively clear cut concept of assessment endpoints and measurement endpoints. Although it is sometime difficult to accept that measurement endpoints actually reflect an assessment endpoint, the concept is relatively straight forward and I think helps to communicate the process by clearly distinguishing between the two. "Measure of effect" is not as concise as measurement endpoint. "Measure of effect" could be interpreted or misinterpreted to be the effect on the assessment endpoint which is not measured in the prediction. On page 53, could the "measure of" items be categorized under measurement endpoints.

11. (On page 18 and elsewhere - uncertainties) Expressions of uncertainty imply that the risk assessor can validly express uncertainties associated with a prediction. If an expression of uncertainty is valid and not just a mathematical extrapolation, we need to expressly include the validating information in the document Is there field data that can be used that verifies predictions? For example, on page 83, lines 26 and 27, implies that data exist to prove predictions, a citation of the proof is needed.

12. A case study for a stressor-initiated action which includes monitoring or other data that verifies the predication would improve the document.

13. The sections on uncertainty are useful, primarily in emphasizing the importance of uncertainty and the need to express uncertainty in the assessment. A case study that demonstrates the use of uncertainty would be useful maybe in conjunction with item 13, above.

14. The introduction section should strive to be honest about the capability of successfully predicting environmental impacts especially associated with stressor-initiated actions.

15. The role of the risk manager in determining the assessment endpoints is critical. My main concern as already mention above is that a risk manager or decision maker may have little to no knowledge of environmental science, ecology, chemistry, etc., and make decisions heavily weighted heavily relative to available resources (personnel and money). Routinely ecological assessment is not well supported and the less the support the more likely an

inadequate assessment will be done. This is a significant catch, e.g., the fewer the resources the poorer the assessment, the poorer the assessment the fewer the resources. As this document indicates, ERA is a complex resource intensive (specialized) process.

16. Categorizing assessments as stressor- or source-initiated, etc. is very useful. It clearly distinguishes that different ERAs require different concepts, information, and conclusions.

17. Management goals and measures can be biased relative to office resources (see item 15 above).

18. In section 5.3.2.1, the "nature" part of "nature and intensity" is not discussed.

Editorial items:

Page 32, line 13 identity

Page 38 line 20, ending sentence with during

Page 6o and other, many periods are missing

page 68, line 9, it the inorganic

page 84, line 16, add to

Anne Fairbrother

1. General Principles

1.1 Underlying assumptions and default positions

This document provides a general guide to ecological risk assessment. Essentially, it provides a review of the principles laid out in the *Framework for Ecological Risk Assessment* and embellished in the subsequent Issue Papers. It does not provide any new information or guiding principles.

In some sections, the underlying assumptions about a particular aspect of a risk assessment are given but not always. Furthermore, default positions are never clearly stated. For example, when estimating wildlife exposure, one underlying assumption might be that only herbivores consume soil and that the default position is to assume a 2% ingestion rate. Such details are never provided.

Another example is provided on page 81 lines 17-19. This paragraph states that "empirically derived uncertainty factors have been used...[that] range from 10 to 100. Use of these factors is contingent on the assessor's knowledge about the chemical and class to which it belongs". First, this is a very superficial treatment of a complex and very controversial subject. Secondly, no guidance is given on how to select an uncertainty factor beyond a knowledge that all assessors are assumed to have. There have been studies conducted both within and outside the Agency regarding the use of uncertainty factors and an examination of the empirical basis for which one to select. Selection depends not only on the chemical of concern but even more on the receptors of concern. Aquatic organisms and terrestrial organisms differ in the amount of information available about chemical effects, mechanisms of action, etc. and so would have different uncertainty factors applied. Furthermore, the use of uncertainty factors is influenced by the requirements of a particular risk assessment in regards to how precise (and accurate) the assessment needs to be. In summary, this paragraph states the obvious but provides no guidance for how to approach a controversial issue.

Still another example is on page 79 lines 10-12 where the document states that "some investigators...have proposed using regression analysis as an alternative approach to hypothesis testing." The reader is left wondering which approach EPA recommends should be used. If both are useful, what criteria should be used to select which one to apply to a particular situation?

Although the guidelines are not intended to be a "cookbook", some guidance should be provided for how to select among the multiple options presented. For example, in section 3.3.2 Considerations of the Ecosystem Potentially at Risk several generic statements are made. "Ecological factors determine how to translate these [management] goals into ecologically relevant boundaries". How should this be done? The two examples that follow are both based on hydrological "forcing functions". If management goals are based on maintenance of populations, should metapopulations be considered (i.e., source / sink populations) or only local populations? Should the ecosystem boundaries be defined as impermeable or porous boundaries (i.e., immigration, emigration, nutrient input/output, etc.)? In other words, there is a myriad of ecological questions to consider when discussing the boundaries of a particular risk assessment. The guidelines indicate that this is the case but provide no guidance on how to address the problem. Granted, this is a complex question but so are most of the components of an *ecological* risk assessment. These "guidelines" highlight this complexity but provide little "guidance" for how to work through the issues involved. The Issues Papers provide a good in-depth discussion of many of the issues. What, then, is the value-added of these synoptic guidelines?

2. Guidelines Balance

2.1 Stressors, biological organization, etc.

In general, the guidelines strive for balance in terms of stressors, discussing chemical, physical, and biological stressors. It is obvious, however, that the authors are most familiar with chemical stressors and least familiar with biological stressors. Section 4.4 (biological stressors) refers to the use of Professional Judgment much more frequently than for the other stressors. The statement is made on line 6-7 page 97 that quantitative exposure and response profiles are not generally attainable at this time for biological stressors. This is not true for pathogenic organisms where LD50s, LC50s, etc. can be generated as easily as they are for chemical stressors. Introduction of exotic species that compete for food and habitat (i.e., are not pathogens) does, indeed, create a problem in terms of quantification of dose-response relationships. However, this categorical statement that quantitative methods are not available for all biological stressors and a relatively superficial discussion of transmission factors, host susceptibility, and available models (e.g., Bailey's book *The mathematical theory of infectious diseases and its applications* (2nd edition) 1975 published by Charles Griffin & Co., LTD) suggests that the authors are outside their comfort zone in this area.

The emphasis that EPA has on chemical stressors (of necessity, given the legislative mandates that the Agency works under), is reflected in the six case studies. One concerns a biological stressor, one concerns a physical stressor, three are related to chemical stressors and one is unclear about what the stressors are. However, given that the preponderance of risk assessments (both within EPA and outside the Agency) are chemical driven, this balance is appropriate.

Spatial/temporal effects are not dealt with in much detail. They are mentioned, such as on page 33 where the Florida Everglades are used as an example of the need to take a landscape perspective in some cases, but guidance is not provided on how to determine what scales are/are not appropriate (see above comments). While it is easy to make the statement that populations and communities are more relevant ecologically than are individuals, there is no guidance given on how to develop exposure/response profiles at these levels of ecological organization. Should distributions of exposure and response profiles be used in a Monte Carlo-type simulation to determine a hazard quotient for a heterogeneous population? When is it appropriate to assume "worst-case" exposure and response scenarios and develop point estimates for population assessments? What types of predictive population models are more or less appropriate for particular types of risk assessments? Landscape level risk assessments are not dealt with at all (other than the above example). How could GIS be integrated into the process to describe heterogeneous exposure patterns over a landscape? How should habitat variability (size, shape, and distribution of patches) be integrated into an exposure assessment? Large scale risk assessments (i.e., greater than 10 square miles) currently are dealt with by breaking the area into smaller "operable units". Is this the proper approach? If so, how should "operable units" be defined? If not, what alternative approaches are available? While references are made to other reviews (for example, John Emlen's review of population models), the guidelines provide little guidance in how to conduct risk assessments at these higher levels of ecological organization.

2.2 Case studies

The case studies in Appendix A illustrate a physical example, a biological stressor, one site with presumably multiple stressors, a retrospective pesticide assessment, a prospective toxic substance assessment, a Superfund site, and a site with presumably multiple stressors. Missing from this mix is an example of how to conduct a future assessment of a new pesticidal product (either chemical or biological) -- i.e., how Office of Pesticide Programs does business. Also missing is an example of how Office of Water set criteria for water and sediments that are protective of various forms of aquatic life and/or terrestrial components of the aquatic food chain.

The following additions would strengthen the utility of the examples:

- description of who the risk managers were
- identification of the stakeholders and when they were/were not involved in the process
- an explicit description of the conceptual model, including flow diagrams indicating exposure pathways
- a more precise description of the level of ecological organization of concern (e.g., "effects on wildlife" is too broad), the spatial scale, and the time frame of concern.
- a listing of uncertainty factors applied to the exposure and/or response analysis

- a statement of whether a particular analysis approach would be considered sufficient/appropriate and what might have been done better.

  * For example, the bottomland forest wetlands case study used "published literature concerning the habitats and the wildlife they support." The assessment concluded that the "analysis was applicable only for the selected species, and effects on other wildlife must be evaluated in a qualitative way based on professional judgment." Was this case an exception in having sufficient literature to provide habitat information on species of particular concern or is this generally the case? Did the species for which the data were available adequately predict "ecological effects"?

  * The Baird & McGuire Superfund Site case study, for example, evaluated only direct toxic effects. Is this sufficient for a Superfund evaluation? How were Data Quality Objectives (DQOs) determined for exposure analysis? This case study could provide a lot more detail on the Superfund process.

2.3 More examples?

As indicated above, there are some EPA applications that were not illustrated by specific case studies. However, rather than adding a long list of case studies (particularly since EPA has previously published two volumes of Ecological Risk Assessment Case Studies), I would prefer to see more detail provided in the six case studies already presented. Having said that, I think that the Waquoit Bay Estuary case study should be replaced. Given how incomplete the case is, it does not help provide insight into how such an assessment should be done correctly or incorrectly. Furthermore, I urge the authors to use the case studies to show how something should NOT be done (or was done insufficiently) as well as examples of how an assessment should be done.

2.4 Uncertainty issues

It is appropriate to discuss uncertainty issues in several places in the document as such issues must be addressed more than once during the risk assessment process. There are times, however, where more precise language would be helpful. For example, using "increased precision" rather than "reduced uncertainty". Section 1.5 does not really discuss uncertainty; it is addressed much more thoroughly in section 1.6.1 on pages 9-10 and in section 4.1 on pages 61-64. I like the way the discussion has been woven through the entire document.

3. Introduction and Scope

3.1 Modifications

The introduction and scope are well laid out but I have concerns about particular points that were made. First, I do not think that these guidelines will replace the widely-used Framework Report as suggested on page 2. The Framework was really a seminal piece of work that significantly changed and focused the thought process behind an ecological risk assessment. It is well-written and short enough to be a usable working document. This guidelines document appears to embellish on the Framework by extracting information from the Issue Papers, but it probably will not (and should not) replace the Framework Report.

Apparently some underlying assumptions were made about the qualifications of an ecological risk assessor that will be reading this document. The top of page 3 says that the assessor will have a "basic understanding of ecology and ecological risk assessment principles." What does this mean? That the assessor has taken an introductory Ecology course at the undergraduate college level and read one text on ecological risk assessment? What about a rudimentary knowledge of toxicology or parasitology/pathology/virology? Similarly, at least a gross level of understanding of environmental chemistry is necessary for someone who will conduct a chemical-based risk assessment. If you are going to assume a knowledge base, you need to be more explicit, particularly since "professional judgment" is so heavily relied upon in the guidelines (it may be instructive to do a word count and see how many times "professional judgment" is used).

3.2 Terminology

These guidelines are backing away from the use of "Measurement Endpoints" in favor of "measures of effect", "measures of exposure", etc.. Personally, I liked the two terms "Assessment Endpoint" and "Measurement Endpoint" as I felt that they adequately characterized the difference between the questions being asked (the Assessment Endpoints) and what was measured in order to answer those questions (Measurement Endpoints). However, I see no problem with breaking "Measurement Endpoint" into more specific terms. It appears to me that the greater confusion occurs in the definition of "Assessment Endpoint" and how this differs from "Management Goals". This is discussed further in my comments related to Risk Manager Interactions. Perhaps the term "Assessment Endpoint" should be dropped in favor of "Management Goals and Objectives".

3.3 Framework

No further modifications are required. I particularly like Figure 1-2 showing the iterative nature of the risk assessment process.

4. Risk Manager Interactions

4.1 Risk Managers' role

I disagree with the statement on the bottom of page 2 that a discussion of the use of the ecological risk information in the risk management process is beyond the scope of these guidelines. I recommend that section 1.4 on *Ecological Risk Assessment and Environmental Decision-Making* and Section 2 on *Planning: Discussion between the Risk Assessor and Risk Manager* be expanded to explicitly discuss how to incorporate stakeholder involvement into the risk assessment process. This needs to be integrated into the risk assessment process at several points, from the beginning until the end.

See attached Figure for an illustration of this. By including stakeholders in the dialogue from the beginning of the process, greater acceptance of the results of the assessment will be achieved. While I recognize that EPA has the final decision on policy, including risk management decisions, allowing stakeholder input to the *process* of endpoint selection, information identification and analysis, and risk interpretation will result in less public dissension and greater political support.

Text Box 2-1 defines who are risk managers. One very important category is left out: Industry. Many companies perform ecological risk assessments in their planning process. Life Cycle Assessment (LCA) is an example of this. Companies that own land frequently need to assess what the ecological consequences might be of a proposed action (i.e., will they run afoul of any environmental protection laws?). There are many reasons why such assessments should be done and it is inappropriate to assume that all environmental risk managers work for public agencies.

On page 19, the word "resources" is used in a confusing manner. On this page it generally is intended to refer to monetary resources, but in an ecological context the word "resources" has a much different meaning. Therefore, I suggest substituting or inserting the word "monetary" where possible.

Page 19 lines 9-15 that suggests that the risk assessor provides insight to appropriate scales, values, and focus for the ecological risk assessment. I believe that it is the role of the risk manager to define these attributes as they are part of the question that is being asked. The risk assessor can help the risk manager (and associated stakeholders) to clearly define these implicit attributes through a dialogue based on a generalized conceptual model of the system at risk. For example, the risk manager may not be aware that a desired fishery is dependent upon the maintenance of a particular benthic community. The risk assessor could make these types of interactions clear so the manager better understands the system dynamics. However, the Assessment Endpoints should not be defined by the risk assessor, but rather by those who must make the management decision and/or have other reasons for involvement in assessing potential risk. Perhaps this is what is intended by the discussion in lines 1-8 on page 19, but I am left with the overall impression that the risk assessor participates too heavily in defining the questions and that the risk manager (and stakeholders) do not participate enough.

In Text Box 2-2, *the following questions should be addressed by* Risk Managers, not Risk Assessors:

- what is the scale of the risk assessment?
- what are the critical ecological endpoints, and ecosystem receptors?
- what is the nature of the problem?

Page 21 discusses that *significant interactions among diverse groups are required for* setting management goals for "places". This is an excellent discussion and should be expanded further to include all ecological risk assessments. This discussion could be expanded to provide guidance on employment of expert facilitators for public meetings and goal setting; methods for consensus building (e.g., Delphi methods, Vital Issues Panels, etc.); methods of information elicitation (e.g., structured interviews or questionnaires). This portion of the risk assessment should not be done by a biologist, but rather by a social scientist trained in these methods.

4.2 Risk communication

Additional points about relating ecological information to risk management decisions after the completion of an ecological risk assessment include:

- an admonishment that the ecological risk assessment is only one input to the risk manager's decision-making process. Human health concerns, economics, social and religious factors are some of the other inputs to the decision process
- a recognition that the risk manager may not always select the alternative leading to lowest environmental risk. However, if the risk manager makes such a decision on the basis of complete, accurate, and precise information (within the constraints imposed on the risk assessment), then the risk assessor has done a proper job.

The success of the risk assessment should not be judged on the basis of which option was selected.

- a discussion of risk/benefit analysis, risk perception versus calculated risk, and expanded discussion of cumulative risk and comparative risk.

5. Problem Formulation

5.1 Assessment categorization

The categorization of assessments as stressor/source-initiated, effects-initiated, and ecological value-intimated is quite useful. It helps to categorize the questions being asked.

I have argued for years that an effects-initiated "risk assessment" is not a risk assessment. Risk, by definition, is the probability of an adverse effect occurring *in the future*. An effects-initiated assessment has a 100% probability that an effect occurred; therefore, there is no risk. The purpose of this type of assessment is to *diagnose* the cause of the observed effect, not to *predict* if a particular action will (or will not) have an undesirable consequence. For example, when you are sick and go to the doctor for help, you don't ask him/her to do a risk assessment of your condition. Rather, you ask him/her to *diagnose* the cause (and hopefully propose a cure). The effects-driven situation is analogous. Here, a deductive reasoning method is used where all potential causes are listed (a "differential diagnosis") and then systematically eliminated until one remains with a causal linkage to the observed ill-effect. Recommendations are then made on how to break the stressor-receptor link and so remediate the problem. This is fundamentally different from a predictive risk assessment where potential future effects of one or more stressors on one or more endpoints are evaluated. Therefore, I will continue to argue that effects-driven assessments (e.g., Superfund site evaluations) be given another appellation (e.g., diagnostic ecology) and not labeled " risk" assessment.

5.2 Assessment endpoints

Assessment endpoints should have a direct relationship to management goals as they are the formal articulation of the ecological components that are of concern to the risk manager and related stakeholders. As mentioned above, I see nothing wrong with keeping the Framework terminology of "assessment" and "measurement" endpoints.

The statement on page 43 line 17-18 that "the best assessment endpoints are those for which there are well-developed test methods, field measurement techniques, and predictive models" is true but must not be taken too literally. The best assessment endpoints have these attributes but also are direct and succinct representations of the ecological concerns of the resource managers and stakeholders. If they are *only* those endpoints that are easily measured, then we will end up defining our questions by what we can measure, rather than defining our techniques by what questions we are asking.

5.3 Risk hypotheses and conceptual models

The Conceptual Model discussion (Section 3.5) was very good. I do not, however, understand how there can be more than one conceptual model for a particular ecosystem (top of page 46). This discussion may result from confusion caused by an effects-driven assessment, where there are multiple hypotheses about what has caused the observed effect (i.e., differential diagnosis). Once again, this refers to my argument about why an effects-driven assessment is not a "risk" assessment.

Figure 3-4: Why are there two arrows from the box *Ingestion of Particles by Birds* to the *Death* box? A box labeled *Ingestion of Invertebrates* is missing and should be placed just below the *Ingestion of Particles by Birds* box. Similarly, the *Ingestion* box in part a) should include soil invertebrates as well as particles.

The Analysis Plan (section 3.6) would benefit from a discussion about the usefulness (or not) of phrasing questions as null hypotheses. This is the method employed in scientific investigations but there is considerable argument about its applicability in ecological risk assessment. If the hypothesis is phrased as a "null", the burden of proof is then to prove that there *is* a probable risk. If it is phrased as a "positive", then the burden of proof is to show that there is *no* probable risk. Innocent until proven guilty or guilty until proven innocent?

Page 53 lines 4-5 states that the analysis plan includes a clear description of assumptions made during the development of hypotheses and models. This is an excellent comment that cannot be overstated.

Human health risk assessments provide significant guidance on selection of Data Quality Objectives (DQOs). This discussion is missing in this document. Is there some reason why it is not applicable to ecological risk assessment?

6. Analysis

6.1 Balance of stressor types

Much more space is given to chemical stressors than to any of the other stressor types. This, of course, reflects EPA's mission and the state of knowledge in regards to applications of ecological risk assessments. The section on biological stressors certainly can be expanded as a great deal is known about conducting monitoring, surveillance, and assessments of insect pests, viral pathogens (particularly arboviruses), and bacteria (e.g., Lyme disease). Less is known about genetically engineered organisms but EPA already has published guidelines on how to conduct ecological risk assessments of GEMs. There is a lot of descriptive *a posteriori* assessments of larger introduced species (e.g., kudzu, starlings, or zebra mussels), but our ability to conduct detailed risk assessments is most limited in this area. Nevertheless, many of the same predictive modeling techniques used for assessing potential risk of chemical receptors could be used to assess risk of biological stressors (particularly community models). Therefore, this section could be expanded.

6.2 Additional points or principles

6.2.1 chemical stressors

Page 68 line 22 introduces the concept of a "reference system." This concept needs to be developed further and guidance given on whether or not reference systems are appropriate. It is alluded to again on line 5 page 80 but is still not discussed in any detail. If reference systems are appropriate, how are they selected (i.e., what are the criteria used)? How many reference systems are needed; is one sufficient? How does the use of a reference system incorporate biological variability and the changing nature of ecosystems? If the purpose of a reference site is to determine if an area of concern is different from the reference area, then a single site is enough. However, if the purpose of reference systems is to determine if the area of concern differs from the norm, then a sufficient number of reference sites must be characterized in order to determine the natural variability of the system. Guidance is needed on how to determine the need for a reference condition or site for various kinds of ecological risk assessments.

Page 70 lines 24-27 state that tissue residue information is difficult to interpret without information on the chemical's distribution and metabolism and knowledge of the organism's behavior. The real difficulty in interpretation of tissue residue data is knowledge of the dose-response relationship. What effect is associated with a liver concentration of 32 ppm of some chemical? The literature is replete with information about tissue residues but is depauperate in regards to dose-response relationships.

The last sentence of the first paragraph on page 71 says that "These [biomarker] measurements, however, can provide valuable confirmatory information that exposure has occurred." What is being confirmed? The beginning portion of the paragraph stated that interpretation of tissue residue data is difficult. Are the biomarkers confirming the tissue residue data? This is not clear.

Page 72 (lines 29-30) to page 73 (lines 1-5) discusses use of averaging concentration and contact rates to develop an estimate of exposure over time. Another approach would be to use distributions of concentration and contact rates in a Monte Carlo approach. The guidelines suggest using toxicodynamic models in an "extreme case". Guidance is needed to define an "extreme" case, more discussion of toxicodynamic modeling would be useful, and an appreciation of Monte Carlo analysis and its potential for application would be helpful

The next paragraph on spatial heterogeneity would benefit from a discussion about the applicability of GIS-based techniques -- concatenation of exposure estimates within individual polygons distributed throughout a heterogeneous landscape. A statement such as is given in lines 10-12 that "A general solution to the problem of incorporating pattern into ecological assessments has yet to be developed; this issue is normally addressed on a case-by-case basis" skirts the issues and does not provide any guidance in this area.

Similarly, the exposure profile section (4.2.2.4) says that the exposure profile may be expressed as a point estimate or distribution. It would be helpful if guidance were provided for when a point estimate would be better than a distribution or vice versa. The subsection on "summarize the most important exposure pathways" could use some embellishment (e.g., is an "important pathway" determined by being the largest contributor to the total loading to a receptor?).

Line 27 on page 73 says there are 3 general dimension so exposure: intensity, time, and space. I believe time should be subdivided to duration and periodicity, resulting in 4 exposure dimensions.

Estimation of primary effects (section 4.2.3.1, page 75) discusses toxicological effects, not ecological effects. While all chemicals cause ecological responses only as a result of toxicological effects on individuals, I believe this should be clearly stated so that the ecological focus of the risk assessment does not become lost in the toxicological details. Indeed, the sentence in lines 28-30 that sates that "...the characterization of ecological effects for chemicals has concentrated on evaluation of effects that are readily observed" contributes to this confusion as the document then goes on to state that these effects include mortality, growth, and reproductions all of which are biological responses. Also, throughout the document, growth is always included on par with mortality and reproduction. While growth is an extremely important parameter in fish and is directly related to longevity and reproductive performance, it is of much less importance in birds and mammals that cease to grow once they reach adult size.

Lines 6 - 20 on page 76 discusses environmental factors that alter bioavailability of compounds (such as metals). This discussion should be in the Exposure section not in the Effects section.

Lines 24-25 assert that a risk assessor needs to be familiar with test protocols and Good Laboratory Practices (GLPs) in order to avoid being fooled by anomalous data. While I agree that familiarity with the test procedures, assumptions, and shortcomings is essential, I am not as certain that GLP familiarity is needed. GLPs are procedures designed to enhance accountability and record-keeping; they have no bearing on whether the study was correctly designed, only if it was carried out according to the written protocol.

The section on Structure-Activity Relationships (page 77) should be caviated to say that they are most applicable to aquatic systems and may or may not be useful for terrestrial systems. Guidance could be given for what type of ecosystem is amenable to this form of estimation (e.g., freshwater only? salt water as well? terrestrial?).

Page 79 lines 8-15 discusses the uses and limitations of hypothesis testing. However, the reader is left wondering what EPA's guidance is on when to use regression analysis or when a hypothesis testing approach would be more appropriate. As these are meant to be guidelines, some indication of the criteria to use for methods selection should be provided.

Page 79 lines 26-30 discusses field experiments and includes laboratory testing with media collected from the field. I do not categorize such bioassays as field studies. They are laboratory studies under well-defined (and generally static) conditions that happen to employ media collected from the environment. A discussion of bioassays may warrant a separate section or may be included in the previous sections on single-species or multispecies assays.

Page 81 lines 1-11 discusses extrapolations between responses, in particular the application of the acute-to-chronic ratio and MATC. The last sentence indicates that "although developed for aquatic organisms, the approach could be used for terrestrial organisms as well". However, this has not been tested and I am not sure what the empirical basis is for making such a statement at this point. Given that this is a guidance document, I would suggest the use of caution in suggesting that the approach be extrapolated to terrestrial systems in a wholesale manner.

As stated previously, the paragraph on uncertainty factors provides no guidance on how they should be applied (lines 17-19 page 81).

Pages 82-83 discuss extrapolations between taxa. On page 82 line 24, the statement is made that "in lieu of actual testing, the only practical approach is to attempt to extrapolate...". When should "actual testing" be done? Should it always be done but is limited due to monetary constraints (or endangered species problems)? The top of page 83 suggests the use of allometric scaling factors for interspecific extrapolations. However, this does not take into account many toxicodynamic differences that influence chemical uptake and elimination. For example, a moose is not merely a large mouse as a moose is a ruminant and a mouse is not. This difference in gut physiology profoundly affects metals uptake and, consequently, sensitivity to dietary concentrations of metals. Allometry provides an incorrect estimation in this instance. Furthermore, Pierre Mineau (Head of Pesticides Registration, Environment Canada) recently did an analysis of allometric scaling factors for birds exposed to organophosphorus, carbamate, organochlorine, or anticoagulant pesticides and determined that almost all the values were greater than one (about 1.4), rather than 0.68-0.75 as determined from mouse-to-elephant mammalian extrapolations. Therefore, I suggest caution in recommending the wholesale adoption of allometry for interspecies extrapolations. This is stated in lines 17-18 on page 83, but it is not clear by what is meant that "allometry adjustments should be used only as one part in the overall process of estimating interspecies differences." What are the other parts? How much weight should be given to allometric estimation versus other approaches?

Page 85 section 4.2.3.4 on Causality states that in effects-driven assessments the assessor should present evidence that a particular stressor could have caused the observed effects. Generally in diagnostics, potential causes are ruled *out*, not *in*, and those that remain are considered plausible explanations. This returns to my argument that an effects-driven assessment is a diagnostic riddle, not a risk assessment.

6.2.2 physical stressors

The introduction to this section (page 88) states that physical stressors include the "exploitation and harvesting of resources". "Exploitation" is a value term and should not be used in this context.

Line 19-20 on page 88 should include industry as a partner with EPA and other agencies in evaluating issues related to physical stressors.

Page 93 lines 19-21 recommend the use of Habitat Suitability Indices (HSIs) developed by the U.S. Fish and Wildlife Service as particularly useful for evaluating impacts of disturbances on wildlife species. However, there are limitations that should be discussed. Foremost is the fact that HSIs have been developed for a relatively limited number of species, almost all of which are found in the eastern U.S. Secondly, HSIs are very simplistic models and may be most appropriate for screening-level risk assessments.

6.2.3 biological stressors

Guidance is given on page 104 line 17-18 to take a delphic approach coupled with a knowledge of past case histories when determining risk from biological stressors. This approach really is no different than what is frequently done in chemical risk assessment, although it is not usually identified as such. Furthermore, there are two inherent properties of biological stressors that are sufficiently different from chemical stressors to warrant a more detailed discussion. These are reproduction and dispersal. Guidance should be given to pay particular attention to reducing the uncertainty in these two aspects of the assessment. Theories of extinction biology could be invoked to provide methods for determining the minimum viable population size. Finally, the concept that an introduced species may have become a valued part of an ecosystem needs to be discussed, not only in light of new biological stressors but also in regards to interactions with other agents. These concepts are all discussed in Simberloff and Alexander 's issue paper and I see no reason why they should not be treated with as much detail as is done for chemical stressors.

6.3 Multiple stressors

The primary shortcoming of this section is that it discusses additivity of stressors but does not address antagonism or synergism.

Page 109 line 29-30 ends the section with the intriguing statement that "multivariate statistical techniques might provide alternative approaches." They most certainly would. What techniques are available? What guidance can be provided for when to use which one(s)? For example, when is principal components analysis better (or worse) than classification analysis? A whole section should be devoted to this issue as it will significantly help in providing guidance for how to look at effects of multiple stressors on multiple receptors.

The last sentence of this section (lines 13-15 page 110) says that the risk assessor may have to rely on weight of evidence analysis to evaluate the causal factors involved. What type of evidence? How is each piece weighted relative to other pieces of evidence? Is this "professional judgment" or is it based on empirical information? This sentence, as written, does not provide guidance and only makes a vague statement about the need to consider all available information.

7. Risk Characterization

7.1 Risk estimation techniques

Overall, this section was quite good. The bullets on page 114 clearly stated that the accuracy of the data is as important as the methods used (i.e., garbage in = garbage out) and that a range of risks is preferable to a single-point estimate. Excellent points.

The paragraph from line 30 on page 114 to line 3 on page 115 needs some clarification. First, the word "benchmark" needs to be defined for ecological risk assessment as it gets used in many ways, all of which are different from the human health definition. Second, the quotient method does not always adjust the risk quotient by an uncertainty factor as stated here. Third, a statement that "the higher the quotient the higher the risk" needs to be made with some caution, as a risk quotient of 100 does not mean that a risk is 10 times greater than a risk quotient of 10. There is a lot of information imbedded in these numbers so they do not necessarily scale in a linear fashion (if at all). Lastly, the actual relationship of the risk quotient to the ecological risk is not understood and should not assume to take any particular function. An increase in the risk quotient may not necessarily mean an increased ecological risk (e.g., if an LC50 is used in determining the quotient, an exposure value that is 100 times greater than the LC50 may not confer 10 times the risk of an exposure value of 10 times the LC50 as many environmental factors may alter the exposure-response relationship).

The sections on point estimates (section 5.2.2.1) and distributions for exposure and effects (section 5.2.2.2) are very good and provide some good guidance of when one is used and another is not.

Section 5.2.3 on simulations should have the following cautions added on line 17 page 118:

> However, simulation models are only as good as the assumptions on which they are based. They should be treated as hypothetical representations of reality until appropriately tested with empirical data.

7.2 Ecological significance criteria

As a general comment, I assert that "ecological significance" is not an inherent property of any ecosystem but rather is a human, anthropocentric construct. One component of an ecosystem is no more "significant" than another unless "significance" is defined in terms of maintaining the general structure of that ecosystem (i.e., the desire to maintain a wetland as such and not turn it into an upland). Having said that, however, I would generally agree with the statement on line 23-24 page 122 that ecological significance is defined as "changes in an ecological component that are important in terms of the structure and function of the ecosystem." (note that the grammar of this sentence as originally written is incorrect as the word "its" refers to the ecological component, not to the ecosystem at risk).

Otherwise, I think that this discussion of ecological significance reads well although the "four criteria" for ecological significance are not clearly stated (bullet statements would help). I assume this is referring to:

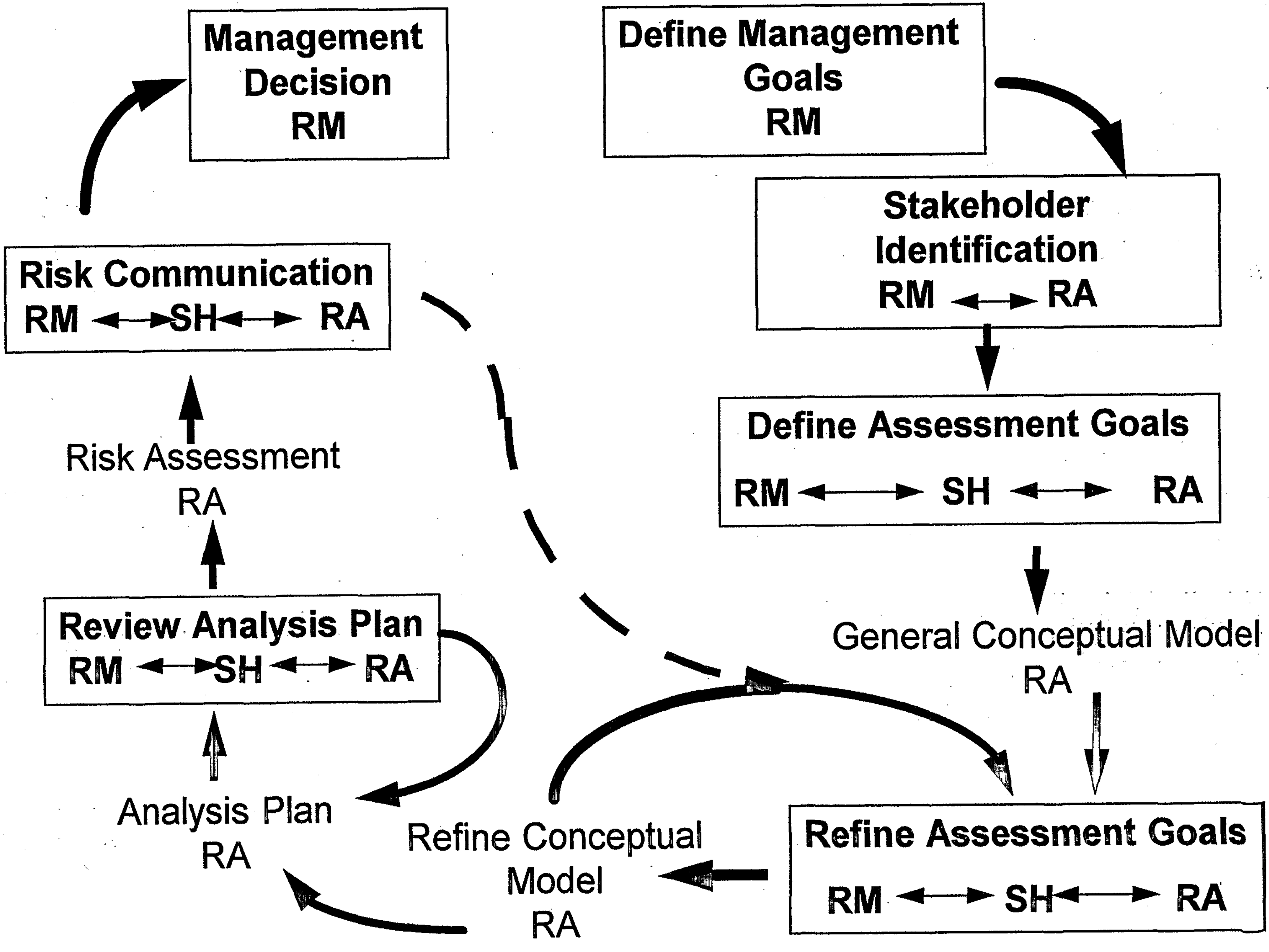
- nature and intensity
- scale (spatial and temporal)
- recovery potential
- natural variability and disturbances

I have not identified any other criteria to add to this list.

8. Summary comments

This document raises many options for the issues associated with ecological risk assessments but does not provide guidance on *how* to select among the options. In many cases, good review papers, books, and other documents are available to provide in-depth analyses of when to use what approach. For example, there are many writings dealing with the application of multivariate statistics to biological questions. At the very least, these references should be provided. Merely raising the issues for consideration does not provide any more guidance than currently is available as most of these issues (and others) are discussed in the published Issue Papers.

These guidelines should not be a cookbook that states which option should be used. Rather, they should provide the criteria for how to choose among options. What is considered appropriate and state-of-the-art today is likely to change in the future as our thinking about ecological processes, structure, and function evolves along with our knowledge of stress ecology. New techniques for measurement of exposure and effects will be developed that may change how we approach the Analysis phase of the risk assessment. These guidelines provide the opportunity for laying the groundwork to direct innovative thinking in ways that will result in ecological risk assessments correctly tailored to the questions being asked.


Management Decision RM
Define Management Goals RM
Stakeholder Identification
RM ↔ RA
Risk Communication
RM ↔ SH ↔ RA
Define Assessment Goals
RM ↔ SH ↔ RA
Risk Assessment
RA
General Conceptual Model
RA
Review Analysis Plan
RM ↔ SH ↔ RA
Analysis Plan
RA
Refine Conceptual Model
RA
Refine Assessment Goals
RM ↔ SH ↔ RA

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Comments on Draft Ecological Risk Assessment Guidelines

Part I. General Principles

The important contributions of this document include its thorough explanation of management goals, assessment endpoints, the new "measures" terms, and the emphasis on careful development of a conceptual model and analysis plan. However, there are inconsistencies in the use of terms (perhaps due to the inherent difficulties of multiple authorship) and a lack of emphasis or consideration of the potential effects of the stressor. The specific comments below detail potential sources of confusion and offer suggestions to clarify the text .

The use of text boxes and full-page tables in this document is generally very effective. However, these graphics occasionally distract the reader's attention rather than reinforce an underlying principle. For example in the Analysis phase, the excerpts from case studies (particularly for Physical and Biological Stressors) should be interwoven in the context of the text to reinforce the major points. The text boxes sometimes appear as disconnected items; the information enclosed should be able to stand alone or be carefully referenced to the issue in the text. The text boxes in the previous Framework Document are very effective in highlighting steps or issues that need to be addressed to ensure a technically adequate ecological risk assessment for any discipline or EPA program. The Draft Ecological Risk Assessment Guidelines document further outlines several series of detailed considerations for steps in the ecological risk process. The Guidelines provide specific questions for risk assessors to be addressed when planning and implementing ecological risk assessments for different types of stressors. These series of questions or recommendations could be highlighted in text boxes (as noted below in specific comments). Ideally, a selected group of these text boxes and tables could be excerpted for an executive summary or as a guide to pages to be used for "quick reference cards" for ecologists and risk assessors in the field.

The last chapters should reiterate that this document provides more detailed guidelines to improve quality and consistency of the ecological risk assessments within EPA and for other agencies. It should be emphasized that there are numerous benefits in using these guidelines for advancing the current state-of-the-art and for promoting the exchange of information and lessons learned. The Risk Characterization chapter (5) now ends rather flatly with the knotty problem of fishery population dynamics and an issue

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of natural variability that should be addressed in conceptual model development and the analysis phase. The reader could be left with the idea that the difficulties of dealing with complex ecological interactions may make it impossible to determine ecological risk and management alternatives. The Risk Characterization chapter should conclude with a summary of the process with an emphasis on how professional judgment is necessary to estimate and describe risk, particularly in terms of ecological relevance. This section should end with a positive discussion of how, given the multiple sources of uncertainties and inherent ecological variability, ecological risk assessment for different types of stressors can be conducted, improved, and communicated in a credible fashion to risk managers. Many lessons could be learned and shared, particularly if guidelines are widely used and ecological risk is communicated effectively as described in Chapter 6.

Problem Formulation

Question 10. The description of effects-initiated assessments in the text box example is not convincingly different from the stressor-initiated example except that it includes an ecological effects component. If effects are observed, causes may be explored, but then this appears to become a stressor-driven assessment. The examples both use pesticides and thus appear to fit under the stressor-initiated (text box 3-3 is a carbofuran assessment) and effects-initiated assessments. Using a pesticide for both examples may cause confusion because we automatically associate predictive assessments with this type of stressor. It might help to emphasize the assumption in the text box for the stressor-initiated example that an adverse ecological effect has not occurred, or at least has not been detected/measured. The goal is to predict risk in order to prevent adverse effects. Source-driven assessments (i.e., point-source discharges) may not share the same characteristics if releases are potentially causing adverse effects. Perhaps these should be a separate category. The text boxes provide useful examples of the different components of problem formulation and analysis phase. The terms "predictive" and "retrospective" also may be useful here in explaining the different approaches. This section could distinguish stressor-initiated or source-initiated (predictive assessments such as for pesticides or point sources) from effects-initiated (which can be both predictive and retrospective, particularly for Superfund), and very complex, ecological-value-initiated assessments (where assessment endpoints need to be tied closely to well-defined ecological values and management goals). The discussion of differences could clarify the terms "stressor," "source," and "effects-initiated." Such a distinction could be beneficial to risk assessors who are developing management goals, assessment endpoints, and conceptual models. However, these assessment categories are not carried through the whole document. Although this is not a fatal flaw, it is unclear how critical these approaches are to developing analysis plan, analysis phase, and risk characterization. This section represents an opportunity not only to discuss differences in approaches but also to stress that all risk assessments should be as site-specific as possible, using field-investigation data where feasible.

Question 11. As mentioned in General Principles, the discussion of assessment endpoints, management goals, and "measures" is a particularly valuable part of the guidelines. Specific comments are offered below to help clarify the discussion of conceptual models and assessment endpoints.

Pages 6 and 7, Figures 1-2 . Iterative nature of ecological risk assessment.: Iterations in the risk process are necessary not only to reduce uncertainty but also to address different types of risk. For example, once baseline risk is established in Superfund, another iteration of the process must occur in consultation with the risk manager. In this iteration, they evaluate the risks associated with various cleanup alternatives (e.g., predominantly physical stressors rather than chemical stressors). They must consider rates of recovery under different cleanup scenarios (disturbance) and evaluation of risk reduction. The measure of effects then ideally will not only be used to estimate risk but to document ecological recovery or effectiveness of risk management and remedies.

Page 24, Section 3.1, line 22: Conceptual models should describe relationships between stressors and assessment endpoints.

Page 24, text box 3-1: Conceptual models should describe pathways for contaminants at the site to reach receptors AND the mode of toxic action (how the contaminants will affect receptors). The outcome of the conceptual model should be assessment endpoints. Although some preliminary assessment endpoints might be proposed before the conceptual model is completed, final assessment endpoints cannot be identified without a conceptual model.

Page 24, Figure 3-1: I would add the extent and magnitude of contamination to the source and stressor characteristics. The arrow between the assessment endpoints and conceptual model should go both ways (see above comment on the text box). In the analysis plan circle, the concept of "system/habitat" is unclear.

Page 26, third paragraph: The discussion of uncertainty is unclear. Much of the uncertainty in the problem formulation phase is due to missing data. These data gaps can be filled in the analysis phase to reduce uncertainty.

Page 28, line 16: This requires that a stressor be identified, turning the assessment into a stressor-initiated assessment.

Page 28, lines 25 and 26: Assessment of reduction of breeding birds from logging or spread of a parasite that kills trees are both stressor-initiated assessments (logging and parasites being the stressors).

Page 29, line 7: The term "damage" should be changed to avoid confusion with natural resource damage assessment.

Page 31, lines 4 and 5: The "sources" and "stressors" in these examples are confused. Oil (or PAHs) is the stressor in line 4; spills and tar pits are the sources. Similarly, air pollutants and sediments are the stressors in the next line; automobiles and non-point sources are the sources.

Page 32, line 15 and line 19: These sentences should be clarified to be consistent with section 3.4.2, which indicates that assessment endpoints are not necessarily equivalent to receptors.

Page 33, text box 3-5: "Type" should indicate chemical, physical, OR biological.

Page 34, line 24: "affects" should be changed to "effects."

Page 35, section 3.4: This section should be consistent with section 3.4.2, which indicates that the terms "assessment endpoints" and "receptors" are not interchangeable (for example, page 35 lines 19-20; page 37 line 23; page 39 line 1; page 39 line 14; and page 45 lines 4-6). This first paragraph indicates that assessment endpoints should be chosen before conceptual models are developed. This may result in a risk assessment that ignores risk to sensitive receptors. For example, bird reproduction may be chosen as the assessment endpoint at a wetland site containing PCBs. A conceptual model may be developed in support of reproductive effects to birds when, in fact, aquatic organisms may also be at risk.

Page 35, line 26: The term "significantly" is unclear. This is also a problem on page 37 line 18.

Page 37, line 10: "Selecting effective assessment endpoints" should be changed to "identifying potential assessment endpoints." Although it is necessary to ascertain what the public views as an important resource to protect, the actual assessment endpoints should not be selected at public meetings. It is essential that professional judgment and ecological risk assessors be used to make those decisions so that components or receptors in ecosystems are not ignored because of lack of expertise in ecological sciences. The Suter reference implies that wetlands would not have been figured into assessment endpoints 30 years ago because of negative public perception. This is particularly disturbing given that ecologists and biologists were very aware of their value and critical functions when wetlands filling was legal. We have a responsibility to the public to protect the environment and, in turn, to solicit their input to help prioritize ecological values. However, this responsibility should not prevent us from using appropriate endpoints. We need to communicate how we are going to conduct good science or scientific evaluations so that the public can understand why seemingly unattractive or insignificant creatures (e.g., midges) are important in a trophodynamic structure that ultimately supports widely valued fish and wildlife.

Page 37, last paragraph: If assessment endpoints are not ecologically relevant, the results may predict risk but money will certainly have been wasted identifying risk to irrelevant ecosystem components. Are there any examples where an irrelevant ecosystem has been assessed? Sometimes an assessment endpoint is chosen involving a receptor that is not actually affected by the stressor (rather than the truly sensitive receptor) and risk is potentially underestimated. Although this would be inappropriate for the particular ecological risk assessment, the ecosystem component is not irrelevant. This is why professional judgment and interaction of qualified ecologists are necessary during all phases of problem formulation and risk evaluation to avoid these pitfalls.

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Section 3.4.2: This is an excellent section that will be a major contribution to future risk assessments. It should be clear that it is possible to have more than one assessment endpoint for any assessment.

Page 40, last paragraph: Definition of assessment endpoints: The sentence discussing "the boundaries of an assessment to 'genetic exchange in regional populations' of an organism rather than 'genetic exchange in local populations'" is confusing. Either phrase helps define the assessment endpoint clearly. The difference is in the scale, which has implications for the level of variability to be addressed in the analysis phase.

The examples in Text Box 3-10 do not reflect the idea of "Common problems encountered in selecting assessment endpoints." Highlighting examples is a good idea but the "Ecological resource is better as a measurement endpoint (e.g., midges example)" and the third bullet with (e.g., turkey and deer example) is confusing. For the midges example the suggestion was to use salmon, which is also an ecological resource, albeit more "charismatic" or appreciated. Of course, NOAA appreciates both the midges and the salmon as ecologically significant.

Page 43, first paragraph: This paragraph should be deleted because it is appears earlier in the report.

Page 43, lines 17-19: The statement "In many applications, the best assessment endpoints are those for which there are ..." is used to reiterate three qualities necessary to provide good information to evaluate the endpoint. However, I disagree that all three conditions must be met. If effective tests and field measurement techniques are available, then predictive models are unnecessary. Perhaps, instead of using a direct quote, these ideas could be captured or reorganized in a sentence reflecting the authors' opinions.

Page 44: The bullets should include the fact that conceptual models should include the mode of action of the stressor.

Page 44, line 30: In addition to the three basic elements, pathways and effects must also be identified.

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<u>Page 45, line 1</u>: This line should be changed to read "identify where hypotheses and data must be generated."

<u>Page 45, first full paragraph</u>: This description of the conceptual model does not include potential effects of the stressor (conceptual models must include more than exposure pathways).

<u>Page 45, text box 3-12</u>: "PMN" should be spelled out. The "effects-initiated" example is really a carbofuran (stressor-initiated) example. The hypotheses in the text box should be simplified. For example: "Reproduction (number of viable offspring) of birds exposed to chemical A will be reduced when compared to that of unexposed birds." Since these risk hypotheses are to be tested using measurements, they should actually be phrased as "null hypotheses."

<u>Page 46, Section 3.5.2</u>: Although flow diagrams are a useful component of conceptual models, the diagrams themselves do not comprise the model. At best, the flow diagrams can only illustrate some of the relationships. Typical examples include food-web relationships and contaminant-migration pathways. Representations of adverse effects are usually not shown in diagrams. This section should make it clear that the diagrams cannot stand alone. The text beginning on page 47 could be reworded or condensed so that the main points of Barnthouse and Brown (1994) are presented without the long description of Odum's diagram, which does not in the end serve as a good example.

<u>Page 47, lines 11-12</u>: Figure 3-2 does not show effects.

<u>Page 50, line 3</u>: Figure 3-3 is an example of a figure that is not readily comprehensible to non-experts; however, it does not stand alone to make that point in this document. It is not helpful as a positive example for the diagrammatic part of a conceptual model. Perhaps this figure could be replaced with an example of complex food web diagrams frequently submitted as (or in lieu of) conceptual models. The relevant portions of this diagram, including the important exposure pathways for the stressor and sensitive receptors (e.g., potentially adversely effected receptors used as assessment endpoints) could be highlighted to demonstrate the ideal for a conceptual model.

Page 50, line 7: The definition of assessment endpoint as used in Barnthouse and Brown is apparently inconsistent with section 3.4.2.

Page 50, line 10: It is not clear why pesticide application rates are the only relevant environmental fate data for the example.

Page 52, line 22: It seems misleading to suggest that some risk hypotheses should be dropped due to feasibility concerns. Risk hypotheses regarding the assessment endpoints must be tested if the assessment is to evaluate risk. However, the actual methods used to test the hypotheses can vary due to feasibility concerns.

Page 52, lines 29-30: I would like to see the use of data from other locations and species discouraged where it is feasible to collect site-specific and species-specific data.

Page 53: I would present the measures in a different order. I think it makes sense to present the measures of ecosystem and receptor characteristics first, followed by exposure measures and effects measures.

Page 53, line 15: Measures of exposure should also include determining how a stressor changes in the environment (for example, methylation rate for mercury).

Page 54, Section 3.6: The discussion of the analysis plan should be clarified to indicate that objectives for the plan must be identified first. Specific measurements that will be made should be described in sufficient detail to document how the measurements will meet the objectives and address assessment endpoints. The plan should indicate very clearly how the results will be interpreted. These questions should come before descriptions of heterogeneity, data gaps, and QA/QC concerns.

Page 55, Table 3-1: These strategies appear to have limited ability to reduce uncertainties. A better way to reduce uncertainty would be to decide up front what constitutes significant risk. For example, one strategy to deal with variability is to determine what will define a "significant" response. This will allow appropriate sample sizes to be determined. Some of these uncertainties can be reduced by collecting more information. For example, one strategy that deals with extrapolation uncertainty is to conduct tests with the species you are concerned about.

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Analysis

Questions 13, 14, and 15.
The balance is appropriate and, at this time, I have no major recommendations for additional principles. I would not characterize the ecological-effect analysis as simply as a "number crunching exercise" (page 74), particularly when dealing with data from field investigations. (This reflects my bias for site-specific assessments using field assessments and toxicity testing and my emphasis on using professional judgment in interpreting results.)

The biological stressor type discussion could be improved with a clear definition of the delphic method and a more explicit example of a fault tree. In addition, the text boxes in this part of the chapter, along with others for stressor types, are not particularly useful. Many of the points should be integrated into the text to be effective examples. On the other hand, several sections contained valuable series of points, issues, and/or questions that could be effectively highlighted in text boxes: a) Exposure Profile—uncertainty associated with exposure estimates (pp. 72-74); b) Stressor-Response Profile (pp. 87-81); c) Physical stressor—list of things to summarize or describe (p. 93); and d) Multiple stressors—issues to address (p. 106).

Risk Characterization

The discussions of risk estimation and weight of evidence are excellent!
The end of the chapter dealing with ecological relevance seems to confuse risk management and risk assessment. For example, determining the potential for recovery is not part of the baseline or primary risk assessment. Recovery could be discussed as to how it affects determining magnitude of risk rather than as a tool for comparing risk due to other stressors or cases in other systems. When the existing or primary risk has been characterized, additional questions regarding the risk of alternatives and potential rates of recovery are usually raised during the risk management phase. The risk of alternative cleanup or management actions can be determined as another iteration of ecological risk assessment (as discussed earlier in response to question 11). For example, in determining the risk of no-action alternatives or various remedial alternatives/ management actions used to reduce existing risk, the potential for, and predicted rates of, natural recovery become important. In the Superfund process, this usually involves a predictive evaluation of risk due to physical stressors (altering contaminated habitat)

that considers potential recovery under different management scenarios or remedial actions. However, the potential for natural recovery does not contribute to determining baseline risk.

Page 122, Section 5.3.2: The beginning of this section provides important information that should feed back into the design of the analysis phase. These issues should be addressed up front in problem formulation. Ecologically significant effects, determined through appropriate measures of effect (if the risk assessment has been designed properly), should be detected with statistical significance. It makes sense that professional judgment concerning issues of ecological significance could override determinations of statistical significance in a situation where uncertainty and susceptibility are high. However, it is not clear that this was the intended meaning here. I am concerned about the potential for ambiguity: it would be unfortunate if the statements regarding statistical significance could be construed to mean that the result of measures of effects and risk estimation could be easily discounted, i.e., the risk is not "significant enough."

Concerns with Ecological Relevance - Recovery and Natural Variability

Page 123, Section 5.3.2: Some indication of ecological significance can provide risk managers with a framework for comparison to other cases. However, the intent of the risk assessment should not be to compare the risk of one situation to other risks (for example, comparing the risk at a hazardous waste site to the risk of filling wetlands in a watershed).

Page 123, section 5.3.2.2: This section seems to confuse risk management and risk assessment. The scale of the risk is important in risk-management decisions. If the risk is over a small area or time, perhaps a reasonable management decision would be to take no action at all.

Page 125, second paragraph: Recovery rates as described for the different communities used as examples are too short. Specifically, fisheries could take several decades to recover or more likely, species composition may shift completely to a distribution that no longer supports other important species or commercial fisheries. Forests and associated productivity may not recover even after 50 or 100 years. Additional factors to be considered include the mode of reproduction (k-selected versus r-selected) and population growth, along with the availability of adequate stock.

It is appropriate to evaluate recovery of a system from adverse effects of original stressor versus recovery under various remedial alternatives; this iteration of risk assessment should be built into the analysis plan at the problem formulation stage (as mentioned before) in consultation with the risk manager. Most of the recovery discussion is appropriate but the last paragraph on page 126 containing a Superfund example is disturbing. In the Superfund process, we frequently agonize over the concept of needing to weigh and balance the existing risks of chemical contamination in sensitive habitats versus the risk of remediation destroying habitat, particularly certain wetlands that are unlikely to recover important ecological functions. In fact, we use this as an example for why site-specific risk assessment is so important to determine significant risk and ecological functions to avoid unnecessary cleanup of habitat to meet numerical criteria. However, we very infrequently find, in situations where significant risk exists, that the contaminants are likely to detoxify in a time frame that will not cause years of irreversible harm to ecological resources.

In wetlands, heavy metals may not be readily bioavailable, the contaminant source may be easily stabilized or hot spots removed to prevent migration, and sedimentation rates may enhance natural recovery. However, usually measured or significant risk is due to persistent toxic contaminants (e.g., PCBs, Hg, PAHs, and dioxin) particularly those that continue to migrate out of the wetland downstream or into the food chain. My concern is by concluding the recovery section with an example that assumes relatively quick recovery from effects of toxic chemicals could lead to the interpretation that if natural recovery is possible the significance of existing risk can be discounted as well as the need to take actions to reduce ecological risk. I agree with the need to consider the risks of remediation, but the particular phrasing of the example and implication of mixtures as problems and "detoxifying chemicals" potentially leads to a conclusion that perhaps is not intended.

<u>Page 126, Section 5.3.2.4:</u> Determining natural variability is part of the analysis phase and seems out of place in the risk characterization discussion. If no effect can be discerned from natural variability, then there is no apparent risk. However, analyses should be designed with sufficient power to distinguish an ecologically significant effect

from natural variability. Taking into account natural stressors and how extremes in natural phenomena could increase risk can be an important part of a risk description. The discussions of natural variability, recovery, and ecological significance raise issues here that should be addressed earlier in the analysis planning phase. A well-conceived analysis plan (achieved using these guidelines!!!) should address these issues to help minimize ambiguity in risk characterization.

Finally, NOAA very much appreciates the opportunity to participate in this review process. This document will be a very valuable tool and reference. I am delighted with many of the detailed recommendations and examples. Although many of the detailed comments are devoted to the Problem Formulation chapter, this section provides excellent clarification of the process and its components. The change and/or additions to terminology should be embraced by risk assessors and the description of four stressor types worked fairly well in the Analysis Phase. I am concerned about the potential for the possible misinterpretation of certain statements in the risk characterization section that may lead to descriptions of ecological risk as insignificant or that may lead to conclusions that no actions are necessary to reduce risk. I would re-emphasize that observed adverse effects equals risk; ecological risk assessments should be site-specific where possible! However, most of these concerns can be easily addressed with some clarification in the discussions or slight recrafting of language. Again, I would like to thank the EPA Ecological Risk Assessment Forum and the authors' outstanding efforts to obtain and meld varied input to produce a well-written and useful document.

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REVIEW OF DRAFT GUIDELINES FOR ECOLOGICAL RISK ASSESSMENT

GENERAL PRINCIPLES

I believe that the report could be more specific as to what exactly is an ecological risk assessment and what are its motivating factors. How does an ecological risk assessment differ from an ecological impact or effects assessment? What is new or unique about ecological risk assessment? What are the advantages or strengths of an ecological risk assessment versus traditional ecological effects or impact assessments? What does the term "risk" imply in the context of an ecological risk assessment? Some people interpret the term to signify an adverse occurrence while others take it to signify uncertainty. These alternative interpretations should be discussed.

The guidelines define ecological risk assessment as being limited to adverse effects. This is too limiting. The approach is equally valuable for neutral and beneficial effects such as outcomes of mitigation actions. Furthermore, as the text points out, the categorizing of effects as adverse depends on the value judgments of the stakeholders. These value judgments can be highly diverse and vary with time.

The text does a very good job of describing the interconnection between risk assessment and management. These two activities are so closely intertwined that it is totally artificial and incorrect to claim as it is done in the text that they are separate. Although one can draw a schematic and stick these activities into two separate boxes, in practice, they are inseparable. The objectivity of the assessment is always at risk of compromise. Calling assessment and management distinct in no way reduces that risk. Environmental management decisions are influenced by scientific, engineering, economic, social and political factors. It is reasonable to expect that decisions will not be based on optimization with respect to a single factor type. In order for the ecological risk assessor to be effective, he cannot separate himself from those who bring the nonscientific factors to the decision process. He must be able to articulate what the ecological trade-offs are with respect to alternative management options.

The text does an excellent job in discussing the relationship between risk assessor and manager. It needs to do likewise for the relationship between risk assessor and traditional environmental scientist. The text frequently refers to risk assessment as scientific, which it is, implying that the risk assessor and the traditional environmental scientist (e.g., ecologist, physiologist, limnologist, oceanographer, geologist, atmospheric scientist, etc.) belong to the same fraternity, which they don't. The risk analyst provides a bridge between the environmental science community and the stakeholder community. The risk analyst modifies through extrapolation and simplification the data and theory developed by environmental scientists so that it is amenable to the risk analysis of alternative management options. In many instances, the techniques of uncertainty analysis and extrapolation used by the ecological risk analyst are not part of the background and toolbox of the traditional environmental scientist. Unless the risk analyst justifies his approach to the traditional environmental scientist, there is a risk that the traditional environmental scientist will oppose the analysis and undermine the ecological risk assessment. Hence the interaction between risk analyst and environmental scientist is as critical as the relationship with the stakeholders.

The text needs to identify what are its most significant points. I assume that the executive summary will be used to do this. Within the main body of the text perhaps bulleting or boldfacing could be used to identify key concepts.

To me, it is the analysis of the sources of uncertainty and how they influence the ultimate assessment that is the essential characteristic of risk analysis. Most of the text, although generally well written and insightful, pertains to ecological analysis in general and is not specific to the risk element. I do not necessarily object to the inclusion of this material, but I would like to see more substantive discussion on uncertainty analysis. A major point of contention in risk analysis is the application of reduced form models. This subject is never mentioned, neither is uncertainty propagation. It is pointed out at least twice that simplification can add uncertainty; however, it is equally true that increasing complexity can increase uncertainty. The uncertainty in a calculated entity is a complex function of the uncertainty of the algorithm used to do the calculation and the input data, which includes values for initial conditions, algorithm parameters, boundary conditions and forcing functions. A motivation for increasing the complexity of an algorithm is to increase its accuracy; however, this also tends to increase input data requirements. Hence, it is possible to decrease the uncertainty in the algorithm while at the same time increasing the uncertainty in the input so as to produce a net increase in the uncertainty in the calculated output.

QUESTION 1

I find that ecology is underemphasized relative to toxicology and that risk (uncertainty) analysis is underemphasized in general. Ecology is not sufficiently underemphasized to be of concern, but the guidelines should be beefed up with respect to how sources of uncertainty are estimated, how uncertainty is propagated in the analysis, and how uncertainty is characterized in the completed assessment. Consultants with expertise in uncertainty analysis in contrast to simply toxicological or ecological analysis should be hired to provide the additional material. Possibilities are Virginia Dale (ORNL) and Bob Gardner (Appalachian State).

More emphasis should be placed on multiple stressors. In the future, this will become the dominant assessment situation. Historically, environmental policy and technical analysis have for the most part treated stresses individually. This is because society's concern was concentrated on only a few stresses. As society has become more concerned about ecological impacts (in contrast to just human health impacts) and has identified a significantly greater number of stresses, the technical community has come to realize that most receptors of concern exist in an environment where they are exposed to multiple interacting stresses, anthropogenic and natural. Analytic approaches that work well for single stresses, do not necessarily work well for multiple stresses; hence, the need to provide additional emphasis on the latter subject.

QUESTION 2

I thought that the document's authors, in general, did an excellent job in clearly integrating the illustrations into the text, hence I find Appendix A somewhat superfluous. I found the illustrations to significantly enrich and enliven the text by providing concrete, real-world examples of presented concepts. However, I think it creates confusion to refer to these illustrations as "case illustrations"; since as the text explains, they are not meant to be used as examples of either what to or not to do.

The weakest of the illustrations was Illustration 5, Assessing Risk of a New Chemical under the Toxic Substances Control Act. Because of the illustration's vagueness as to the exact chemical and its source, the illustration tended to be somewhat confusing. Cannot more specifics be added without identifying the chemical, which I assume is the reason for the vagueness. If not, can another example be chosen where more specifics can be given?

If Appendix A is retained, the descriptions of Uncertainties for each of the illustrations need to be beefed up. At present, they are too perfunctory. This relates to my answer to the previous question where I identified a general need for more depth and insights in the guideline's treatment of uncertainty.

QUESTION 3

I did not note such a deficiency and have no recommendations.

QUESTION 4

The approach is okay but the information needs to be expanded to included more depth and insight. Please refer to my answer to question 1.

QUESTION 5

Please see comments under general principles. The Introduction needs to clarify what makes an assessment a "risk assessment" and how risk analysis differs from traditional environmental science. The insistence that risk assessment and risk management can be separated is incorrect and misleading. The limitation of risk assessment to adverse effects is unwarranted.

The discussion (page 4, lines 8-15) of when a risk assessment may not be required provides no guidance. Issues concerning habitat protection and endangered species are certainly amenable to ecological risk assessment. Furthermore, professional judgment is a valid risk assessment tool as presented in the Chilean log illustration.

QUESTION 6

I thought that the approach taken in the text tended towards being pedantic. The concepts are common sense and can be explained well in one or a few paragraphs. The concern about and need for concise, precise definitions seems unwarranted and probably is the source rather than the solution to the controversy referred to in the question. As stated before, I would not limit risk assessment to adverse effects.

QUESTION 7

I think that the framework is okay.

QUESTION 8

I think that this is done well.

QUESTION 9

I find this question confusing, since it is my impression that the text does not include any discussion of the interaction between assessor and manager (stakeholders) after the completion of the assessment. This is an important topic and should be included. It falls into the category of risk communication which has also been left out of the document.

QUESTION 10

It is okay.

QUESTION 11

I thought there was a tendency to be pedantic. It was not clear what material had specific applicability to risk assessment versus assessment in general.

It should be pointed out that policy goals and/or societal values often do not form a self consistent set.; e.g., recreational and flood control goals for impoundments. There should be a discussion of methods to help resolve this type of situation.

QUESTION 12

Again, what is the specific relevance to risk assessment versus assessment in general?

QUESTION 13

As stated in the answer to question 1, more attention should be given to multiple stresses. In addition it is preferable to separate exposure analysis into source and pathway analysis; since, source and pathway calculations usually draw on different data sets and models, involve different groups of technical experts, have distinct uncertainties, and are the focus of different control and mitigation options.

QUESTION 14

On page 83, lines 26-27, it is stated that it is reasonable to assume, when there is no data to the contrary and exposure profiles are similar, that laboratory effects represent field effects. No backup support or citations are given for this statement which I disagree with since it ignores the possibility of environmental mediation as well as secondary and indirect effects. The stated assumption is not even conservative, since secondary effects can be more adverse than primary effects.

On page 84, lines 5-6, it is stated that extrapolations across geographic regions require coordination between exposure and effects analyses. What is needed is a mechanistic receptor model.

On page 84, on the discussion of cosms one might want to mention open-top field chambers as a more complex cosm. It would also seem appropriate to mention here ecosystem experiments; e.g., addition of nutrients or acids to lakes, modification of precipitation or canopy throughfall, field fumigation, etc.

On page 84, lines 21-22, it is stated that as the cosm increases in complexity, variability among the control and treated replicates can mask effects. The reader should be cautioned not to infer from this statement that the increase in variability is an artifact of the cosm design. Variability is a property of the real system. The purpose of this report is to guide the reader on how to deal with the variability.

On page 84, the discussion of secondary effects abruptly switches from cosms to ecosystem models, with no explanation that the ecosystem models, unlike the cosms, are mathematical models.

The statement on page 85, line 15-17 is confusing. Predictive risk assessments that utilize field data also rely on hypothesis testing, regression analysis and other statistical techniques. What is meant by the phrase, " but not absolutely prove causality"? An hypothesis can be a causal hypothesis. The causality section is written from a toxicological perspective. It needs ecological perspective.

Figure 4-6 has a stressor one and three, but no two? The figure also tends to be confusing because there is a general flow of information from right to left instead of left to right.

Page 95, lines 15-16, the statement that opinions about whether a biological stressor is beneficial or deleterious can differ provides additional support as to why ecological risk assessment should not be limited to adverse effects.

QUESTION 15

Traditionally, environmental policy and regulations have been source oriented. As society in general and the environmental community in particular become more sophisticated with respect to identification and analysis of environmental issues, identify an increasingly larger number of potential stressors and their sources, and become more concerned about ecological effects, there will be a greater recognition of multistress issues. In an environment where one is dealing largely with multistress issues, it is advantageous to switch one's focal point from source to receptor, since the receptor is the natural integrator of the multiple stresses. One can calculate the total risk for a receptor of concern and decide whether it is acceptable. If it is not acceptable, one can analyze the ecological and cost effectiveness of alternative management strategies to reduce the risk. As the text states on page 107, lines 8-9, "The most accurate predictions will result from a sound understanding of system structure and function." Thus a major thrust of the ecological assessment community should be to develop and verify mechanistic model of ecological receptors at levels of temporal and spatial resolution that are of concern. The level of detail required by these models is a function of how the various sources of uncertainty affect the uncertainty of the final assessment. This is one of the most important facets of ecological risk analysis and it is not at all treated in the guidelines.

QUESTION 16

As I have already noted, there should be some guidance as to how risk (uncertainty) is treated mathematically within the context of a risk assessment.

I have two comments about Fig. 5-1. There should be a two-way arrow connecting the data box on the extreme right with the problem formulation-analysis box on top. There should be a one-way arrow leading down from risk management to another box called management decision to signify that ultimately the process should culminate in a decision. The process cannot go on indefinitely without some decision. Of course, the process can be restarted at some later time leading to a modification of the original decision.

QUESTION 17

The fourth criteria mixes two different subjects which should be separated. One is to what extent can an effect be recognized against a background of natural variability. The second is to what degree do natural disturbances interact with anthropogenic stressors to alter risk.

Lawrence Harris

I. IDENTIFYING AND HIGHLIGHTING IMPORTANT GUIDANCE PRINCIPLES

A. INTRODUCTION.

1. The following 'general principles' are very laudable:
   can't eliminate all risk
   we must operate under much uncertainty, and that
   we must explicitly evaluate uncertainty, and that
   both magnitude and likelihood of risk are important, and
   we must work toward well-defined endpoints or measures of effect
   and that there will be increasing
   interactions between assessors and managers. Figure 1.1 is a good representation of the overall process. I also give high marks to figures 1.2 and 1.3 (with some provisos).
2. The following 'general principles' are conspicuous by their absence and need to be dealt with. I hope that we deal with them in the workshop.

   a. The introduction as illustrated by Figure 1.1 and examples is strongly biased toward single-factor effects and neither explicates nor implies much importance to simultaneous multiple stressors. I conclude that this is a serious issue (even though it is treated considerably in the analysis section). Most of the real-world examples that I am aware of (e.g., the Everglades) are infinitely more complex than can be handled by this simplistic portrayal. Therefore, even though I find the progress made in Risk Assessment to date very laudable, I think it very important to note that this greatly over-simplified material in the first 50pp. is only a prelude to the much more complex material dealt with yet another 50pp further along (i.e. around p 100).

   b. Equally, if not more, disturbing is the lack of explicit acknowledgement that interaction effects of multiple, simultaneous stressors and/or ambient conditions are very real, but also very difficult and discussion is deferred to the end of the analysis section (where it is weak). It seems to me that both the wording and the illustrations lucidly portray how to handle single-factor stressors, one at a time, but both the text and the figures fail to either implicate or explicate the importance of interaction effects.

   c. It is laudable to explicate that both magnitude and likelihood of effect must be evaluated. But equally important is the notion of reversibility vs. irreversibility. Destruction of a sawgrass or Spartina marsh may be lamentable, but it is reversible. Extirpation of the Dusky Seaside Sparrow is not reversible. I suggest that reversibility be added to the list and that magnitude, likelihood, and reversibility must stand as a trio. Reversibility is probably the most important of the three.

L. Harris

d. Regarding unclear communication (p.9,l.14).
Yes, dropping down a scale to simple demographic parameters allows the full power of the Cartesian (reductionist) approach to science as opposed to those nasty qualitative terms such as health or healthy. But this occurs at great cost too. In almost every year during the last decade there has been more births than necessary deaths of the Florida panther; the Florida panther population is demographically exemplary. But do any occur in Everglades National Park, no!!! Is the Florida panther population 'healthy', no!!!

Simple demographic parameters miss the point regarding a majority of the endangered species on earth!!!! What is the population viability???

e. Regarding the issue of Default and non-default. I conclude that this needs clarification, I do not know what an agency default for a model structure is. Lets try to clarify this.

f. Regarding definition of ECOLOGICAL RISK ASSESSMENT. This is a seductively cogent and clear definition. It is good. But it's so simple and beguiling as to lead to great problems later on. Should not this definition be made explicitly more complex so as to reflect the complexity of the real world. For example, should we not strongly imply or explicitly state that there are a least a dozen simultaneous and interactive stressors at work in destroying the Everglades as a viable system????

If this were a document on health hazards of lead-based paint I would not be as concerned about the apparent single-factor, no-interaction orientation that comes across to me to this point in the document. But big systems are going to the happy hunting grounds because of very complex interactions of multiple, simultaneous stressors, not because of identifiable single-factor effects.

Inasmuch as the document does treat some significantly complex material later on, it seems quaint that this first 50pp comes across as so overly simplistic.

g. Definitions of ENDPOINT/MEASURE OF EFFECT and SOURCE are good.

h. Definition of STRESSOR is, in my view, too simplistic and naive.
For example, it explicates only nouns, not verbs. It neither implies nor explicates that rising sea level, urbanization, sprawl, habitat fragmentation, and lack of burning were interactive forces that caused extermination of the Dusky Seaside sparrow. It neither calls for nor openly allows that free-ranging cattle (overgrazing), lack of burning due to Smokey-The-Bear, and forestation led to the extinction of Bachman's warbler. I believe it is the interaction effects of multiple, simultaneous stressors are the stressors we must get at.

Inasmuch as the last part of the analysis section treats some much more complex situations and scenarios, I wonder if the complexity of the real issues should not be signalled up here in the early sections. The two cases just cited are among many that I tried to elucidate in a 1988 paper THE NATURE OF CUMULATIVE IMPACTS ON BIOTIC DIVERSITY OF WETLAND VERTEBRATES, Environ. Manage. 12:675-693.

i. Definition of EXPOSURE seems too narrow for practical application to many of the problems that I am aware of. It is the lack of burning that threatens scores of species in the Southeastern Coastal Plain. Exposure to fire is necessary. How do we say that 'exposure' to no fire (very common) and to fire prevention (not uncommon) is the stressor. This is dealt with in some considerable degree toward the end of the document and so it is puzzling that these simple, categorical statements would ring so loud and clear in the early sections.

j. Definition of 'Disturbance' seems too narrow and jaded. Fire is not a "disturbance" in the Southeastern Coastal Plain, it is a necessary fact of life. To call these necessary fires a 'disturbance' is not consistent with what we know about southeastern ecology. It would be helpful to find a few better words here. The exact same case can be made for flooding in the bottomland hardwood forests. We need floods in order to maintain any semblance of a natural system. How do we describe "exposure" to a no-flood regime?

(I am now aware that this is treated somewhat toward the end of the paper, still, at this early stage it seems to come across as a red flag).

k. Text box 1-6. STRESS REGIME.
I understand what is being said very well. Still, the phrase comes closer to describing the native environmental dynamics that are needed in the Southeastern Coastal Plain than what we are replacing it with.

B. PLANNING

1. The following points or principles are worthy of note

p.17,l 3-4
Purpose of R.A. to provide scientific information about risks
p.17,l 13-14
By using scientific info, the R.A. <u>ensures</u> (?) attention to all important ecological concerns
p.17,l 18-22
Keeping the planning distinct from the R.A. helps keep politics separate from science.
p. 21,l 1-6
The agency increasingly emphasizes "place-based" or "community-based" management. This is good but begs a critical question.

P.21, l 28-30
R.A. involving multiple stressors. This could profit from some expansion of the idea and perhaps examples.

2. The following points are cause for concern:
Use of scientific information in a Risk Assessment will not ensure that attention is paid to all critical ecological concerns. It is my experience that contracts such as R.A.'s are farmed out to consulting firms that see it as a job to execute with minimum fuss and muss. Rarely are top-of-the-line thinkers and scientists involved in the planning and problem formulation stage. Thus, the R.A. becomes little more than a voluminous statement of the obvious with little or no probing of the more far-reaching questions.

While "place-based" or "community-based" management sounds good on the face, it is increasingly out of step with reality. Take our National Parks and biodiversity preserves as an example. 100 years ago, it would have been adequate to do 'place-based' assessment of impacts on Yellowstone or the Everglades. With today's knowledge about landscape and region-wide phenomena at work the 'place-based' approach seems almost like an oxymoron. Regional Landscape analysis is the key to relevant analysis in growth states such as occur in the sunbelt. Even the putative 'advanced' ecosystem management is already out-of-date because of the rapidity of developments in the physical environment and in the science of landscape ecology.

p.21, l.27-30. I believe that this section on region or watershed analyses that involve multiple stressors and their interactions need much more emphasis if ecological risk assessment is to be relevant to big systems such as the Everglades.

C. PROBLEM FORMULATION

1. Positive points or principles worthy of note

a. p. 24, l 7-9
the statement here about consistent shortcomings is good and important

b. p. 26, l 21-24
the statement here about why/how ERA's are initiated is good

c. p. 28, l 29-31, and p.29, l.1-6
the statement about complexity and landscape scale are exemplary. More of this is needed. As the science of ecology continues to grow, Landscape ecology continues to play a greater and greater role. This is demanded and forced by the increasing isolation of ecosystems and thus the increasing irrelevance of ecosystem analysis without a landscape contextual analysis.

d. p. 30, l 7-10
selection of assessment endpoints and being overwhelmed.
This is so important as to beg expansion/elucidation.

e. Text box 3-4
The complexity of issues implied herein is getting close to reality, but it still misses the landscape scale.

f. P 33, l 1-5
I judge this to be very important, it begs elaboration.

g. p 34, l 7-24 and box 3-6
This is very important. Perhaps it is here that we can/should elaborate the complexity of multiple simultaneous interactive stressors and large-scale cumulative effects issues.

h. p. 39, l 18-31
This is good, it is getting preciously close to important landscape processes such as fire and flood, and the pulsing paradigm. Perhaps expand.

2. *Questionable points of concern*

a. p.28 l 15-20
causality. must add that cause must precede effect

b. p.28, l 23-26
this is a nice clean-cut single factor example, it would get real messy real fast if we put in multi-factor complexity.

c. p.36, l 6-14
popularity and political correctness

I understand the importance of what is being said here, but this is a matter of education too. Scientists must be allowed and encouraged to fight for the arcane and the difficult to articulate. concepts such as beauty can not be reduced to quantitative measures and there would be no classical music or good painting in the world if laypeople got to dictate who protects what.

d. p. 37, l 14-24
As noted above, this paragraph is good and has potential to bring in the landscape-level issues that are critical to systems such as the Everglades. Can we expand/elaborate.

e. p. 38, l 9 needs elaboration

f. p. 38, l 18-31 re: exposure
I am concerned that this section does not explicitly elucidate time-lag and space-lag effects. What do you do with birds that are exposed to toxic chemicals in other countries but do not manifest their reproductive impairment until they return to the boreal forest.

what do you do with marine turtles nesting at Cape Canavaral that have gender and the population sex ratio determined this decade by incubation temperature, but the effects will not be manifest (and there is no way we can know) until 25 years from now (because they are so long-lived) ????

g. p.38, l 29-31

The business of degraded habitats badly needs to be considered at the landscape scale because of issues such as configuration, adjacency, etc.

h. p.43, l. 7-23

I know that this is logical and nice, it is also problematic. The implications are horrendous. Can or should we soften this. Frank Egler made a famous statement one time that said: 'the computer has encouraged the belief that the only things that count are those that can be counted"

i. p.44, l. 8 hypotheses

I would prefer to state that they are falsifiable predictions rather than assumptions.

D. THE ANALYSIS PHASE

1. Positive points and principles

a. p. 59, l.4-7

It is good to see this discussion of natural driving forces, which I noted above, are not necessarily stressors. I believe it is important to hammer this point home that driving forces (the pulse paradigm) are indeed commonplace and that they are not disturbances, and that the real disturbance comes into play when humans or our structures prevent or mitigate the 'natural' pulses.

b. p. 60, fig 4-2

This figure goes a long way to allay anxieties that the Ecol. Risk Assessment process can handle some complexity. I would advocate inclusion of an even more complex one. Although I do not have one in mind, I believe we can develop one based on cumulative impacts that I am well aware of.

c. p. 63, l. 21-24

This is a good example but should be fleshed out a little more to drive home whatever point is being made.

d. p. 71, l. 19-24

This is a good point about interaction effects but even it is simplistic

e. p. 88, l.17-20

This is an important paragraph. Could/should we expand on the SAB conclusion that habitat alteration ranked so highly and could/should we develop an example or even a box to drive this point home. I think it is very important and is presently being slighted.

f. p. 90, l21-27

This is an important point to make, but do we really want to stick to the word disturbance when all of the species and communities are well-adapted to these pulses??

g. p. 92, l. 20-23
Its good and reassuring to see that we are finally getting around to secondary effects. May want to amplify.

h. p. 93, l. 5-11
This is a good point/principle, in my judgement it should be expanded/elaborated/amplified.

j. p. 93, text box
Good to include the indicator species approach but this is problematic

k. p.96, table 4-4
The use of Hydrilla as an example really shows that values do encroach on science etc. It is highly debatable that Hydrilla increases "habitat", yeah, but at what cost in other 'habitats'. I recommend we drop this example, it is polemical to say the least.

What about including a really complex example of secondary, tertiary and/or quaternary effects in here???

l. p. 99, l. 22-30
It is good to bring this point of one-sided science out. Should we amplify the now obscure notion that this whole scenario must change in the future.

m. p. 103, l. 4-5
Simberloff and Alexander make a good point here.

n. p. 105, l 4-10
This is a very important paragraph, as far as I am concerned it must be emphasized more, perhaps expanded. The problems that I had with the first 50 pp of the document is that they did not imply or state that ecol. risk assess would/could get into the complexities of the real world.

o. p. 105, l. 13-15
I believe this is so important as to beg for expansion

p. p. 106, l. 5-7
re: assume lack of interactions. This is probably a true statement, but it is lamentable and ecologists should not let it pass. Something must be done about this.

p. p. 108, l. 4-13
It is encouraging that progress is being made at the levels of higher complexity and larger scales and we should encourage it. To my mind, this is what is called for. Perhaps we should develop a box and say something about present limitations.

L. Harris

2. Points of concern or problems
    a. p. 58, l 30-31
    evaluating stressor individually is indeed a major problem and it is one that should concern all ecologists and resource managers with regard to future ERA's.

    b. p.88, l21-24
    As I have mentioned repeatedly, the word "disturb" and the phrase 'disturbance regime' are problematic (in my view). A disturbance regime is hardly a disturbance regime if everything that lives there is highly adapted to it. Events such as the Yellowstone fire of 1988 were disturbing to humans, it crushed our illusions, but it was hardly a disturbance to the Yellowstone system.

    c. p. 93, text box 4-10
    The business of "indicator species", especially the ones cited here, is very tricky. There is a very rich early 20th century literature on indicator species and one of the principles drawn from all that work is that indicators had to be stenotypes and not eurytypes. In today's applications, the indicator species are almost always chosen because they are generalists (eurytypes). It is for this reason that use of species such as the gray squirrel and downy woodpecker are almost laughable. What they indicate is that managers can make all sorts of errors and still maintain their favorite small galaxy of "indicators" that things are o.k.

    d. p. 95, l. 15-20
    We must give serious thought to this description of Hydrilla's effects; I submit that we are too ignorant to say much about the pluses and minuses. Surely, the increase of largemouth bass does not compensate for all the other negatives, or does it??

    e. p. 96, table 4-4
    remove Hydrilla

    f. p. 97, l. 18-20
    need to explain and or elaborate on "fault trees"

    g. p. 103, l. 9-14
    This seems like a good example but the point being made is not made well. Moreover, there needs to be a caveat about the effects of outbreeding depression.

    h. p. 104, overall

    Do we not need an overall conclusion statement about the generalities of exotic species problems????

L. Harris

i. p. 105, l. 12-15.
I conclude that our ability to conduct good ERA's is much more limited by the nonparticipation of good minds, inadequate dollars and motivation, and the fact that they are usually done at too small a scale.

j. p. 105--107
This section on predicting effects of multiple stressors almost immediately falls back to the 'assumption of additivity' and other simplistic examples. I would like to see the cases involving a big system such as the Everglades emphasized, and then describe our inabilities against that light.

Richard Kimerle

Richard Kimerle
Nov. 15, 1995

Premeeting Comments For Workshop On "Draft Ecological Risk Assessment Guidelines"

I. General Comments Reflecting My Initial General Reaction To The Draft Guidelines

A. The Draft Guidelines are an enhancement of the old Framework document addressing many of the deficiencies. It is a real improvement. Everything that has been done and included in the Guidelines is quite good and very difficult to find significant faults. I can see that it will be useful guidance in conducting all stages of an ecological risk assessment helping the risk assessor and manager understand what needs to be considered in an ecological risk assessment and why it is important. However, this draft document, which was stated to "....replace the widely-used Framework Report" still does not adequately address many of the important suggestions made in the past "peer review" meetings over the past couple of years. I would suggest additional consideration of the many excellent comments made at the May 3rd Colloquium, and other meeting like the "Issues Papers Workshop". Several of the common concerns brought up in the May 3rd review have been covered quite well, (i. e. the needed discussion off the risk assessor and manager). Many of the others concerns expressed are mentioned in the new Guidelines but it is as if they were only given "lip-service" to satisfy the participating reviewers by including their points (i. e., tiers and the iterative process are only discussed in a superficial manner; more helpful guidance on probabilistic approaches to risk characterization; non-chemical stressors; and terrestrial environment risk assessments). If some of these issues were handled in a more comprehensive manner it would add to the useful of the guidance. In other words the breadth of coverage is reasonable and could be improved but the depth of coverage in some of the key areas could use significant improvement.

B. The inclusion of the section on "Planning: Discussion Between The Risk Assessor And Risk Manager" provides much needed guidance on this issue that was not adequately addressed in the previous Framework Report. However, the statement that "economic, legal, political, or social implications (I add societal and the concept of availability of resources) of the risk assessment results is beyond the scope of these guidelines" leaves the risk managers and assessors without much needed guidance. I believe that many persons feel that these difficult issues cannot be ignored and must be viewed as part of the total ecological risk process.

C. I think I understand why the EPA has developed these guidelines for almost exclusive use by its internal technically qualified professional risk assessors and managers. However, I wonder if the entire Guideline process and end product would be more valuable if more consideration were given to the needs of other potential users at local, state, regional, international levels and by industries and businesses that must make ecological risk assessment decisions on a regular daily basis? What will be the next step to be taken by the EPA to enhance the benefits of this general ecological risk assessment guidance at the user level, including your own EPA program offices?

D. I was somewhat disappointed because of a lack in details and need for embellishment of many technical guidance points with more specific help in the form of discussion of references or in some cases at least references to turn to for more help. Again this may reflect the stated intent that this document is primarily for use by highly qualified professionals within the EPA. Recognizing that these guidelines will likely be around for numerous years, and we are all going through changes in the way we go about our business, would it not be an opportune time to provide a bit more generic and useful detail than to leave it out and assume that the expertise is available to get the job done right? What will the technology transfer program be to make the Ecologcial Risk Assessment Guidelines as useful as possible to users both within the EPA and in outside industries and businesses?

E. The case history used as examples were very helpful but they seemed a bit superficial and contrived at times in order to satisfy earlier stated needs for including specific items and covering more issues (i.e., stressors other than chemical, non-aquatic examples, use of QSARs, etc.).

F. I liked the use of shadow boxes to emphasize key important points.

G. I did not see a need to change the terminology on measurement and assessment endpoints.

Response To Questions We Were Asked To Address

Part I. General Principles

* How can ERA Guidelines be improved to more clearly indicate assumptions and default positions? The biggest assumption that will detract from the intended success of the Guidelines is that the not enough detail is provided in most of the sections. It is all good guidance but depends very heavily on the expertise involved in carrying out the risk assessment.

* Changes in each section? Look for places where additional details would better assure a quality assessment.

AIHC Perspective On Ecological Risk Assessment Framework And Guideline Development

Presented By Richard Kimerle
American Industrial Health Council ()AIHC)
Ecological Risk Assessment Subcommittee

EPA Public Colloquium On
Ecological Risk Assessment
Guideline Development
May 3, 1995
Alexandria, VA

AIHC Perspective On Ecological Risk Assessment Framework And Guidelines

Slide 1

The American Industrial Health Council (AIHC) thanks the EPA Risk Assessment Forum for this opportunity to speak at this important Colloquium on the Ecological Risk Assessment Framework and Guideline Development process. I am Richard Kimerle from Monsanto Company and am vice chairperson of the Ecological Risk Assessment Subcommittee of AIHC, which is chaired by Dr. Charles Pittinger of Proctor and Gamble. A group of about 10 members of the subcommittee met for a couple of days, reviewed numerous materials on ecological risk assessment, and prepared this presentation.

Slide 2

AIHC welcomes this opportunity to participate with the EPA in these early stages of development of Ecological Risk Assessment (ERA) Guidelines. The industrial segment of the regulated community, as represented through AIHC, is interested in helping to assure that the Guidelines are technically sound as is possible, practical so we can all use them, appropriately protective of our natural ecosystems, and flexible enough to be of value to all users. Although the Guideline process may be just beginning, AIHC is well aware of the excellent progress made over the past couple of years by the Risk Assessment Forum in the development of the Framework, Issue Papers, and Case Histories. The series of "Purple" books have become a standard reference on the desks of ecological risk assessors. We look forward to the next book on Guidelines.

Slide 3

We perceive that there is a clear benefit when governmental regulatory agencies work with industry in a partnership. There are many examples of this type of cooperation producing quality products that are more widely accepted by all the stake holders in regulatory guidance through compliance. I personally have had the privilege participating in many of these joint regulatory programs going back into the 1970s: ie. Algal Assay Procedure (AAP); Acute Toxicity Testing Methods For Invertebrates, Fishes, and Amphibians; developing ASTM consensus methods; Whole Effluent Toxicity (WET) testing; and numerous SETAC Pellston workshops.

Slide 4

We in industry believe we have considerable experience in ecological risk assessment. We would like to maximize the utilization of that expertise in the development of the forthcoming ERA Guidelines. Ecological scientists in most major industries have been practicing ecological risk assessment for many years in guiding internal decisions for product development, manufacturing site emission issues, hazardous waste site assessments and in working with regulatory agencies all over the world. We are prepared right now to commit whatever resources that are necessary to assure that future developments in ERA are as technical should as is possible.

Slides 5

One of the purposes of this Colloquium was to review the appropriateness of the ERA Framework. AIHC considers the Framework to be a sound foundation which can provide a useful and consistent approach for ecological programs across all EPA program and offices and other federal and state agencies needing to address ecological issues. It also provides a useful basis upon which to build future Guidelines. The technical components of problem formulation, characterization of exposure and effects, and then ecological risk characterization, when properly used, are a proven useful tool for judging ecological risks.

Slide 6

However, AIHC believes that the overall usefulness of future ERA guidelines will be improved by implementing several changes in the Framework and suggested recommendations for ERA guideline development:

1. Provide additional guidance on the nature of the policy issues that need to be dealt with in the initial and final discussions between the risk assessors and risk managers. To date, the EPA has appeared to focus its attention on technical issues inside the technical boundaries of risk assessment. This simply does not meet the needs of society, the regulated community, or "Mother Nature" herself.
2. There needs to be a clearer incorporation of the concept of "tiers" in the Framework. We can not afford to collect all the data we would all like to have before making a risk management decision. We must learn to rely not upon the size of the data base but on the margin of safety between exposure and effects concentrations. We need a stronger foundation on the use of an iterative process that would assist us in collecting only the data needed to resolve the adequacy of the margin of safety.
3. Address several technical and programmatic issues.

Slide 7 & 8

The usefulness of the Framework itself, and future ERA Guidelines, will be enhanced if more guidance is provided on what policy issues need to be discussed before and after conducting the technical part of an ecological risk assessment. Initial planning discussions need to consider the following points in Problem Formulation:

I. Policy Considerations.
    - Existing laws and regulations.
    - International implications.
    - Corporate Stewardship policies.
    - Societal values and concerns.

II. Scaling the risk assessment problem.
    - Valuation of the ecosystem at risk.
    - Protection of which species and to what extent.
    - The magnitude, duration, and scale of risk.
    - Balance in consideration of negative impacts and benefits.

III. Constraints.
What is a reasonable amount of money to spend?
How much of our private and public personnel resources should be used?
What are the timing and duration consideration?

During and after risk characterization, risk assessors and managers need to discuss risk policy issues. Some of the points that need to be considered in the Frame work include the following:

I. Was the right problem worked on or should the problem be re-formulated?
II. Was the characterization adequate to achieve the goal of the assessment?
III. Is there a need to conduct another "tier" of data collection and risk characterization in order to better resolve technical issues in the risk assessment?
IV. Does the risk assessment meet the need of the risk manager?
V. Before making the final risk decision are then any constraints, values, or policies that should be considered?

Slide 9 & 10

Special consideration should be given by the Risk Assessment Forum to alter the Framework document, and also include in the Guidelines, more explicit information on the use of "tiers". There are numerous technical issues which should be part of educating the ERA assessors and managers on potential components of data collected in the tiers from the more simple to complex studies on exposure and effects. Topics include: use of QSARs; role of single species tests; modeling to measuring to monitoring; role of micro and mesocosms; primary, secondary, and tertiary effects; and field ecosystem studies. Guidance is also needed on when the existing exposure and effects data bases are inadequate to make a risk decision, that is the pass-fail-need more data criteria. Their needs to be an explanation on the role of assessment factors in transposing data from simplifying assumptions of early tiers to assessment endpoints desired in advanced tiers. Dealing with the uncertainty is of paramount importance. For risk characterization there is a need to balance the appropriate use of the more simplistic quotient approach with the growing field of probabilistic risk assessment. The latter offers more opportunities for making risk management decisions.

Slide 11

There are a number of technical and programmatic issues that if addressed now, will enhance the effectiveness of the Guidelines and risk assessment process in the future. In the Problem Formulation phase, it is exceedingly important to fully understand the ecological significance of the stressors so that risk assessors and managers focus on developing the right conceptual model and attainable goals. Uncertainty is one of the major technical challenges that must be dealt with more effectively than it has to date. Too often, ecological scientists are viewed as not being able to deal with all the uncertainties of their "complex" ecosystems. We need a system that supports understanding, communicating, and managing data uncertain. This will prevent "uncertainty" from becoming the driving force that leads risk assessors and managers on useless and costly "witch hunts". An emphasis has traditionally be placed on chemical stressors and point source discharges and thus many of the "tools" of ecological risk assessment don't adequately address the non-chemical and nonpoint source stressors. Through the forth coming process to develop ERA Guidelines an opportunity exist to correct this situation. Consistency or harmonization of the ERA methods within the EPA, across governmental agencies, and at the international level is a recognized need. In order for this to occur there needs to be opportunities for multi-stakeholder involvement in the Guideline development process and in the peer review on an ongoing basis. Ultimate acceptance and widespread use of the ERA Guidelines will be assured if they are technically sound, practical, flexible, and have been communicated in a specifically planned technology transfer program.

Slide 12

Many of the principles and concepts of the Ecological Risk Assessment Framework are contained in EPA's Framework publication Figure 1 page 4 (EPA 1992). The AIHC has modified this figure to present some of their ideas for improvement. First, the flow as depicted by the arrows has been altered significantly reflecting what we perceive as a significant philosophical change. First there is no separation by a heavy line of technical ecological risk assessment issues from initial or final policy issues. Starting with the initial planning discussion between the risk assessor and manager, in which policy issues are more comprehensive and spelled out, there is a one way flow of information into the Problem Formulation Phase, down into the Analysis Phase and into Risk Characterization. After Risk Characterization, the risk assessor and risk manager review the results. They can either decide to make a "final" risk management decision or decide that there needs to be an iteration back to Problem Formulation or collection of additional exposure and/or effects data. Results from this iteration are once again considered after Risk Characterization in a second discussion between the risk assessor and manager. They can once again decide to iterate back up for more information or make a "final" risk management decision. Notice that there are no back and forth arrows. Instead, arrows better reflect the iterative process, going in one direction, through tiers of data collection after discussions between the assessor and manager. This modified figure more accurately reflects state-of-the-science practices.

Slide 13

The AIHC Ecological Risk Assessment Subcommittee feels confident that the window of opportunity exist now to develop ecological risk assessment Guidelines that will be scientifically sound, practical, and prove very useful under a wide variety of program needs. We are committed to making the expertise of AIHC member companies available to the EPA to assist in whatever manner would be most appropriate to attain our mutual goal.

AIHC Perspective On Ecological Risk Assessment Framework And Guidelines

EPA Public Colloquium On Ecological Risk Assessment Guideline Development

May 3, 1995

Alexandria, VA

American Industrial Health Council
AIHC
Ecological Risk Assessment Subcommittee

AIHC Welcomes This Opportunity To Participate In And Contribute To EPA's Ecological Risk Assessment Guideline Development Process.

- Mutual Goal Is Technically Sound, Practical, Protective And Flexible ERA Guidelines
- AIHC Applauds The Accomplishments Of The Risk Assessment Forum To Date - Framework, Issue Papers, Case Histories
- Early Involvement And Partnerships Are Productive And Useful

Clear Benefits Exist When Industry And Government Regulatory Agencies Work Together.

- Algal Assay Procedure
- Acute Toxicity Testing Methods
- ASTM
- SETAC
- Pellston Workshops

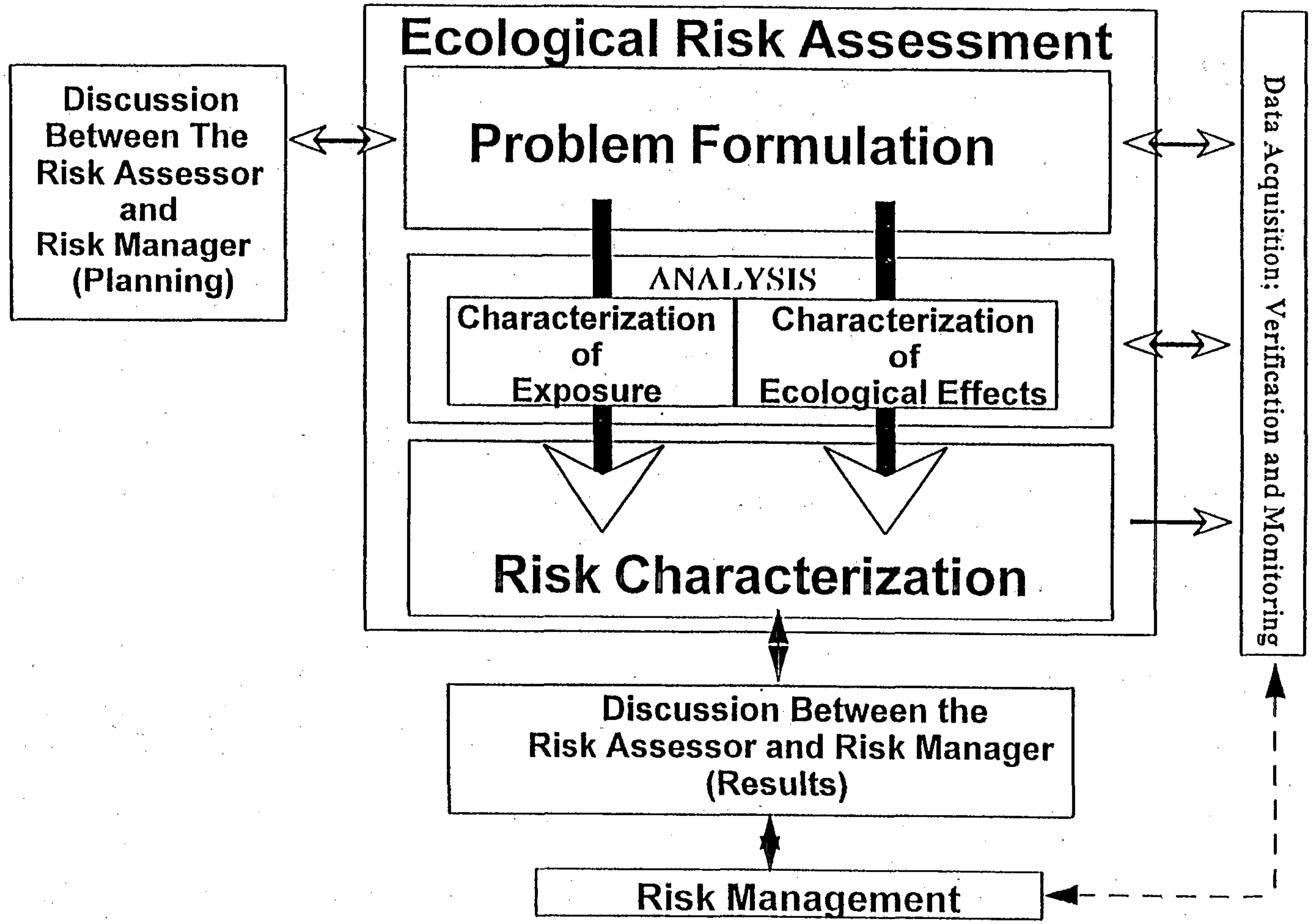
Industry Has Much To Offer To Ecological Risk Assessment.

- Corporate Commitments And Actions To Environmental Stewardship
- Many Years Experience In Using ERA
- Interface Routinely With Regulatory Agencies, Programs, And Countries
- Commitment Of Resources -Time, Money And Personnel
- Source Of Useful And Relevant Data

Regulatory Impact of Ecological Risk Assessment Guidelines Is Important To Industry.

- Cuts Across All Regulations
- Often Becomes Enforceable In Regulations And Standards
- Impacts Competitiveness At National And International Level
- Affects Allocation Of Resources

EPA's Ecological Risk Assessment Framework Is A Sound Foundation On Which To Build Guidelines That Will Be Used By Regulators As Well As Regulated Community.



AIHC Believes That The Overall Usefulness Of Guidelines Will Be Improved By Implementing The Following Framework Changes And Recommendations For Guideline Development.

- Provide Additional Guidance On The Nature Of The Policy Issues - Discussion Between Risk Assessors And Managers.
- Incorporate Tiers Of Data Acquisition In An Iterative Process.
- Address Several Technical And Programmatic Issues.

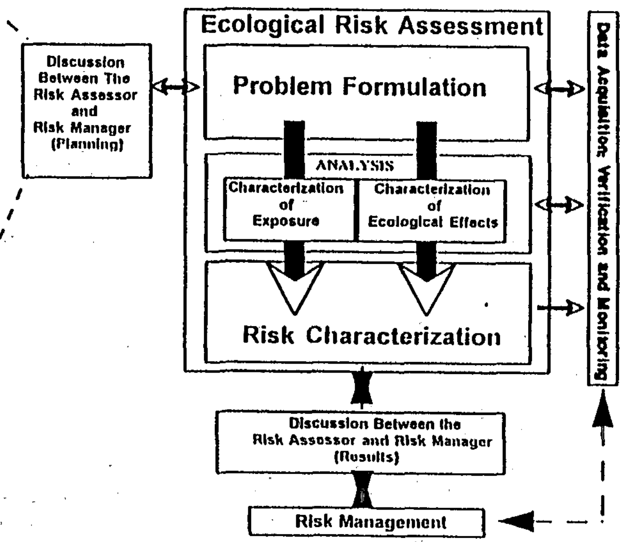
What Policy Issues Should Be Discussed By Risk Assessors And Risk Managers Before Starting The Risk Assessment Process?

Planning Discussion Between Risk Assessors and Managers On Related Policy Issues

I. Policy Considerations
- Laws / Regulations
- Corporate Stewardship Policy
- Societal Concerns
- Environmental Justice

II. Scaling The Risk Assessment Problem
- Valuation Of Ecosystem At Risk
- Protect Which Species And To What Extent
- Magnitude And Scale Of Risk
- Benefits Of Technology

III. Constraints
- How Much Money Is Reasonable
- Timing / Duration
- Personnel / Resources - Private And Public



What Policy Issues Should Be Discussed By Risk Assessors And Risk Managers During And After Completing The Risk Characterization Process?

Discussion On Assessment And Policy Issues During Or At Completion Of Risk Assessment

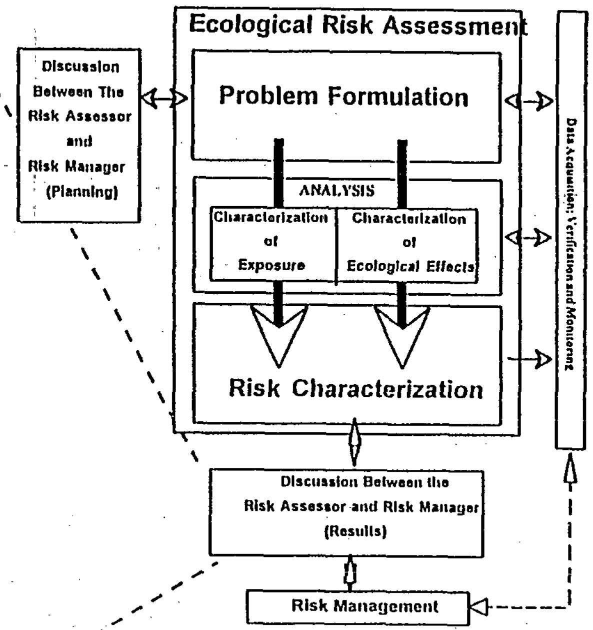
Was It The Right Problem?

Was The Problem Adequately Characterized?

Is There A Need To Conduct Another Tier To Better Resolve Technical Issues In Risk Assessment?

Does Risk Assessment Meet The Need Of The Risk Manager?

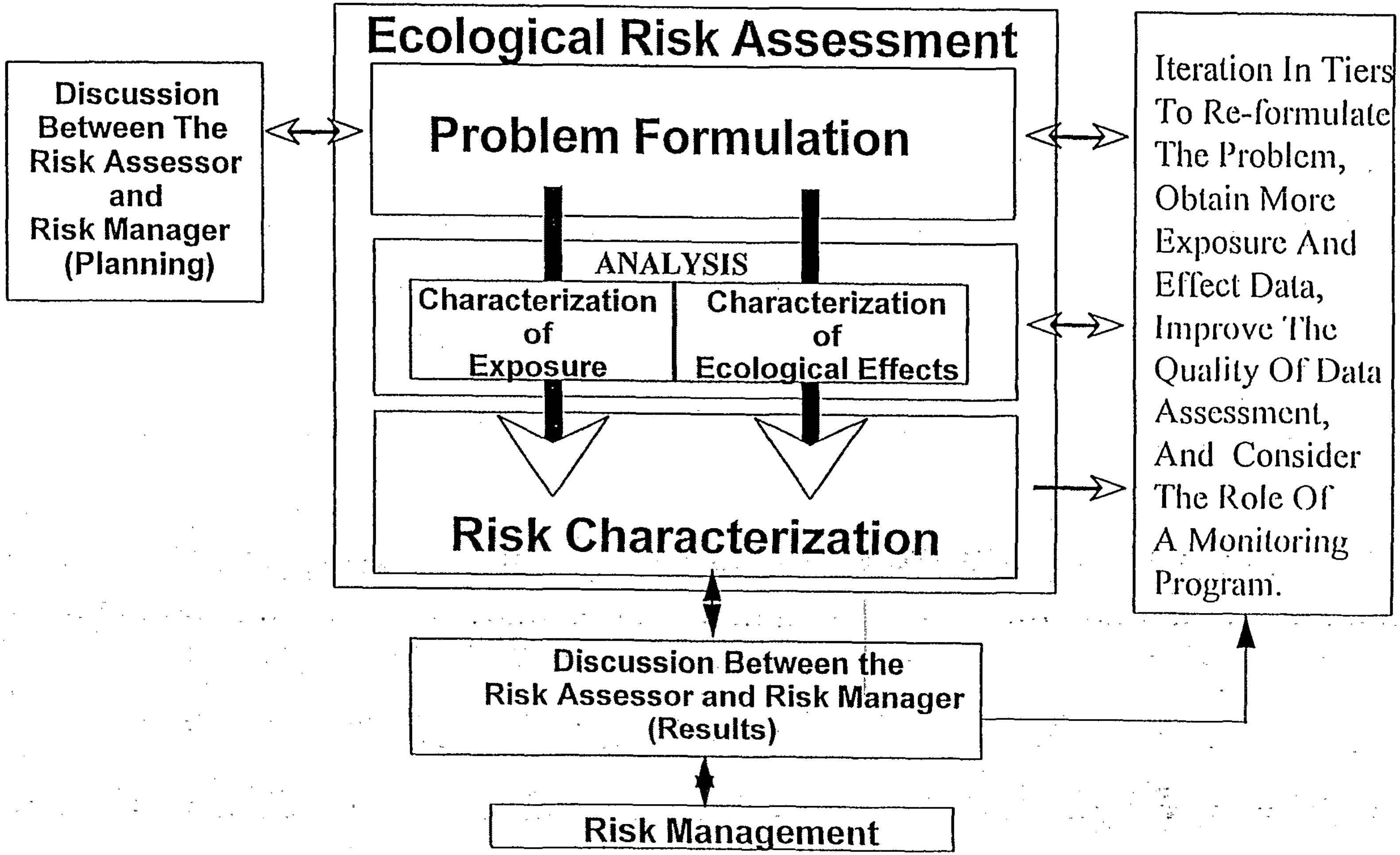
What Constraints / Values / Policies Influence Risk Manager Decision?



Guidelines Should Recommend A Tiered Approach To Data Acquisition For Exposure And Effects Assessment And Rely On Risk-Based Decisions.

- Simple To Complex (Exposure And Effects)
  - QSAR
  - Single Species Tests
  - Modeling To Measuring To Monitoring
  - Micro / Mesocosms
  - Primary, Secondary, Tertiary Effects
  - Field Ecosystems
- Clear "Pass / Fail / More Data" Criteria
  - Assessment Factors Are Useful
  - Quotient Approach Valuable
  - Probabilistic Easier To Make Choices
- Risk Assessor / Manager Discussion Provides Direction
- Increased Efficiency And Quality Decisions

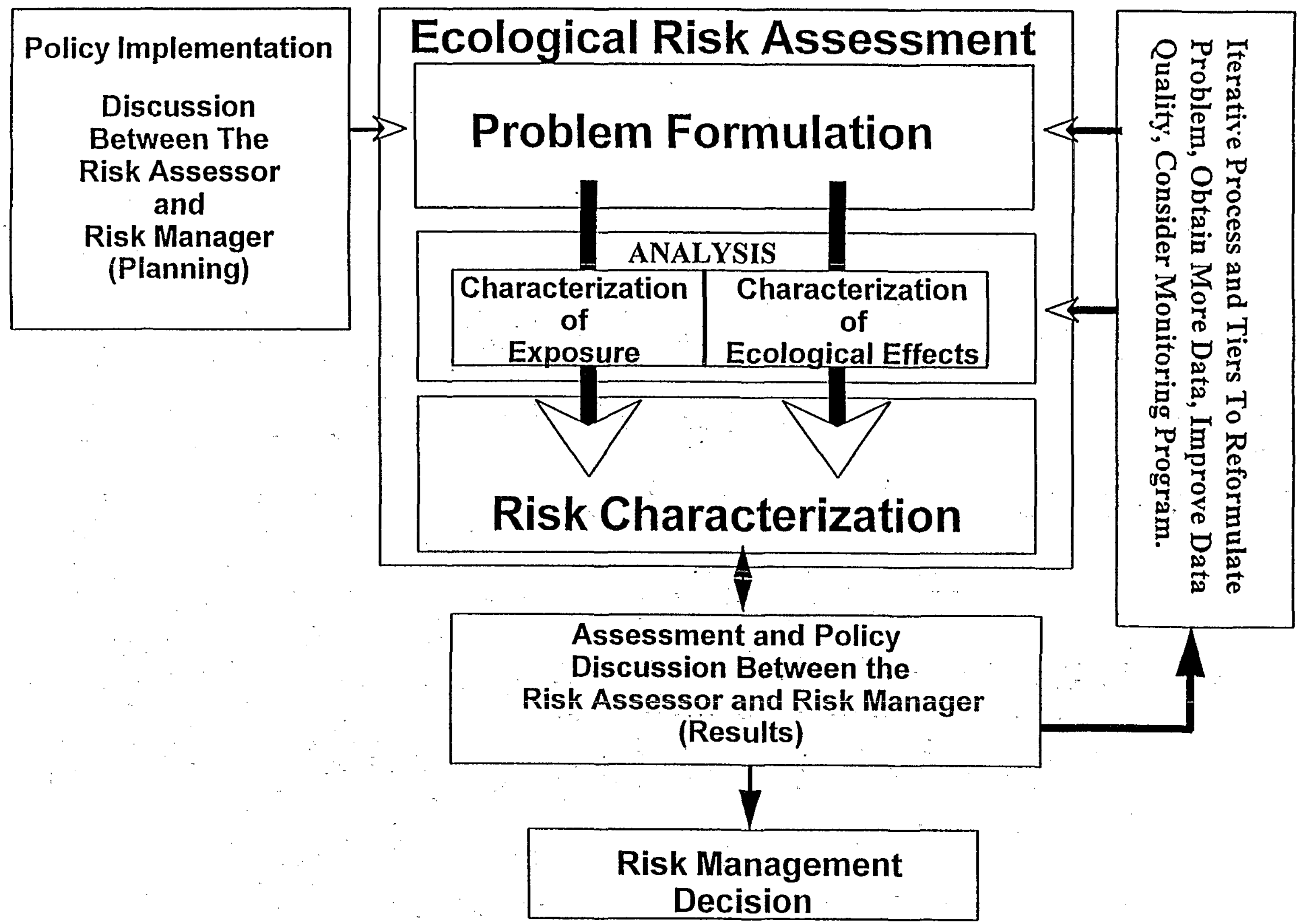
After The Risk Characterization Step, The Risk Assessor And Risk Manager Need To Determine If Additional Work Is Needed: Use An Iterative Process And Tiers.



Consideration Of Certain Technical And Programmatic Issues Will Enhance The Effectiveness Of Ecological Risk Assessments In The Future.

- Ecological Significance / Conceptual Models Need Clear Goals
- Uncertainty Needs To Be Described
  - Transparency
  - Assumptions
  - Defaults
- Inclusion Of More Probabilistic Assessments When Needed
- More Attention To Physical And Biological Stressors
- Opportunity For Flexibility, Site Specificity, Mitigation
- Consistency / Harmonization Needed
  - Within EPA
  - Across Agencies
  - Internationally
- Communication / Technology Transfer On Guidelines
- Opportunities For Peer Review

AIHC's Suggested Framework Changes For Use In Guideline Development.



AIHC Feels Confident That An Opportunity Exists To Develop Ecological Risk Assessment Guidelines That Will Be Scientifically Sound, Practical, And Will Prove To Be Useful For Many Years To Come.

Timothy Kubiak

Timothy Kubiak

PREWORKSHOP COMMENTS

EPAs DRAFT ECOLOGICAL RISK ASSESSMENT GUIDELINES

On a general first read, I was impressed with the overall content, scope and organization of the draft ecological risk assessment guidelines (guidelines). As someone who has been involved with articulating risks and effects of multiple limiting factors on our natural resources as well as recognizing the difficulty thereof, I commend the authors and cooperators for the effort that has been expended to date and the overall result of containing the potential to write more than can be absorbed by practicing risk assessors in their daily duties. The complicated workings of natural systems, species associations and their relationships to various limiting factors will always be difficult because our scientific knowledge is imperfect and the process of modeling risk and documenting effects (given this lack of knowledge and properly described as uncertainty in these guidelines) is sobering to all professionals tackling such endeavors. Regardless, the structure is well-developed. What is needed is a further iteration of examples and qualifications of the textual presentation so as to begin to operationalize the paradigm without compromising flexibility and innovative thought by those participating in such activities. I would hope that EPA will endeavor to update these guidelines at frequent intervels once a decision is made to finalize initial deployment.

Questions 2 & 3: A schedule for extensive use of technical guidance documents to allow for communication across the scientific community that will reduce uncertainty to the use of the process and promote new and better ways of articulating risk as well as documenting causality with the weight of evidence approach.

Question 8: The introduction needs to stress the need for risk assessors and managers to take a multidisciplinary approach to the risk assessment process. The nature of the environmental sciences today requires the use of many discreet, but related, disciplines. Risk assessors and managers need to make a conscious effort to facilitate acquisition of the needed talent and assure that the process is supported by the expertise that is needed to drive a credible, timely and scientifically defensible process.

Question 9: The risk assessment guidelines do include the process of using cause -effect epidemiological criteria but the guidelines do a relatively poor job of providing guidance on how they are to be used and factored into the decision-making process. The question that needs to be answered for use of this information once it is generated is: What do I as a risk manager/assessor have to ignore as scientific understanding of cause-effect information and what remains uncertain with regard to the understanding of risk and as well as cause-effect? These questions are most important when undertaking a retrospective assessment of existing problems, but many of EPAs actions, within its varied programs, deal with these problems.

There is a need for the manager and assessor to have a visible reminder to acknowledge the bidirectional feedback loop from operational risk assessment and the research needs and research input into the process. The diagrams could be improved by having a double pointed arrow between research and the risk assessment process. Language should be added that uncertainty and the resulting needed research should not be used as a shield to make informed management decisions given that there is always going to be some degree of uncertainty. Further, the risk manager needs to be informed by operational specialists of the need to identify secondary management actions or issues that come about because of the initial risk management decision. For instance, not fully remediating a degraded aquatic resource to "criteria or standards" may result in the secondary decision to propose and adopt temporary variances and/or losses of a beneficial use. Intragency action is clearly the intent of the guidelines but these decisions can have effects on other agencies and related statutory responsibilities. There are not many "actions" for which there are not "reactions". There is a need to fully define the scope of the risk management decision that very often goes beyond the immediate primary decision.

Question 10: Categorization of the types of assessments is valid. It would be my wish to have sufficient guidance developed for/by EPA programs that routine use of the process is not held hostage by lack of technical support guidance.

Question 13: I believe EPA needs to consider a more important issue relative to stressors as a definition and relative to adverse effects assessment. Consider using Liebigs Law of the Minimum as the overarching synonym for stressor. This law states that if all but one of the substances necessary for growth of a plant are present in appropriate concentrations, the inadequacy of the one that has too low a concentration will prevent growth. This law can be used to address excessive concentrations as well. Indeed, the law is the basis for all stressors identified in the guidelines and regardless of whether the limiting factor exposure is negative or positive. Two things are important here, 1). the identification of limiting factors relative to management issue and 2). appropriate rank-ordering of the major limiting factors (chemical, biological or physical) for effective management actions to be undertaken, if action is the selected option.

EPA also needs to more fully discuss the interrelationships among and between stressors/limiting factors. For instance, if a chemical insult is remediated absent the knowledge that the habitat is physically or biologically incapable of providing for minimum sustainability for restoring a target species, both limiting factors would have to be addressed and acted upon for management actions to succeed. Many wildlife disease outbreaks are mediated by host organisms, some dead, that are caused by physical and biological inteactions. Chemically- induced immune suppression which leads to disease is also a well established risk although less is known about actual cause and effect.

Page 86 of the guidelines concludes the brief discussion of causality. This discussion is particulary weak and contains no citations from which the authors can draw examples of the cause-effects linkage process which shows how the analysis of these criteria is performed. Examples are the two cause-effects linkages meetings on Great Lakes contaminants effects and resulting analyses that are published in the full volume of the Journal of Toxicology and Environmental Health (Vol.33, No 4, 1991) and the partial volume of the Journal of Great Lakes Research (Vol 19, No. 9, 1993). Since the discussion ends on the issue of importance of causality in retropsective analyses, it would seem prudent to include these references since they collectively depict a range of "certainty" with respect to causality and would serve to provide the background for seeing how difficult generation and assessment of causality information really is. This should not be viewed as diminishing the need for inclusion of this concept into the guidelines, but rather to help focus attention on the difficulty as well as the utility of assessing and demonstrating causality to various degrees.

Lyman McDonald

Review of

DRAFT PROPOSED GUIDELINES
FOR
ECOLOGICAL RISK ASSESSMENT

Prepared for the
Risk Assessment Forum
U.S. Environmental Protection Agency
Washington, DC

by

Lyman L. McDonald
WEST, Inc.
Cheyenne, Wyoming
November 14, 1995

PART I. GENERAL PRINCIPLES

- How can the ecological risk assessment guidelines be improved to more clearly indicate underlying assumptions and default positions?
  - I recommend that a distinction be made between evaluation of risk of a present stressor(s) (e.g., the Baird & McGuire Superfund Site) and the risk of a future stressor (e.g., the New Chemical case study). The evaluation of risk of present stressor(s) allows study designs and data collection similar to those used in "impact evaluation" due to the release of hazardous substances under the Comprehensive Environmental Response, Compensation and Liability Act. The U.S. Department of the Interior has promulgated regulations for the performance of natural resource damage assessments and those regulations should be referenced in this document on risk assessment.
- A discussion should be given of the value of monitoring after risk assessment and risk management decisions are made.
  - Monitoring for occurrence of ecological effects provides a reality check on the predictive capability of risk assessment. For example, if the levee is constructed in the Bottomland Forest Wetland case study, are the predictions of loss of wildlife values realized. Are there fewer birds being killed by insecticides now that carbofuran is not being used?
  - Monitoring allows for development of data bases which will be of value should reanalysis of risk assessment be necessary.

Lyman L. McDonald, 14 November 1995

PART II. SPECIFIC QUESTIONS

Guidelines Balance

2.
- I found the case studies to be very useful and recommend that they be included in the Introduction Section. At least, the Foreword and Executive Summary should include a recommendation that the appendix containing the case studies be read first if the reader is not familiar with the jargon of the text.
- Specific comments
    - Clarify differences between "assessment endpoints" and "measurement endpoints"; if there are any, in lines 25-4, pages 11-12. Indicate which endpoints are in each category in the case studies if appropriate. See lines 22-26, p. A-9.
    - Re-emphasize in the case studies that choice of a model is itself a subjective (qualitative) decision and quantitative results depend on the professional judgement that the model is appropriate. In particular, see lines 12-16, page A-5.
    - Stress future monitoring of ecological effects of management decisions as a means of advancing predictive ability of risk assessment.
    - In the carbofuran case study, Ecological Effects and Endpoint Selection (lines 17-22, p. A-6) emphasize the population level ecological effects on birds. Later in the case study, population level effects seem to be the target, not the death of individual animals. Include discussion of uncertainties associated with population level effects (lines 25-30, p. A-7).
    - Give a map or figure showing the location of Waquoit Bay (p. A-17).
    - Eliminate most of the acronyms in case studies, particularly in the New Chemical case study. There are 20 acronyms on p. A-16.
    - The New Chemical case study is understandable on pages A-16 to A-18, but is not presented very well in the text of Section 4, The Analysis Phase.

4. Guidance on uncertainty issues?

- Some additional work is necessary to clarify the relationships of "statistical inferences" and "uncertainty" as used in this guidance document.
  - Statistical inference; for example, in the form of a confidence interval on a ratio or EC_{50}, is one of the sources of uncertainty.
  - Statistical inferences are to the experimental protocol or to a study area (with data collected by a specific protocol).
  - Uncertainty in risk assessment includes questions concerning whether the experimental protocol or data from a study area are appropriate for evaluating risk in the situation under investigation.
  - Statistical inferences; with the associated uncertainty concerning applicability of the protocols, are but one source of information for further deductive professional judgements in risk assessment. Final risk characterization will always be deductive, regardless of statistical inferences or model predictions.
  - I recommend that the sections which mention statistical tests of hypothesis and power analysis be rewritten to emphasize use of confidence intervals for summary of statistical inferences. Present the inference in the form of a confidence interval when possible. Most of the problems associated with misuse of statistical inferences go away.

5. Modification of the Introduction?

- Move the case studies to the introduction.

6. Terminology?

- Expand section 1.6. Definitions and terminology.
  - Emphasize the definitions in section 1.6.1. as was done in section 1.6.2. For example, ecological risk assessment in line 5, p. 11, should be in a bullet. Also, retrospective risk assessments, assessment endpoints, measurement endpoints, etc. should be in separate bullets (Lines 10-16, p. 35 should be repeated with the definition of assessment endpoints).....etc.....risk characterization, risk estimation, risk description, conceptual model, transparency of the risk assessment, Ecologically relevant endpoints, exposure profiles, stressor-response profiles, group boundaries, outer boundary, effects characterization, intensity of stressor, synoptic index, ...

- My copy does not have Appendix B - Key Terms, but there are many terms which need definitions. For example: variability should be contrasted to uncertainty in a statistical inference,
- Some words are not in my pocket Webster's dictionary. For example, connotes and delphic (lines 21-22, p. 13), overarching (line 3, p. 29), and colocated (line 9, p. A-19). Try to simplify the text when possible.

8. Risk manager's role?

- If possible, a member of the risk manager's staff should be on the risk assessment team.

Problem Formulation

11. Your intent with "assessment endpoints" and "measures" was not clear to me on first reading and I may not understand now. I suggest that the case studies be rewritten to separate the assessment endpoints from the measures under different bullets. In the Bottomland Forest Wetlands case study, assessment endpoints included forest community structure and habitat value to wildlife as measured by the HSI and FORFLO modes. Measures included tree species present, abundance, canopy cover, ...?

12. Risk hypotheses and conceptual models?

- Rewrite the case studies to include the risk hypotheses and conceptual models. The carbofuran, importation of logs, New Chemical, and Baird & McGuire Superfund case studies do not appear to mention risk hypotheses or conceptual models in separate bullets. Risk hypotheses were implied in the Waquoit Bay case study, but none were given.

Analysis

13. Changes to the Analysis section?

- First, the section does not flow well with the preceding and following sections. Terminology is not always consistent and it appears that the section may have been written by a different team without sufficient editing to tie the sections together. For example, in lines 9-10, p. 63, should the terms "assessment endpoint" and "measures" be used rather than "attribute of interest" and "attribute being investigated"?
- The New Chemical case study is not effectively introduced and appeared naive on first reading until I reread it in the Appendix.
- There are entirely too many acronyms in this section.

- Are secondary stressors "stressors" or "assessment endpoints"? It seems that they could be both and maybe this point should be addressed in the definitions section.
- The concept of measurement error presented on line 3, second sentence, p. 63, is incorrect. Measurement error is the difference between the measured value of a variable on an experimental or sampling unit and the "true value".
    - Repeated measured values of a variable on the same experimental unit will not necessarily give the same "true value", but rather a distribution of values. The characteristic of interest is not changing on the unit during measurement (it is not random).
    - To clarify the situation, I suggest introduction of the terms "experimental unit" and "sampling unit". For example, the sampling unit may be a liter of sediment from a point in a wetland. Variation from point to point in the wetland is sampling variability. The liter has a true value for, say lead; but, no matter now ones tries, the liter can not be homogenized to the point that repeated measurements of lead on the liter of sediment will be exactly the same. This is measurement error on the sampling unit.
- Some general rewriting seems to be necessary. For example, what are "Mismatches between hypotheses...." (line 17, p. 63), and "...Canonical or reference environment...." (line 19, p. 68).
- In general, I liked the candor of this section. However, some editing and rewriting seems to be necessary.

15. The discussion of multiple stressors would be improved with inclusion of a case study. The Waquoit Bay Estuary case study may be appropriate.

Specific comments

- Lines 29-8, pp. 3-4. These seem to be objectives of risk assessment, not necessarily results of risk assessment.
- Section 1.6, p. 11. Include examples from the case studies.
- Line 10, p. 19. What are "values"?
- Be consistent with terminology. For example, in Box 2-4, p. 22, areal extent and patch size of eel grass beds might be described as assessment endpoints.
- Lines 4-6, p. 30. Unclear to me.
- Section 3.4.2. Some assessment endpoints are inherently less variable than others.

- Box 3-10, p. 42. Where is the turkey and deer example?
- Line 8, p. 44. I have used the term "testable hypotheses" rather than "risk hypotheses" in my past writing. To me, "testable hypotheses" is more intuitive.
- Figure 4-5, p. 72. I missed the point of the figure.
- Pp. 78-79. The discussion of the statistical methods would benefit with illustrations from the case studies.
- lines 17-19, p. 85. Rewrite. Specifically, the sentence starting in line 17 is misleading. I suggest "Effects deemed significant at the 0.05 level have a 5% chance of a false positive (Type II error) under the null hypothesis that there is no effect". As I indicated above, I suggest rewriting the entire document with respect to hypothesis testing; replacing results of hypothesis testing with confidence intervals (when possible).
- Line 9, p. 94. Mention identification of assessment endpoints and measurement endpoints.
- Box 4-19, p. 109. One major problem with indices not mentioned is that they do not keep up with technology very well. An index is sensitive to the methods for collecting data and when new data collection methods come along, it is extremely difficult to compare an old index with new assessment endpoints or better measurement endpoints.
- line 25, p. 111. Emphasize the goal.
- Lines 7-16, p. 117. This section seems to be out of place.
- Lines 28-31, p. 117, and lines 17-30, p. 122. Again, confidence intervals on endpoints is a better approach than testing of hypotheses.
- Lines 25-27, p. 118. Unclear to me.
- Line 7, p. 127. Transparency? Rearrange with lines 25-30.

Dwayne Moore

Dwayne Moore

Comments on EPA's Ecological Risk Assessment Guidelines

In my opinion, the guidelines are concise, well written and helpful to ecological risk assessment (ERA) practitioners both within the US EPA and elsewhere. The careful and logical process begun several years ago by the US EPA Risk Assessment Forum (workshops, framework report, issue papers, case studies, etc) has obviously been successful and is a model for others to follow.

Before addressing the questions raised in the *Charge to Reviewers*, I offer the following comments that apply to the entire document.

(1) For a draft document, I was pleasantly surprised to find relatively few spelling or grammatical errors. Further, all but two of the references cited in the text were included in the references section.

(2) Most of the important contributions to the science of ERA by European scientists have been ignored (or at least uncited). This is a serious oversight, particularly given the many advances that have taken place in the Netherlands in assessments of chemical stressors. For an overview of this work, I suggest the recently published *Risk Assessment of Chemicals: An Introduction* edited by Cees van Leeuwen and Joop Hermens and published by Kluwer Academic Publishers. In retrospect, it would probably have been a good idea to have had several European scientists review the guidelines.

General Principles

(1) In general, I agree with the scope of the guidelines (*i.e.*, not program-specific guidance, not a text book). The guidelines, however, could be improved by specifying default positions on difficult topic areas. Many times in the guidelines, issues were raised, briefly discussed and then left hanging. For example, the guidelines correctly note that the use of hypothesis testing to determine NOELs and LOELs in toxicity testing has been much criticized recently. The alternative approach (regression analysis) is, however, inadequately described. What are the

recommended underlying models (*e.g.*, probit, logistic, Weibull, etc)? How low can the "x" in the EC_x be before model dependence becomes a problem? When is it appropriate to use hypothesis testing? When is it appropriate to use regression analysis? More discussion and recommendations could also have been provided for other difficult issues (*e.g.*, when and how to do quantitative uncertainty analysis, recommended methods for characterizing sources and releases, deriving uncertainty factors using empirical methods, recommendations on the use of multivariate statistical techniques). If the guidelines are not program-specific, not a textbook and rarely make recommendations on important issues, then I am unclear as to how they differ from the framework report.

(2) In general, I liked the layout of the chapters, particularly the inclusion of text boxes and figures to describe case studies. I would suggest, however, that figure titles be more complete in order that readers can fully grasp what is being shown.

Guidelines Balance

(1) In general, I believe that the guidelines are balanced with regard to range of stressors, ecosystem types and spatial/temporal scales. Assessing effects at the community and ecosystem levels of organization was not discussed as much as lower level effects, but this is probably more a reflection of the state of the science, than author bias. I also found that the discussion of physical stressors in chapter 4 to be somewhat superficial and so general that little was gained over the preceding discussion of chemical stressors.

(2) The case studies in Appendix A are useful, particularly in giving readers an idea of the breadth of problems currently being addressed by ERA. The case studies would be even more useful if they had more detail to help readers understand why certain decisions were taken, to illustrate complex issues, and to show how the results were used in decision-making. Although I am somewhat biased on the issue, I found it rather surprising that not one of the case studies included a quantitative uncertainty analysis.

(3) The Superfund and carbofuran case studies are examples of terrestrial

assessments that incorporated field approaches in estimating risk. These case studies should be expanded to illustrate how the field approaches were used in estimating risk to the wildlife receptors.

(4) The discussion of uncertainty in various places throughout the document was useful to a point and certaintly highlighted the importance of the issue to readers. Where the discussion came up short, however, was the failure to describe and illustrate specific methods for quantifying uncertainty (*e.g.*, Monte Carlo simulation, Bayesian methods, fuzzy arithmetic, etc). Even semi-quantitative approaches for dealing with uncertainty (application factors, empirically-derived uncertainty factors) were only briefly described with little guidance provided to readers. Qualitatively describing uncertainty is a very useful exercise (as shown in the case studies), but this is really only a preliminary step in many ERAs. The state of the art in higher tier assessments is to quantify uncertainty.

Introduction and Scope

(5) I found that this chapter was well written and clear. Perhaps the discussion of uncertainty under ERA "principles" is better placed elsewhere since it is not principles that are being described here. Also, I would have finished the chapter with a brief description of what follows, rather than finishing on a very small issue (definition of stress regime). These are, however, minor comments.

(6) Key terms were well defined in chapter 1 and in Appendix B and I really have no major difficulties with any of the definitions provided. Perhaps, my only suggestion would be to change "measure of effect" back to "measurement endpoint" since the latter is now well understood, and has found its way into several key textbooks (*e.g.*, Suter, Landis and Yu). Our guidance document for assessments of priority substances in Canada also uses the term "measurement endpoint". There was also a tendency in places in the document to use several terms where only one was required (*e.g.*, ecological entity, assessment endpoint, ecological resource, endpoint response, receptors, etc in chapter 3).

(7) I like the ERA framework as it now stands. I would suggest only two minor

modifications. The discussion between the assessor and manager during problem formulation should be: (i) expanded to include other interested parties or stakeholders, and (ii) continued throughout the analysis and risk characterization phases.

Editorial and Other Comments on Chapter 1

p1, line 3	"draft" and "proposed" are redundant
Text Box 1-1	title for case study a-2 is awkward
p3, line 29	sentence is wordy and awkward
p4, line 1	this point does not state how the evaluation of uncertainties is linked to decision-making (see bottom of page 3)
p4, line 7	see preceding comment
p4, line 9	I don't see how the second sentence is implied from the first
p4, line 11	good point
Figure 1-2	label successive tiers; no need for 3D arrows
Figure 1-3	why is risk communication not included in the framework?
p10	avoid writing in the second person
p10, line 22	sentence is awkward
p13, line 4	delete "for" from "useful for in"
p13, line 22	define "delphic approaches"
p15, line 31	replace "agent" with "stressor" as per box 1-5

Risk Manager Interactions

(8) Chapter 2 provided a useful description of the risk manager's role in the initiation of the ERA and setting appropriate management objectives. However, since many assessments (particularly value-based assessments) involve community groups, industries and other governments, it would be useful to describe how these and other interested parties should be involved in the process. Text box 2-2 provides useful questions to be addressed by risk managers and assessors. A somewhat related set of questions was listed in an editorial by Greg Biddinger and myself that will be published in the December, 1995 issue of *Environmental Toxicology and Chemistry*. These questions are listed below, not because they

are any better, but for comparison purposes:

- What management decision will the risk assessment support (*e.g.*, permit decision, decision to approve a new chemical, cleanup level for a contaminated site)?
- What are the time constraints on performing the risk assessment?
- What is the budget for the risk assessment, including the collection and generation of additional data and/or modeling?
- How many assessments will be made? Will more than one alternative be examined?
- What is the maximum level of uncertainty that will still allow for a decision to be made?
- What are the reference conditions against which poosible adverse effects will be compared?

These questions require numerous iterations before satisfactory answers are obtained. Further dialogue involving stakeholders will lend credibility to the assessment process in the eyes of industry, academia and the general public.

(9) The discussion of how ecological information may be related to risk management decisions was useful as far as it went. However, more information could have been provided on how to communicate risk to different audiences (many articles have been published in *Risk Analysis* in recent years on this subject; also see Morgan *et al.* (1992) *ES&T* 26: 2048-2056). Further, it would have been useful to describe how ERA may be used to evaluate alternative risk mitigation strategies once a problem has been identified, and how decision analytic tools may be used for optimal decision making (see, for example, papers by Finkel [1994] in *Risk Analysis* 14: 751-761, and Frederick and Peterman [1995] in *Canadian Journal of Fisheries and Aquatic Sciences* 52: 291-306).

Editorial and Other Comments on Chapters 2 and 6

p19, line 25 — first sentence should read "Management goals <u>help to</u> define the ecological values to be protected" since assessors are also key in identifying such values

Text box 2-2 — "How likely will recovery occur?" is poorly worded (suggest "How likely is

	recovery?") and also very difficult to answer prior to problem formulation
Text box 2-2	suggest adding "lack of appropriate methods and/or data" as potential constraints under questions for risk assessors
p21, line 26	water quality criteria are not risk assessments since they do not consider exposure nor estimate risks
Text box 2-4	introduction to Waquoit Bay problem is required so that reader can understand the context of the management goal and subgoals
p22, line 25	re "Questions to ask ... "; only one question follows, many more could have been added
chapter 2	much of what is requested of the risk assessor during planning will change during the course of the assessment; suggest re-emphasizing iterative nature of planning
chapter 2	this chapter was somewhat repetitive and could be shortened
chapter 6	what is the role of the risk assessor in risk management?

Problem Formulation

(10) The classification of assessments as stressor-initiated, effects-initiated or value-initiated is useful and captures the major differences in how each of these assessments is eventually formulated. For consistency sake, it would be nice to have used the classification system used in the analysis chapter (chemical stressors, physical stressors, biological stressors, etc). I am unsure which classification system offers the most advantages and it may be worth discussing at the workshop.

(11) For the most part, the discussion of assessment endpoints and their relationship to management goals and measures was helpful and useful although I have several criticisms. For example, I found that the term "assessment endpoint" was often used in a vague manner. According to Suter (1993) the operational definition of an assessment endpoint includes a subject (the ecological value to be protected), a characteristic of the subject (*e.g.*, local extinction, reduction in population size), and a numerical expression of the effect (*e.g.*, probability of a >10% reduction in harvestable yield). None of the examples in text boxes 3-2, 3-3 and 3-4 included a numerical expression and most were quite vague as to the

subject and characteristic of interest (*e.g.*, "trophic status of freshwater ponds and rivers" in text box 3-4). I recommend that the text include more operational examples of assessment endpoints. Similarly, several of the "management goals" provided as examples are factual statements, not goals (*e.g.*, text boxes 3-3 and 3-4). Finally, I disagree with the sentiment that societal values have an important role to play in the selection of assessment endpoints. I believe that the objective of ERAs is to estimate risks to exposed receptors, whatever their perceived value to society. It is during the risk management phase that societal values become important, if for no other reason than the fact that "society" (community groups, non government groups) is (or should be) present at the decision making table. Perhaps the only exceptions are ERAs in which societal values were addressed in the appropriate legislation or ERAs where community groups had a strong role in the problem formulation stage (*e.g.*, Waquoit Bay). Bottom line: I do not believe that risk assessors and risk managers by themselves have the right to define societal values.

(12) I do not feel that the discussion of conceptual models and risk hypotheses was very useful. Most importantly, the use of risk hypotheses implies that the objective of ERA is to derive conclusions (*e.g.*, causes an effect or not). However, the objective of ERA is to describe risk. That is, ERA is a descriptive tool, not a conclusionary one. Further, much of section 3.5 was superficial (*e.g.*, "Depending on what initiated the assessment, different elements are known and unknown"), wordy and repetitive (*e.g.*, section 3.5.1 just repeats what was stated on the preceding pages). This section needs work.

Editorial and Other Comments on Chapter 3

p24, line 9	last sentence in paragraph is awkward
Figure 3-1	how are the bullets under "Source and Stressor Characteristics" any different from the title; where are "measures of effect"?
Text box 3-3	title is awkward
p30, line 7	paragraph repeats earlier material
p32, line 24	"affects" should be "effects"
p33, line 3	define "forcing functions"

p35, line 24	sentence is a run on
Text box 3-7	good example
p38, line 20	add "exposure" at the end of the sentence
Text box 3-8	good example
Text box 3-9	assessment endpoints require some sort of numerical expression (*e.g.*, what is the baseline value of concern for species diversity, what is the direction of concern for species abundance, since an increase in abundance of one species can lead to a decrease in species diversity?)
p42, line 28	Barnthouse et al. (1990) is not in the references section
p43, line 1	example is repeated from previous page
p44, line 31	"receptor" is a better term than "ecological entity"
p45, line 11	point repeats what was stated on previous page
Text box 3-12	define PMN
p47, line 19	quotes should only be used to highlight a key point, not regurgitate a large chunk of another paper
p47, line 24	Odum (1971) is not in the references section
Figure 3-3	figure is not very helpful unless it is explained; words are hard to read; spell out "FORFLO"
Figure 3-4	what is the difference between items in squares and those in circles
p52, line 2	how does one show "degree of confidence" in a flow diagram?
p53, line 24	"important" should be "importance"

Analysis

(13) The balance in the discussion of different stressor types was quite good, except for the discussion of physical stessors, which I found ignored much of what has been written in the literature on disturbance and, as a result, is somewhat superficial.

(14) As I noted earlier, the discussion of analytical methods for the various types of stressors was useful. However, principles or defaults were rarely stated (*e.g.*, method A is preferred to method B, and method C is not to be used). Since ERA is not prescriptive, the alternative route is to note the circumstances for which certain methods are preferred. For example, in characterizing sources and

releases, the guidelines could recommend measuring chemical levels in effluents and multiplying by volumes released as the preferred approach for characterizing point source releases. The second approach could be to use of models to predict levels, and the third could be to use emission factors. It would also have been useful to make a commitment to full lifecycle characterization of sources and releases. As it now stands, the discussion of sources and releases is to generic to be helpful. Similarly, preferred approaches could be specified for characterizing fate (*e.g.*, preferred models for local and regional scales), characterizing toxicity test results (see earlier comment), population modeling, deriving empirically based uncertainty factors, etc.

(15) The section on multiple stressors is in my opinion an accurate reflection of the state of the science (*i.e.*, not very well developed) and is well written. There was an inconsistency with the preceding section because the multiple stressor section did not finish with instructions on preparing a stessor-response profile.

Editorial and Other Comments on Analysis Chapter

p58, line 22	why provide such a specific example?
Figure 4-2	what do the different box shapes indicate?
p62, line 5	what are "study group boundaries"? Also the strategy has little to do with the example or source of uncertainty
p63	periods went missing on this page
p63, line24	how can "proportion of animals ... exceed a toxicity threshold"?
p64, line30	"ecological component of concern" seems to be yet another term for assessment endpoint
Figure 4-3	caption should be more explanatory; specify what different shapes of boxes mean
Text box 4-2	this example is so generic that it is not very helpful
p68, line 9	delete "it" from "it the"
p68, line 19	define "canonical"
Sect. 4.2.2.2	although section is not intended to be educational, key fate and transport references could be cited to assist the reader
Figure 4-4	suggest deleting figure since it is not helpful

p72, line 5	again, I suggest you provide key references
p73, line 11	I suggest you emphasize the importance of estimating exposure variability here
p73, line 24	how are important exposure pathways to be summarized?
p74, line 12	is the term "ecological response analysis" really necessary; seems to overlap stressor response profile
p75, line 16	add "when" before 'preparing"
Text box 4-6	Rand and Petrocelli reference should be by chapter since different authors prepared different chapters
p77	I am a little surprised that a general discussion of QSAR could fail to cite many of the important contributions from the Netherlands and others outside USEPA
p78, line 17	what does "q.v." mean?
p78, line 24	my own experience with toxicity test modeling is that 5% is too low because at this level the estimated effects concentration is usually model dependent; much less dependence is observed at the 15 or 20% levels
p79, line 11	references to Suter 1993a throughout the text should be by chapter since different authors prepared different chapters
p79, line 11	many others have recommended using regression analysis instead of hypothesis testing (Environment Canada, the Netherlands, OECD, etc)
p80, line 29	John Cairns has argued in many papers that credible extrapolations cannot be made at this time
p81, line 6	many others have contributed to the literature on extrapolating between responses – is there some sort of rule preventing citations from non US residents?
Text box 4-7	without supporting text, this box is not helpful; also bioenergetic models are ignored here and in the accompanying text
p81, line 17	the section on empirically deriving uncertainty factors is much too brief and needs expansion
p82, line 29	many would argue that such extrapolations can be made with "fair certainty"
p83, top	a case study would help to illustrate the concept of allometry
p83, line 8	last sentence in this paragraph is very difficult to read
p83, line 21	I disagree with the notion that toxicity tests prevent mitigation of effects;

	laboratory animals are well fed, free from predation and other stresses and therefore may be less sensitive to effect of chemicals than organisms in the natural environment
p83. line 26	this statement is pure nonsense; no such proof exists nor are any references cited to support this point; also, delete "absent data to the contrary"
p83, line 30	replace "as" with "an"
p84, line 28	the Suter and Bartell chapter on Ecosystem-level effects in Suter's ERA book (1993) also reviews ecosystem models for the terrestrial environment
p86, line 13	a paper by Glen Fox (1991) provides an excellent expansion to Hill's criteria for evidence of causality [see *J. Toxicol. Environ. Health* 33: 359-373]
p88, line 7	also note that, where possible, variability and/or uncertainty should be quantified (*e.g.*, EC_{20} ± 95% confidence limits)
Figure 4-6	title should be more descriptive; difficult to read text inside shaded boxes; what do the box shapes indicate?
p92, line 27	add references for readers interested in exploring the use of GIS for assessing disturbance effects
p93, line 8	guidelines correctly point out that identifying consequences of disturbance is "challenging"; however, little help is provided below to assist with this challenge
p94, line 24	note that many biological introductions have been accidental
Table 4-4	could add *Lythrum salicaria* (purple loosestrife) to the list as it has caused serious effects to plant communities since its introduction to eastern North American wetlands
Figure 4-7	title could be more descriptive; what do varying box shapes indicate?
p101, line 11	very useful list
Section 4.4.2	section is well written
p105, line 11	"give" should be "given"
p105, line 13	provide citations for approaches to assessing effects of chemical mixtures
p106, line 20	Lynn McCarty and colleagues have written extensively on the subject of assessing chemical mixtures using tissue residues and knowledge of modes of action

p106, line 21	"chemicals in" should be "chemicals is"
p107, line 9	statement is probably true, but not very helpful
Text box 4-18	box is not cited in text; Cirone and Pastorak (1993) is not the original reference for the AET approach, please cite appropriate reference
p108, line 24	define synoptic index
Text box 4-19	Ott (1978) is missing from the references section

Risk Characterization

(16) As I noted above, I believe that quantitative uncertainty analytical methods should have been discussed in much more detail (*e.g.*, Monte Carlo simulation, dependency bounds analysis, fuzzy math, etc) and recommendations provided on when and how to use each of the various methods. Such methods are the current state of the art for higher tier ERAs. Excellent general texts on the subject can be found in Covello and Merkhofer (1993; *Risk Assessment Methods: Approaches for Assessing Health and Environmental Risks*, Plenum Press, New York), Finkel (1990; *Confronting Uncertainty in Risk Management: A Guide to Decision-makers*, Resources for the Future, Washington) and elsewhere. For a discussion of the pros and cons of using deterministic versus probabilistic methods for estimating risk, see the upcoming debate in *Human and Ecological Risk Assessment* (e.g., Moore and Elliott (1996). Should uncertainty be quantified in human and ecological risk assessments used for decision-making? *HERA* 2(1) in press; Bartell (1996). Some thoughts concerning quotients, risks, and decision making. *HERA* 2(1) in press).

Decision analytic models should also have been discussed as these tools are now being used to assist decision-making in the face of uncertainty (see, for example, Frederick and Peterman (1995) *Can. J. Fish Aquat. Sci.* 52: 291-306).

Communicating risk estimates is a tricky endeavor, particularly in complex situations with high uncertainty. Guidance is required in this area.

(17) The list of criteria for assessing ecological significance is, in my opinion, complete

and useful. Discussion and guidance, however, could have been provided on the use of population and ecosystem models to assess ecological significance.

Editorial and Other Comments on Chapter 5

Figure 5-1	suggest adding "and other stakeholders" to discussion box; can the tiered nature of risk estimation be indicated in figure?; where is risk communication?; what do the different box shapes indicate?
p113, line 2	suggest "Risk Estimation" would be a better title
p115, line 3	quotient is semi-quantitative at best; therefore, the statement that "the higher the quotient the higher the risk" is only true when quotients are orders of magnitude apart
p116, line 10	much could be added to the list of quotient limitations; for example, quotients provide little information to the risk manager (*e.g.*, how many resources should be allocated to a stressor with a quotient of 1.5 is not at all obvious)
p116, line 20	please cite original references
Text box 5-3	there are many better examples of "going beyond the quotient method" than PDM3; an excellent example can be found in MacIntosh *et al.* (1994) *Risk Analysis* 14: 405-419
Table 5-1	title is not very accurate; strategy for unclear communication is too generic to be helpful
p122, line 20	the phrase "change exceeds the variance" should more precisely stated (*e.g.*, inter-treatment variance exceeds intra-treatment variance)
p122, line 25	sentence just repeats preceding sentence
p123, line 26	add appropriate references
p126, line 2	the first and third points in the list should be expressed in terms of the assessment endpoint rather than in terms of the stressor
Text box 5-4	box not referred to in text

Comments on References and Appendices

p135, line 8	"Risk Analy" should be "Risk Anal"
A-3, line 27	endpoint selected is vague

A-4, line 19	define "net subsidence rate".
A-5, line 6	figures would be useful to illustrate model predictions
A-5, line 9	"general trend toward loss of wildlife values" is vague
A-6, line 21	"on" should be "of"
A-8, line 11	this example would seem to be amenable to a quantitative uncertainty analysis
A-11, line 12	what does "quarantine importance" mean?
A-13, line 8	define endpoints more precisely
A-14, line 2	what exactly is a "fuzzy set" approach?
A-18, line 21	why are soil biota, wildlife and plants not included as receptors potentially at risk?
A-19, line 28	please provide examples of when lines of evidence converged or diverged; figures would help
A-21, line 25	journal number, pages?

Gerald Niemi

Gerald J. Niemi

COMMENTS ON DRAFT ECOLOGICAL RISK ASSESSMENT GUIDELINES

Prepared for Eastern Research Group, Inc, 110 Hartwell Avenue, Lexington, Massachusetts 02173- 3134, FAX - 617-674-2906.

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The format of this review follows the **Charge to Reviewers** document provided by the Eastern Research Group; however, the questions are not restated. In addition, I have provided comments relative to each section of the draft document.

Part I. General Principles

A. I appreciated the text box approach provided throughout the document. These provided an easy means to clarify particular points and topics.

B. I found the document quite boring to read, primarily because there was much duplication of the text material across the different sections. For example, how many times must it be restated the various issues that a risk assessor must consider in the risk assessment process. I would suggest that first a good technical writer and second a good technical editor go through the document very carefully. I would especially encourage them to look for duplicative material and a means to simply express the concepts presented. In my opinion the document could be reduced in size by 40 % - at least this is what I would suggest if I were doing a peer-review of the document.

C. I would have preferred to see a better literature review incorporated into the document. The document is about "ecological" risk assessment, yet there is really very little ecology presented. I am not suggesting that the document read like an ecological text. I am suggesting that because many of the concepts, background, etc. have an ecological basis, but there are few references to this ecological basis. For instance, most of the references are reasonable; however, the same old material is cited such as a plethora of EPA technical reports, and articles from Environmental Toxicology, Environmental Management, and Chemistry and Aquatic Toxicology. There is a wealth of new information in journals such as Ecology, Ecological Applications, Limnology and Oceanography, and Conservation Biology. Moreover, a wealth of science in foreign journals such as those from Canada (Canadian Journal of Fisheries and Aquatic Sciences) or Europe (e.g., Nature, Oikos, and Oecologia). In my opinion, the document should at least be a springboard to some of these other sources of information. This information is badly needed to eventually do ecological risk assessment and especially to improve it. Some examples include pg. 34, text box 3-6 on ecosystems at risk and ecological effects, pg. 68, l. 9 on mercury, and pg. 73, l. 5 on toxicodynamic model (a peer-reviewed citations here would be very useful). If too many references become a problem go to a numbering system so as to not distract the reader.

Consistent with this relatively narrow focus of material cited, is the absence of some material from the document. I was somewhat surprised to not see reference to economics (e.g., Costanza's work), indices of biological integrity (indices are mentioned briefly but again no good citations to relevant material), and meta-analysis to name a few. I realize that economics would come into play during the risk management phase, but the earlier we begin intergrating some of this information into the risk assessment picture it might help in focusing on the most pressing issues. Meta-analysis most assuredly will need to play a bigger role in doing ecological risk assessment because we will be forced to combine, collate, and mix data from different studies and places.

D. I am concerned about what God-like person could ever do a reasonable ecological risk assessment. A risk assessor should, at minimum, be a biologist, chemist, and ecologist and certainly a data analyst, good communicator (written and oral), and manager. Show me one. A few times within the document it is acknowledged that risk assessment "probably" is a team effort - it **must** be a team effort. The document throughout should emphasize and refer to the risk assessment management team.

E. Ecological risk assessment, as pointed out in the document, is likely easiest and maybe possible for individual chemicals. The document makes reasonably candid remarks about the lack of information about "real world" ecological system structure and function and, hence, our inability to make make predictions of future events (risk). This, of course, is the major drawback in EPA's ability to actually succeed in doing ecological risk assessment. The general feeling I had from reading the document is that the author(s) were also pessimistic about this ability. Hence, the tone, if EPA is to succeed in working through this process must be more positive. Of course, one must identify the weaknesses/uncertainties, but a path to the necessary information or process to do ecological risk assessment should be identified. The underlying assumptions and default positions to do many of the more complex ecological risk assessments will be based on professional judgment, educated guesses, delphic approaches, and concensus methods, but most likely not on data or facts. Will this be the case until eternity?

Part II. Specific Questions

Guidelines Balance

1. The document hits on a wide variety of potential stressors, biological organization, ecosystems and scales - it probably is a reasonable balance. However, the greatest weakness is the lack of references to the primary literature on some of these topics. For example, much has been written on disturbance in the ecological literature, yet there are few references to this literature. Again, the document does not need to go into detailed definitions, but a logical step would be appropriate references so that the reader could pursue some of this material if necessary. Similarly, there are many good papers on scale, yet these are not mentioned. One can only assume that the author(s) is not familiar with this work. The document makes frequent reference to "appropriate consideration of spatial and temporal scales must be included." Why not included more specific reference to explicit acceptance of various spatial scales (e.g., patch, landscapes, biomes) from the landscape ecology literature?
2. The case studies are blended reasonably well into the document. If they are emphasized any more within the document, I think the generality of the document would become lost in the specifics. I found Appendix A to be so abbreviated that it was less useful, perhaps

more details with an overall abstract for each would be better. If there is a particularly "good" ecological risk assessment (e.g., reasonable amount of data and careful analysis), then I would suggest that such a case study be included to represent a potentially good example. This could also be contrasted with a data poor example.

3. Reiterating part of question 2, the document should be recognized as a general document with selected examples. I do not see a great reason to include more "terrestrial" assessments, but I would agree that a good example as well as reference to "good" approaches would be useful.

4. I did not find the tables very useful (e.g., Table 3.1) and again they contained much duplicative material. I am also relatively confident that many of the sections (e.g., pg. 9 and 10 - discussion of variability (pg. 9, l. 20) and measurement error (pg. 10, l 0-15)) were not written by a statistically-trained individual (e.g., "Systematic error cannot usually be reduced."). There are a variety of techniques that can help to eliminate or reduce systematic error. Note also pg. 85, on causality needs revision regarding statistics. The author (s) have confused regression and correlation analysis. Regression is used to examine the dependence between one or more variables, while correlation analysis is concerned primarily with association, not necessarily dependence.

Introduction and Scope

5. In general, I have few comments for improving the introduction; however, it might be useful to include some phraseology that was included in our "Charge to Reviewers" which included a sidebar on what the Guidelines **are** and **are not**. Even though the guidelines were primarily written for risk assessors at EPA, they most likely will be used (abused) by many individuals who will find the guidelines useful.

6. Terminology is always troublesome. However, the definitions of key terms are included in Appendix B. I am glad this was included. My major suggestion would be to include the source for each definition (even if it is Webster's dictionary - version ?). It was adapted from U.S. EPA 1992a - but most do not have ready access to that document. Minor comments: 1) (pg. 9, l. 17) - suggest change reducible to "uncertainty can be

controlled," and 2) (pg. 10, l.8) - "field mice" - either be more specific such as saying *Microtus spp.* or be more general by just saying mice.

7. Fine.

Risk Manager Interactions

8 & 9. There are two concerns I have 1) pg. 19, l. 18 - 19 - there seems to be great latitude in how the risk manager and risk assessor "interpret the goals of the ecological risk assessment." For instance, they are using their information on the "ecology of the area" and "publicly perceived environmental values." Hence, the limitations or problems in this interpretation will reflect the knowledge level of the manager and assessor regarding knowing the ecology and their "self" designed interpretation of the values of the public. I suggest tightening this language so it is less subjective in interpretation. 2) Pg. 22 - l. 15-22 (and other places) - ecological risk assessment and the outcome (decisions) is clearly dependent on "financial resources available" and the "local economic impact." Hence, a process that does not consider the economics along with ecological is flawed. It implies that economics is above the ecological considerations. In practice that may be true, but it should not be so. In reality, there are a wide variety of scenarios such as risk assessments with a) high ecological impact, but low economic impact, b) low ecological impact, but high economic impact, or c) high ecological impact and high economic impact. I like the analogy that the economy is a subsidiary of the ecosystem (including its resources), especially in economies that are highly dependent on natural resources. In this way, the strength of the economy is dependent on the healthy functioning of the ecosystem.

Problem Formulation

10. I had no problem understanding either of these initiated risk assessments. However, ecological-value is the most subjective which would ultimately lead to some controversy in interpretation. The term "biodiversity" (pg. 28, l. 31) is too vague to be used in this

context. A watershed, pond, vista, etc. are all distinct entitites. Biodiversity is not. It would be better to use an endangered or threatened species as an example. The use of the term "habitat destruction" (Pg. 28, l. 3) is also not value neutral. Many would interpret logging as habitat "change" since the habitat is not necessarily destroyed. The old-growth forest may have been destroyed or eliminated, but the habitat is free to again become old-growth forest in the future (albeit a long time).

11. As pointed out in the document the most controversial aspect of defining assessment endpoints is to define what has "environmental value." Everyone has their own value system, so this is almost impossible to operationally define. I would suggest focusing on the concensus-building process for defining assessment endpoints at the initial phase of the risk assessment process. Concensus should be developed among a wide variety of constitutents within the potentially affected area (e.g., business, scientists, and environmentalists).

12. I continue to be concerned with the paperwork that is required of the risk assessor. For instance, throughout the document the risk assessor needs to document many parts of the process. On page 44, l. 18-19 - "justification for selecting and not selecting hypotheses are documented." There are many other places within the document where the risk assessor needs to justify this or that, or document reasons for this decision or for that decision. All of these areas should be scrutinized and placed within the context of the scale (size of area) of the risk assessment project. Some common sense could be applied. Small projects may require less documentation, while large projects that affect an area the size of a city, a state, or the nation would obviously require more documentation.

Conceptual models or models in general are useful vehicles to convey the problem and the connections between the various elements of the problem. However, models can quickly become very complicated - Figure 3-3 (Pg. 49) is a good example. What modelers and scientists usually know, however, is that certain connections are more important than others. A focus on the most important connections can be a means of simplifying the conceptual model.

13. The overall balance is reasonable.

14. In general, the document has done a reasonable job in recognizing the gaps in abilities to do risk assessment on individual chemicals and the quantum leaps to attempt risk assessment for many biological and multiple stressor problems. However, even with chemical stressors the document focuses on, for example, using SAR's for risk assessment (e.g., pg 77) and primarily cites some EPA documents as the primary sources of information. Similarly, the description of physical stressors includes an analysis using habitat suitability indices (HSI) (pg . 93). The problem here is that federal documents continue to cite many of their own models and analyses, which then perpetuate themselves more with the federal government and other agencies. As far as I know HSI has never been peer-reviewed. Is there real science and science acceptability behind these models? If these models are now to be used in ecological risk assessments, then there should be some review or at least documentation that these methods and models are accepted by the general scientific community.

Another general problem reflects some ecological naivete reflected in the document. In several places (e.g., pg. 59, l. 20-23; pg. 71, l. 11-18) there are suggestions that we really know more "ecologically" than we do. In how many systems do we know how abiotic factors will influence the degree of contact? How much do we really know about competition (assuming here interspecific competition is implied?) and its effect on resource utilization ("force some organisms to utilize contaminated areas"). These are still interesting ecological problems - their usefulness in ecological risk assessment is very, very limited.

15. Regarding multiple stressors (pg. 105, l.4), the document should distinguish between two types of potential multiple stressors - 1) past stress plus present (or future) stressor which I believe is "cumulative impact", and 2) multiple stressors - a combination of several stressors applied coincidentally (e.g., mixtures).

The discussion on additivity or "synergy" among combinations of chemicals could be clarified. A key point here is to identify the mode of action of a chemical which may or may not allow for the prediction of toxicity, depending on the mode of action. Some combinations can be predicted and for others with different modes of action the uncertainty is very high. I am also surprised that there is no mention of the ASTER system (a computer system for the analysis of risk) developed by the EPA's Environmental Research Laboratory in Duluth. The system can make a number of predictions about chemicals including mode of action.

Some aspects of biocriteria or indices of biological integrity should be weaved into the discussion on page 109. In addition, as previously mentioned, a meta-analysis approach would logically fit into the discussion on weight of evidence approaches on pg 110.

Risk Characterization

16. Chronic toxicity should be weaved into the discussion on the Quotient Method. Also the overall issue of recovery should be discussed throughout the document. For instance, recover is finally mentioned on pg.. 123. If a stressor produces a high impact, but recovers in a few days, then the stressor may not be a problem.. However, if a stressor has a relatively low impact, but the system may never recover, then this stressor may be of more concern. Sorry to cite my own work, but Niemi et al. (1990) - Environmental Management 14:571-587 and Detenbeck et al. (1992) - Environmental Management 16:33-53 would be highly relevant to this discussion.

The discussion on Scale (5.3.2.2) seems out of context. It primarily deals with habitat and landscape issues which are appropriate, but there is not an appropriate lead into this material. For example, landscape fragmentation to me appears from nowhere. Page 125 - l.17-18 - "continuous logging of old-growth forest will eventually eliminate the forest ecosystem." No - logging reverts the forest back into an early-successional stage, but normally does not eliminate it as forest. Conversion of forest to a corn field or a shopping mall eliminates the forest. Page 126 - l. 20-29 - I suggest putting anthropogenic disturbance into the context of the natural disturbance regime.

17. As discussed above - recovery should be emphasized more. Also ecological (biological)

significance must always use a common sense approach over "statistical" significance. Statistical significance can simply be a result of a statistical experimental design with high power for detecting differences (unfortunately this is seldom the case). In any event, the risk assessor (scientist team) must be the statistical evidence in the proper context.

Richard Orr

Date: November 13, 1995

Richard L. Orr
USDA APHIS PPD
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COMMENTS ON DRAFT ECOLOGICAL EPA RISK ASSESSMENT GUIDELINES

Part 1: General Principles

A "*risk assessment*" can be based on sound science but it is incorrect to claim that risk assessment is a "*scientific process*" (page 4, line 8; page 12 box 1-4). Indeed, many claim that a good risk assessment is more art than science. The traditional methods/processes of science are still sound and it would be inappropriate and dangerous to give the impression that a risk assessment process could provide answers that are best answered by basic or applied ecological research. For example, it will always be easier and cheaper to pool a couple of "experts" and ask them what they think will happen and call it "professional judgement" than it will be to apply the scientific method to address the same issue using an experimental approach.

Consequently, the statement on page 17 (lines 3,4) "*The purpose for an ecological risk assessment is to provide scientific information about ecological risks to managers making environmental decisions*" would be more correctly stated as "*The purpose for an ecological risk assessment is to organize scientific, and other pertinent information, into a format that can be understood and used by managers in making environmental decisions*". The wording between the above two statements may be subtle but the philosophical repercussions are major.

The scope of the definition of ecological risk assessment (on page 11 line 6 & 7, "*The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors*") is too limited. Risk Assessment is universally recognized as the likelihood and magnitude of an adverse event. The EPA definition focuses only on the likelihood and not the degree of the severity which will occur. Half of the risk formula is being played down in this definition.

Part II. Specific Questions:

Page 40, line 6, states that "*Assessment endpoints are not management goals*". This is too absolute and probably should read "*Assessment endpoints are usually not management goals*" or "*Assessment endpoints need not be management goals*". For example, the establishment of an exotic pest due to a specific pathway of introduction can be both an assessment endpoint and a management goal.

Page 97, the Text Box states that "*A team of six APHIS experts evaluated...*". This is not true, the experts were not from APHIS (Animal and Plant Health Inspection Service, USDA) but were individuals from various disciplines brought together by the Forest Service to conduct the assessment. It should read something like "*A team of six experts under the auspices of the Forest Service evaluated...*". Also, page 103, in the Text Box replace "*APHIS*" with "*The assessors*". Again this was not an APHIS document.

Page 99, last sentence, line 28 through 30. If "Agency" is referring to APHIS then the statement in not correct. In fact, APHIS has completed nearly 100 environmental assessments in support of management decisions to allow releases of nonindigenous biological control agents. Each evaluation considered, in general, the potential ecological impacts, and specifically considered the host ranges of the released organisms and how host range would ultimately impact upon the ecology and agricultural of North America. In addition, for the past several decades, APHIS has subjected all proposed releases of phytophagous arthropods to very extensive review often consulting with a variety of Federal agencies (including EPA), State agencies, as well as both academic and industry representatives.

On page 100, line 13 and again on page 102, line 4, the word "*bilge*" should be replaced by "*ballast*". Bilge water is a minimal pathway for aquatic organisms, ballast water is the real problem.

On page 100, line 26, the third bullet (line 24 & 25) needs to be changed to read *"Are there current mitigation requirements or conditions that would kill or mitigate the pest prior to entry, during transport, or at the port of entry"*.

Page A-10, line 2, the reference for the USDA process should be included (Orr et. Al., 1993) after Inspection Service.

Page A-10, line 20 please replace *"(the pest's capability to hitchhike on log shipments)* with *"(the pest's capability to be with the log shipment at origin)"*. "Hitchhiking" usually refers to an organism that is not normally associated with the commodity, but gets on it anyway. For example a wheat pest moving with logs.

Page A-11, line 10, please replace *"influences"* with *"repercussions from pest establishment"*.

Page A-11, lines 27 & 28 reads *"Although these species could be important, they are not considered in the assessment."* This is misleading, all organisms identified underwent evaluation using the hazard identification process outlined on page 18 of the Chile log risk assessment. Only those organisms meeting certain criteria were further evaluated using the risk assessment process. Therefore, the sentence should read *"Although some of these species may become plant pests if established in North America they were not assessed in detail because the initial hazard identification process identified them as minimal risk."*

Part III. Minor Corrections:

- Page 12, lines 10 & 20, should read *"figure 1-1"* not *"figure 1-2"*.
- The end of the sentence is missing on page 39, line 20.
- Page 63 is missing periods.
- On page A-9, line 11, please replace *"7 CFR Parts 300 to 319"* with *"7 CFR 319.40"*.

Kevin Reinert

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11/15/95

Comments on the Draft Ecological Risk Assessment Guidelines

Specific questions listed in the Charge to Reviewers:

1. Certainly, more text is devoted to the discussion of chemical stressors. Although more space should be devoted to physical and biological stressors, the state of the science around these stressors is not as advanced nor are there as many risk assessors experienced in these 2 areas. Additionally, more emphasis is placed on single organism and population levels of organization. Again, more text should be devoted to higher levels of organization (e.g., community and ecosystem), but these have not been developed to the same extent as lower levels.

2. See comments specifically on Appendix A.

3. More examples of terrestrial assessments and field approaches should be added; the aquatic matrix is better represented in the text. However, fewer studies have been conducted in terrestrial and other field scenarios and therefore these areas could probably not be enhanced without substantial effort.

4. Several comments on uncertainty are described in the following text. Most of the uncertainty sections are written well.

5. These guidelines will certainly be used by more than just regulatory risk assessors and managers. Use by others (e.g., industry) should be considered. See comments specifically on section 1 in the following text.

6. The listing of Key Terms is essential. Possibly, more than one definition could be listed for some terms as many programs may interpret these terms a bit differently.

7. I have attached revised versions of the framework figure as presented by the American Industrial Health Council (AIHC) at the EPA colloquium held on May 3, 1995. Changes to the planning, risk management and data validation boxes should be made in order to better define these aspects of the framework.

8. See comments in following sections concerning the role of the risk manager in ecological risk assessment (ERA).

9. See number 8.

10. The categorization of assessments into 4 categories probably will not assist the reader in understanding ERA concepts. New terminology is introduced that may in fact confuse even the seasoned risk assessor. Additional comments are listed later in this document.

11. Specific comments are listed later in this document.

12. Please see the specific comments for suggestions.

13. Please see specific comments.

14. Please see specific comments.

15. As discussed later, J. Foran at the ILSI Risk Sciences Institute should be consulted on the issue of multiple stressors. He is currently working on a project supported by EPA concerning multiple stressors.

16. Probabilistic ERA approaches have not been discussed in detail. Such methods form a significant portion of many ERAs conducted in industry and are part of the Aquatic Risk Assessment and Mitigation Dialog Group (ARAMDG) approach to aquatic risk assessment (tier 2). Additionally, although an iterative approach is described in the guidelines, the concept of tiers in ERA is not well developed in the document. Some sort of screening assessment should also be described. Such a screen (as described in the draft Superfund ERA guidance) is useful to set priorities and address those issues that need specific ERA.

17. Ecological significance is a function of 3 factors, contaminant variables, exposure pathways and site-specific factors (see Brown and Reinert, 1992. Env. Tox. Chem. 11:143-144) The four factors listed in the guidelines encompass these factors.

Page by page comments:

1. Introduction

P. 2, Text box 1-1: Although each of the case illustrations are useful, could examples of case studies discussed earlier during the guidelines development been chosen that more closely follow the ERA framework?

P. 2, line 31: Risk management (RM) always is addressed in another document or is out of the scope. This is an extremely important aspect of the whole decisionmaking process that must be addressed. Where and when will this issue get some text devoted to it?

P. 3, line 1: Cite examples of other Agency-wide guidelines prepared by the EPA Risk Assessment Forum (RAF).

----, line 16: delete issues.

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—, line 19-21: This statement is incorrect; all risk cannot be eliminated. Insert 'addressing and' before eliminating and delete all.

—, line 23: Insert risk before management.

P. 4, line 2: Uncertainty analysis helps focus both research and risk input refinement.

—, line 15: In some cases, a risk assessment (RA) may not be conducted because the data cannot be gathered and RM alone takes care of the decision without the benefit of RA (e.g., precautionary principle).

P. 5: The boxes on the right and bottom in this figure deal primarily with RM; during the May 3 Colloquium, AIHC provided additional detail for each of these boxes which begins to 'beef-up' the RM aspects of ecological decisionmaking. Aspects such as review of existing legislation and regulation, international implications of the decisions, corporate stewardship policies, and societal values and concerns should be discussed during the planning stage. These aspects should be seriously considered for these guidelines or at a minimum be included in an addendum to the ERA guidelines. The figure is attached. The additions address the planning discussion prior to the conduct of the ERA and the RM interface after the ERA has been completed. Discussions between the risk assessor(s) and risk manager(s) should not only occur before and after the conduct of the ERA, but continue throughout the process so that both parties can chart the progress of the ERA and provide for fine-tuning during completion.

P. 6, line 27: Add 'often' before reduces.

—, line 28: Industry has also been conducting ERAs for many years, some specifically under regulatory programs and other to better understand their products in the environment. Not only regulatory organizations should be listed here. Also, reference to various groups in the European Union (EU) conducting ERAs should be listed.

P. 7: I am not sure what this figure brings to the text. The iterative nature of ERA is described directly in the text. The tiered concept of ERA should also be discussed on page 6 while discussing the iterative nature.

P. 9, line 6: Uncertainty should be thoughtfully addressed whether qualitatively or quantitatively documented. Dr. G. Charley, Executive Director of the Congressional Commission on RA and RM recently stated that the Commission did not want to see uncertainty described quantitatively because most RMs are only able to understand a qualitative or at best semi-quantitative discussion of ERA uncertainty.

P. 9: A subsection on Uncertainty would make this section read clearer.

P. 10, line 1: The use of a model not suitable for the scenario because other models do not exist would also lead to uncertainty.

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----, line 7: Insert 'a' before quantity.

P. 11, line 31: I am not convinced that measurement endpoint needs to be redefined as measure of effect. I would prefer to keep the terminology consistent with Suter.

P. 12, line 6-18: This section further supports the need for continuing discussions between the risk assessor and risk manager.

P. 13, line 22: Delphic is used several times throughout the document. Perhaps a better term such as obscure or ambiguous should be used to define these approaches.

----, line 24: Add 'al' to ecologic.

----, line 27: This section should note that not all impacts cause a measurable effect.

P. 14, line 9: Hazard assessment only addresses the effects side of the ERA process and I agree that the term hazard assessment should not be used in the guidelines. However, as written, the text implies that it may be similar to ERA.

----, line 25: What about enhanced responses? Enhancement of various properties may not be detrimental or adverse directly, but could be negative with respect to secondary effects (e.g., biological introductions, algal growth, etc.).

P. 15, line 28: A disturbance is still a stressor and I am not sure I agree that it should be separately defined.

2. Planning

P. 17, line 10: The risk assessor and risk manager should discuss various aspects of the ERA throughout the process, not just during problem formulation. This is essential as a progress check, reality check and discussion concerning changes in outside influences on the ERA needs and management goals.

P. 18, line 8: Add 'the presence of' before stressors.

----, line 16: Is tolerate the correct term? Accept seems more appropriate.

P. 19, line 16: Both the manager and assessor also need to agree upon treatment of uncertainty and additional data collection needs.

P. 20, text box: Goals and resource should be defined in the 3rd bullet for RM. The existence of previous risk assessments should be specifically listed in bullet 5 for RM.

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P. 21, line 18: From the goals, the risk assessor, in communication with the risk manager, derives a series of pertinent, applicable assessment endpoints.

—, line 25: The risk assessor needs to know when the RA will be used to establish national or other policy. This is part of the discussion concerning how the RA will be used by the risk manager.

3. Problem Formulation

P. 24, line 9: *Please add '4) poor or lack of uncertainty characterization'.*

P. 25: The current diagram implies that one could construct the conceptual model without addressing the assessment endpoint circle. Also, measurement endpoints should be listed as a separate step prior to analysis. Additions to the box to the left of the Problem definition phase are discussed in section 1 of these comments. Some of the main points have been added.

P. 26, line 18: Replace product development with problem definition.

P. 28, line 4 and 26: Text boxes corresponding to physical and biological stressors would be helpful. Physical and biological stressors are more difficult to understand and less understood than chemical stressors.

—, line 16: When biomarkers are used, their ecological relevance and significance should be understood.

—, *line 28: Is resource-initiated more appropriate? I suppose there could be a* difference between ecological value and resource value.

P. 29, line 10: Replace value with 'resource"?

P. 31, bullet 5 in text box: Is land subsidence the correct term? It seems that flooding and its periodicity are the primary factors.

P. 33, last bullet in text box: Chemical fate may include transport; physical transport is redundant.

P. 37, line 20: Reference?

—, line 27: If the assessment endpoints in an ERA are not ecologically relevant, the assessment may predict risk, but not to ecologically significant components.

P. 38, line 20: Delete along with the and during and add 'occurring during a particular'.

—, line 21: Please refer the reader to text box 3-8.

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P. 39, line 8: Reference?

----, line 12: Change is to 'maybe'.

----, line 21: Delete through and measures and add 'ly' to indirect.

P. 42, line 12: Change affect to 'effect'.

----, text box: The cited items should be referenced to the text in a clearer manner.

----, lines 23-28: Whose citation, Suter or Barnthouse?

P. 43, lines 1-6: Delete, repeated from p. 42, lines 19-23.

----, line 25: Should the risk manager be involved with the assessor rather than have the assessor develop assessment endpoints which may not be agreeable to the manager?

Should there be a separate section on measurement endpoints rather than have them buried in the assessment endpoint section? See p. 53.

----, text box 3-11: Where is this box cited in the text?

P. 44, line 4: Change verbal to 'written.'

----, line 7: Doesn't the conceptual model also contain a description of the various exposure scenarios and pathways?

P. 45, line 31: Add, 'but potentially important' before risk.

P. 47, line 10: Change 'to' to 'causing.'

P. 52, line 14: These flow diagrams should be presented/discussed with the risk manager, addressing clarity, completeness and any changes before proceeding to the analysis phase.

P. 53, line 7: The initial figure in this section needs to describe the selection of measurement endpoints. I am not convinced that the term measures of effects is necessary. Also, some thought concerning the measurement of the assessment endpoints should occur while selecting assessment endpoints. A lot of time will be wasted if assessment endpoints that are not clearly defined or cannot be measured are chosen.

----, line 24: Change important to 'importance'.

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P. 54, line 26: *This line is repeated below at line 29 and should be integrated or* deleted.

P. 55: Reference for the table is needed.

4. The Analysis Phase

P. 57: AIHC suggested some revision to the Data box on the right of this figure. These are listed in the attached figure.

P. 58, line 14: Model calibration should be defined.

P. 59, line 3: This statement may be misleading; Is a stressor at natural background in an ecosystem really a stressor? There may be some confusion regarding this concept.

P. 60: Is this example appropriate for demonstrating the relationship between primary and secondary stressors? It seems that the primary stressor causes the smothering of the benthic organisms (not just insects) from increased siltation due to logging and concomitant erosion. I am not sure that a difference exists.

P. 62, line 7: Does high end *mean upper 95% confidence limits (CL) or otherwise?* High end is not a useful description.

P. 63: Periods are missing from this page.

----, line 25: Change communication to communicate.

----, line 27: Add 'uncertainty' between quantitative analysis.

P. 64, line 5: Often risk managers and others are unable to understand complex uncertainty presentations. The level of uncertainty analysis should be agreed upon prior to the conduct of the ERA. See comments earlier on Congressional Commission.

----. line 6: Add to the end of the line -'in some manner appropriate to the ERA necessary for decisionmaking and agreed to by the risk manager.'

P. 66, line 23: Should adventitious be changes to inadvertent?

----, line 28: Add 'of the primary stressor' to the end of the sentence.

----: Where are text boxes 4-2, 4-3 and 4-4 cited in the text?

P. 67, line 5: Why is background in italics?

----, lines 20-24: Are there any references that can be cited for this section?

----, line 25: Should the paragraphs following this line be a separate subsection (e.g., chemical distribution)?

----, line 30: Add effluents to the complex mixture examples. Also, I would argue that PCBs and dioxins do not have significant differing properties within their cluster; I do agree that effluents would be different.

P. 69, figure 4-4: Does this figure add anything to the text discussion? It seems obvious from the text.

----, line 15: No need for a colon or an ellipse on the next line.

P. 70, line 24: Some discussion or mention of the need to determine ecological significance of biomarkers is needed.

----, footnote: This should be restated from an ecological perspective and not human as currently written.

P. 71, line 4: Again, need to discuss ecological significance of the assay.

----, line 9: No need for a new paragraph.

----, line 18: Such competition also creates additional stress for organisms.

----, line 19-24: Relates to a secondary exposure; could increase competition for 'clean areas.'

P. 72, text box 4-5: Where is this box cited?

P. 73, line 11: Can an example be cited?

----, line 24: Some additional verbiage should be inserted here concerning the pathways.

P. 74: Inconsistent use of bullets in document.

----, line 13: Number crunching is not a technically precise term; substitute toxicity inventory? Also, a separate section should be listed for Ecological Response Analysis.

P. 76, text box: The new Rand publication should be reviewed and cited if possible.

----, line 23: What does the phrase 'test protocols may not always be followed' mean? I find that this is not the norm.

—, line 30: LC values are more often used in ERA than LDs.

P. 78, line 16: F_0 hatchability is also included in these studies as well as the growth of the F_1s.

—, line 25: Is lethality the correct term? The LC5, NOEC, etc. are used to assess the risks of pesticides. The lethality is determined by the LC50.

P. 79, line 8-15: The NOEC and LOEC from hypothesis testing are artifacts of the doses chosen and should be noted in this section.

—, line 19: Axenic culture does not necessarily imply single species, just bacteria free.

P. 80, line 6: This line is not a sentence.

—, line 19: Confronted is a poor word in this situation; is 'presented' a better term?

—, line 28: Change paramecia to protozoa to be less specific.

P. 82, line 10: Change group to population.

P. 83, line 12: Reference?

—, line 22-23: Mitigating measures in the field are not only duration, but bioavailability.

P. 84, line 16: Add 'to' before large.

—, line 20: Please cite the SETAC European Union (EU) document concerning the design and use of microcosms and mesocosms

P 86, line 1: Cite reference for Koch.

—, line 11: Cite reference for Hill.

P. 89, Table 4-3 title: Change disturbances to stressors. I do not agree with the text discussion on p. 88; it may confuse the reader.

P. 90, line 11: Are physical stressors different from other stressors in that the characterization is described in 2 components here? Is this line necessary?

P. 95, line 7: Remove and and insert a comma.

P. 97, line 12: Use another term besides delphic.

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P. 101, text box 4-13: Some discussion or listing of whether the organism caused problems in these countries should be added.

P. 105: The work being conducted by Jeff Foran (Risk Sciences Institute) for the EPA concerning multiple stressors should be consulted.

P. 107, line 9: Assuming additivity is certainly better than singularly assessing the various stressors (without some sort of combination) that may be included in an ERA.

5. Risk Characterization

P. 112: More detail is needed in the risk estimation box. Also, see the attached additions to the box on the right of the figure.

P. 114, line 21-22: Either number or bullet these 2 items for clarity.

----, line 24: For ease in reading, the additional information and methods should be listed here.

P. 115, line 13: Managers should not only be familiar with the method, but also understand its derivation and limitations.

----, line 22: A 100 percent change of adverse effects occurring is not correct when the quotient is exceeded; there is a high probability of an adverse effect occurring based on the tier of ERA conducted. With further refinement (e.g., higher tier ERA, additional input data) the risks may be lower.

P. 116, line 1-6: The risk assessor may be able to qualitatively approach this issue with the ERA and the manager.

P. 117, line 26: Should 'effects' replace defects?

P. 119, line 29: Need to discuss why these were specifically excluded from the ERA.

P. 123, line 10: The next items are discussed as a subset to ecological significance. A lead in sentence is needed here listing the next four items.

P. 125, line 1: A reference is needed here.

P. 126, line 28-29: Perturbations in ecosystems may be extremely difficult to observe (detect) among the various natural variations. This concept should be specifically stated.

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6. Relating Ecological Information.....

P. 127: This section should be expanded to include more of the risk management issues if a separate addendum is not prepared. There is a substantial void in how the ERA information is used in decisionmaking and numerous inconsistencies among the various programs within the Agency. There needs to be feedback to the risk assessor. Is rework needed (i.e., another iteration; higher level tier ERA)? Are additional data collection tiers needed? Does the ERA meet the needs of the risk manager?

----, line 20: The items listed are not procedures but are check list items.

P. 128, line 4: Add 'and understandable' before manner

Appendix A

The specific EPA case study documents should be cited along with the specific authors of the case studies.

Appendix B

Will a single definition suit all programs? Are the authors expecting each of the program offices to rework and redefine these terms specific to their programs?

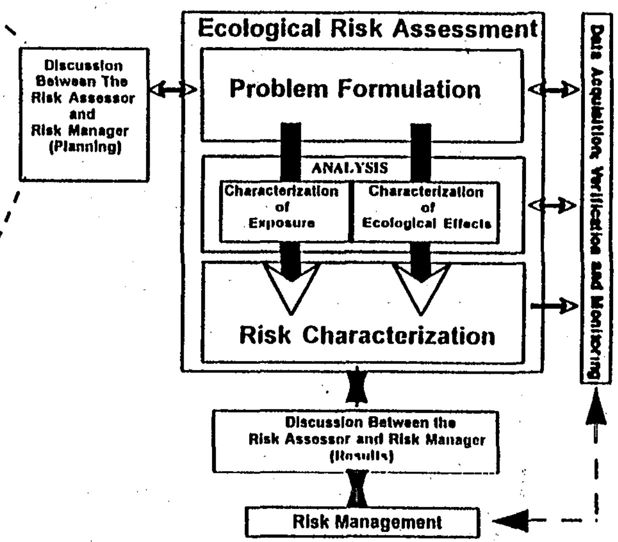
What Policy Issues Should Be Discussed By Risk Assessors And Risk Managers Before Starting The Risk Assessment Process?

Planning Discussion Between Risk Assessors and Managers On Related Policy Issues

I. Policy Considerations
- Laws / Regulations
- Corporate Stewardship Policy
- Societal Concerns
- Environmental Justice

II. Scaling The Risk Assessment Problem
- Valuation Of Ecosystem At Risk
- Protect Which Species And To What Extent
- Magnitude And Scale Of Risk
- Benefits Of Technology

III. Constraints
- How Much Money Is Reasonable
- Timing / Duration
- Personnel / Resources - Private And Public



What Policy Issues Should Be Discussed By Risk Assessors And Risk Managers During And After Completing The Risk Characterization Process?

Discussion On Assessment And Policy Issues During Or At Completion Of Risk Assessment

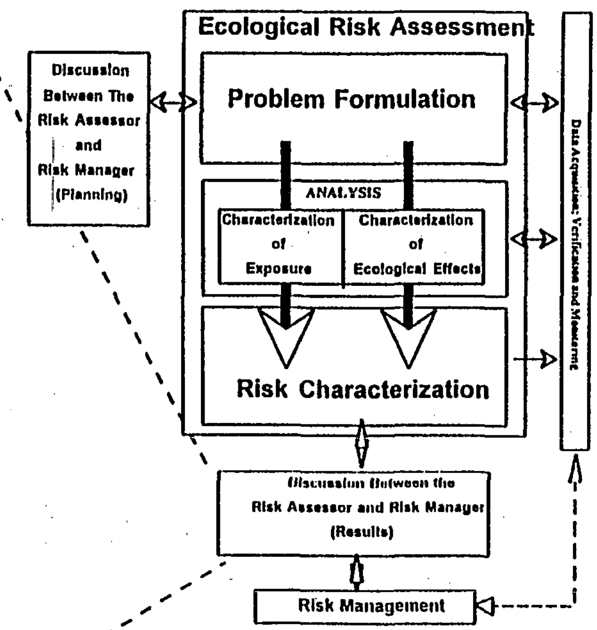
Was It The Right Problem?

Was The Problem Adequately Characterized?

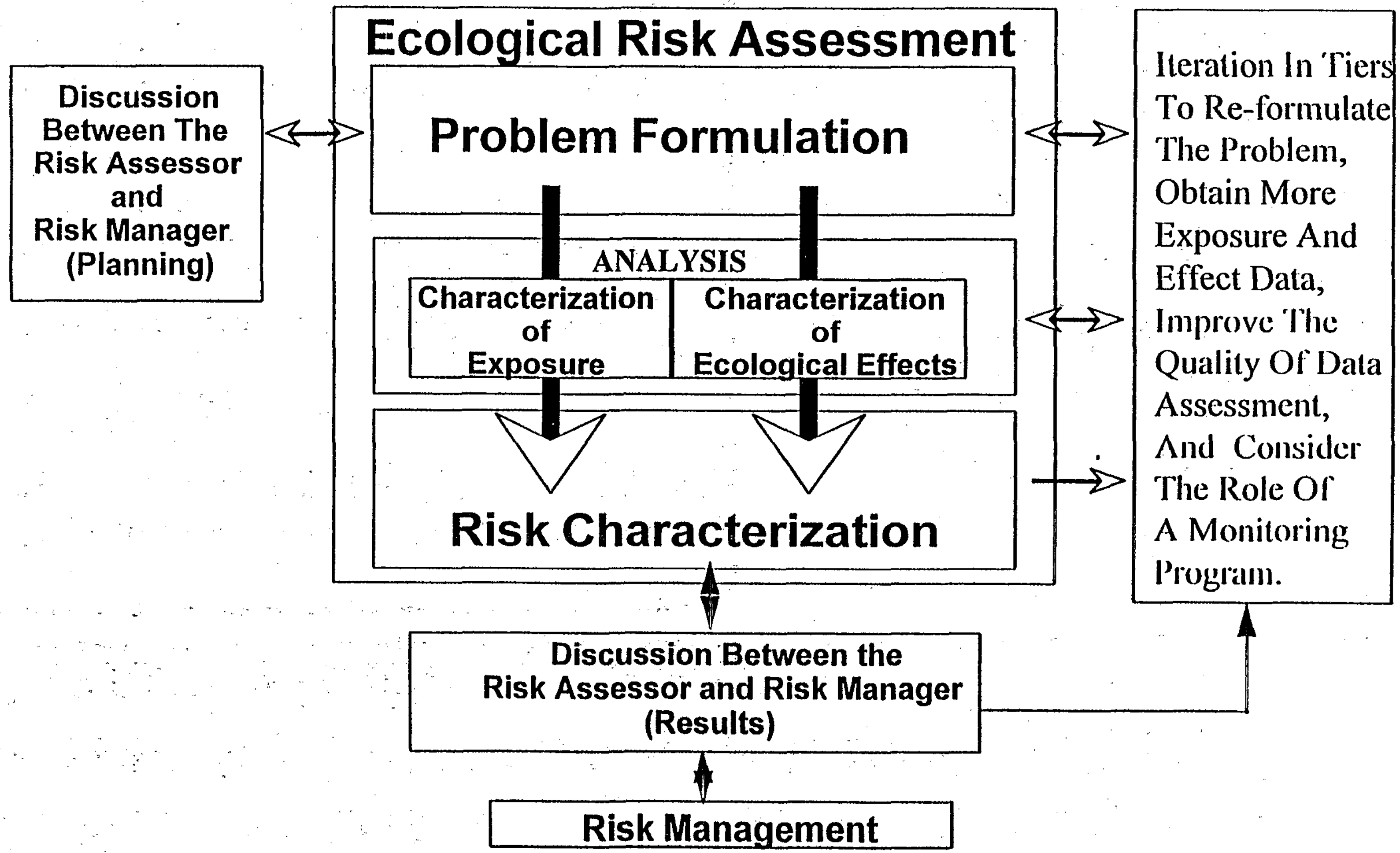
Is There A Need To Conduct Another Tier To Better Resolve Technical Issues In Risk Assessment?

Does Risk Assessment Meet The Need Of The Risk Manager?

What Constraints / Values / Policies Influence Risk Manager Decision?



After The Risk Characterization Step, The Risk Assessor And Risk Manager Need To Determine If Additional Work Is Needed: Use An Iterative Process And Tiers.



William Smith

Guidelines for Ecological Risk Assessment

Comments for *Ecoguide Workshop*

William H. Smith

Yale University

November, 1995

I. Introduction and General

An appropriate definition of ecological risk assessment is "the qualitative or quantitative estimation of the probability that some factor will cause an adverse effect on some ecological resource". In either an informal or formal sense human beings have been making these estimations for a very long time. In some applications, for example, agricultural and forest pest management, the literature and experience is quite extensive (e.g. Baker et al. 1993, Byler et al. 1990, Gansner et al. 1994, and Maclean 1980). Even in the absence of "formal" risk assessment guidelines, ecological risk assessments will continue to be made. Ecological risk assessments are essential for effective natural resource management. Ecological risk assessments are extremely useful for prioritizing environmental regulatory, monitoring, research and education efforts; establishment of environmental standards; and in conducting environmental cost-benefit assessments. To quote Warner North (1990) "estimating risk is a process for summarizing science to support decision making".

There are advantages to a systematic approach to ecological risk assessments. These include consistency in assessments over time, comparability of assessments conducted for various purposes, and completeness of assessments.

Ecological risk assessments should be explicit regarding four dimensions. These dimensions include time, space, biological hierarchy, and societal values. Due to variability in time, i.e. dynamic successional and natural disturbance processes characteristic of all ecosystems, temporal bounding is essential for effective ecological risk assessment. This is particularly true for long-lived ecosystems subject to multiple, interactive stressors such as forests. Ecosystem management can pursue the sustainability of dynamic ecosystems. Ecosystem management should not pursue the sustained maintenance of static ecosystems for extended time. Ecological risk assessments should be place-based and the spatial boundaries of the ecological resource must be clearly described. Surface waters, estuarine systems, dry lands, wet lands, and forests exhibit enormous variability. Forests, for example, differ in soil type, climate, aspect, elevation, species composition and age. Forests may be uneven aged, even aged, all aged, or over mature. Forests may be reproduced by seed, by coppice, or by planting. Some forests have their structure completely shaped by natural forces, some may be influenced by human forces as well as natural forces, while other forests may be completely artificial in design and establishment. Forest trees may be arrayed along a continuum of human management efforts ranging from no management to intensive management. All of this variability necessitates the need to spatially bound ecological resources prior to risk assessments in order to focus the evaluation on specific type/range of ecological resource variation. The endpoints of ecological risk assessments should be clearly "nested" in the biological hierarchy from cell to biome. While species, population, community, ecosystem and landscape scales are all conceptually convenient "stopping points" within the hierarchy, the scientific understanding of stress response at these various scales is very different. In general, scientific understanding declines rapidly from species to landscapes. As a result, the most informed risk assessments will be conducted at the species or population levels. All ecological resources are influenced, directly or indirectly, by human beings. The human values associated with ecological resources are extremely varied. In the case of forests, for example, values represent both products and services provided by the forest (Table 1). Some ecological resource values are traditional, long and widely appreciated, and quantifiable in standard economic terms. Other values are of more recent appreciation, developing in acceptance and sophistication, and are not quantifiable in standard economic terms. In any case, endpoints selected for use in ecological risk assessments should be clearly linked to one or more societal values.

The linkage between ecological risk assessments and stressor and ecological resource monitoring is intimate. The full value of risk assessment will not be realized unless and until we develop and maintain a scientifically sound and cost-effective environmental monitoring strategy.

It is less important to have an ecological risk assessment framework that fits all stressor and ecological resources types, than to have a framework that works well for some stressors and some ecological resources.

II. Major Elements of Ecological Risk Assessment

As proposed, the Ecological Risk Assessment Guidelines call for three major elements for all risk assessments; problem formulation, analysis, and risk characterization. Organizationally these represent reasonable elements for all assessments.

A. *problem formulation*

The most important aspect of this element is the clear articulation of the answer to the question, Why is this assessment necessary? The question is answered interactively by the relevant parties which include scientists ("risk assessors" per Guidelines) and environmental managers ("risk managers" per Guidelines).

The focus of the assessment is some ecological resource. It is imperative that the ecological resource be clearly defined by bounding the spatial, temporal, biological hierarchy and human value dimensions of the resource.

The stressor, or agent capable of imposing an adverse effect on the ecological resource, must also be clearly defined. Sources should be identified if possible. Relevant monitoring efforts that can reveal status and/or trends of the stressor must be identified. Information regarding the interaction of the stressor with other agents capable of causing adverse effects on the ecological resource must be reviewed.

The societal values associated with the ecological resource ("endpoints" per Guidelines) must be clearly defined. Quantitative measures ("indicators" per Guidelines) of the status of these societal values must be established. Ambiguity of these measures must be evaluated by reviewing other factors (stressors) that may influence the indicators selected and by reviewing the uncertainty inherent in the information available.

Problem formulation must recognize that risk assessment generally contributes to environmental and natural resource management decision-making and will be only rarely the sole "driver" of environmental decisions. Ecological risk assessments have great utility, as indicated in the Introduction for a very broad array of environmental/natural resource managers and decision-makers. Only a fraction of these users will be regulators.

It is very important to minimize the development and use of unnecessary jargon in the development of risk assessment guidelines. Where possible, vocabulary should be presented using common and conventional terms rather than inventing and defining new ones. The Agency is to be complimented for keeping the "glossary of key terms" (Appendix B) to 38 entries. Even in this case, however, selected terms such as "community" and "ecosystem" could be deleted due to common appreciation; while the "relative risk assessment" and "comparative risk assessment" terms could also be deleted as they represent unnecessary linguistic "fine-tuning".

B. *Analysis*

This is the "science" section of the assessment. It is the section that provides all relevant detail regarding the nature of the stressor ("exposure" per Guidelines) and response of the ecological resource ("indicator(s)" per Guidelines) along with a discussion of relevant uncertainty and incomplete information. While uncertainty can be introduced in the problem formulation stage, it should be addressed in detail in the analysis section.

With chemical stressors in particular, it is extremely important for the analysis phase to emphasize the distinction between stressor presence in the environment and stressor bioavailability in the environment. Equally important is the distinction between the amount of stressors present, as revealed by environmental monitoring, and the amount of stressors present at a potential site of biological action.

The development of exposure detail (e.g. intensity, time, and space dimensions) and ecological effects detail (e.g. structure-activity relationships, single-species assays, multispecies assays, and field experiments) should be presented as useful options/elements, but not as exclusive alternatives or as absolute requirements.

It is important to agree on the primary purpose of the risk assessment framework. If the primary purpose is to inform environmental/natural resource management decisions, rather than test scientific hypotheses, then the issue of causality will be less central. Presumably, most risk assessments will be carried out to evaluate the probability that *an established* cause-effect relationship will or will not occur in a specific system. This will eliminate the need to discuss the application of "Koch's Postulates" to pollutants rather than to microbes!

C. *risk characterization*

This is the most important part of the risk assessment framework as it provides the product that will actually inform the decision-making process. As a result, ideal charactristics of risk characterization include:

1. qualification
   -regarding temporal, spatial, biological hierarchy, and social-value boundaries
   -regarding uncertainty and incomplete information
2. clarity
   -minimal use of technical jargon
   -danger of extrapolation to situations with other boundaries
   -clear conclusions
3. conciseness
   -usefulness and impact will be facilitated by brevity!
4. linkage
   -risk assessment should be referenced in the context of similar assessments done with the same or related stressors or ecological resources
   -risk assessment should be stated in the context that will most usefully inform a management decision

III. Specific Questions

1. Q. Considering both the present state of the science and present and future Agency needs, how well are the guidelines balanced regarding the range of stressors, levels of biological organization, ecosystem types, and spatial/temporal scales? Specifically, what would you emphasize or de-emphasize?

   A. The most effective risk assessments will be those conducted for ecological resources that are explicitly defined regarding time, space, and biological hierarchy and for which societal values are clearly articulated. Further, it is more important to develop risk assessment guidelines that will work well for some stressors, than it is to develp a single framework that will work for all stressors. A workable framework for chemical stressors, even if it failed to work for biological/physical stressors would be a contribution!

2. Q. What would you suggest to improve the use of case illustrations in the guidelines? How useful is Appendix A in illustrating a range of applications of the risk assessment process?

   A. Rather than retrofit previous case studies to the propsed framework, it would be more useful to apply the framework to new (and preferably actual) environmental decision-making needs. Ideally these case studies would cover a range of ecological resources and a range of stressors.

3. Q. Some Agency reveiwers of the guidelines have suggested that more examples of terrestrial assessments and field approaches (e.g., bioassessment techniques) should be used. Specifically, what, if anything, should be added?

A. Clearly the framework is intended to serve both "terrestrial" and "aquatic" decision-making. As a result, both terrestrial and aquatic cases are appropriate.

4. Q. Areas of uncertainty are summarized in the problem formulation (section 1.5), analysis (section 3.7), and risk characterization (section 5.2.4). How useful is this approach in providing guidance on uncertainty issues?

A. The emphasis on "uncertainty" should be focused in the Analysis section. This section presents the science and should detail the uncertainty. Also, gaps in our knowledge should be highlighted in this section. The risk characterization section must effectively convey the uncertainty and gaps to the decision maker.

5. Q. How could the Introduction be modified to more clearly communicate the scope and content of the guideline?

A. Some reduction in the length of the introductory section is desirable. Sub-sections that could be reduced include; background (1.1), scope and audience (1.2), and framework report (1.5).

6. Q. Terminology, especially related to endpoints and exposure, has always been controversial. What changes, if any, would you recommend in guidelines terminology?

A. Endpoint and exposure concepts are important and reasonabley defined. In general, however, new terminology (jargon) and unnecessary refinement (e.g. "comparative risk vs. "relative risk" should be minimized wherever possible.

7. Q. The overall framework figure for the ecological risk process has been retained, although some changes have been made to the diagrams for problem formulation, analysis, and risk characterization. What further modifications, if any, are required?

A. The diagrams as presented are reasonable and useful.

8. Q. Please comment on the description of the risk manager's role at the initiation of an ecological risk assessment and on the principles for selecting management goals.

A. I prefer to susbstitute environmental/natural resource manager for "risk manager" as I feel the users of risk assessments will be a variety of environmental and natural resource professionals, with only a minority being "risk managers" ie. environmental regulators. Because clarity regarding "social values" at risk are central to problem formulation, environmental mangers must be involved in the iniation of an ecological risk assessment. Presumably, they know what their goals of professional management are!

9. Q. What additional points, if any, should be covered about relating ecological information to risk management decisions after the completion of an ecological risk assessment?

A. No further perspective needed. I feel the "product" or end result of the risk assessment process provides a qualitative/quantitative estimation of the probability that some stressors will adversely impact some ecological resource.

10. Q. How useful is the categorization of assessments as either stressor- or

source-initiated, effects-initiated and ecological value-initiated?

A. Human values, associated with specific ecological resources, must be clearly defined in order to initiate an ecological risk assessment, therefore they are fundamentally important. The distinction between stressor-, source-, or effects-initiated assessments is interesting but NOT of fundamental importance.

11. Q. Please comment on the discussion of assessment endpoints and their relationship to management goals and "measures".

A. It is critically important that assessment endpoints be linked to management goals which must be directly linked to societal values.

12. Q. What, if anything, would you add to the discussion of risk hypotheses and conceptual models to give the reader a clearer understanding of their nature and content?

A. In initially defining a risk assessment, the clarity of the question being asked is critical. Most risk assessments will serve environmental/natural resource decision-making NOT advancements of science. Hypotheses testing is not a necessary ingredient of all assessments. Conceptual models are very effective tools through which science can be summarized for decision makers.

13. Q. How would you change this section, if at all, to improve the balance in the discussion of the different stressor types?

A. I would not change it. I would emphasize, however, that it is not necessary to develop a single framework that can be applied to all stressor/ecological resource situations. A "single-strategy" or "one-size-fits-all" objective is NOT necessary. If EPA were to develop a framework that would cover most chemical stressors this would be a useful contribution!

14. Q. Are there additional points or principles that should be emphasized for either chemical, physical, or biological stressors?

A. No, but reveiw answer to 13.

15. Q. What additional principles would you suggest, if any, for the analysis of multiple stressors?

A. As we move "up" the biological hierarchy (e.g. from species to ecosystems) and as we lengthen the time boundary (e.g. from growing season to decade) we must become more concerned with multiple stressors and stressor interactions. The current "state-of-science" strongly favors risk assessments focused on single species for relatively short time periods.

16. Q. What additional principles should be highlighted in the discussion of risk estimation techniques?

A. Any approach that links both stressor exposure and ecological resource effects, whether qualitative or quantitative, can be considered "risk estimation". Expert opinion, empirical approaches, quotient methods, exposure/effects distributions, field surveys, and simulation appear to cover the primary options.

17. Q. The guidelines propose four criteria for ecological significance. How

should this list of cirteria be modified, if at all? What additional guidance, if any, might be added to the discussion of these criteria?

A. This is an important consideration! Numerous statutes include the term or "concept" of ecological significance and very few include specific reference to statistical significance. I feel ecological significance, absent any reference to the value of specific ecological resources to human beings, is of limited usefulness/importance. It is more reasonable to identify specific human values (products/services) that flow from ecological resources, and then evaluate adverse effects in the context of these values. If this is done, then intensity, scale, recovery rate, and sustainability become "useful" descriptors of the significance of specific stressor interactions with specific values.

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Table 1. VALUES ASSOCIATED WITH FOREST SYSTEMS:

Products	*Services*
Wood Lumber Particle Board/Plywood Paper Fuel wood Mulch	Existence Value
Wildlife (game)	Recreation
Wildlife (non-game)	Tourism
Forage (wildlife, livestock)	Biological Diversity Genes Species Communities Ecosystems
Other Seeds Edible nuts Syrup (sugar maple) Drugs (e.g. Taxol) Pesticides (e.g. Neem) Chemicals (e.g. turpentine) Christmas trees Mistletoe Edible mushrooms	Landscape Diversity
	Amenity Function Microclimate Amelioration Sound Attenuation Aromatic Hydrocarbons Visual Attractiveness, screening
	Runoff/Erosion Management
	Soil/Nutrient Conservation
	Pollutant Sequestration/ Detoxification

Smith (1995).

Ralph Stahl, Jr.

COMMENTS ON DRAFT ECOLOGICAL RISK ASSESSMENT GUIDELINES
RALPH G. STAHL, JR

PART I. GENERAL PRINCIPLES

The ecological risk assessment guidelines can be improved to more clearly indicate underlying assumptions and default positions in several ways. The first is to reinforce the requirement for transparency throughout the guidelines - that is, that the risk assessor be required to clearly document all underlying assumptions and default positions in the assessment. Secondly, I believe that the guidelines could suggest that the risk assessor have a separate appendix in the risk assessment that includes example calculations, where default values and underlying assumptions are detailed would also be a way to improve the clarity on this point. Hand in hand with this documentation would be an explanation or justification for using these defaults and assumptions so that the reader is not left with the impression that the risk assessor uses these without some basis or rationale. In the situation where these defaults and assumptions are actually policy driven, not scientifically driven, the text should so state.

I have made suggestions on how to change specific areas of the document in my comments that follow.

PART II. SPECIFIC QUESTIONS

A. Guidelines Balance

1. I found the emphasis on higher levels of biological organization to be appropriate.

2. I found the case examples to be adequate for the purposes of this document. They should not be overly detailed but illustrative of the

various situations in which ecological risk assessments were conducted. Improvements in the case examples would be to include two other examples. One example would illustrate how human health risk assessment and ecological risk assessment are considered in parallel (or tandem) and how the risk management options were developed. It would be important for both ecological and human health risk assessors to see their efforts interlinked rather than as separate. Another example that should be included would be one where only a screening level assessment was used. This would illustrate how the scope of an assessment must be tailored to the particular issue.

3. It is true that there have been fewer ecological risk assessment on terrestrial systems than aquatic. For that reason I would agree that an additional example of a terrestrially-driven assessment would be beneficial. It may be appropriate to develop a case where soil is the medium of concern since so little data have been developed in this area.

4. I found the approach of discussing uncertainty in the various phases to be beneficial as I was able to understand uncertainty as it pertained to the specific areas.

B. Introduction and Scope

5. I my opinion the scope and content of the guideline is adequately addressed in the Introduction section.

6. There are no specific changes to terminology that I would suggest. I believe that the guidelines provided the needed clarification of assessment and measurement endpoints through additional discussion and slight changes in terminology. This was very beneficial and addressed two terms which I believe were greatly misunderstood.

7. At the EPA's May 3, 1995 Colloqium, modifications to the framework figure were suggested by Rich Kimerle representing industrial

viewpoints. I would encourage EPA to review Rich's written comments and suggested changes to the framework figure.

C. Risk Manager Interactions

8. The added details and emphasis on the risk assessor / risk manager interface were long overdue. I think that this has strengthened the guidelines considerablly and applaud the authors for doing this. I believe however that there should be greater emphasis placed on what the risk manager's role is when interacting with the public. For example, the public should have input to the assessment endpoints or ecological valuation process. The gathering of public input and the communication about the need for and results of the risk assessment are clearly the job of the risk manager. I believe this should be noted in the guidelines.

9. Additional points that would be useful in the guidelines would include those related to risk communication. Although these guidelines are not for risk communication, they would benefit from some brief discussion of potential communication options, problem areas, etc. that should be known early in the risk assessment. Public discourse on the risk assessment should be regular and open so that when the risk management options are discussed with the public they have been part of the process from the beginning. Ultimately the results of the risk assessment must be communicated to the impacted stakeholders directly, perfereablly in a face-to-face format.

D. Problem Formulation

10. I'm not sure the categorization of the assessments into three groups helped my understanding, but may prove useful to others who view the assessements as fitting into one category or another. I tend to view the assessments in three categories: screening, prospective, and retrospective.

11. As I noted earlier, I believe the discussion of assessment endpoints and their relationship to management goals and "measures" was long overdue. I believe the discussion throughout the guidelines have clarified some of the more confusing aspects of ecological risk assessment / risk management.

12. I think the discussion of risk hypothesis is adequate and may not need additional work. However, the discussion of the conceptual model would benefit from either an example or greater detailing perhaps in an appendix. Some still believe that the conceptual model is just that - a "model" in the sense of a software program that one puts numbers into and gets results out of. Using terms such as a summary of current knowledge about the issue, or brief overview, or background, may dispel some of the confusion that stems from using the word "model". Maybe just saying "conceptual diagram" would help so that the risk assessor knows that the purpose is simply to illustrate the situation at hand.

E. Analysis

13. In later text, I have provided comments on specific paragraphs in this section. Briefly, I think the sections on non-chemical stressors could be expanded and upgraded. I still have the impression that non-chemical stressors are not considered very important by EPA, yet loss of habitat (physical stressor) and exotic species' expansion into native habitats (biological stressor) are probably responsible for more ecological risk than the great majority of chemical stressors. Quite frankly, the discussion of non-chemical stressors still "feels" like an also-ran, or add-on, put there to placate critics rather than to provide a serious discussion.

14. I believe that the section on biological stressors is still incomplete. Perhaps it is my bias but I can't understand why there is no discussion or mention of predation, competition, etc. as biological stressors. I

recognize that we cannot regulate these to a large degree, but we should at least acknowledge their importance as biological stressors that all plants and animals face each day. I think that this needs to be stated in the guidelines so that the risk "picture" is not missing some of its most important components.

15. Multiple stressors is a difficult issue and one that will not be resolved in these guidelines. I have no additional principles to add.

F. Risk Characterization

16. There are several additional principles that could be useful. One is that the risk assessor should clearly document (or reiterate) underlying assumptions and default values that were used in the estimation. Another is that the estimates be communicated in simple terms, especially those which are understood by the public.

17. I believe there are two additional points that should be included in the discussion of ecological significance. The first is the time-scale. Risks which may manifest themselves over decades or longer are much more significant than those which are short-lived. The concept of time is not given much if any discussion in this section. Secondly, I believe that risks to the sustainability of a population, community or ecosystem are more significant that those which not threaten the sustainability.

PART III. GENERAL COMMENTS

- There needs to be some upfront discussion about the level of effort involved in the risk assessment. For example, the guidelines should note that risk assessments come in all shapes and sizes and will be dependent on many factors. I find little discussion about this in the current document and would prefer to see some discussion of when a screening assessment would be appropriate compared to a more extensive risk assessment.

- I am uncertain whether the concept of tiering the risk assessment is clear to the reader. After reading the guidelines I certainly did not feel as if the concept were clearly discussed, nor given an appropriate level of visibility. I would encourage EPA to give the concept more priority and visibility in the next draft.

- I believe the guidelines should briefly note the linkage with human health. This will be most important for retrospective risk assessments where site clean ups are driven by human and ecological risks. For example, the guidelines could note that remedies to protect human health can also provide some level of protection to ecological receptors. In addition, the guidelines could indicate that there will be situations where remedies to protect humans will not be protective of ecological receptors.

- I suggest that EPA consider adding a figure similar to the one shown below to illustrate the various stressors present in the ecosystem. The concept is that there is a total stress in the system that can be broken into its various components: biological, chemical (nutrients) physical and contaminants. It is also important to help the readers understand that the relative contributions of the various stressors is dynamic and not evenly distributed.

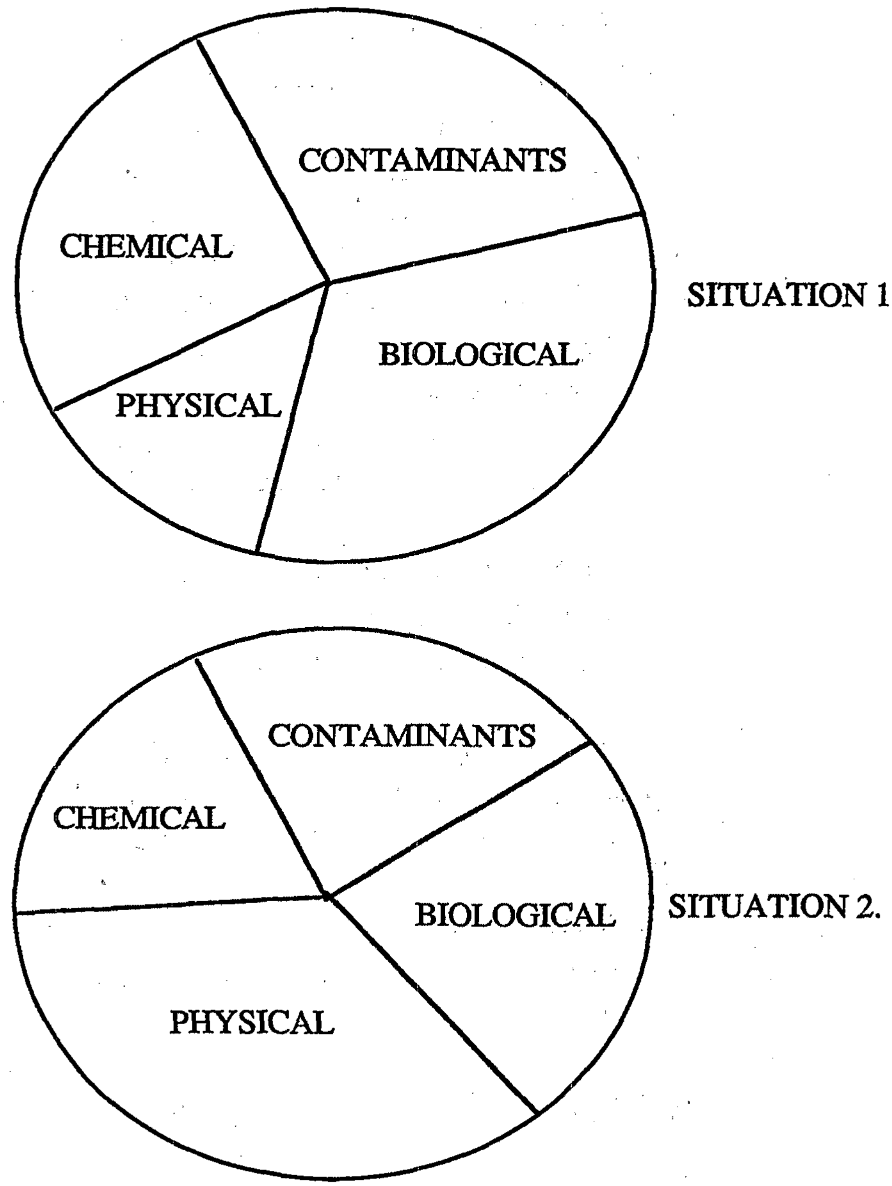

FIGURE < >. THE MAIN GROUPS OF STRESSORS IN THE ENVIRONMENT. Note that the relative proportions of the stressors to the whole stress is dynamic and not evenly divided.

- I believe that the guidelines would benefit from the inclusion of a flow diagram to illustrate the risk assessor / risk manager interactions. A similar flow diagram was used by EPA OERR in their revised guidelines for ecological risk assessment.

- I agree with the inclusion of simulation models in the guidelines and would encourage EPA to more fully discuss this topic, either in the text directly or in an appendix. Because these models offer such promise (or opportunity for misuse in some cases) for improving risk assessments I believe they deserve more discussion and visibility in the document.

- I am most encouraged by EPA's use of several key terms in the guidelines. The use of terms and concepts such as risk ranges instead of point estimates, transparency in the risk assessment, the separation of science from policy, the focus on higher levels of biological organization for the risk assessment (population, community, ecosystem) all suggest a greater appreciation by EPA of how to improve risk assessment within the Agency.

- Finally, I am also highly encouraged by EPA's recognition that destroying habitats to clean them up is not a viable approach in most instances.

PART IV. SPECIFIC COMMENTS

- p. 3, L 2-4 Given that EPA acknowledges the lack of understanding of ecological principles and processes of risk managers, there should be a short preamble that would be specific to risk managers. Some if this information may be provided in the Primer for Risk Managers prepared by EPA's Risk Communication Group.

- p. 4, L 16 I agree with the statement. There should be a clear understanding of the drivers behind why an ecological assessment is being undertaken, and these should be acknowledged by the risk assessor and risk manager before the risk assessment is undertaken.

- pp. 11 - 12 The change in terminology from measurment endpoint to measures of effect is an improvement due to its clarification of what the endpoint really is (ie effect). However, this is not clearly translated in Text Box 1-3 where the measure of exposure is not as precise or clear to the reader. This section discussing exposure and effects would benefit from greater parallelism between the terminology for effects and exposure.

- p. 13, L 2-4 The statements contained in this part suggest that it is important for the risk assessor to continue to look for impacts until they are found. I don't believe that this is what the authors intended. The guidelines should not give the risk assessor the impression that their job is to undertake an exhaustive and never ending effort to find impacts regardless of their significance or relevance.

- p. 14, L 27 I believe that the definition of biological stressors is too restrictive. What is the reasoning for not including other types of biological stressors such as predation, competition, etc. in the assessment? I recognize that trying to do that would be difficult, and may require far more knowledge about life history, etc., but at the very least the guidelines should note that there are other biological stressors at work and that they also play a significant role in the overall stressor / receptor scheme.

- p. 15, L 19 Does co-occurance really equal exposure? If the material is biologically available, then perhaps it does. But without knowing whether something is bioavailable, it seems inappropriate to consider co occurance as equivalent to exposure.

- p. 18, L 4 The timing for the risk assessment must also be included as one of the key issues discussed by the risk assessor and risk manager.

- p. 20, Text Box 2-2 Great! Glad to see this written as is.

- p. 21, Text Box 2-3 While sustainability is a very important management goal, shouldn't other examples of management goals be used as well? Could improvement or enhancement also be goals in this process as well as sustainability?

- p. 24, L 17 This sentence would suggest that ecological risk assessments could not be performed for natural phenomena such as those not resulting from human activities. Is that really the case or just an oversimplification? Why couldn't the guidelines and framework be used to assess the risk of fire for example?

- p. 24, L 17-24 This section is a bit unclear to me. For example, what about reaching agreement on Data Quality Objectives, expected products, decision points, etc. ? In addition, Text Box 3-1 would benefit from expansion and greater detail reflecting the comments made about lines 17 - 24.

- p. 27, L 28 What about the situation where there is no exposure? Does that mean that there is no need to proceed with the risk assessment? Shouldn't there be a statement that if there are no potential exposure pathways, or complete exposure pathways that the risk assessor may not need to go further in the assessment?

- p. 36, L 30 & p. 37, L 1 This discussion seems to imply that the risk assessor should search or select assessment endpoints that will be popular with the public, or at the very least should be changed to gain public acceptance. I believe this is the problem with the current practice today and should not be encouraged with language of this sort. In my opinion it is up to the risk manager to make the case with the public as to what is or is not valuable to them, as well as what should or should not be protected. Once this is agreed to, then it is up to the risk assessor in concert with the risk manager to provide the public with a clear understanding of what that means. Providing the public with a lay-level explanation of the risk assessment and the ecological resources that will be part of the study (amphipods for example) is a key responsibility of the risk assessor and risk manager. Attempting to change the assessment endpoint to gain wide popularity seems to be counter to the need for openess, clarity and transparency in the entire process.

- p. 38, L 9 The last sentence in this line seems to beg the question of what types of information would be needed. I believe it would be helpful to give some suggestions rather than to leave this open ended.

- p. 38, L 21 I don't understand how "absence of contact" can still be considered exposure as noted in this sentence. This should be clarified.

- p. 44, L 31 What is an ecological entity? Does this mean the ecosystem at risk, the river or lake being impacted, all of the these or something else?

- p. 46, L 4 I think this section would benefit from a diagram rather than text. It would be beneficial to develop a diagram that illustrates the iterative process and how the risk manager is kept in the process loop.

- p. 46, L 11 I think it would be useful to briefly discuss how developing a testable hypothesis is or is not useful to the risk assessment. While I agree with the intent behind doing this, I' m not sure it is very practical in all cases. The ability to develop a clearly testable hypothesis requires a fair knowledge of the system under study, confounding variables and other influences. This level of understanding will seldom be present especially when the situation involves multiple stressors.

- p. 52, L 23 Both the feasibility of obtaining the data and the relevance of that data to overall risk must be taken into account. This is particularly noteworthy in the case of using biomarkers where the technology involved may only be managed by a few individuals or laboratories and where it is nearly impossible, without substantial effort, to link the results of biomarker measurements to risks to whole organisms, populations or communities.

- p. 53, L 30 How the results will be interpreted should also be one of the important decisions made early in the process. It would be useful to use Test Box 3-13 to illustrate this point. For example one could say that " a 50% reduction in egg hatching rate will be interpreted as...." to illustrate the point.

- p. 58, L 6 While I agree with the concept that data used in the assessement would be better having come from refined DQOs, I don't want to restrict the risk assessor to using only data obtained that way. There may be scientifically valid data originating from non-DQO type studies that the risk assessor should have the option of using provided they give the scientific justification for their use and can attest to their validity. When the risk assessor is planning new studies to obtain new data then those studies should adhere to the development of clear DQOs.

- p. 58, L 14 In addition to the points made in this sentence it would be important to have the risk assessor provide example calculations. Showing how the numbers are "crunched" allows the reader to conduct simple "spot checks" on their own and thus gain a better understanding of the results.

- p. 59, L 3 This particular section needs to be expanded. For example there is no mention of the possible biological or physical stressors that may be present in the ecosystem under study, or the stressors associated with the particular land use of the area. The focus is tied too heavily to other chemical stressors.

- p. 63, L 9 - 17 This discussion would benefit were the risk assessor to be required to establish criteria by which data would be judged as to their scientific validity. At the very least the risk assessor should be required to demonstrate adequate knowledge about the types of test data being utilized in evaluating the risk to a particular receptor. While the risk assessor cannot be versed in all facets of laboratory and field studies, they can establish criteria, perhaps in concert with co workers or peer review groups, to judge studies and data that will be used in the risk assessment.

- p. 64, L 28 - 30 I believe a table would more clearly illustrate the three main objectives compared to the text that is currently provided.

- p. 67, L 6 The background is very important in retrospective risk assessment such as those conducted for waste sites. For that reason the discussion on background would benefit from some examples on how one could apply background information to the risk assessment.

- p. 71, L 8 It should be emphasized that these data are at best qualitative in nature and will not be refined sufficiently to provide a quantitative estimate of exposure. Even tissue residue studies, due to the mobility of organisms and the materials in question, are not highly quantitative unless they can be coupled with a substantial amount of information on the life history of a particular organism.

- p. 73, L 1-2 This point would benefit from an equation. It is difficult to grasp the point in the currently presented form.

- p. 74, L 19 This point seems to beg the question of when it would not be appropriate to analyze the cause and effect relationship. Either give some examples of when / where it would not make sense or delete the sentence.

- p. 76, L 25 I agree with the general concept put forth in this section. However, some high quality tests are not conducted according to Good Laboratory Practices and vice versa. Adherence to GLPs tends to insure that one can reconstruct how the study was done, not whether the study was scientifically valid. I believe it is important for the risk assessor to understand the strengths and weaknesses of testing protocols so that they can better appreciate the results from protocol driven studies. Yet adherence to GLPs may or may not be indicative of a good study or help an inexperienced risk assessor understand the strengths and weaknesses of a particular study.

- p. 81, L 18 I'd prefer to see some additional discussion about the range of factors given in this sentence less the reader is left to believe that only multiples of 10 can be used in the emphirical approach. It would be useful to note that ranges from 10 to 100 for these values is based primarily on historical precedent and not necessarily on scientific facts.

- p. 88, L 4 I still believe that causality needs to be discussed even when detailing information from laboratory studies that maximize the cause / effect relationship.

- p. 90, L 12 - 20 Why not reiterate the three dimensions of exposure as noted earlier on page 71, lines 27 - 28? Was it intended for this section to take a different view of exposure?

- p. 91, Figure 4-6 Unfortunately I cannot read the inside text of this figure and thus cannot comment on its usefullness.

- p. 103, L 23 Shouldn't all risk assessments involve a team approach? Until this point in the guidelines the suggestion of using a team approach has not been made. Are biological stressors so unique that they require a team approach while chemical and physical stressors do not? If the risk assessment would benefit from a team approach, then say so up front.

- p. 114, L 5 I whole heartedly agree that the risk should be reported as a range and not as a point estimate whenever possible.

- p. 117, L 15 I believe that the risk assessor should provide a range of quotients rather than just one. Even though the results / data may not be continuous, using a range of quotients will nonetheless give a better indication of the range of hazard (risk) involved.

- p. 118, L 9 - 31 This entire discussion would benefit from more detail of simulation models and examples of applications. Perhaps adding such a section to the appendices could be accomplished in the next draft of these guidelines.

- p. 121, L 5 There needs to be a stronger wording of what the risk assessor should do. Using the wording of "indication of" does not convey the appropriate level of importance that this requires.

- p. 125, L 2 This end of this sentence is misleading as it suggests the risk assessor should consider the time before "introduction of a stressor". The more appropriate "before the introduction of the stressor under study" should be used.

- p. 125, L 16 - 18 The example of old growth forests should be re-written as it now conveys something that does not seem to be what the authors intended. For example, the continuous logging of an old growth forest may eliminate the old growth trees, but it will not eliminate the forest ecosystem except if the trees and other plants are not allowed to regrow. The forest ecosystem will not be eliminated, but changed.

Randall Wentsel

COMMENTS ON EPA DRAFT ECOLOGICAL RISK ASSESSMENT GUIDELINES

Randall S. Wentsel
U.S. Army

In 1989, the EPA Risk Assessment Forum started on a process to develop ecological risk assessment (ERA) guidelines. In 1992, they produced the "Framework" which I consider to be the ecological equivalent to the "Red Book" for human health risk assessment. Following their six year plan, they have now produced draft ERA guidelines. I would like to commend the Forum, and Bill van der Schalie in particular, for their leadership, knowledge, and management of this complex subject area.

Part 1

I don't think we need a "Framework II" at this point as much as we need guidance for ERA. The refining of definitions, the identification of additional types of uncertainty, and changing rectangles to hexagons in the paradigm; may be necessary but I don't think that is what we need to move the process forward. On a spectrum of very applied to very theoretical, the discussion of ERA in this guidance is more theoretical in scope. While I have read what the guidelines are and are not intended to be, I still think more can be done in the applied area to support increased quality and consistency of ERA. For example, in the problem formulation phase (or possibly in the risk manager/risk assessor discussions) it is never discussed what criteria would have to be met to determine that no ERA was necessary. In the analysis phase, the use of benchmarks are never discussed. In the risk characterization phase, the use of probabalistic distribution is only briefly mentioned. These applied areas are difficult to present and controversial, but I think they need to be included.

Randall S. Wentsel

I have several comments in the policy area of ERA within EPA. First, the EPA goes in four or five directions in the use of ERA. The EPA needs to present a more uniform approach to ERA than they are currently doing. The Offices and Regions need to brought in so that EPA speaks with one voice on this subject. I do not believe most EPA Headquarters Offices and Regional Offices have enough personnel with the breadth of expertise required to generate their own ERA guidelines. They need to be brought into the HQ discussions to support the uniform approach.

Second, I think these guidelines should focus on the statutes and areas where EPA is the primary Federal agency involved, i.e. TOSCA, FIFRA, and Superfund. It seems like these guidelines go out of their way to present examples in watershed and land management areas where the Departments of Interior and Agriculture have leadership. While these may be more ecologically interesting in scope, critical issues relevant to specific statutes, where EPA leads, should be discussed.

Third, ERA is a tool to assist risk mangers in decision making. Applied guidance is needed. While scientific debate and theoretical issues have their place, eventually factual information must be supplied from the risk assessment to the managers. If ERA is to be an effective tool in the risk management process, it must supply information in a more standardized format in a timely fashion to the risk manager. Endless debate and data collection will reduce the value of ERA in environmental policy decisions. The guidelines should ask the question - Where is the science now in environmental chemistry, environmental toxicology, and risk characterization? Currently, too much expert judgment is used by the risk assessor in conducting an ERA and too often scientific or personnel values are used by the regulator to judge whether an ERA is appropriate.

PART I GENERAL PRINCIPLES

o Specifically, how can the ecological risk assessment guidelines be improved to more clearly indicate underlying assumptions and default positions?

The ERA guidelines are currently written too generally to establish default positions. Worst case assumptions and default positions are controversial subjects. They are open to criticism when they deviate from sound scientific principles or are so conservative that they don't pass the common sense test. I believe default positions imply a cook book approach which ERA doesn't always fit.

o What changes would you recommend in each section of the document?

ERA is referred to as a scientific process in the document. I do not believe that is the most prevalent opinion.

PART II SPECIFIC QUESTIONS

Guidelines Balance

1. Considering both the present state of the science and present and future Agency needs, how well are the guidelines balanced regarding the range of stressors, levels of biological organization, ecosystem types, and spatial/temporal scales? Specifically, what would you emphasize or de-emphasize?

I would emphasize simple over complex ERAs. Discuss what we can do. Phrases like "can be difficult" or "is complex" do not provide anything new to the audience.

2. What would you suggest to improve the use of case illustrations in the guidelines? How useful is Appendix A in illustrating a range of applications of the risk

assessment process?
Case studies are too brief. The reader needs to know how equations, models, and scientific judgment was used. Consider using specifics from issue papers with page numbers.

3. Some Agency reviewers of the guidelines have suggested that more examples of terrestrial assessments and field approaches (e.g., bioassessment techniques) should be used. Specifically, what, if anything, should be added?
A discussion of important issues for terrestrial assessments is needed. What tools are available and what tools are needed in the analysis phase for soils.

4. Areas of uncertainty are summarized in the problem formulation (section 1.5), analysis (section 3.7), and risk characterization (section 5.2.4). How useful is this approach in providing guidance on uncertainty issues?
Communication and human error should be discussed but not given equal treatment to the other areas. The three tables should be combined into one. Specifics on uncertainty reduction should be expanded.

Introduction and Scope

5. How could the Introduction be modified to more clearly communicate the scope and content of the guideline?

6. Terminology, especially related to endpoints and exposure, has always been controversial. What changes, if any, would you recommend in guidelines terminology?
The Framework established common terminology. Refinement of terminology has its place, but that must be balanced against the confusion changes generate. I would place less priority on terminology changes than in providing guidance to assessors.

7. The overall framework figure for the ecological risk process has been retained, although some changes have been made to the diagrams for problem formulation, analysis, and risk characterization. What further modifications, if any, are required?

I think the workshop participants should review the necessity of changes to the paradigm. Additional discussion of the thinking behind the changes would be beneficial.

Risk Manager Interaction

8. Please comment on the description of the risk manager's role at the initiation of an ecological risk assessment and on the principles for selecting management goals.

In initial risk manager and risk assessor discussions or possibly in the problem formulation phase, I think guidance is needed to address - Do we have a problem? Is an ERA necessary?

9. What additional points, if any, should be covered about relating ecological information to risk management decisions after the completion of an ecological risk assessment?

Problem Formulation

10. How useful is the categorization of assessments as either stressor- or source-initiated, effects-initiated and ecological value-initiated?

It is an interesting discussion. Policy impacts from specific legislation could be stressed as examples.

11. Please comment on the discussion of assessment endpoints and their relationship to management goals and "measures."

12. What, if anything, would you add to the discussion of risk hypotheses and conceptual models to give the reader a clearer understanding of their nature and content?

Tiers are discussed in the document. How would tiers be addressed in the three phases of ERA?

Analysis

13. How would you change this section, if at all, to improve the balance in the discussion of the different stressor types?

I would expand the exposure section to include more specifics on pathways. I would slant the discussion toward statutes where the majority of ERAs are prepared (probably by number and dollar amount) and where more detailed information can be presented. Areas where the science and risk management decisions are complex and undeveloped should receive less space.

14. Are there additional points or principles that should be emphasized for either chemical, physical, or biological stressors?

Environmental chemistry should be stressed. The impacts of water and soil chemistry on the transport, fate, and bioavailability of chemicals is important. Environmental chemistry principles should be presented or referenced to issues papers. Background concentrations are discussed on the top of page 67. I think the guidance should consider a definition or at least a more quantitative discussion of addressing background. Without some specifics much of the discussion in section 4.2.2. is of little value.

In section 4.2.3.2. in the discussion on uncertainty factors for extrapolation between responses, factors between 10 to 100 are put forward. I believe these have been adopted from human health risk assessments where protection of the individual is the endpoint. I think uncertainty factors for protecting endangered species may be similar to human health but factors for non-threatened populations or ecological systems would be less. This section should differentiate these issues.

15. What additional principles would you suggest, if any, for the analysis of multiple stressors?

Risk Characterization

16. What additional principles should be highlights in the discussion of risk estimation techniques?

A further discussion of the impact of professional judgment, scientific values, and the incorporation of conservatism into risk estimation should be presented. For example in section 5.2.2.1. limitations of the quotient method do not mention conservatism that is often built into the method. Use of distributions in risk estimation needs to be expanded.

17. The guidelines propose four criteria for ecological significance. How should this list of criteria be modified, if at all? What additional guidance, if any, might be added to the discussion of these criteria?

APPENDIX E

REVIEWER WORK GROUP ASSIGNMENTS

WORKSHOP ON THE DRAFT ECOLOGICAL RISK ASSESSMENT GUIDELINES

Washington, DC
December 6-7, 1995

WORK GROUP ASSIGNMENTS

William Smith (Workshop Chair)

Each work group will address the following topics:

- Problem Formulation
- Analysis
- Risk Characterization

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APPENDIX F

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Risk Assessment Forum

Workshop on the Draft Ecological Risk Assessment Guidelines

Holiday Inn - Georgetown
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APPENDIX G

WORKSHOP CHAIRPERSON'S OPINION SURVEY

WORKSHOP CHAIRPERSON'S "MODIFIED DELPHI" REVIEWER OPINION SURVEY

At the conclusion of the workshop, Workshop Chairperson William Smith conducted a "modified Delphi" survey of reviewers' opinions on several issues discussed during the workshop. He invited reviewers to record their reaction to 14 statements as follows: Strongly Agree (SA), Agree (A), Disagree (D), Strongly Disagree (SD), or Unclear/Uncertain (?). Of the 25 reviewers, about 10 were out of the room or otherwise did not participate in the survey.

1. The Draft Guidelines represent a useful next step from the *Framework Report*.

   SA (3) A (10) D (2) SD (0) ? (0)

2. The Draft Guidelines are not intended to be a technical manual.

   SA (5) A (8) D (2) SD (0) ? (1)

3. The Draft Guidelines certainly can express preferences and they should, in fact, identify criteria for selecting alternative techniques.

   SA (6) A (10) D (0) SD (0) ? (0)

4. The Draft Guidelines include the key elements of what we perceive to be a reasonable risk assessment.

   SA (3) A (10) D (1) SD (0) ? (1)

5. The Draft Guidelines contribute to the hope for some degree of consistency of application, at least within EPA.

   SA (2) A (8) D (5) SD (0) ? (1)

6. Societal values translated via management or regulatory objectives bound/define risk assessment questions.

   SA (3) A (8) D (1) SD (0) ? (2)

7. Revision of the Draft Guidelines should not be delayed by major supporting documents (e.g., an Issue Paper on multiple stressors) judged to be needed.

   SA (5) A (10) D (1) SD (0) ? (0)

8. Teams, rather than individuals, represent "people" in the risk assessor and risk manager boxes in the framework diagram.

SA (6) A (9) D (0) SD (0) ? (0)

9. The importance of biological and physical stressors is recognized to be increasing.

SA (3) A (8) D (1) SD (0) ? (3)

10. Resources directed to technology transfer of the Guidelines would represent a wise investment.

SA (4) A (6) D (1) SD (0) ? (4)

11. Linking risk assessments to ecological resource monitoring is important.

SA (2) A (7) D (1) SD (0) ? (5)

12. Minimal use of technical jargon and careful explanation of phrases with multiple meanings (e.g., multiple stressors) will maximize the clarity of the Draft Guidelines.

SA (6) A (10) D (1) SD (0) ? (0)

13. As drafted, the Guidelines are suitable for "micro" site-specific assessments and "macro" policy assessments.

SA (3) A (10) D (1) SD (0) ? (0)

14. The Draft Guidelines have no major "fatal flaws," and EPA should move ahead.

SA (6) A (8) D (0) SD (0) ? (1)

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