August 1, 1997

EPA-SAB-EPEC-ADV-97-001

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

Subject: Advisory on the Problem Formulation Phase of EPA's Watershed Ecological Risk Assessment Case Studies

Dear Ms. Browner:

The Watershed Ecorisk Subcommittee of the Environmental Processes and Effects Committee (EPEC) of the Science Advisory Board (SAB) met on July 18-19, 1996 to review five Watershed Ecological Risk Assessment Case Studies being developed under the auspices of the Agency's Risk Assessment Forum. The case studies were undertaken to demonstrate the utility of ecological risk assessment for setting management priorities for watersheds. This initial review, which focuses on the planning and problem formulation steps of the ecorisk process, is considered an SAB advisory since it provides peer review of an Agency work-in-progress. The goal of an SAB advisory is to provide suggestions to the Agency for mid-course corrections that will refine the ultimate product. In this case, the intent of an early SAB review of the planning and problem formulation step is to facilitate the completion of high quality case study examples. The Subcommittee expects to review the completed case studies in late 1997, at which time a significant number of new participants will be added to the reviewing panel -- by changes in EPEC membership and/or inclusion of additional consultants -- to ensure independent assessment of the Agency's work.

However, following the review, Agency Staff have indicated to EPEC that efforts to complete the cases studies all the way through the characterization phase may be suspended. This change of plans is of concern because much of the value of the case studies will lie in the Agency's ability to demonstrate to communities the utility of the ecorisk assessment process in supporting decisions and in capturing lessons leaned from these five examples. Therefore, we urge the Agency to complete the case study exercises and fully utilize the substantive and procedural lessons that they are sure to yield.

Although the Agency's *Framework for Ecological Risk Assessment* (U.S. EPA, 1992) (ecorisk framework) and *Proposed Guidelines for Ecological Risk Assessment* (U.S. EPA, 1996) describe a process for assessing ecological risks from chemical, biological, and physical stressors, the Agency felt that these approaches should be tested in a watershed context relevant to communities. Place-based ecological risk assessment highlights the need to deal with multiple stressors that affect the watershed or place, as well as the importance of interactions between risk assessors and community decision-makers. The five watershed case studies are intended to provide an illustration of the application of the ecorisk assessment process in watersheds and, when completed, to serve as the basis for guidance to the Agency and communities who wish to conduct ecorisk assessment to guide community-level management decisions.

The materials provided to the SAB for review consisted of draft guidance on problem formulation in a watershed context and draft case study examples for five watersheds: Big Darby Creek, OH; Clinch River Valley, VA; Middle Platte River Floodplain, NE; Middle Snake River, ID; and Waquoit Bay, MA. The charge to the Subcommittee (Attachment A) contained 14 specific questions in the following six categories:

a) establishing management goals (questions 1-3);
b) selecting assessment endpoints (questions 4-7);
c) selecting measurement endpoints (questions 8-9);
d) developing conceptual models and the analysis plan (questions 10-12);
e) the overall process for watershed risk assessment (question 13); and
f) case study presentation (question 14).

Although the Subcommittee reviewed all five preliminary case studies, the focus of our comments, as requested by the Agency, is on the overall problem formulation process that was used by the case study teams, especially those aspects that depart from the problem formulation process described in the ecorisk framework. Differences include the approach for developing management goals and defining and selecting assessment endpoints, and the introduction of analysis plans.

1. General Comments

The Subcommittee agrees that case study applications of the ecological risk assessment framework are essential to test and improve its applicability to watershed-based analyses, and we commend the Agency for their willingness to undertake this effort. The case studies were well selected and represented diverse environmental and

historical situations. Further, the composition and leadership of the case study teams were especially good. Consistent application of the framework across the case studies was recognized, and the comparisons among the case studies were instructive and useful. The efforts to secure public involvement were good, and the utility of "place-based" and "value-initiated" risk assessments was demonstrated. We are pleased that the Agency views the ecorisk framework as an adaptable strategy, and we agree that the proposed changes are an improvement.

2. Establishing Management Goals (Charge Questions 1-3)

The Subcommittee applauds the Agency for its efforts to obtain stakeholder input to establish place-specific values. To be most effective, however, the Agency should develop a consistent strategy to ensure that a full complement of stakeholders and technical experts is brought together from the early stages of planning and problem formulation. Although local values should clearly drive the establishment of management goals, development of these goals should be fully informed by the scientific community. For this reason, the process should include open discussion of the ecological considerations associated with specific goals and other ecological attributes of the system that may be overlooked if local management goals are too narrowly focused.

The Subcommittee does not think that a strict separation between the planning and problem formulation steps is desirable. In fact, this separation may be counterproductive to establishing appropriate goals. The interaction between risk assessors and risk managers, however, should in no way compromise the scientific rigor of the risk assessment to be conducted. When the watershed risk assessment teams include diverse viewpoints and expertise, the participants should recognize that different elements of the team will take the lead during different parts of the process, although the iterative consultation should proceed throughout.

The effectiveness of the approaches used to define meaningful goals and objectives varied considerably among the five case studies, demonstrating that the success of the process depends on the composition of the team assembled. The process appeared to work best where the teams assembled for problem formulation involved a broad representative group of the public and individuals with technical expertise, as in the Waquoit Bay study. It did not appear to work as well in the Middle Snake River study, for example, where the public was not effectively engaged.

In some cases, the team's choice of ecologically relevant assessment endpoints did not connect well with the management objectives. Nonetheless, the endpoints were

appropriate because the selected endpoints address the integrity and sustainability of component ecosystems independent of societal values. One goal of any risk assessment should be public education. Thus, for these case studies, the environmental situation in the watersheds being evaluated should be put in context relative to the ecological landscape and other ecosystems regardless of the selected management goals, and this in turn may allow reassessment of these goals.

An important first step in the planning process, and a good team-building exercise, is for the risk assessor/risk manager team to gain a historical perspective on the social, political, geological, and ecological history of the region, drawing upon either the knowledge of team members or outside experts. Indeed, a sufficiently broad team should include members with knowledge in each of these areas

In the problem formulation stage of the risk assessment, it is important to recognize that watersheds have many boundaries in addition to the topographic boundaries of water flow. These include their relationship to ecological, geographic, and political boundaries. In the formulation of assessment goals, all of these boundaries need to be recognized and considered in order to select appropriate assessment and measurement endpoints, as well as to translate the risk assessment into risk management. For example, a surface watershed is also part of an airshed and a groundwatershed, which almost certainly will not have the same boundaries and could have a significant impact on the watershed. The team needs to be aware of these other units, particularly in identifying stressors and formulating management strategies. In addition, a number of the case study areas represented only portions of a watershed. For these reasons, it is critical to consider factors external to the assessment area that may be important influences on watershed processes.

The five case study areas, while highly variable in terms of their spatial scales, were justified as conveniently bounded systems for assessing ecological risks. However, the concerns focused on ecological structure and function within the watershed (or portion of the watershed), not on ecological structure and function at the scale of the watershed. For example, habitat manipulation within a watershed suggests different kinds of risks (and assessment methods) than atmospheric deposition at scales encompassing entire watersheds. Thus, the Agency should clarify what is meant by the term "watershed-level ecological risk assessment" and should acknowledge that once the hydrologically determined boundaries are set, the scale of the assessments is often effectively limited to the “people shed”, not the watershed. Since place-based ecorisk assessments frequently do not address a whole watershed, but only a segment of it, watershed teams should identify and explicitly state what portion of the watershed their assessment concerns; describe the extent to which the

assessment may be applicable to other portions of the watershed; and state clearly those issues or portions of the watershed for which the assessment is not applicable.

Finally, it was not clear from the oral presentations or the draft case study materials whether watershed management is to be conducted within the framework for ecological risk assessment, or whether ecological risk assessment should support watershed management. A distinction should be made because the two are quite different; ecorisk assessment provides an estimate of the adverse effects of environmental stressors on ecological resources, whereas ecosystem or watershed management strives to achieve specific ecological and societal goals for a regional environment.

3. Selecting Assessment Endpoints (Charge Questions 4-7)

The draft guidance on problem formulation for watersheds identifies three key components for selecting assessment endpoints: a) linkage to management goals; b) ecological relevance; and c) susceptibility to stressor. We believe these are relevant selection criteria, although they do not appear to have been consistently applied by the case study teams. For example, as noted in the previous section, the derivation of assessment endpoints from management goals was evident in the Waquoit Bay case study, but not in the Middle Snake River case study; in the latter case, the assessment endpoints are related to biota--fish, benthic fauna, macrophytes, and algae--while the management goals are related primarily to water quality and quantity.

In addition, the Subcommittee suggests a slight modification of the third criterion. Sensitivity of response to a stressor is desirable, especially in terms of implementing and measuring success toward a management goal, but it should not always be used as an *a priori* criterion for excluding a given assessment endpoint. In some instances, the most ecologically relevant endpoint may not be the most sensitive, but should still be included in the risk assessment. For example, if an important management goal is the protection of bird populations, then selection of a population endpoint for amphipods, although it might be the most sensitive, would not be the most ecologically relevant assessment endpoint. Thus, assessment endpoints should be selected primarily for their ecological relevance and their ability to be measured.

The Subcommittee supports the efforts evident in the case studies to clarify terminology in the ecorisk framework dealing with assessment and measurement endpoints. The use of the word “measures” as a replacement for the term “measurement endpoints” appears clearer and more inclusive since it can include stressors as well as ecological effects. With respect to the definition of "assessment

endpoints" as "entities and their attributes," the Subcommittee did not feel that this assisted in clarification or in providing separation of assessment endpoints from management goals. We suggest that a better definition of an assessment endpoint should be an ecological characteristic that the stakeholders identify as being at-risk, based on their identification of values to be protected.

Ecological risk assessments can be performed either using known stressors for purposes of selecting assessment endpoints or using assessment endpoints (associated with known or perceived effects and management goals) to build conceptual models and identify stressors. The latter approach was appropriately used in the case studies and is an effective technique for focusing the ecological risk assessment. It can also be used to provide technical guidance on achieving management goals.

4. Selecting Measurement Endpoints (Charge Questions 8-9)

Data availability is certainly one aspect to consider when selecting what to measure in support of assessing ecological risk. However, ecological measures should be selected primarily based on their relevance to what has been identified as being potentially at risk; e.g., risk to the ecological structure and function of the watershed as a whole. If the corresponding data necessary to support the risk assessment do not exist, then they should be collected, or relevant data from similar systems that address the issue might be substituted in a preliminary risk assessment. General guidance about the selection of measurement endpoints needs to be expanded; additional points might include selecting different and independent measures of the same assessment endpoint, and selecting measures at different levels of ecological organization that address the endpoint. For example, a population-level risk (e.g., unacceptable decline in the production of a commercially valuable species) might be measured at the level of the population (e.g., birth rate, death rate) or at a physiological process-level (e.g., consumption, respiration).

When selecting measurement endpoints, assessors must decide whether segregation of the relative contributions of different stressors is an important purpose of the watershed-level risk assessment. Teasing apart the relative contributions of different stressors to a single ecological effect remains an issue at the forefront of ecological research. Perhaps the only reasonable guidance that might be given is to break down further the effect of interest into greater detail, in the hope that the different modes of action of the different stressors might become apparent. For example, if unacceptable increases in noxious algae are of concern, and the set of stressors includes nutrient enrichment, metals, and organic contaminants, then primary

production might be examined at the level of the physiological processes that determine it, in this case the effects of nutrients on increased photosynthesis and growth. This in turn might be contrasted with the relative toxic effects of the metals and the organics. Such a perspective may allow nutrient effects to be separated from toxic effects and might also permit examination of the indirect effects, for example, the reduced grazing pressure on algae resulting from toxic impacts on consumer populations in the system.

5. Developing Conceptual Models and the Analysis Plan (Charge Questions 10-12)

The use of conceptual models, as envisioned in the draft guidance, and the hierarchical nested approach leading from the general to the specific, in at least three tiers, is quite good. However, a broader, watershed-level conceptual model would be useful as a common starting point for all watershed case studies, present and future (i.e., as part of the "lessons learned" guidelines). Such a model might include, for example, stream order, long-term seasonal runoff and thermal regime patterns, and seasonal schedule of riparian zone inputs in order to define the boundary conditions for organism life cycles in watersheds. Also, some of the paradigms developed to explain the structure and function of stream river ecosystems could be used as general models to set the stage for watershed risk assessment. These paradigms include the River Continuum Concept (RCC), Flood Pulse Concept (FPC), Riparian Influence Concept (RIC), Nutrient Spiraling Concept, and Patch Dynamics Concept (Cushing et al., 1995; Cummins, in press). The RCC, FPC, and RIC are conceptual models that address generalized spatial and temporal relationships in watersheds. The RCC and FPC propose a model describing how running water ecosystems change in predictable fashion longitudinally (RCC) and laterally with their floodplains in the lower reaches. The RIC conceptualizes interactions between the terrestrial fringe and running waters along the riparian ecotone. There are also some conceptual models that could help set the stage for formulating risk hypotheses; e.g., the Serial Discontinuity Concept (SDC) would have been useful in the Snake River Case Study. The SDC is applicable to an impounded river, such as the Snake, because it addresses structural and functional attributes that are displaced by damming.

Conceptual models allow for the identification of multiple stressors and facilitate the consideration of cumulative, interactive effects. To this end, continued development and refinement of multi-layered conceptual models are, and likely will continue to be, the most effective method to ensure the development of the most appropriate analysis plans and the identification of complex, cumulative effects. Incorporation of an analysis plan in problem formulation has been correctly identified

as an important step. It is also important to examine multiple exposure pathways simultaneously in the analysis.

6. How the Process Can Be Improved (Charge Question 13)

Many of the opportunities for improvements in the case study process are related to research needs that will be identified during the ecological risk assessments. For example, there is not a great deal of "watershed level" data available because past research has been either narrowly focused on a specific stream or stream segment, or broadly focused on an ecosystem. In order to improve the watershed case study process, the Subcommittee recommends that consideration be given to the following:

a) watershed management requires continued improvement in terms of understanding the science of watershed-scale processes (e.g., energy flow, productivity, and nutrient cycling);

b) watershed management requires more data actually collected over full watershed systems;

c) identification of multiple watershed boundaries is critical and must consider the distinction of ecological, geo-physical, and political elements;

d) the influence of societal values and forces external to the watershed may be important in watershed processes and should be recognized;

e) the current case studies focus on surface-water issues -- full watershed assessment must also consider terrestrial, atmospheric, and groundwater components and the important linkages among these elements;

f) river segments are not "watersheds" and thus their assessment must include upstream and downstream perspectives; and

g) assessments should strive to provide only the minimum information necessary to inform decisions.

7. Case Study Presentation (Charge Question 14)

Capture of "lessons learned" will be a very important output of the case study exercise, and while it is useful to include this information in summary documents aimed

at community-level risk assessors and managers, it is also important that these lessons be incorporated into the Agency's *Proposed Guidelines for Ecological Risk Assessment*. Therefore, it is important that these case studies be carried through to completion and that a special effort be made to extract the generic lessons learned and to use these to develop a brief narrative and a template that other groups can use to apply the place-based, ecological risk assessment approach to new situations.

The planning and problem formulation sections of the draft Waquoit Bay case study contain an appropriate level of detail and meet the general project objectives. While the case study drafts represent a good start, the Subcommittee believes much more work is required to meet the objectives of the individual case studies and the overall project. For example, we offer the following specific suggestions for improving the present documents: a) each case study report should have a parallel structure, including an executive summary--not an abstract--up front and summary and conclusions sections at the end of each case study report; b) lessons learned should be highlighted and accompanied by a brief description of how they would change the process if the study were re-started, and how they would affect future applications; and c) all case study reports should be written concisely, clearly, and with a minimum of jargon.

In addition to the case study reports designed for a science audience generally familiar with the ecological risk assessment process, less technical documents with minimal (or no) jargon would be necessary for other audiences (e.g., state and local governments, community groups, and other institutions). We recommend, therefore, that the Agency develop a concise, consumer-friendly, version for use by communities that uses "plain English" to explain the concepts and principles of ecological risk assessment and something of the process that will be conducted. Illustrations and graphic material would also be helpful in communicating the ecorisk approach to a broader audience. This non-technical version should include a brief section on the advantages and limitations of ecological risk assessments, points that should also be discussed as part of the team education process at the beginning of any watershed ecological risk assessment.

For both the technical and non-technical writeups of the watershed case studies, the power of the place-based ecological risk assessment approach will be far more evident and the reasons for using it more compelling if the basic underlying principles and processes and the benefits are clearly understood by the reader. Relating these concepts to other decision-making models would further strengthen the argument for using the ecorisk paradigm, rather than weaken it.

In conclusion, the Subcommittee found the planning and problem formulation stages of the watershed case studies generally to be well done, the assessment endpoints selected by the watershed teams to be ecologically relevant, and the conceptual models developed to be good summaries of the science available. We emphasize the importance of completing these cases studies and look forward to reviewing the completed analysis and risk characterization stages for each of the case studies in the near future.

Sincerely,

/signed/
Dr. Genevieve M. Matanoski, Chair
Executive Committee

/signed/
Dr. Mark A. Harwell, Chair
Ecological Processes and
Effects Committee

/signed/
Dr. William H. Smith, Chair
Watershed Ecorisk Subcommittee

Attachments

LITERATURE CITED

Cummins, K.W. In Press. The River Continuum Concept: A Worldwide Model for Running Water Ecosystems. Prospettive di Ricerca in Ecologia delle Acque, Instituto di Ricerca sulle Acque del C.N.R., Italy.

Cushing, C.E., K.W. Cummins and G.W. Minshall (eds.). 1995. Ecosystems of the World, 22. River and Stream Ecosystems. Elsevier, Amsterdam. 882p.

U.S. Environmental Protection Agency. 1992. Framework for Ecological Risk Assessment. EPA/630/R-92/001, February 1992.

U.S. Environmental Protection Agency. 1996. Proposed Guidelines for Ecological Risk Assessment. EPA/630/R-95/002B, August 1996.

ATTACHMENT A: CHARGE TO THE SUBCOMMITTEE

WATERSHED ECOLOGICAL RISK ASSESSMENT

Science Advisory Board Review
18-19 July 1996

Subject: Review of watershed level ecological risk assessment case study planning and problem formulation

Requesting Organizations: Risk Assessment Forum

Contact: Suzanne Marcy, Technical Panel Chair
National Center for Environmental Assessment, ORD (8601)
(202) 260-0689

The Risk Assessment Forum is requesting the review of documents describing and illustrating the process of watershed ecological risk assessment in the form of five case study examples and a summary of what was learned from their development. This is the first part of a two stage review process. The initial review (termed an SAB Advisory), will focus on the planning and problem formulation sections to obtain early feedback on the process used to: (1) obtain watershed level management goals; (2) interpret the goals for the risk assessment; and (3) define the problem at the landscape scale for multiple stressors, including a plan for analyzing data and characterizing risk. SAB review of the process used for planning and problem formulation will facilitate the completion of quality case study examples. A second review will be requested in FY97 to focus on the analysis and risk characterization component of the case study examples.

BACKGROUND

As the Agency shifts emphasis from command and control toward voluntary compliance and community-based environmental protection, it becomes critical that EPA provide the scientific basis for community-level management decisions. States and local organizations need a process and tools they are able and willing to use for determining what ecological resources are at risk and how best to protect those resources through management action.

In 1992, the Agency published the *Framework for Ecological Risk Assessment*

(*Framework*). The *Framework* provided a good foundation for conducting ecological risk assessments for individual chemical or physical stressors. However, it does not address risk from multiple chemical, physical and biological stressors that combine within watershed ecosystems, the kinds of problems communities will need to manage. The case studies were initiated to address this need. They were intended to provide a process for learning how to apply the principles of ecological risk assessment to a watershed scale problem, and when completed, provide case study examples of the process. Lessons learned from case study development were intended to be incorporated into future Agency *Guidelines for Ecological Risk Assessment*. Because of interest by the Office of Water in watershed protection, and the Risk Assessment Forum in testing and expanding the ecological risk assessment *Framework*, the case studies were jointly sponsored by these offices to illustrate the application of the *Framework* to watersheds impacted by multiple stressors.

The project officially began in September 1993 with the initiation of five watershed ecological risk assessment case studies: Big Darby Creek, OH; Clinch River, VA; Middle Platte River Wetlands, NE; Snake River, ID; and Waquoit Bay Estuary, MA. Watersheds were nominated for inclusion in the project by organizations concerned about the watershed. Specific selection criteria included data availability, willingness of local professionals to participate, diversity of stressors, and the presence of significant and unique ecological values. The case studies are being conducted by interdisciplinary and interagency teams of risk assessors and risk managers. The projects are organized to approximate the kinds of expertise, resources, and data likely to exist in communities that would use this guidance.

CHARGE

We request that the Committee focus primarily on the process used to conduct problem formulation at the watershed level, including those aspects of the process that depart from that described in the *Framework*. These include changes in: the process based on why the risk assessment is initiated, how management goals were developed and defined, selection and definition of assessment endpoints, development of conceptual models for watersheds and multiple stressors, and the introduction of analysis plans. Suggestions for improving individual case studies, while valuable, are considered tangential to the primary intent of the review. The Waquoit Bay case study will be used to illustrate the process of planning and problem formulation, with additional examples being drawn from the other case studies where appropriate. Committee members should read the entire Waquoit Bay Watershed case study and at least one other case study in full, and the executive summaries for each case study.

We ask the Committee to evaluate the following specific issues:

Establishing Management Goals

1) The watershed risk assessment teams found it essential to work with local, state and federal managers and scientists to generate management goals prior to conducting the problem formulation stage. To emphasize the importance of this step, we established a full "planning" section in the case study which describes the goal and how it was derived. How well does this process make the link between risk management and risk assessment? How responsive is the problem formulation to the identified management goals?

2) In the *Framework*, interactions between managers and risk assessors (planning) was considered to be outside of risk assessment and was not emphasized. We have maintained this separation between planning and problem formulation to help ensure the scientific foundation for the risk assessment while being responsive to management concerns. Currently within the Agency, there is interest in adopting the expression "problem formulation" and redefining it as a combination of planning and problem formulation. How important is the separation of risk management from the scientific evaluation of ecological risk? How effective was the approach used in the case studies in maintaining separation but ensuring management input?

3) Goals for a watershed or other landscape ecological unit, when generated by a diverse constituency, are often very general and broad. Teams confronted with these general goals defined their meaning by generating sub-goals or objectives that made implicit assumptions in the goal explicit. How effective was this process in defining the goal in ecologically relevant ways? What other approaches may do this more effectively?

Selecting Assessment Endpoints

4) Assessment endpoints were defined based on the management goals and objectives. Each assessment endpoint was evaluated by comparing its relationship to specific management objectives, and by determining its ecological relevance and susceptibility to stressors within the watershed. How effective is this approach for selecting a quality set of assessment endpoints? How well do the assessment endpoints reflect their respective sub-goals?

5) Because of the breadth of the goals and potential assessment endpoints, teams had difficulty selecting which set of assessment endpoints to use. Some are specific, some may be better as measures, some remain fairly broad. What guidance can reviewers provide on the level of specificity appropriate for assessment endpoints and the best complement of endpoints to use for this type of risk assessment?

6) Assessment endpoints are defined as entities and their attributes (e.g., bird reproduction, wetland areal extent). This definition is more specific and differs from other definitions (e.g., USEPA, 1992; Suter, 1993). It was used to clarify and focus the problem formulation on definable characteristics that were not goals or adverse effects. The definition is used to clarify the focus of the assessment, and to separate assessment endpoints from management goals. How effective is this definition in providing separation from management goals? How well do assessment endpoints defined in this way establish a framework for generating appropriate conceptual models?

7) Assessment endpoints were selected prior to targeting stressors in the watershed. This was a significant, although seemingly simple, change in the process of ecological risk assessment where generally stressors and observed affects initiate the process instead of ecological values. This provided a basis for developing conceptual models containing multiple stressors. How effective was this approach for focusing the assessment on management goals, and multiple stressors?

Selecting Measurement Endpoints

8) The *Framework* describes the selection of measurement endpoints, intended to be measures of the effects on assessment endpoints from exposure to stressors, as occurring in direct conjunction with the selection of assessment endpoints. However, as the case studies were developed, greater success was achieved where teams identified an array of measures of effect, exposure, and ecosystem and life history characteristics at a later stage, during conceptual model development and analysis planning. This approach helped to prevent the selection of measures based primarily on data availability, and targeted other measures important to the process. Do these measures encompass the array needed for these risk assessments and is there a more systematic approach for their selection that the reviewers can identify?

9) One challenge of value-initiated risk assessments is to ensure that there are good conceptual connections between the assessment endpoints and the measures chosen to evaluate their potential response to stressors. This is particularly problematic when there are multiple stressors that may combine to cause the same type of response in an assessment endpoint. There has been mixed success in the case studies in achieving distinctions among stressors through the measures chosen. What guidance can reviewers provide to overcome this problem?

Developing Conceptual Models and the Analysis Plan

10) The teams approached the development of watershed conceptual models at multiple levels. Teams developed a conceptual model for the watershed as a whole, featuring the entire array of identified sources, stressors, ecological effects and assessment endpoints. These models were augmented by a second level of conceptual models that featured a single assessment endpoint, and all the stressors relevant to that assessment endpoint. More detail on processes and relationships was included at this second level. A third level is also appropriate, though not well represented in the case studies, where the pathways for one stressor are shown for one assessment endpoint. What mix of conceptual models should be developed to best represent the watershed ecosystem, communicate important relationships, and highlight important risk hypotheses?

11) One of the principal objectives of these case studies is to feature the assessment of multiple stressors. The potential for interaction among multiple stressors is primarily represented in the conceptual models. Much work remains to be done to develop analysis plans that help us evaluate the combined and cumulative effects of multiple diverse chemical, physical and biological stressors. What guidance can reviewers provide on the process, conceptual models and analysis plans to help evaluate combined and cumulative effects?

12) One significant addition to problem formulation was the incorporation of an analysis plan. Although implicit in the *Framework*, the need for an explicit formal plan seems essential to problem formulation for watershed risk assessments. As currently envisioned, the plan would lay out specifics on data, analyses and their expected results (including presentation format for management decisions), uncertainties and research needs. In the Committee's view, what are the critical elements of such an analysis plan?

Overall Process

13) A multi-step winnowing process was developed to help focus the risk assessment from the broad management goals to a plan for data analysis. The process included the development of management sub-goals and objectives, definition of assessment endpoints, development of conceptual models and prioritization of assessment endpoints during analysis planning. How effective was this process? How could it be improved? What other factors or steps could assist the teams in their selection process?

Case Study Presentation

14) The case study write-ups are intended to communicate to a diverse audience, including the scientific community, risk assessors and managers, and members of the local watershed communities. The write-up is intended to clearly describe the process of risk assessment, including how and why decisions were made and results obtained. The document should also educate decision-makers about potential risks to the watershed and provide the basis for management action. Finally, the document must be scientifically valid. How well do the planning and problem formulation sections of the draft Waquoit Bay case study fulfill these objectives? Does the draft contain the appropriate level of detail? What other format would fulfill these objectives more effectively?

NOTICE

This report has been written as 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 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, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

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