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# EPA PLANNING FOR ECOLOGICAL RISK ASSESSMENT: DEVELOPING MANAGEMENT OBJECTIVES: An SAB Report

A Review by the Ecological Processes and Effects Committee (EPEC) of the EPA Science Advisory Board (SAB)



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

February 19, 2002

EPA-SAB-EPEC-02-005

OFFICE OF THE ADMINISTRATOR SCIENCE ADVISORY BOARD

Honorable Christine Todd Whitman Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

> Subject: Planning for Ecological Risk Assessment: Developing Management Objectives: an SAB Report

Dear Governor Whitman:

On July 18-19, 2001, the Ecological Processes and Effects Committee (EPEC) Panel on Ecological Risk Management (hereafter, the Committee or EPEC) of the EPA Science Advisory Board reviewed the Agency's draft: *Planning for Ecological Risk Assessment: Developing Management Objectives* (EPA/630/R-01/001A, June 2001) (US EPA, 2001a), a document prepared by the Agency's Risk Assessment Forum. The stated purpose of the draft guidance document is to help decision-makers work with risk assessors, stakeholders, and other analysts to plan ecological risk assessments that will effectively inform the decisions they make.

The Committee strongly supports a concerted, cross-Agency effort to develop sound, consistent principles and guidance for ecological risk assessment and management. The current Ecological Risk Assessment Guidelines (US EPA, 1998) continue to provide valuable structure and discipline for the assessment of ecological risks. The draft guidance document being reviewed is intended to complement the Ecological Risk Assessment Guidelines by providing additional detail about the planning that should precede the actual risk assessment. Specifically, the draft guidance addresses the development of objectives that summarize a community's desires regarding the outcome of a risk management decision. It is the Agency's initial attempt to outline consistent principles and procedures for ecological risk management, in parallel with the principles and procedures for risk assessment.

Once completed, the guidance will be broadly useful not only to the Agency's program offices, but also to other federal and state agencies and the private sector. The draft guidance incorporates recent experience in building broader stakeholder networks, integrating public values, and balancing diverse and sometimes conflicting expectations and values. The resulting dialogue among risk managers and risk assessors is critical for ecological risk management decisions, for which there are often more diversified views and fewer initial areas of initial consensus than in human health risk decisions.

In the attached report, the Committee provides responses to the charge questions posed by the Agency. These questions covered: a) usefulness of the draft and its ability to help decision-makers improve planning of ecological risk assessments; b) whether steps outlined in setting management objectives are clear, the process is logical, and key concepts are well defined; c) whether the depth of discussion and level of technical detail is appropriate; d) flexibility of the guidance; and e) effectiveness of the graphics and tables used in the draft. While the Committee found the document to be generally useful, we provide the following recommendations for improvement:

- a) <u>Definition of Focus</u> In order to be of optimal value to decision-makers, the focus of the document needs better definition. While we understand that the guidance is intended to address the planning process prior to an ecological risk assessment, the document also alludes to the broader issue of setting risk management objectives for environmental decision-making. While it may not be inappropriate for this planning document to do both tasks, the focus and purpose of the guidance should be made clearer throughout the text.
- b) <u>Presentation</u> Although the general procedure that is outlined appears fundamentally sound, the description of each step and the relationships among the steps should be presented more clearly and succinctly. The attached report provides several specific examples and suggests potential remedies.
- c) <u>Distinguish Planning from Problem Formulation</u> We recommend clarification of the distinction between "planning" in preparation for the risk assessment (which involves a wide range of participants in addition to the risk manager) and "problem formulation" within the risk assessment itself (which involves the risk assessor in consultation with the risk manager). The current Guidelines for Ecological Risk Assessment (US EPA, 1998) envision risk assessment as primarily a science-directed process that provides objective information to the risk manager and other participants and, therefore, distinguish "planning" steps from "problem formulation" steps. The draft guidance muddles this distinction without providing a well-defined alternative.
- d) <u>Substantive Definitions of "What to Protect"</u> We recommend that the Agency either delete or substantially redraft the section that provides advice regarding the types of ecological attributes that the objectives should consider. Several portions of this section lacked a recognizable scientific foundation. As a result, the list of relevant ecological "objects" omits important ecosystem components. We are concerned that this section, if left unchanged, will impede rather than enhance sound, long-term ecological risk management. For the Agency's convenience, the Committee has provided two detailed examples showing how this section might be redrafted to effectively accomplish its intended purpose.
- e) <u>Validation with Current Practices</u> We recommend that experienced risk managers in each of the Program offices lend their expertise and perspective to ensure the document reflects their principles and experience in developing management objectives. The Agency could retrospectively review past decision processes to assess how these may have benefitted from the guidance offered in this document. The document should also be systematically revised to make it more consistent with previous guidance from the documents on the "ecological risk assessment bookshelf" (and to the extent possible, other key advancements in risk management in the Federal government.)
- f) <u>Scope</u> We recommend that the Agency identify whether and how future guidance in ecological risk management will be developed. Importantly, this topic includes the considerations and criteria which the Agency employs in the crucial decision-making process, and the means for communicating the risks and management decision to interested parties.

In light of these needs and the Committee's strong support for this initiative, we would appreciate the opportunity to again review this Guidance once our recommendations have been addressed.

We appreciate the opportunity to review and provide advice on the Agency's draft document *Planning for Ecological Risk Assessment: Developing Management Objectives*, and we look forward to your response.

Sincerely,

## /Signed/

Dr. William H. Glaze, Chair EPA Science Advisory Board

# /Signed/

Dr. Terry Young, Chair Ecological Processes and Effects Committee EPA Science Advisory Board

# /Signed/

Dr. Charles Pittinger, Chair Ecological Risk Assessment Panel Ecological Processes and Effects Committee EPA Science Advisory Board

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## ABSTRACT

The Ecological Processes and Effects Committee (EPEC) of the EPA Science Advisory Board reviewed the Agency's draft: *Planning for Ecological Risk Assessment: Developing Management Objectives* (EPA/630/R-01/001A, June 2001). This draft guidance document is designed to help decision-makers work with risk assessors, stakeholders, and other analysts to plan ecological risk assessments that will effectively inform the decisions they make.

The Committee was asked to responded to the following charge questions: a) usefulness of the draft and its ability to help decision-makers improve planning of ecological risk assessments; b) whether steps outlined in setting management objectives are clear, the process is logical, and key concepts are well defined; c) whether the depth of discussion and level of technical detail is appropriate; d) flexibility of the guidance; and e) effectiveness of the graphics and tables used in the draft.

While the Committee found the document to be generally useful, it provided the following recommendations for improvement: a) In order to be of optimal value to decision-makers, the focus of the document needs better definition; b) Although the general procedure that is outlined appears fundamentally sound, the description of each step and the relationships among the steps should be presented more clearly and succinctly; c) The distinction between "planning" in preparation for the risk assessment (which involves a wide range of participants in addition to the risk manager) and "problem formulation" within the risk assessment itself (which involves the risk assessor in consultation with the risk manager) should be clarified; d) The Agency should either delete or substantially redraft the section that provides advice regarding the types of ecological attributes that the objectives should consider; e) The authors should request that experienced risk managers in each of the Program offices lend their expertise and perspective to ensure the document reflects their principles and experience in developing management objectives; and f) The Agency should identify whether and how future guidance in ecological risk management will be developed.

In light of these needs and the Committee's strong support for this initiative, the Committee asked to review the revised document.

**Keywords**: Ecological risk assessment; ecological risk management; management objectives

# U.S. Environmental Protection Agency EPA Science Advisory Board Ecological Processes and Effects Committee Panel on Ecological Risk Management

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## **1. EXECUTIVE SUMMARY**

There is no question that sound, consistent principles and guidance in ecological risk management will be useful for decision-makers within and beyond the Agency, including other federal and state agencies and the private sector. Principles for sound ecological management would be a valuable complement to the Guidelines for Ecological Risk Assessment in order to demonstrate the respective roles of risk managers and risk assessors. It is also timely to summarize the Agency's emphasis on building broad stakeholder networks, integrating public values, and balancing diverse and, sometimes, conflicting values. This dialogue among risk managers, risk assessors, and the public is particularly critical for ecological risk management decisions, for which there is often a more diverse range of views and less consensus than in human health risk assessments.

The draft guidance, however, needs additional input and development to ensure it can support the breadth of Agency needs and concerns related to ecological risk management. It is not clear that the process and principles outlined represent a consensus among program office risk managers or have been validated by systematic application of the process. In addition, confirmation is needed that the document is consistent with other Agency guidance documents on risk assessment and management.

In the attached report, the Committee has provided responses to the charge questions posed by the Agency. These questions covered: a) usefulness of the draft and its ability to help decision-makers improve the planning of ecological risk assessments; b) whether steps outlined in setting management objectives are clear, the process is logical, and key concepts are well defined; c) whether the depth of discussion and level of technical detail is appropriate; d) flexibility of the guidance; and e) the effectiveness of graphics and tables used in the draft.

While the Committee found the document to be generally useful, we provide the following recommendations for improvement:

- a) <u>Definition of Focus</u> In order to be of optimal value to decision-makers, the focus of the document needs better definition. While we understand that the guidance is intended to address the planning process prior to an ecological risk assessment, the document also alludes to the broader issue of setting risk management objectives for environmental decision-making. While it may not be inappropriate for this planning document to do both tasks, the focus and purpose of the guidance should be made clearer throughout the text.
- b) <u>Presentation</u> Although the general procedure that is outlined appears fundamentally sound, the description of each step and the relationships among the steps should be presented more clearly and succinctly. The attached report provides several specific examples and suggests potential remedies.
- c) <u>Distinguish Planning from Problem Formulation</u> We recommend clarification of the distinction between "planning" in preparation for the risk assessment (which involves a wide range of participants in addition to the risk manager) and "problem formulation" within the risk assessment itself (which involves the risk assessor in consultation with the risk manager). The current Guidelines for Ecological Risk Assessment (US EPA, 1998) envision risk assessment as primarily a science-directed process that provides objective information to the

risk manager and other participants and, therefore, distinguish "planning" steps from "problem formulation" steps. The draft guidance muddles this distinction without providing a well-defined alternative.

- d) <u>Substantive Definitions of "What to Protect"</u> We recommend that the Agency either delete or substantially redraft the section that provides advice regarding the types of ecological attributes that the objectives should consider. The Committee found this section to be inconsistent with ecological principles and a potential detriment to sound, long-term ecological risk management. For the Agency's convenience, the Committee has provided two detailed examples showing how this section might be redrafted to effectively accomplish its intended purpose.
- e) <u>Validation with Current Practices</u> We recommend that experienced risk managers in each of the Program offices lend their expertise and perspective to ensure the document reflects their principles and experience in developing management objectives. The Agency could retrospectively review past decision processes to assess how these may have benefitted from the guidance offered in this document. The document should also be systematically revised to make it more consistent with previous guidance from the documents on the "ecological risk assessment bookshelf" (and to the extent possible, other key advancements in risk management in the Federal government.)
- f) <u>Scope</u> We recommend that the Agency identify whether and how future guidance in ecological risk management will be developed. Importantly, this topic includes the considerations and criteria which the Agency employs in the crucial decision-making process, and the means for communicating the risks and management decision to interested parties.

There was general consensus among the EPEC members that the current planning guidance is too general to help decision-makers significantly improve planning of ecological risk assessment. The Committee, therefore, suggests that the Agency consider revising the draft guidance prior to its release.

# 2. INTRODUCTION

#### 2.1 Background

For many years, the US Environmental Protection Agency has been assessing risks associated with environmental stressors and adverse effects to human health. The risk assessment guidelines resulting from these efforts have provided general procedures for assessing these risks in a systematic and consistent manner. To ensure the scientific adequacy of these guidelines, most have been subjected to rigorous peer review by the EPA Science Advisory Board (SAB).

The SAB's Ecological Processes and Effects Committee (EPEC) has had a long and fruitful interaction with EPA on the Agency's development of its ecological risk assessment guidelines. In September 1996, the Committee favorably reviewed (EPA Science Advisory Board, 1997a) EPA's draft Ecological Risk Assessment Guidelines (US EPA, 1996), a document designed to provide structure and discipline to the assessment of ecological risks. In July 1997, in its report on the need to develop Ecological Risk Management Guidelines (EPA Science Advisory Board, 1997b), the EPEC encouraged the Agency to develop additional guidance on planning for and communicating results of risk assessments. In July 1998, the Committee consulted with the Risk Assessment Forum on proposed projects to complement and extend the guidance contained in the final Guidelines for Ecological Risk Assessment (US EPA, 1998). Now, the Agency has asked that the Committee peer review the Agency's external review draft: Planning for Ecological Risk Assessment: Developing Management Objectives (EPA/630/R-01/001A, June 2001) (EPA, 2001a) that was prepared by the Agency's Risk Assessment Forum. The stated purpose of this draft guidance document is to help decision-makers work with risk assessors, stakeholders, and other analysts to plan ecological risk assessments that will effectively inform the decisions they make.

To perform this review, the Ecological Processes and Effects Committee formed the EPEC Panel on Ecological Risk Management (hereafter the Committee or EPEC). This EPEC Review Panel consisted of Members of EPEC plus an additional Member of the Executive Committee of the SAB.

#### 2.2 Charge to the Committee

The following questions and requests were posed to EPEC for this review.

- a) The primary audience for the guidance is EPA risk managers, but the guidance also should be useful to managers and decisionmakers outside the Agency. Overall, does the SAB think this guidance may be useful and help decisionmakers improve the planning of ecological risk assessments? What additional principles should be included or excluded in the document?
- b) Are the steps in setting management objectives clear and is the overall process logical? Are the key concepts well defined?
- c) Is the depth of discussion and level of technical detail appropriate? If not, how would SAB change it?

- d) Discuss the flexibility afforded by the guidance and its applicability to different situations (e.g., site-specific, national level, etc.)
- e) Comment on the effectiveness of the examples, figures, tables and text boxes

## **3. RESPONSE TO THE CHARGE**

There is no question that sound, consistent principles and guidance for conducting ecological risk management will be useful for decision-makers, both within the Agency and in other federal and state agencies and the private sector. Principles for sound ecological management would be a valuable complement to the Guidelines for Ecological Risk Assessment (US EPA, 1998), which continue to provide valuable structure and discipline for the assessment of ecological risks. The Committee applauds the Agency for generating this draft guidance on one primary component of ecological risk management – developing objectives that summarize the community's desires regarding the outcome of the risk management decision.

#### 3.1 The primary audience for the guidance is EPA risk managers, but [the guidance] also should be useful to managers and decision-makers outside the Agency. Overall, does the SAB think this guidance may be useful and help decision-makers improve the planning of ecological risk assessments? What additional principles should be included or excluded in the document?

#### 3.1.1 Utility in Planning Ecological Risk Assessments

There was general consensus among the EPEC members that the current planning guidance is too general to help decision-makers significantly improve planning of ecological risk assessment. The Committee, therefore, suggests that the Agency consider revising the draft guidance prior to its release. Specific suggestions for making the draft guidance more focused and improving its practical utility are provided below and in answer to other charge questions.

a) <u>Definition of Focus</u> - In order to be of optimal value to decision-makers, the focus of the planning guidance needs better definition. Our understanding of this document is that it is an extension and expansion of the 1998 Guidelines for Ecological Risk Assessment (US EPA, 1998), specifically providing additional guidance for the planning process prior to an ecological risk assessment. Setting management objectives for environmental decision making, as alluded to in the second Charge Question, is a much broader issue. While it may not be inappropriate for this planning document to do both tasks, the focus and purpose of the guidance should be made clearer throughout the text.

A useful means to clarify the focus would be for the Risk Assessment Forum to define its ultimate vision for additional guidance on ecological risk management. Is additional guidance envisioned? If so, some of the discussion on setting management objectives may not be necessary in this document. If not, then additional principles pertaining to how management decisions are made and communicated should be considered.

The title of this document implies a focus on the Planning Dialogue preceding the formal ecological risk assessment process. Therefore, one might presume that similar guidance will be developed for the two processes following ecological risk assessment in the pivotal 1998 ecological risk assessment diagram (US EPA, 1998): ["Communicating Results to the Risk Manager," and "Risk Management and Communicating Results to Interested Parties"]. Will supplemental guidance be developed that addresses the processes of identifying stakeholders, identifying management alternatives, characterizing the decision criteria and process,

identifying other information tools that may be required beyond risk assessment, etc.?

- b) <u>Validation with Current Practices</u> As the Agency is revising the draft guidance, we suggest that the authors gather additional input from experienced risk managers in each of the Agency's Program Offices in order to test or ground-truth the draft guidance. The risk managers could provide insight into the draft's utility, as well as its consistency with current best practices and policies of risk management. In addition, the Committee suggests that the guidance be validated by applying it retrospectively to ecological risk assessments (preferably regional in scope) that the Agency has already produced in order to determine whether those assessments would have been significantly improved by application of the new guidance. If the answer is yes, then the value of the guidance has been validated.
- c) <u>Consistency with Previous Guidance</u> Confirmation is needed that the draft document is consistent with other Agency guidance documents on risk assessment and management. In particular, the present guidance needs to be fully consistent with the 1998 Guidelines on Ecological Risk Assessment (US EPA, 1998) pertaining to problem formulation. In some respects, it is not clear whether and how the planning process described in the present document differs from or contributes to problem formulation.

The draft planning guidance suggests that the fundamental distinction between planning and problem formulation advanced in the Guidelines be removed. EPEC members were uncomfortable with this abrupt change. Such a change requires justification and the demonstration of consensus among the scientific community that is not readily apparent. As we understand it, the rationale behind the Guidelines distinction is that the planning process should include input from all stakeholders, while the subsequent phases of problem formulation and conceptual model development should remain in the scientific/expert realm. The draft guidance muddles this distinction without providing a well-defined alternative.

The planning document could be further strengthened by explicitly describing how it feeds into the process of problem formulation, exposure analysis, effects assessment, and risk characterization. Specifically, both the Executive Summary and the introduction should state that the document is meant as guidance for planning prior to ecological risk assessment, as a supplement to the 1998 Guidelines (US EPA, 1998), but that this guidance could be extended to general environmental decision-making.

#### **3.1.2 Additional Principles**

This draft planning guidance framework emphasizes key features of ecological risk assessment planning that have not been brought out in prior ecological risk assessment frameworks. These features include the need for a clear formulation of both the problem and the goals (or objectives) for environmental management, clear identification of the decision context, and inclusion of risk managers and other affected and interested parties in ecological risk assessment planning. Regardless of whether this document will be a "stand-alone" document or be supplemented with additional guidance, we recommend addressing the following additional principles:

- Combining Ecological Risk Assessments with other Studies In addition to the a) problem formulation feedback loop described above, the planning document could describe how ecological risk assessments interact with parallel assessments such as socio-economic studies or technological feasibility analyses. The planning guidance should clearly distinguish those aspects of planning that incorporate scientific expertise versus those that rely more on social and economic considerations. In this vein, Figure 4 is effective in presenting the multiple considerations involved in a management decision, but the text is inadequate. This discussion will certainly benefit from the completion of several documents evidently underway (e.g., "A Framework for the Economic Assessment of Ecological Benefits", cited as USEPA (2001b); "Improving Science-Based Environmental Stakeholder Processes, cited as USEPA (2001a)). [Note: cited as US EPA (2001) and EPA Science Advisory Board (2001), respectively, in the References Cited section of this report]. Perhaps these documents would be key supplements to the "bookshelf" of guidance documents originally envisioned.
- b) <u>Integrating Other Assessment Tools</u> The draft planning guidance should include references to other information tools such as ecological assessment (e.g., monitoring), and eco-epidemiological techniques that emphasize dose-response information. The document describes hierarchies of objectives, but other decision tools might contribute usefully to the ecological risk assessment process (e.g., contributing factors diagrams, influence diagrams, operation decision models).
- c) <u>Striking the Balance</u> Pivotal to a sound management decision is finding an acceptable and defensible balance among conflicting values and priorities. How the risk manager and/or decision maker identifies and weighs scientific, social, economic, and, sometimes political criteria may be the most valuable guidance that this or other documents must address. This topic may warrant separate guidance in itself.

# **3.2** Are the steps in setting management objectives clear and is the overall process logical? Are the key concepts well defined?

The planning process as presented in Figure 2 (US EPA, 2001a) includes three main components: a) identifying the decision context; b) developing objectives; and c) identifying information needs. Each topic contains a series of sub-components, which collectively identify the major considerations for planning virtually any type of risk assessment. As described in our response to the first Charge Question, however, steps for setting management objectives for environmental decision making or ecosystem management are fundamentally different from those for planning a risk assessment. The decision of which is being addressed by the report will determine the validity of the logic. In any case, the steps require expansion and clarification. For example, it is not clear that the process is flexible and iterative, (i.e., that any of the three steps can come first or can proceed concurrently with the other steps).

#### 3.2.1 General Recommendations

a) <u>Roles of Risk Assessors and Managers</u> - In many areas the document supports close interaction between risk managers and risk assessors; yet it remains tentative in describing where and how interactions should occur to maximize cross-functional collaboration. In particular, the respective roles and responsibilities of risk managers and risk assessors across the boundary of

"planning" and "problem formulation" need to be explicitly presented. For example, does the process of identifying information needs (Figure 6) belong in planning or in problem formulation? Is it the responsibility of the managers or the assessors to decide?

b) <u>Feedback Mechanism</u> - We suggest that the Agency consider a feedback mechanism between the problem formulation step of a risk assessment and the steps of developing risk management objectives. Risk assessors should have the opportunity to provide decision-makers with information relevant to defining the management objectives, as well as to identify other risks relevant to specific ecosystem management and decision issues. In addition, a more direct presentation is needed of the process for developing Risk Management Objectives and associated roles and responsibilities of risk managers and assessors.

#### 3.2.2 Recommendations for Components

- a) <u>Identify Decision Context</u>
  - If the Presidential Commission on Risk Assessment and Risk Management (1997) formed the basis for this discussion, it would be valuable to explicitly reference this source. Perhaps a relevant figure from the Commission's Report could be substituted for Figure 3, which does not seem to capture all aspects that are subsequently discussed in this section. There also appear to be other ecological risk management documents in press or under development that should be incorporated.
  - 2) The sub-sections of Section 2 do not seem of equal stature. For example, "Legal, Regulatory and Institutional Context" (Section 2.2.2) and "Geographic and Temporal Context" (Section 2.2.4) are titled differently than "Risk Management Options" (Section 2.2.3) and "Public Values" (Section 2.2.1). Public values might be described as the "social context." The process of identifying and engaging stakeholders needs to either be expanded or addressed separately in a whole other work (e.g., EPA Science Advisory Board, 2001).
  - 3) It seems that "Risk Management Options" could be elevated as its own component, as it is in the Presidential Commission on Risk Assessment and Risk Management (1997) and the SETAC Workshop Proceedings on Ecological Risk Management (SETAC, 1999).
  - 4) Certain other "contexts" appear missing, such as the economic context, the ecological context (e.g., which communities and ecosystems are threatened, and through which media), and the human health context. These contexts are represented in Figure 4 but are not discussed.
- b) <u>Develop Objectives</u> See EPEC's response to the Charge Question below pertaining to the critical question of "what to protect".
- c) <u>Identify Information Needs</u>
  - 1) See 3.1.1(c) for discussion of whether this component fits under "planning" or "problem formulation".

- 2) Section 4.2 needs to be rethought and revised accordingly. The title, "What do we need to know to decide what to do?" is cumbersome and the logic is weak. Impacts of "decision alternatives" upon management objectives seems to be circular reasoning. Does this topic refer to management options? Questions such as: "If we leave this Superfund site as is (or register this pesticide), how will that affect our objectives?" imply that the selection of management options or the decision itself could be pre-ordained or influenced by the consequences. The text doesn't appear to say what the authors likely intended. Also, consideration of "money available for remediation" seems more related to Section 4.3 ("What do we have to work with?") than "what information may be needed".
- 3) Section 4.3 similarly requires extensive revision. It contains a statement that, even if true in a probabilistic sense, speaks poorly of the Agency and the discipline of risk assessment: "we are never 100% certain about our conclusions or that our decision is in fact the correct one." Other statements advocate "personal rules of thumb" and "a network of colleagues who can offer advice and perspective" that would be chaotic if not illegal.

# **3.3** Is the depth of discussion and level of technical detail appropriate? If not, how would SAB change it?

To better identify specific areas the guidance should address, EPA organized three colloquia for EPA users, other government users, and private-sector users, respectively. Participants in these colloquia asked for advice such as "*criteria* for deciding *what to protect, types of ecosystems or ecological values to protect*, how to define protection, and how to engage interested parties (draft report (US EPA, 2001a), section 1.1)." EPEC feels that the draft document, while providing procedural guidance that may be too detailed and redundant in some respects, gives inadequate guidance on the substantive questions raised by colloquium participants. In particular, guidance for deciding what types of ecological attributes, ecosystems, and ecological values to protect is inadequate. This omission is glaring, particularly given the fact that protection criteria is the area most needed by non-technical managers. There is a well-developed literature on ecological condition assessments, classifications, and valuation of natural resources that could be used for such guidance. In addition, the invited papers by Daily (2000) and by Noss (2000) to the colloquium for private-sector users provide valuable suggestions.

The following discussion provides one option for rewriting section 3.2.1 ("Keys to What to Protect"), as an example. Other equally valid options certainly exist. We suggest, for example, replacing the first key with the option presented in Figure 1.

Gretchen Daily's (Daily, 2000) classification (Table 3.1) provides one good method for categorizing "Ecosystem Services" and could be used as the second key. One of the attractive attributes of Table 3.1 is that it highlights many ecosystem services, such as pollination, attenuation of floods, and self-sustaining option values that are often overlooked by both managers and the public. The Table, therefore, provides a useful tool for eliciting preferences and subsequently defining objectives for ecosystem service categories as an appendix to the guidance document for those readers who want additional detail regarding the definition or value to society of a particular category of ecosystem service.



# Figure 1 - Suggested Option for the "First Key"

Several options are available for the "Ecological Integrity or Condition" key, but we recommend that the key be based on fundamental ecological principles and that it systematically characterize the attributes required to sustain ecological systems. One method of accomplishing this task was outlined in the invited article by Noss (2000), as follows:

"...biodiversity and ecological integrity can be decomposed into structural, functional, and compositional components, and measurable indicators can be selected that correspond to these components (Noss, 1990; Noss et al.,1999). A comprehensive index or collection of metrics should include measures of structure, function, and composition at several levels of biological organization (e.g., ecosystem, community, species) and be measurable at a variety of spatial and temporal scales."

Noss (1990), in particular, presents a graphic (Figure 1) that could be converted into a table, then expanded upon with examples in order to provide a key.

Similarly, the Ecological Processes and Effects Committee (EPEC) will shortly release a white paper (EPA Science Advisory Board, 2002 - under development) that provides a similar hierarchical checklist of ecological attributes that should be addressed in order to assess the condition of an ecosystem, with sample indicators for each attribute. The attributes are derived from categories that represent ecological patterns and processes, and systematically incorporate structural, functional, and compositional elements at each hierarchical level of ecological organization. The EPEC checklist includes each of the elements of the Noss (1990) graphic (and vice versa), but may promote greater emphasis on attributes that are commonly unrecognized, such as landscape structure. Either of these examples could be used as a key to guide the discussion regarding suitable objectives for ecosystem management and analysis of risks to the system.

The items that were listed in the keys in section 3.2.1 of the EPA Draft are embedded in both the Noss (1990) and the EPEC (EPA Science Advisory Board, 2002 - under development) checklists. For example, "special places" relate to landscape patterns and composition, and can be highlighted accordingly. The invited article by Noss (2000) provides a solid proposal for

identifying ecosystems warranting special protection. In sum, the Committee recommends that section 3.2.1 be omitted or substantially redrafted so that it systematically presents the complete array of important ecosystem characteristics.

# **3.4** Discuss the flexibility afforded by the guidance and its applicability to different situations (e.g., site-specific, national level, etc.)

Among reasons the planning guidance is so general and may be of limited utility to "front-line" risk managers is that it attempts to generically address virtually all types and scales of ecological risk assessment. This undertaking is indeed enormous. It begs the question of how much practical advice a risk manager in the Office of Pollution, Pesticides and Toxics Substances or the Office of Solid Waste and Emergency Response, for example, could give to a manager in the Office of Water dealing with very different issues? The compromise to maximizing the guidance's flexibility is lessening its specificity and practical applicability. Only the most fundamental and generic principles can be presented in a document that spans the breadth of ecological risk assessment and management.

One way to provide more specific guidance might be to categorize types of risk assessments and management decisions. This breakdown could be approached in a number of ways (recognizing that each could be a thesis in itself, likely requiring resources beyond the Risk Assessment Forum). For example, risk assessments and management decisions regarding, for example, a new commercial chemical, a Superfund site, a municipal discharge or a proposed land development project certainly involve different sets of stakeholders, legal and economic criteria, and scales of authority. Consideration should be given to how these issues might require different planning processes, as well as the commonalities they share.

Site-based risk assessments and management decisions affecting large geographic areas are more complex and involve a greater variety of natural and anthropogenic stressors than those affecting smaller areas. The geographic scale and the number of stressors influence the management objectives at the onset, the precision of the data during the assessment, the degree of specificity in the interpretation of the results, and the authority and cost required to implement a management decision. Risk assessments on a large geographic scale would seem to support broader, longer-term, and yet less specific management decisions than localized assessments, for which more immediate and targeted solutions may be possible.

To the authors' credit, this concept of scale was recognized in Section 2.1, in distinguishing among "unique and wide-impact decisions," "repeated wide-impact decisions," and "routine and narrow-impact decisions." EPEC concurs with the logic but feels these concepts deserve better definition and expanded discussion. It is not stated, for example, why routine and narrow-impact decisions "are more amenable to standardization." Perhaps expansion of the references would help, particularly the "somewhat standardized routines" (for decision-making) that are cited by the National Research Council (1996).

Finally, the types of chemicals (e.g., metals, nutrients, polar organics, pesticides, etc.) and their physical-chemical properties (e.g., persistence, bioaccumulation potential, toxicity, bioavailability) logically influence the design of the conceptual model in problem formulation. This approach has implications in planning and may deserve special consideration in providing practical advice in forming management objectives. This concern again argues for greater involvement in the development and validation of this guidance document by risk managers across the Agency's Program Offices.

#### **3.5** Comment on the effectiveness of the examples, figures, tables and text boxes.

#### 3.5.1 Examples

The use of a series of examples is valuable for demonstrating the implementation and potential efficacy of this planning document. Examples can illustrate where the implementation of this process is successful or demonstrate how a better outcome would result through the implementation of this process. For example, the Salton Sea example (Appendix A-1 of the draft document) did a good job of demonstrating the problems that can result from conflicting objectives. However, the selected examples should focus on demonstrating the elements of the guidance document. The use of examples should demonstrate how things could be done better if planning as prescribed is carried out. The Committee thought one approach that could be instructive would be to send the draft document to those who provided the Case Examples given in Appendix A of the draft document and ask for feedback (i.e., had they followed the procedures outlined in this document, would the objectives turn out differently or would the process have been more efficient?).

#### 3.5.2 Figures

Figures offer a compelling and succinct way to provide information about the structure and context of the document. It could be instructive to include a figure at the beginning of the document showing the constellation of activities within EPA involved with ecological risk assessment and highlighting how this initiative of the Risk Assessment Forum relates to other units of the Agency. For example, Figure 4 could be moved to the front of the document, as it illustrates the parallel processes ongoing with ecological risk assessment and the cross-linking of the planning process across all of these initiatives. Figure 1 might follow to demonstrate how the focus of this document was an elucidation of one element of Figure 4. Figure 2 is excellent in that it allows the reader to track the evolution of the discussion.

Figures 3, 5 and 6 should be reevaluated, as it is not clear how they relate to the larger diagram. There is no numbering of the elements of the figure to coincide with the text. In addition, the Committee felt the questions posed were overly simplistic and somewhat redundant. They could be rewritten as clear statements of what was to be accomplished in each step (see our discussion in section 2.2.1 of this report).

Figures dealing with the Keys do not have a graphic context to demonstrate how they fit into the larger scope of the document. It is not clear what "keys" are, and why they are not included as part of the figure series of the overall document. In addition, they are not easily linked to the critical unifying figures of the document, namely figures 1, 2 and 4. Where would the "keys" fit into or be utilized in Figure 2?

Since the figures are critical in providing the framework for the document and the document describes a process, showing how these are components are related is important to the document. Figures could also be developed to clarify how Problem Formulation and the Planning Process are carried out and how these processes map to one another. In a number of instances (e.g., Figures 1 and 4), there may be the opportunity to emphasize the iterative nature of the process.

In both the figures and text, the process described appears linear, rather than emphasizing the multiple opportunities for feedbacks. Correct this misconception with additional emphasis in the text and by modifications of figures (e.g., arrows showing these feedback opportunities, such

as between Problem Formulation and Risk Characterization in Figure 1, and across parallel activities in Figure 4).

To help managers use this guidance, the document should have a summary text box or figure that outlines the new and expanded features in this guidance relative to the 1998 ecological risk assessment guidance.

#### 3.5.3 Text Boxes

The Committee felt that information in the text boxes was valuable, and often was developed in a clear and succinct manner that should be the model for revisions to the text. Indeed, rather than text boxes being used as elaborations of some point in the text, this document appeared to succinctly organize and summarize information in the text boxes and to detail at great length the concepts in the text itself. If the document is to be tightened up by making it shorter and more structured, then perhaps text boxes should take on a different role and should be used for a few key elaborations.

#### 3.5.4 Tables

Tables were effectively used to summarize information in a succinct and organized manner in several instances in the document. It may be possible to make greater use of tabular information in a revision that is shorter in text but not in content. One table of critical importance that could be developed would identify how this document fits into a bookshelf of current and planned documents from EPA on ecological risk assessment. Are other documents planned for communicating the results of an ecological risk assessment to Risk Managers? Interested Parties? Is there an overall plan for how many documents will exist in this ecological risk assessment bookshelf, how they are integrated in content and in time, and perhaps even how the process of their development and revision is expected to take place? On a more trivial note, an additional table in the back that could complement the glossary is a table of acronyms used in the document and their definitions.

#### 3.6 Other Issues

The language used to describe the sub-components of the process is too colloquial and, therefore, imprecise.

In several respects, the current Guidance does not appear to be consistent with that provided for Planning in the Ecological Risk Assessment Guidelines from 1998 (US EPA, 1998). Some definitions differ, e.g., ecological risk assessment and the definition of management goal in Table 1-1 on page 15 of the planning document differs from that given in Text Box 2-7 of the 1998 Guidelines. These discrepancies should be resolved or the new definition of these terms and reasoning behind any changes made clear.

A title change to reflect that the document is primarily meant as guidance for a planning process prior to ecological risk assessment (as a supplement to the 1998 Guidelines) might be considered. Use of a version of Figure 4 in the introduction would be one way to illustrate that the type of planning discussed in this guidance could lead to a formal ecological risk assessment, and/or other analyses, leading up to risk-management decisions.

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