January 21, 1997

EPA-SAB-EPEC-97-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

RE: Science Advisory Board (SAB) Review of the Agency's Ecological Risk Assessment Guidelines

Dear Ms. Browner:

In its 1990 report, Reducing Risk, the Science Advisory Board (SAB) recommended that "EPA should attach as much importance to reducing ecological risk as it does to reducing human health risks". During much of the 1990s the Agency has responded by paying increased attention to ecological risks.

Now, we are pleased to transmit to you the results of the SAB's review of the Ecological Risk Assessment Guidelines (Eco RA GLs) which mark the culmination of a nearly decade-long development process that has involved scientists both inside and outside the Agency. The goal has been to generate a guidance document that will provide structure and discipline to the assessment of ecological risks.

We believe that the Agency has successfully achieved that goal.

The conceptual outline for these ecorisk principles was first developed at the Pellston workshop in 1977. At that time, the mutual importance and co-dependency of environmental chemistry and fate testing with ecotoxicology were first identified. The current guidelines advance ecological risk assessment well beyond that early conceptual stage to what is now a truly functional practice.

The proposed Eco RA GLs outline the entire process and provide details on how each of the steps of problem formulation, analysis, risk characterization, and risk management can be successfully completed. Sufficient balance between specific guidance and flexibility is maintained so that the user can adapt the process to highly variable problems. The SAB review comments are generally supportive of the guidelines, while offering numerous suggestions for improvement on a wide range of issues, including risk assessor/risk manager interaction, assessment endpoints, use of tiered assessment, field data, and multiple stressors.

The Eco RA GLs document provides a template for dealing with many environmental programs and problems; e.g., new chemicals, water and air quality issues, waste site assessment, and spills. As such, these guidelines, like the Agency's ecological risk assessment framework from which they sprang, will likely be widely accepted and used by regional, state, and local authorities, as well as by many in the private sector. Indeed, the Eco RA GLs appear destined to be as seminal and trend-setting in their field, as the Cancer RA GLs have been in theirs. This achievement reflects well on science at EPA and all those who were involved in the guidelines development process.

We look forward to your response to these comments.

Sincerely,

Dr. Genevieve Matanoski, Chair
SAB Executive Committee

Dr. Alan Maki, Acting Chair
Ecological Processes and Effects Committee

NOTICE

This report has been written as a part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency; and hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency or other agencies in Federal government. Mention of trade names or commercial products does not constitute a recommendation for use.

ABSTRACT

The Ecological Processes and Effects Committee (EPEC) of the Science Advisory Board (SAB) met in Washington DC on September 19-20, 1996 to review the Agency's draft Ecological Risk Assessment Guidelines (Eco RA GLs). The Committee commended the Agency on its multi-year effort and its frequent contact with the outside scientific community during the development of the Eco RA GLs. The Committee responded to a charge covering ten specific areas: a) Risk Assessor/Risk Manager Interactions; b) Assessment Endpoints; c) Tiered Assessments; d) Field Data; e) Background Variability; f) Landscape Ecology; g) Multiple Stressors; h) Risk Estimation Approaches; i) Terminology; and j) Future Products.

While making suggestions for further improvements and for specific extensions of the work, the Committee endorsed the process and product of Agency's efforts on this project.

Keywords: ecological, risk assessment, guidelines, endpoints, landscape

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1 Recused, due to participation in development of Agency's document.

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1. EXECUTIVE SUMMARY

The Ecological Processes and Effects Committee (EPEC) of the Science Advisory Board (SAB) met in Washington, DC on September 19-20, 1996 to review the Agency's draft Ecological Risk Assessment Guidelines (Eco RA GLs) (5). The Committee commended the Agency on its multi-year effort on the project and its frequent contact with the outside scientific community during the development of the Eco RA GLs.

The Committee responded to a charge covering ten specific areas:

a) Risk Assessor/Risk Manager Interactions - "Overall how compatible are these Proposed Guidelines with the National Research Council concept of the risk assessment process and the interactions between risk assessor, risk managers, and other interested parties?"

   Answer: The Committee found the Eco RA GLs to be generally compatible with the recent NRC reports. They recommended further elaboration in some parts of the GLs.

b) Assessment Endpoints - "Assessment endpoints are an 'explicit expression of the environmental value that is to be protected'...Some reviewers have recommended that assessment endpoints also include a decision criterion that is defined early in the risk assessment process (e.g., no more than 20% reduction in reproduction, no more than a 10% loss of wetlands.)...[T]he Proposed Guidelines suggest that such decisions are more appropriately made during discussions between risk assessors and managers in risk characterization at the end of the process. What are the relative merits of each approach?"

   Answer: The Committee agrees with the approach proposed in the Eco RA GLs, at the same time noting the importance of retaining an appropriate balance between allowing risk managers/interested parties to inform the risk assessment process, on the one hand, and while maintaining the independence of the risk assessor and the risk assessment process, on the other. Given the intended broad application of the Eco RA GLs to the full range of ecological issues, the Committee does not believe that a single set of quantitative decision criteria are appropriate from a technical point of view. Further, the Committee recognizes the inherently policy aspect of reaching final quantitative decisions. Scientific information can--and should--inform the selection of quantitative numbers in any decision, but there are factors beyond those in the strictly technical realm that the risk manager must also consider.

c) Tiered Assessments - "While the Proposed Guidelines acknowledge the importance of tiered assessment, the wide range of applications of tiered assessment makes more specific guidance difficult. Given the broad scope of the Proposed Guidelines, what additional principles for conducting tiered assessment can be discussed?"

Answer: The Committee endorses the concept of tiered testing as an efficient use of resources in ecological risk assessment. The Committee also encourages the development of guidance criteria for determining when higher tiered assessment is necessary.

d) Field Data - "[Beyond the material already in the Proposed Guidelines], what, if any additional material should be added on these topics and, if so, what principles should be highlighted?"

Answer: The Committee report provides a discussion of the comparative advantages of field data and lab data, including a set of "principles" to guide in the evaluation and use of field data.

e) Background Variability - "[Beyond the material already in the Proposed Guidelines], are there additional considerations concerning this issue that should be included in the Proposed Guidelines."

Answer :The Committee recommends specific approaches to addressing this problem: 1) use of information on the mechanisms involved, particularly for bioaccumulative substances; 2) use of caged organisms; and 3) use of improved statistical techniques for dealing with highly variable data sets.

f) Landscape Ecology - "...given the Agency's present interest in evaluating risks at larger spatial scales, how could the principles of landscape ecology be more fully incorporated into the Proposed Guidelines?"

Answer: The Committee agrees that the Agency should pay more attention to landscape effects and its report offers several specific suggestions for expanding the Eco RA GLs so that they more effectively include consideration of landscape issues. Among the suggestions are improvements in the Figures, presentation of a "hierarchy of scales", and use of landscape-based indicators.

g) Multiple Stressors - "[Beyond the material already in the Proposed Guidelines], what additional principles can be added?"

Answer: The Committee acknowledges this difficult problem and proposes specific statistical methods of analysis that would illuminate the situation. Specifically, path analysis, multiple-regression analysis, canonical analysis, or partial correlation analysis are often useful in discerning the effects of multiple stressors on an effect variable.

h) Risk Estimation Approaches - "The Proposed Guidelines use simple exposure and stressor-response curves to illustrate some aspects of risk estimation. What other examples could be used to represent risk estimation for nonchemical stressors or more complex situations?"

<u>Answer</u>: The Committee provides several examples of empirically derived non-chemical stressor-response phenomena that illustrate the generality of such curves for decision making. In addition, they note the utility of process models for estimating the shape of stressor-response curves, even in the absence of field data. Finally, the Committee notes that many phenomena appear to exhibit practical thresholds that may be useful benchmarks in the risk management decision-making process.

i) Terminology - The Agency asked for SAB input on the use of a few specific terms and phrases.

<u>Answer</u>: The Committee felt that the terminology issues were simply a question of semantic choices and decided not devote time to reaching a consensus position on them.

j) Future Products - "[Beyond the material already in the Proposed Guidelines and] considering the state of the science of ecological risk assessment, what topics most require additional guidance?

<u>Answer</u>: The Committee generated a list of items which they recommend that the Agency study in order to generate additional information and/or guidance.

In addition to responding to the specific elements of the charge, the Committee went further and provided additional comments on issues that arose during the course of the review. These additional comments cover the following areas:

a) The use of accurate language

b) Case studies

c) Hypothesis testing

d) Adaptive management

e) Risk estimation techniques

f) Risk characterization

g) Different levels of sophistication for different needs

h) Lines of evidence

2. INTRODUCTION

The U.S. Environmental Protection Agency (Agency) has a considerable history in assessing risks associated with environmental stressors and adverse effects to human health. Over the years, in order to conduct such assessments in a systematic, consistent manner, the Agency has developed a range of risk assessment guidelines (RA GLs) that articulate the general procedures to be followed when the Agency assesses these risks (1). Given the significance and wide applicability of these RA GLs, the Agency has asked the Science Advisory Board (SAB) to conduct an independent, public review of the scientific basis for these documents (2).

In the mid-1980s the Agency became increasingly concerned about ecological risks associated with environmental problems, in addition to any risks that those problems might pose to human health. In its 1990 report on comparing risks, Reducing Risk, the SAB explicitly recommended that the Agency "attach as much importance to reducing ecological risk as it does to reducing human health risks" (3). This report increased awareness of the need for systematic, consistent procedures for assessing ecological risks that would match those developed for human health risks. Consequently, the Agency embarked on a multi-year effort to develop ecological risk assessment guidelines (Eco-RA GLs) in a manner that would involve participation and review by a wide range of scientists across the country, including the SAB.

The current report--the seventh Eco RA GLs-related product since 1990 (4)--documents the SAB's review of the Agency's draft Eco-RA GLs (5), which builds, in particular, upon the Agency's Ecological Risk Assessment Framework document (6). This review is an objective assessment of the document, informed by--but independent of--the earlier efforts. This independence results from the fact that the composition of the Ecological Processes and Effects Committee (EPEC) has changed significantly, in the intervening years. In addition, as noted in the roster at the beginning of this report, three EPEC members recused themselves from this review due to their participation in previous aspects of the development of the Eco-RA GLs. They have been replaced for this exercise by two consultants who have not been involved in prior SAB reviews.

2.1 Statement of the Charge

The charge to the SAB from the Agency (7) covered ten questions:

a) Risk Assessor/Risk Manager Interactions - "Overall how compatible are these Proposed Guidelines with the National Research Council concept of the risk assessment process and the interactions between risk assessor, risk managers, and other interested parties?"

b) Assessment Endpoints - "Assessment endpoints are an 'explicit expression of the environmental value that is to be protected'. Some reviewers have recommended that assessment endpoints also include a decision criterion that is defined early in the risk assessment process (e.g., no more than 20% reduction in reproduction, no more than a 10% loss of wetlands.)...[T]he Proposed Guidelines suggest that such decisions are more appropriately made during discussions between risk assessors and managers in risk characterization at the end of the process. What are the relative merits of each approach?"

c) Tiered Assessments - "While the Proposed Guidelines acknowledge the importance of tiered assessment, the wide range of applications of tiered assessment makes more specific guidance difficult. Given the broad scope of the Proposed Guidelines, what additional principles for conducting tiered assessment can be discussed?"

d) Field Data - "[Beyond the material already in the Proposed Guidelines], what, if any additional material should be added on these topics and, if so, what principles should be highlighted?"

e) Background Variability - "[Beyond the material already in the Proposed Guidelines], are there additional considerations concerning this issue that should be included in the Proposed Guidelines."

f) Landscape Ecology - "...given the Agency's present interest in evaluating risks at larger spatial scales, how could the principles of landscape ecology be more fully incorporated into the Proposed Guidelines?"

g) Multiple Stressors - "[Beyond the material already in the Proposed Guidelines], what additional principles can be added?"

h) Risk Estimation Approaches - "The Proposed Guidelines use simple exposure and stressor-response curves to illustrate some aspects of risk estimation. What other examples could be used to represent risk estimation for nonchemical stressors or more complex situations?"

i) Terminology - The Agency asked for SAB input on the use of a few specific terms and phrases.

j) Future Products - "[Beyond the material already in the Proposed Guidelines and]considering the state of the science of ecological risk assessment, what topics most require additional guidance?

2.2 Process

As announced in the Federal Register (8), the Ecological Processes and Effects Committee (EPEC) convened in public session on Sept 19-20, 1996 in Conference Room 17 of the Washington Information Center at Waterside Mall near EPA's Washington Headquarters Offices to carry out the review of the draft Eco RA GLs (5). The Committee was also briefed by Agency scientists who were most directly involved in preparation of the Eco RA GLs over a period of years. As noted above, three EPEC members, including the Chair, Dr. Mark Harwell, recused themselves and did not attend the meeting. The group was augmented by two consultants for this meeting. After leading the Committee through the review, the Acting Committee Chair (EPEC Vice-Chair), Dr. Alan Maki, speaking in public session, summarized the overall findings and recommendations to Agency representatives and expressed the Committee's appreciation for the Agency's cooperation throughout the process.

3. COMMITTEE FINDINGS AND RESPONSE TO THE CHARGE

3.1 Overall Findings

The Agency's Ecological Risk Assessment Guidelines are the product of an almost 10-year effort within EPA to produce a model document that can guide the implementation of ecological risk assessments. The conceptual outline for these ecorisk principles was first developed at the Pellston workshop in 1977 (10). At that time, the mutual importance and co-dependency of environmental chemistry and fate testing with ecotoxicology were first identified. The current guidelines advance ecological risk assessment well beyond that early conceptual stage to what is now a truly functional practice.

The proposed guidelines outline the entire process and provide details on how each of the steps of problem formulation, analysis, risk characterization, and risk management can be successfully completed. Sufficient balance between specific guidance and flexibility is maintained so that the user can adapt the process to highly variable problems. The SAB review comments below are generally supportive of the guidelines while offering numerous suggestions for improvement. Comments address a wide range of issues, including risk assessor/risk manager interaction, assessment endpoints, use of tiered assessment, field data, and multiple stressors.

The Eco RA GLs document provides a template for dealing with many environmental programs and problems; e.g., new chemicals, water and air quality issues, waste site assessment, and spills. As such, these guidelines, like the Agency's ecological risk assessment framework from which they sprang, will likely be widely accepted and used by regional, state, and local authorities, as well as by many in the private sector. Indeed, the Eco RA GLs appear destined to be as seminal and trend-setting in their field, as the Cancer RA GLs have been in theirs. This achievement reflects well on science at EPA and all those who were involved in the guidelines development process.

3.2 Responses to the Charge Questions

3.2.1 Risk Assessor/Risk Manager Interactions

Among the refinements that the Agency has made to the Framework for Ecological Risk Assessment is the addition of an expanded discussion of the type of interaction that should occur among risk assessors, risk managers, and other interested and affected parties at the outset of the Eco RA process.[2] The importance of this dialogue has been further emphasized by adding an explicit “planning” phase, with associated outputs, to the process. The Committee fully supports these additions and the manner in which they have been incorporated in the Guidelines.

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[2] "Interested and affected parties" should include local residents, who, especially in rural areas, may have important ecological knowledge that is important to include in the analysis.

At the same time, the Committee recognizes the importance of conducting the scientific risk assessment analysis in a manner that keeps it insulated from inappropriate influence by other components of the decision making process. This relationship has recently been described in a National Research Council report as an iterative process of "analysis", on the one hand, and "deliberation", on the other. (9b) The Committee feels that this delineation of the scientific component of the process--separate from social, political, and economic considerations--is important and, therefore, supports the Agency's use of the "bold black line box" in Figure 1-2 of the Eco RA GLs (See Figure 1-2 from p. 34 of Eco RA GLs - overleaf) to highlight the boundary that should separate the consensus process from the scientific process. We further recommend that the following statement, that now appears in the text on page 36, be added to the Executive Summary:

> "... it is imperative to remember that the planning process is distinct from the scientific conduct of an ecological risk assessment. This distinction helps ensure that political and social issues, while helping to define the objectives for the risk assessment, do not bias the scientific evaluation of risk."

In order to further clarify the draft Eco RA GLs' discussion of the respective roles of risk assessors, risk managers and other interested parties, we suggest that "interested parties" be added to the planning box in the framework diagram that appears first as Figure 1-2. In addition, a slightly expanded discussion of the benefits of tapping the scientific expertise of the risk assessment team could be added (perhaps at the top of page 37). For example, while the current text makes it clear that the risk manager can help to make the risk assessment more relevant to decision making by clearly articulating societal goals, the document should also note the benefit associated with information flowing in the opposite direction; e.g., the risk assessor can help to define management options that are more likely to achieve the stated goals because they are ecologically grounded. (See also Section 4.4 on "Adaptive Management".)

The Committee felt strongly that Eco RA GLs should have a fuller discussion of the continuing communication that should occur between risk assessors and managers throughout the entire process. In concert with the recent reports of the National Research Council on risk assessment (9), the Committee views the decision-making process is an iterative one, involving continual interaction between the parties. The "dotted line" at the bottom of Fig 1-2 that links "Risk Management" and the "As Necessary: Acquire Data, Iterate Process, Monitor Results" should be replaced with a solid line to emphasize the need for and utility of these continuing connections as the scientific assessment and the risk management needs evolve.

3.2.2 Assessment Endpoints

The Committee agrees with the definition for assessment endpoints, as an entity and an attribute, and with the approach described in the draft Eco RA GLs to generate them. The Guidelines should not, in general, contain specific decision criteria for these endpoints, although they should acknowledge that some decision criteria may be mandated by statute or established by regulatory policy.

The balanced involvement of interested parties; e.g., industrial/environmental and public/private communities, is necessary in order to identify endpoints that are valued by society. At the same time, the involvement of technical experts is necessary to ensure identification of endpoints that are ecologically sound and relevant to decision making.

Development of assessment endpoints for landscape-scale risk assessment may benefit from explicit consideration of a hierarchy of ecological scales. For example., assessment endpoints might be derived at the population, community, ecosystem, and landscape scales. At each of these scales, consideration could be given to structural, compositional, and functional attributes. Using this type of hierarchical "checklist" would help to assure the ecological relevance of the assessment endpoints, as describe in Section 3.3.1.1 of the draft Eco RA GLs.

3.2.3 Tiered Assessments

The Committee strongly agrees with the need for and value of tiered testing in ecological risk assessment. As a general rule, the scope of a particular assessment should be commensurate with the scope and importance of the risk management decision. The Eco RA could better describe some of the considerations and criteria for determining when higher tiered testing is necessary, particularly in those cases in which adequate data are available to conduct such a higher tier assessment. Some of those criteria would be science-based, with a firm technical logic connecting the results of lower tiered testing to the need for additional testing in higher tiers. At the same time, the Committee recognizes that there are non-technical, risk management considerations that can legitimately come into play (e.g., time and resources available, "importance" of the decision, etc.) when the Agency is reaching a decision on how much additional information to gather and assessment to conduct. In any case, risk managers need to be sensitive to the need for a firm scientific foundation for the decisions they make.

3.2.4 Field Data

The Committee believes the Eco RA GLs should provide more discussion on topics related to the use of field observational data in ecological risk assessments. Historically, the use of field data to make ecological decisions has preceded and subsequently paralleled the use of laboratory data. The first Pellston Workshop (10) endorsed the idea of collecting data in sequential tiers, the last of which would be the collection of field data in a “confirmatory” tier. The concept embedded here is that field data can be an important component of a risk assessment and, when obtained from properly designed studies, can be used in lieu of, or in support of, decisions based on laboratory data or theoretical constructs.

The Committee, while not responding to all aspects of the EPA “field data” question, proposes the following ecological principles relative to the use of field data:

a) The overall intent of ecological risk assessments is to evaluate risk to organisms (populations, communities) in the field. Therefore, data from well-defined field studies, both exposure and effects, is usually preferred over other forms of data.

b) Field studies should be designed with sufficient statistical rigor to define one or more of the following:

1) Stress-response regime for organisms and endpoints of interest.

2) Differences in measurement endpoints between reference sites and or controls from study areas or treatments, respectively.

3) Demonstrate a lack of observed field effects in a study with an appropriate statistical design capable of detecting reasonable changes (detrimental) in measurement endpoints.

c) Field data may be used to help characterize the stressor-response regime, as done in the laboratory, but are often used to document the "health" of the ecosystem (population, community) relative to the same site historically, a reference site, or a conceptual reference site. Biocriteria are often used for these comparisons.

d) Field data are not needed for all risk assessments. For example, screening level assessments and prospective risk assessments often do not incorporate field data.

e) Field data are more important for some risk assessments than for others. This typically occurs when assessments are performed on large areas, such as whole watersheds, where multiple stressors are present, or where site-specific factors significantly control the stressor-response regime.

Additional factors favoring the use of field data that the Agency might include in their Eco RA GLs discussions include the following:

a) Species of interest and assessment endpoints of interest can often be observed/measured directly in the field.

b) Uncertainty associated with extrapolating from laboratory data to field relationships, from acute to chronic ratios, and from one species to species extrapolation can often be avoided by utilizing field data.

c) Exposure regimes in the field are often vastly different from those in laboratory experiments. The use of field data can reduce uncertainty associated with the exposure regime, including those factors associated with stressor duration or fate and transport, as in the case of chemicals. At the same time, the Eco RA GLs should note that most site or watershed risk assessments will be site-specific and that data collected there will not necessarily reflect other situations.

3.2.5 Background Variability

There are several approaches that could be described in the Eco RA GLs that can be used to investigate potentially important effects that are difficult to distinguish from "background" variability in natural systems.

One approach would emphasize the importance of understanding the nature of the chemical or physical insult to the population or community at risk. Usually low-level stressors would be expected to have little toxicity or--by definition--have a relatively low or diffuse impact on the population, community or ecosystem under assessment. However, in some cases, such stressors may be potentially dangerous because they bioaccummulate to levels sufficient to induce developmental, teratogenic, or tumorigenic effects; e.g., PCBs in the Great Lakes. Therefore, the risk assessment of such low-level stressors needs to take into account the potential for bioaccumulation.

A second approach to assessing the significance of low-level stressors is to use previously unexposed organisms caged or maintained for periods of time on-site in order to enhance the potential for measuring uptake and/or effects. It is possible to obtain direct measures of body burden, biomarkers, and behavior characteristics during these extended exposures. An example of such research is the work of Dickerson et al. (11), who are exposing previously unexposed rodents on the Rocky Mountain Arsenal, CO and trapping them after season-long exposures. Biochemical and physiological biomarkers are being linked to population-level effects; e.g., the relationship between body burden data and reproductive success. This approach will explain some, but not all, of the variability seen in the population of the native animals that have had varying degrees of exposures in the field. Therefore, there will be a greater possibility of detecting effects due to the stressor.

A third approach is to employ appropriate statistical techniques to ferret out the variance components due to natural variation from those due to exposure to the stressors of interest. A range of statistical analytic methods could be employed to address this issue, including factor analysis methods (e.g., principal components) and canonical or partial correlation techniques. Non-linear distributions can be treated by analysis of frequency approaches, appropriate transformations, or polynomial regression techniques.

3.2.6 Landscape Ecology

Ecological risk assessment is typically applied to toxins that are stressors at a particular site. The Eco RA GLs attempt to move the ecological risk assessment concept to larger spatial scales which means that the process must consider multiple stressors, multiple ecosystem types, and multiple levels of biological organization, as well as spatial heterogeneity. Some of these issues have been addressed more directly and more completely than others. Overall, the Committee has some concerns that the attempt to extend the ecological risk concepts to broad spatial scales is not fully balanced across the document. The Committee recommends that future versions of the Eco RA GLs incorporate guidance at the landscape scale. Some particular cases where landscape concepts should be considered are given below:

a) The document should keep the temporal and spatial scale in mind when data evaluation is discussed (cf. p.75 and following).

b) The Figures should include concepts and examples that are not toxins and that are spatial in nature.

c) The concept of thresholds needs to be added as a criterion. That is, while theoretical linear stressor-response curves do not have ecologically based break points (e.g, , "thresholds"), non-linearities or chaotic responses are particularly possible "in the real world" where broad scales issues, such as multiple factors on levels or organization, come into play. (Also see Section 3.2.8 below)

d) As a general matter, the Agency should consider presenting a variety of concepts in the document through a "hierarchy of scales" that considers both spatial resolution and extent. Among the concepts that seem well-suited for such a presentation are setting management goals (p.38), integrating information (p.46), defining “key” information (p.46) and ecological relevance (p.50), and selecting assessment endpoints (pp 56-57).

e) A discussion of landscape-based indicators needs to be added. For example, on p. 52 of the document there is a discussion of fragmentation, but it does not include species gap crossing ability as a critical metric (12).

f) Although the discussion of exposure includes mention of multiple stressors, the concept of landscape influences on these stressors is not addressed; cf. pp 52-53. For example, topography can affect the temporal and spatial distribution of exposure regimes, such as temperature and air-borne pollutants.

g) A regional scale analysis would not only include impacts on single organisms as a metric of stress, but it might also include physical indicators on a complex of biotic responses as indicators.

3.2.7 Multiple Stressors

The multiple stressor problem is very likely the “rule” in ecosystems, as discussed briefly in 5.2.2, “Determining Ecological Adversity.” The difficulty lies in discerning which of the stressors have a predominant influence on the endpoint of interest, in knowing how the multiple stressors interact, and in understanding how they contribute to the added risk for the population or community of interest in the risk assessment.

Multiple stressors can be analyzed using many of the same statistical techniques described in Section 3.2.5 above on “low-level effects.” Path analysis, multiple-regression analysis, canonical analysis, or partial correlation analysis are often useful in discerning the effects of multiple stressors on an effect variable.

3.2.8 Risk Estimation

Stressor/response curves are commonly used to depict the effects of chemical stressors on organisms. Such curves are much less commonly used to describe the effects of non-chemical stressors on organisms and the effects of non-chemical stressors on non-biological responses, particularly at ecosystem and landscape scales.

However, just as with chemical stressors, empirical relationships can be developed between non-chemical stressors and non-biological responses. For example, there is a demonstrable relationship between wetland extent and downstream flood peak (13) and between land use activities and downstream nutrient concentrations (14). In addition, the U. S. Geological Survey and USDA Natural Resources Conservation Service have developed many empirical relationships pertaining to water quantity and quality (15).

Stressor-response curves can also be generated through the development and manipulation of process models. That is, the magnitude of a stressor can be varied incrementally so as to generate response curves. For example, a non-point source pollution model could be used to predict the response of stream sediment transport to increases in cropland area.

Risk managers are increasingly acknowledging the connection between watershed stressors and downstream responses. Examples include the effect of upstream land use activities on the water quality of Chesapeake Bay and New York City's water supply. It is often difficult to prove cause and effect of stressors/responses at such large scales because a) the location of stressor generation is often different from the location of the response, b) there are often multiple sources of a particular stressor; e.g., phosphorous from septic system leakage, accelerated erosion, and run-off from impervious surfaces, and c) base line values are not sufficiently well-known. In such cases, the use of process models is usually the only viable method of risk estimation. If a process model is spatially explicit, specific locations for implementing risk management practices may be suggested. "Spatial decision support systems", in which a process model is linked to GIS input and displayed, may be useful in such complex cases.

If a stress/response relationship is non-linear, inflection points in those relationships may suggest natural thresholds that could be useful for risk management purposes. For example, the Everglades Forever Act explicitly directs a coalition of Agency scientists and their consultants to determine the "threshold" of phosphorous concentrations (somewhere between 0 and 50 ppm) that leads to changes in Everglades Wetlands plant community composition; e.g.. replacement of sawgrass by cattail. Also, work by Oberts (16) has shown that in watersheds in which wetlands constitute less than 10% of the land area, the total suspended solids loadings to streams draining those watersheds are significantly greater than in streams draining watersheds that have more than 10% of their area in wetlands.. Similarly, there may be natural thresholds of stress below which no response occurs because an organism or ecosystem can tolerate or assimilate that stress without an adverse response. For example, some amount of phosphorous input to a wetland could be assimilated by soil and vegetation uptake processes, while excessive amounts would be detrimental to the wetland.

3.2.9 Terminology

The Committee felt that the terminology issues were simply a question of semantic choices and decided not to devote time to reaching a consensus position on them.

3.2.10 Future Products

The Committee commends the Agency on the significant contributions it has made to the field of ecological risk assessment through the development and dissemination of the Framework (6) and these draft Eco RA GLs (5). At the same time, it is clear that more work needs to be done as a part of an overall effort to continually improve ecological risk assessment. In this subsection, the Committee briefly lists a number of the more important outstanding issues the Agency should address in a timely manner through exposition and guidance.

a) Reference sites

The selection of appropriate reference sites for use in data collection or field studies is a difficult issue.   However, recent EPA documents (17) have presented imaginative approaches to selection of reference sites, even when there are little or no field data available. The Agency has discussed categories of reference site information, including a hierarchy of actual reference conditions; i.e., from “best system” (which can mean least disturbed or most pristine), to “best site" or population in an ecosystem, to present defined conditions, to historical reference data.

A useful new approach is to define conceptual reference conditions which represent a best professional judgement of where a particular site fits along a spectrum of sites exhibiting the full range of possible values of all (or as many as possible) relevant parameters, both those sites for which data exist and those sites for which they do not. This approach is free from the compromises that are necessary in selection of specific reference sites and flexible in that the position of the specific site along the spectrum can change as more data are generated or site conditions change. An added advantage of the approach is its capability to compare different ecosystems or sites; i.e., they are simply at different points along the gradients. Further, it is also a useful way to compare--albeit conceptually--different management scenarios or alternatives based on how they would move the ecosystem along the various gradients.

In the face of this significant progress in addressing selection criterion for reference sites, using of reference data, and exploring new approaches to reference concepts, the Committee recommends that the Agency consider pulling this information together into a single guidance document that could be used in many places, both inside and outside the Agency.

b) Landscape issues

The question of how risk assessment approaches can be applied to a complex ecosystem or at landscape scales has not been addressed in either a research or an applied mode. Since there is increased recognition that there are important environmental protection issues at the landscape scale, it is important there be explicit guidance on how to conduct ecological risk assessment on this scale. Issues to be resolved include how the multiple stressors should come into play, how spatial heterogeneity affects the stressor impact, how human actions may enhance or deter any effects, and how risk analysis should be viewed over the long-term. The Committee encourages the Agency to provide needed leadership by pressing forward to investigate these important issues in the coming years.

c) Risk Characterization: How to...

The Committee recommends that in the future the Agency prepare a supporting guidance document summarizing techniques for synthesizing exposure and effects data into a risk characterization. The entire process of risk assessment is focused on providing a sound technical basis for a decision on potential risk posed by the stressors of interest. Hence, the process of deriving risk estimates and formalizing the risk characterization is very important.

In particular, techniques for preparing risk characterizations have been emerging and expanding over the past 3-5 years. For example, there are now methods available for estimating risk that go beyond the traditional hazard quotient-point estimate approach. Other recent advances include the use of probability and cumulative distribution functions, as referenced in the Eco RA GLs. In addition, the current technical literature contains numerous approaches for using these results in making decisions about ecological risk.

Therefore, the Committee recommends that the Agency collect this information and synthesize it into a guidance document for use both inside and outside the Agency.

d) Risk Communication

The question of how information about risk is communicated to the public is crucial to the success of any overall risk management approach. The characteristics and perceptions of the various stakeholders need to be included and evaluated throughout the process (9). How best to communicate with interested parties in a given situation has yet to be determined. Options include everything from direct one-on-one exchanges to worldwide internet linkups. In addition, the appropriate language for communication of risk information needs to be carefully considered, since it is clear that scientists and the public do not always share a common understanding of such terms as risk, biodiversity, landscape, etc.

In short, there is an important role for the Agency to play in exploring better ways to communicate risk information--including the results of Eco RAs--to the public. While this Committee is not in a position to describe the means by which this might be accomplished, it has identified the need.

e) Indicators: biological and others

The role of indicators in risk assessment needs to be fully explored. Indicators may be physical or biological metrics and may be as simple as one species or as complex as a diverse ecosystem that only occurs in a particular physical environment. An example of an important physical indicator is a change in temperature during a critical phase of the life cycle of the organism. An example of a physical indicator relevant at a larger scale might be the length of shaded riparian habitat along a river segment (a measure of edge habitat quality and extent) or the frequency of flood events large enough to transport gravel and sand-sized sediment . The questions to be addressed here include the following:

1) How do these indicators change with different levels of a stressor?

2) How does one measure an indicator or a surrogate for it?

3) How does one identify situations under which physical indicators may be sufficient to represent the risk of the species at hand?

4) How might these indicators change with geographic region and/or changes in spatial or temporal scales?

5) Are particular life stages of an organism or successional stages of an ecosystem more susceptible to a stressor?

The Agency could improve the quality and future utility of ecological risk assessment methods by developing guidance on the appropriate selection and use of indicators.

f) QA/QC

In conducting ecological risk assessments, the assessor is often faced with a dearth of site-specific data, compounded by a lack of time and/or resources available to collect the needed information. In such instances, the assessor most often seeks existing data from other sites, organisms, or stressors to bridge the gaps. The proposed Eco RA GLs, however, provide little guidance to help the assessor select, evaluate, and use such "foreign" data.

Clearly, there are significant differences in the quality and utility of these foreign data that depend, in part, on their intended use in the assessment. For example, there is a gradient between well-conducted field and laboratory data collected specifically for a particular risk assessment, on the one hand, and data from the literature on a different species in a different environment, on the other.

Judgments can and should be made to clarify the situation. For example, published values of LD50 for the same species, partition coefficients for a specific chemical of concern, etc. can probably be used with little impact on the uncertainty of the overall assessment. Toxicity data from related species (e.g. two different species of fish) should be used with caution for specific assessment endpoints, and data from totally different species (e.g. birds) probably should not be used at all. The mechanisms of the effect should be considered in making such decisions. For example, some changes to a system may have different effects within a taxa, but similar effects for unrelated organisms with similar behavioral patterns.

In short, there is a need for a guidance document on the selection and use of "foreign" data in risk assessments. This guidance should address both issues of appropriateness and of quality and how they are related to the overall uncertainty of the assessment.

4. ADDITIONAL POINTS

During the course of the Committee's deliberations, a number of items were discussed that went beyond the questions in the charge per se. In this Section, the Committee presents its observations on these additional points in the belief that attention to these issues will further enhance the Eco RA GLs.

4.1 Use of accurate language

In a number of areas, the text makes generalizations that may not apply to all applications of ecological risk assessments. Some statements specifically relate to

a) Prospective vs retrospective assessments

b) Assessments used for 1) chemical evaluation, 2) site evaluation, or 3) natural resource evaluation.

c) Assessments used for 1) chemical stressors, 2) biological stressors, or 3) physical stressors.

The document would be improved by more precisely qualifying statements according to the contexts listed above.

4.2 Case studies

The Committee applauds the Agency for taking the time to carry out some model ecological risk assessments in the watershed case studies. The utility of these studies to potential practitioners of ecological risk assessment is so great that their prompt completion should be an Agency priority.

Specifically, the Committee urges the Agency to consider carefully its watershed case studies and the SAB's pending report on their review of that information. There are relevant insights and advice in those documents that merit incorporation into the Eco RA GLs For example, the discussion of the outputs of the planning phase--goals and objectives--and their relationship to the assessment endpoints developed in the problem formulation phase could be expanded and clarified through reference to some of the watershed case studies. Specifically, the Eco RA GLs text currently provides a very brief definition of management goal and only mentions the development of more specific objectives by reference to text note 2-6. Because the development of goals and the more specific, ecologically-based objectives is so critical to the success of the planning phase, the Committee suggests that an expanded explanation of management goals and associated objectives be included in the Eco RA GLs, and as well as the Waquoit Bay management goal and its ten associated objectives.

In the Waquoit Bay example, the management goal defines the ecological value that the community wants to protect. The objectives translate this goal into more detailed subunits that incorporate the properties of the ecosystem that are relevant to achieving the goal. Assessment endpoints can then be derived that not only meet the tests for ecological relevance and scientific validity but can also be related directly back to the objectives. Using this progression, the scientific rationale for translating the goal through the objectives into the assessment endpoints can be illustrated quite well.. The process of translating the general goal into the objectives also provides a focal point for productive early interaction among the risk manager, interested parties, and the risk assessor and holds the promise of generating results that are socially valued, as well as ecologically meaningful.

Also, once the watershed case studies are completed and the SAB has reviewed them, the Agency should prepare a synthesis of "lessons learned" from the experience. Approaches that proved to be effective should be highlighted, along with identification of approaches that proved to be ineffective. The compilation of the Eco RA GLs, the case studies, and the lessons learned will be an extremely useful compendium for those faced with conducting ecological risk assessment.

In addition, the SAB suggests that, over time, the Agency compile a list of completed case studies that span a wide variety of stressors, environments, and levels of complexity and scale. This list should include both prospective and retrospective analyses of single and multiple stressors, different sites, and various resource evaluations. Since risk assessments usually are not published in their entirety in the open literature, compiling a list of representative studies would provide a wide range of risk assessors and managers with access to information they might otherwise miss.

4.3 Hypothesis testing

The Committee believes that the Eco RA GLs should have a greater emphasis on the use of the scientific method, specifically a sharper focus on hypothesis testing and guidance for its use. The rigor of the risk assessment process would be significantly enhanced if the problem formulation discussion provided more and better guidance on hypothesis development and if the analysis phase contained more and better guidance on hypothesis testing. For example, problem formulation should articulate what questions are being asked, how the answers to those questions will be sought, and the possible interpretations of the answers that might emerge. In many applications, by following the hypothesis testing model in risk assessment methodology, the entire ecological risk assessment process would be more useful, better understood, and more widely accepted.

4.4 Adaptive Management

The concept of "adaptive management" has proven beneficial in a number of areas. The Agency should seek to maximize the benefits derived from "an adaptive management mind set" as it implements the new Eco RA GLs.

First, the Eco RA GLs should make the point even more clearly that the consideration of assessment endpoints need not be constrained by data from monitoring programs nor even to the availability of data per se. In some cases, an ecologically relevant assessment endpoint may be one for which data are currently unavailable, but for which data could begin to be collected. The assessment endpoint would then be a useful tool for adaptive management, would be able to inform future iterations of the risk assessment, and would contribute to data generation that might be useful in other arenas.

Second, Figure 1-2 should be modified in order to emphasize the need for "technology transfer" that will inform risk managers of research findings on a continuing basis. A general model for the process of technology transfer is found in the health arena in which pharmaceutical companies and other suppliers of health care related products move continuously and aggressively to transfer findings from the research lab to clinical application. The important point is that neither the pharmaceutical researcher (cf., risk assessor, including both conceptual modeling and analytical work, in the present context) nor the doctor/surgeon clinician (cf. risk manager in the risk context) performs the tech transfer function, but rather a third for-profit group. However, no such separate group is established in the ecological risk area. For example, in Figure 1-2, an arrow should be used to indicate the adaptive management link between analysis (i.e., ecological response analysis) and the conceptual modeling activity. In this model, the tech transfer that undoubtedly occurs is performed largely by the risk assessor. Yet, as the diagram clearly shows, this is not a primary function of the risk assessor activity.

In the current draft, technology transfer is included in problem formulation; cf., Fig 1-2 depicting the integration of available data which involves linking the assessment of impacts and conceptual models. Although not specifically characterized as such, the elements included in the "side-bar" in the Figure; i.e., "Acquire Data, Iterate Process, Monitor Results", are also technology transfer activities.

It is not clear that each of the technology transfers would be the sole responsibility of the risk assessor per se; cf., the functions described on pp.29, 69, 153, and 196, for example. The Eco RA GLs should acknowledge the need for coordinated efforts of several experts in order to effect the appropriate data collection, data analysis, and, most important, the translation of this new information into formats (such as conceptual models) that are useful for risk managers.

This problem could be addressed by discussing the fundamental importance of explicit adaptive management feedback loops throughout the process. As an example that was noted earlier, the dashed double arrow line at the bottom of the Figure should be changed to solid and bold. The other "doubled-headed" arrows depicting feedback loops could be made more explicit. Also, the Agency should consider modifying the text to clarify the technology transfer process involved and to describe explicitly the agents responsible for such transfers, whether they are to be performed by risk assessors or other parties.

4.5 Risk Estimation Techniques

The Committee applauds the Agency's inclusion of information and references on risk estimation techniques that go beyond the traditional "comparison of point estimates." Since risk estimation is arguably the most critical part of the risk assessment and new techniques are being introduced regularly, users of the Eco RA GLs would benefit from a fuller discussion of available techniques, together with additional examples of how data have been or could be utilized to provide risk estimates.

The discussion on mixtures in section 5.1.2 references Broderius (1991) and indicates that overall "Caution should be used when predicting that chemicals in a mixture will act independently of one another." While caution should be used in utilizing approaches which attempt to accommodate component toxicity from multiple chemicals, the general conclusion to be drawn from the literature is that on the basis of acute toxicity to aquatic organisms, chemicals do act independently and the responses are generally additive.

Similar comments apply to the discussion section 5.1.3 also. The document should have examples illustrating the applicability of the approach to multiple species, in addition to a stressor-response curve (Figure 5-4 on p. 138) for a single species. While it may seem that this is an obvious extension of what the Eco RA GLs already present, the additional detail will demonstrate the greater depth to the risk estimation approach.

4.6 Risk Characterization

It should be recognized that the ecological risk assessment process includes a number of science policy positions that are mandated by Congress or have been formulated by the Agency. Examples of such science policy positions include the following:

a) The specification of test organisms and test conditions for certain tests.

b) The manner in which multiple effects measures are aggregated and summarized.

c) The selection of exposure concentrations used in quotient methods; e.g. 50th vs 90th percentile and mean-flow vs low-flow conditions.

d) The use of 10-fold "uncertainty" factors.

For this reason, it is imperative that all science policy assumptions be clearly distinguished in the risk characterization portion of the report. In fact, these admonitions are contained in the Agency's Risk Characterization Policy (18), which should be highlighted in the Eco RA GLs.

4.7 Different levels of sophistication for different needs

The Eco RA GLs describe an in-depth model for an ecological risk assessment . That is, they provide guidance for the broadest and most comprehensive of ecological risk assessment that the Agency (or those outside the Agency) is likely to perform. In point of fact, given the logistical constraints existing inside and outside the Agency, explicit performance of all steps and elements of the idealized model may not be necessary, appropriate, or feasible. For example, screening level assessments performed by the Office Pollution Prevention and Toxics in its Pre-Manufacturing Notification reviews may not require an explicit and unique conceptual model or analysis plan for each review.

In summary, ecological risk assessments conducted with little data, few resources, or brief time spans may be adequate for certain applications.

4.8 Lines of evidence

In discussing the contents of Section 5.2.1 on "Lines of Evidence", the Committee noted that confidence in risk assessment conclusions can be increased using several lines of evidence (weight of evidence) which may be derived from different sources. Recognizing the overall importance of the quality of the information and its utility for reaching decisions, the Committee offers the following general guidance on the use of data from different sources (lines of evidence) since not all data are equal in “weight” or value in supporting risk estimates:

a) The strength and value of data for risk assessments is usually derived from the rigor of the experimental design, the careful manner in which the data are collected, and the quality assurance and quality control built into the study.

b) Data obtained via qualitative approaches may be of less weight than similar data obtained via quantitative approaches.

c) Data from screening level studies may be of less weight than data from more definitive studies related to the same endpoint.

d) Data obtained by species-to-species extrapolation may be of less weight than data for the species of interest from a similar site outside of the study area.

e) Data generated by quantitative structure-activity relationships are of less weight than similar data obtained in well-designed laboratory or field studies.

f) Data generated by computer model simulations are valuable, but may be of less weight than quantitative laboratory or field data, depending on the extent of the model validation and the strength of the laboratory or field data.

g) Data generated in laboratory studies may be of less weight than comparable data generated from well-designed field studies.[3]

[3] In general, lab studies provide for control of variables at the expense of reality, while field studies maximize reality but may offer little insight into cause and effect, since few, if any, parameters can be controlled under field conditions. Thus, the weighting of lab vs. field data from equally well-designed studies must carefully consider the ecological question being asked. For example, if the principal concern is the effect of a single stressor, then a lab study might well be weighted more heavily than any field study. On the other hand, if there is clear evidence of multiple stressor involvement or of overriding control by a complex of environmental parameters, the field may be the only appropriate place to pursue the cause and effect possibility, since there are simply too many variables to control. The compromise, i.e., the field experiment where some subset of environmental factors are more or less controlled, may potentially merit the heaviest weight, but only if the lines of evidence are clear and some sort of "control site" or "control treatment" is included in the study.

5. CONCLUSION

The Committee is generally pleased with the Agency's draft Eco RA GLs. While this SAB report identifies a number of ways in which the document could improved, the Agency is to be commended for carrying out this work. This seminal work will evolve over time--and appropriately so--in response to comments and suggestions such as those in this report. However, those further improvements and enhancements will be building upon the solid foundation that is established in the Agency's draft.

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AN SAB REPORT: REVIEW OF THE AGENCY'S DRAFT ECOLOGICAL RISK ASSESSMENT GUIDELINES

PREPARED BY THE ECOLOGICAL PROCESSES AND EFFECTS COMMITTEE (EPEC)