EPA/600/R-99/111
February 2000

Workshop Report on Characterizing Ecological Risk at the Watershed Scale

July 7-8, 1999
Arlington, VA

National Center for Environmental Assessment–W
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC

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ABSTRACT

As ecological risk assessment evolves, it is moving beyond a focus on single species toward addressing multiple species and their interactions, and from assessing effects of simple chemical toxicity to the cumulative impacts of multiple interacting chemical, physical, and biological stressors. While EPA and others have developed guidance and have considerable experience in applying the ecological risk assessment paradigm in source-based approaches (such as those focused on particular chemical contaminants), specific guidance for using it in “place-based” approaches (such as those conducted on a watershed-wide scale) is still limited.

One of the principal challenges in applying ecological risk assessment to watershed management and decision making is the need for a framework for characterizing risks that involve numerous stressors, interconnected pathways, and multiple endpoints. To develop the needed guidance in this area a workshop was held that gathered 35 participants with extensive experience in relevant disciplines such as watershed ecological risk assessment, ecological risk assessment, watershed management, or regional-scale assessment. To focus workshop discussions, several charge questions addressing the issues of greatest concern for characterizing risk at the watershed scale were developed prior to the workshop. This report provides the proceedings from the workshop and includes an introduction, a synthesis of discussion and recommendations, and summaries of presentations and breakout sessions.

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FOREWORD

Risk assessment is playing an increasingly important role in determining environmental policies and decisions at the U.S. Environmental Protection Agency (EPA). EPA's first Agency-wide guidelines for ecological risk assessment, published in May 1998, provided a broad framework applicable to a range of environmental problems associated with chemical, physical, and biological stressors (U.S. EPA, 1998). However, while EPA has considerable experience in applying the ecological risk assessment paradigm in source-based approaches (such as those focused on particular chemical contaminants), specific guidance on "place-based" approaches (such as those conducted on a watershed-wide scale) is still limited.

As ecological risk assessment evolves, it is moving beyond a focus on single species toward addressing multiple species and their interactions, and from assessing effects of simple chemical toxicity to the cumulative impacts of multiple interacting chemical, physical, and biological stressors. Ecological risk assessment will play a major role in bringing science into place-based decision making, but its application faces several challenges. Among those challenges is the need for a framework for characterizing risks that involve numerous stressors, interconnected pathways, and multiple endpoints.

The risk characterization phase of ecological risk assessment is the culmination of planning, problem formulation, and analysis. The objective is to weave together the various lines of evidence to formulate a clear and compelling summary of the exposure and effects data. Because it is intended to support scientifically sound decisions by risk managers, the risk characterization must also address the uncertainties, assumptions, and qualifiers embedded in the risk assessment. The recommendations developed from this workshop represent a significant step forward in meeting the challenges of risk characterization on a watershed scale.

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ACKNOWLEDGMENTS

This workshop was funded through an interagency agreement between EPA and the Tennessee Valley Authority (TVA). I would like to thank TVA, EPA, and other staff for their support and hard work in making this workshop a success. First, thanks to Bill van der Schalie and Sue Norton for their insight provided in the many discussions we held to plan the workshop. From the TVA group, Angela Stiles coordinated the vast majority of the logistical activity to get the right people in one good place at the same time. Jennifer Moses, Janice Cox, and Bruce Yeager took the notes that formed the basis for the workshop report. Forrest Rich conceived the idea that EPA and TVA should work together in putting on this workshop because TVA was already involved in addressing watershed risk communication issues and had experience putting on workshops. Janice Dockery helped with formatting, typing and distribution of the report.

Although many panel members provided input into developing the charge questions, the extensive assistance of Sue Norton and Bill van der Schalie (EPA National Center for Environmental Assessment [NCEA]), Maggie Geist (Waquoit Bay National Estuarine Research Reserve), Pat Cirone (EPA Region I) and Jerry Diamond (Tetra Tech) warrants specific acknowledgment. Jerry Diamond and Pat Cirone also made a major contribution to the workshop by developing draft watershed ecological risk characterizations that provided examples for participants to consider in responding to the charge questions. Jerry Diamond and Pat Cirone's presentations on Clinch Valley and Middle Snake assessments, respectively, provided the basis for many of the recommendations contained in this report. The success of the Clinch Valley assessment would not have been possible without the dedicated efforts of Don Gowan (The Nature Conservancy) and Roberta Hylton (U.S. Fish and Wildlife Service).

The initial plenary sessions successfully set the stage for the discussions that followed, and I wish to thank Mike Slimak, Sue Norton and Bill van der Schalie, all from the EPA NCEA, for their various perspectives on ecological risk assessment and interactions with risk management. Several others presented their work on watershed or regional-scale ecological risk assessments, including Susan Cormier (EPA National Exposure Research Laboratory, Cincinnati); Bob Fenemore and Marla Downing (EPA Region 7); Maggie Geist and Patti Tyler (EPA Region 1); Jack Gentile (University of Miami); William Smith (Yale University); and Patrick Bourgeron (University of Colorado). Their presentations contributed to the workshop discussion and recommendations. Drs. Gentile, Smith, and Bourgeron also served as facilitators to guide and maintain the focus of the break-out discussions in developing responses to the charge questions.

Finally, while there are too many to list individually here (see Appendix A), I acknowledge with gratitude everyone who participated in the workshop and contributed to this report. Addressing the charge questions was not an easy task, and the subject required open and frank communication and sharing and documenting this collective wisdom.

Victor B. Serveiss, Workshop Organizer
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SECTION ONE
INTRODUCTION

1.1 BACKGROUND AND PURPOSE

The workshop described in this report was conducted to further develop and document the process for the risk characterization phase of watershed-scale ecological risk assessment. The recommendations reflect the responses of workshop participants to charge questions addressing those aspects of watershed-scale ecological risk characterization deemed most in need of a procedural framework.

Participants were invited to the workshop because of their experience in ecological risk assessment, watershed management, or regional-scale assessment. Many of the attendees have been active in five EPA-sponsored watershed assessments that were initiated in 1993 to demonstrate application of the ecological risk assessment process to large scale, place-based studies. The idea to hold this workshop originated when a few of the chairs of these assessments noted a lack of specific guidance for developing such watershed risk characterizations. The workshop was also designed to provide feedback to help complete and improve these five watershed-scale assessments.

The recommendations developed through the workshop are intended to supplement the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998) and the *Risk Characterization Handbook*, presently being developed by EPA (U.S. EPA, 1999). While the proceedings from the workshop include comments that replicate material in the 1998 EPA *Guidelines* and the *Handbook*, this report assumes the reader is already familiar with the principles of risk characterization as described in the *Guidelines* (included as Appendix C).

1.2 WORKSHOP ORGANIZATION

The workshop was held on July 7 and 8, 1999, at the Crystal City Marriott in Arlington, Virginia. Participants at the workshop represented federal agencies, academia, consulting firms, and environmental organizations. The workshop was led by three facilitators with extensive experience in large scale ecological assessment. The other attendees included 13 participants in one or more of the prototype watershed assessments, five authors of the *Guidelines* and 22 others with backgrounds in ecological risk assessment or ecological resource management at various spatial scales. The program began with individual presentations, then continued as breakout group discussions that generated recommendations for conducting watershed-scale ecological risk characterization. A list of workshop participants is included as Appendix A.

The workshop began with opening remarks from four EPA National Center for Environmental Assessment (NCEA) staff. First, Mike Slimak, Associate Director of Ecology, welcomed everyone to the workshop and provided a historical background. Next, Vic Serveiss, the workshop organizer, provided an overview of the workshop plans. Bill van der Schalie then summarized the major principles of risk characterization as described in the *Guidelines* and

Handbook, and Sue Norton discussed different traditions in environmental management and their implications for watershed ecological risk assessment. The remainder of the day was dedicated to presentations on the five prototype watershed assessments.

The second day of the workshop opened with presentations from each of the three facilitators based on their experience in ecological assessment as related to the charge questions. The group then divided into three facilitator-led breakout sessions, each with the goal of developing recommendations for conducting watershed ecological risk characterization. The results from each breakout session were reported back to the entire group. The workshop agenda is included as Appendix B.

1.3 CHARGE QUESTIONS

The following charge questions were developed to focus workshop discussions:

- How can the watershed assessment drafts (or plans) for Clinch Valley, Middle Snake, and Waquoit Bay be improved, especially in regard to the other charge questions listed below?

- How should exposure and effects data be integrated in a watershed context to generate a risk estimate?

- How should uncertainty be addressed and presented (e.g., incomplete data or analyses, qualitative estimates, data at different spatial and organizational levels)?

- What are the best ways to address and present the integration of qualitative and quantitative lines of evidence for a) an individual assessment endpoint and b) drawing overall conclusions?

- How should the degree of adversity of predicted or observed effects in watersheds be described (e.g., considering nature and intensity of effects, spatial and temporal scale, and the potential for recovery)?

- How are alternative management options selected to have their risks characterized and how is management informed of the consequences?

- How should ecological risk be communicated to the manager and the public (journal articles, computer programs, presentations, town meetings, Internet, fact-sheets)?

SECTION TWO
DISCUSSION AND RECOMMENDATIONS

2.1 SYNTHESIS OF DISCUSSION POINTS AND GENERAL RECOMMENDATIONS

This section summarizes recommendations made in response to the charge questions and is based on the individual presentations, the three breakout team sessions and the report-back presentations that followed the breakout sessions. More complete documentation of the individual break-out group discussions is included in Section 6 of this report. Attempts to characterize the degree of agreement on discussion points or recommendations below are based on notes taken and observations made during the discussions among the participants who actively expressed opinions. The group was not polled on any of the points presented.

CHARGE QUESTION: How should exposure and effects data be integrated in a watershed context to generate a risk estimate?

Use the conceptual model to review the purpose

- As an introduction to presenting the data, revisit the purpose of the assessment, the assessment endpoints, and the pathways described by the conceptual model. This helps reiterate the value of the findings to the risk manager.

Use models, associations, and multivariate analysis

- Dose-response curves are very effective in a single stressor - single endpoint scenario. However, in watersheds the more common scenario will require analyzing the impacts of multiple stressors on multiple endpoints. In such situations, models and multivariate analysis can be used to analyze and present associations between stressors and impacts.

Work with multiple lines of evidence

- Lines of evidence may be brought together to increase confidence in associations between stressors and responses. This effective approach was taken in the Middle Snake River assessment and is presented in summary form in Tables 17-20 of the draft project report (see Table 2-1). References to the literature are supportive. Using multiple lines of evidence from observations in the field may actually be more useful than dose-response information derived from laboratory data.

Look for associations by category

- Risk assessors often strive to present the relationships between stressors and effects in the form of dose-response curves. However, categorical information can sometimes provide a clearer picture of a relationship than is evident from continuous data. In examining relationships between stream habitat quality and biological condition in the Clinch Valley risk assessment, for example, continuous "dose-response" relationships were not apparent. However, by categorizing habitat quality as either poor, fair, good, or excellent (based on predetermined decision criteria) and relating these habitat categories to either continuous or

Table 2-1. Middle Snake River Case Study: Sample Table Integrating Stressors, Responses, and Recovery Potential

Factors limiting reproduction, growth, and survival of the rainbow trout population in the Middle Snake River.

Factor	Stressor	LOE[1]	Risk	Uncertainty	Assumption	Recovery Potential
Number of spawning fish	Loss of adult habitat (e.g., stream side vegetation, overhanging banks, and woody debris)	LIT, Field, BPJ	An increase in the population size is not possible with low or no reproduction	Low, field studies show low numbers of adult fish are present in the Middle Snake River	Lack of habitat is a main factor limiting the size of the adult population	Good, if habitat improvements can be improved, but low if a stable annual flow regime is not maintained
Spawning	Sedimentation, high water temperature, and land use on tributaries	HSI, WQS, LIT, Field, BPJ	Population of native fish can not recover without successful reproduction	Moderate, historic spawning areas in the main channel have not been documented	Poor spawning success attributed to poor water quality conditions	Low, without improving water quality, reducing sedimentation, and controlling land/water use on tributaries
Rearing	Unstable stream flow during the spring and high water temperatures	HSI, WQS, LIT, Field, BPJ	Population can not recover without successful recruitment	Rearing areas in the main stem of the Middle Snake River identified using habitat suitability indices	Rearing habitat important for maintaining and increasing adult populations	Low, the carrying capacity for native fish was likely permanently reduced by dam construction in the Middle Snake River
Overwintering	Loss of habitat (e.g., deep holes and large woody debris)	LIT, BPJ	Unknown	High, no information available on the amount of overwintering habitat in the main stem	Overwintering habitat can limit the size of the adult population	Unknown
Food supply	Sedimentation and increased water temperature	LIT, Field, BPJ	Poor growth as invertebrate fauna do not support cold water fish	Moderate, adequate analysis of sampling information has not been completed	Food supply can limit the size of a rainbow trout population	Low, without improving lotic conditions, lowering water temperature, and controlling sedimentation
Genetic diversity	Hybridization with stocked fish	LIT, BPJ	Poor survival with mixed genotype	Low, effects of hybridization on native fish are known	An adequate population of native fish remains	Good, provided that existing native fish are protected from stocked hatchery fish

Note: 1. LOE - lines of evidence, HSI - habitat suitability indices, WQS - water quality standards, Field - field surveys in the Middle Snake River, LIT - literature, BPJ - best professional judgement.

categorical expressions of the biological condition, the relationships between habitat and biology were much easier to visualize.

Use the right scale and data

- Consider partitioning the spatial scale into smaller units with regard to availability of data, occurrence of problems, subwatersheds or sub-ecosystem types, and management authorities. In some cases, it may be possible to assess relationships within subwatersheds that have comprehensive data bases, and then extrapolate to the larger area. On the other hand, some problems may impact only a small subset of the area being assessed. More discussion on the scale issue is available in a workshop report intended to develop a problem formulation process for large spatial scales (TN & Associates, 1999).

- Partitioning a watershed into smaller units, especially those with similar attributes such as hydrology, structure, function, and habitats, makes the effort more manageable. An example of this is described in more detail on Page 5-1.

- The data should be appropriate for the scale being addressed: for example, satellite remote sensing data might be appropriate for larger scales, but smaller scales may require field observations.

CHARGE QUESTION: How should uncertainty be addressed and presented (e.g., incomplete data or analyses, qualitative estimates, data at different spatial and organizational levels)?

Focus on confidence

- It is preferable to discuss the "degree of confidence" in the results rather than the "level of uncertainty," especially when communicating with a relatively non-technical audience.

- Recognize that most decision makers don't require the degree of certainty that scientists seek to attain.

- In cases where the information is inadequate to define a stressor-response curve or even document a causal relationship, the discussion should address the strength of association using standard models or methods for causal inference, such as those presented in the EPA *Guidelines* (U.S. EPA, 1998).

Consider the risk manager's perspective

- The "acceptable" degree of uncertainty (or level of confidence) in a risk assessment may be influenced by the perspective of the audience (e.g., scientist, risk manager, stakeholder), the magnitude of the risk, and the cost associated with decreasing the degree of uncertainty. Tables can be used to compare accuracy and precision versus the degree of risk or the cost to reduce uncertainty, although it may be preferable to use such tables for generating estimates without incorporating them into the actual risk characterization report.

- Information may be characterized simply as having a low, medium, or high degree of confidence. This approach can be applied to the integrated effects and exposure data or to each set of data individually.

- Risk characterization should consider the context in which risk management decisions are being made and the implications of risk management decisions. For example, reducing uncertainties in data may have a low priority if there are no feasible management options.

- The simplified form of the Clinch Valley conceptual model is a good example of how to illustrate and communicate the pathways, linkages, associations and locations of uncertainties (see Figure 2-1).

<u>Focus on the key uncertainties but acknowledge all of them</u>

- Participants were divided on the issue of the scope for the discussion of uncertainties. Some participants preferred a narrow focus to address only "key" uncertainties (those with the potential to influence the outcome), thus avoiding an exhaustive "laundry list" of all potential uncertainties. Others preferred presentation of a comprehensive list of uncertainties, feeling that omissions were more costly errors than inaccuracies.

- An intermediate approach mentioned was to assemble a comprehensive inventory of uncertainties, but then to partition the list based on importance (e.g., ranking as high, medium, or low). However, one danger identified with using ranking is that it adds another layer of judgment and may lead the reader to disregard important information.

- Although it can be useful to identify the factors most likely to affect the outcome, the risk characterization should strive to make the uncertainties transparent so the reader can judge which ones are more important.

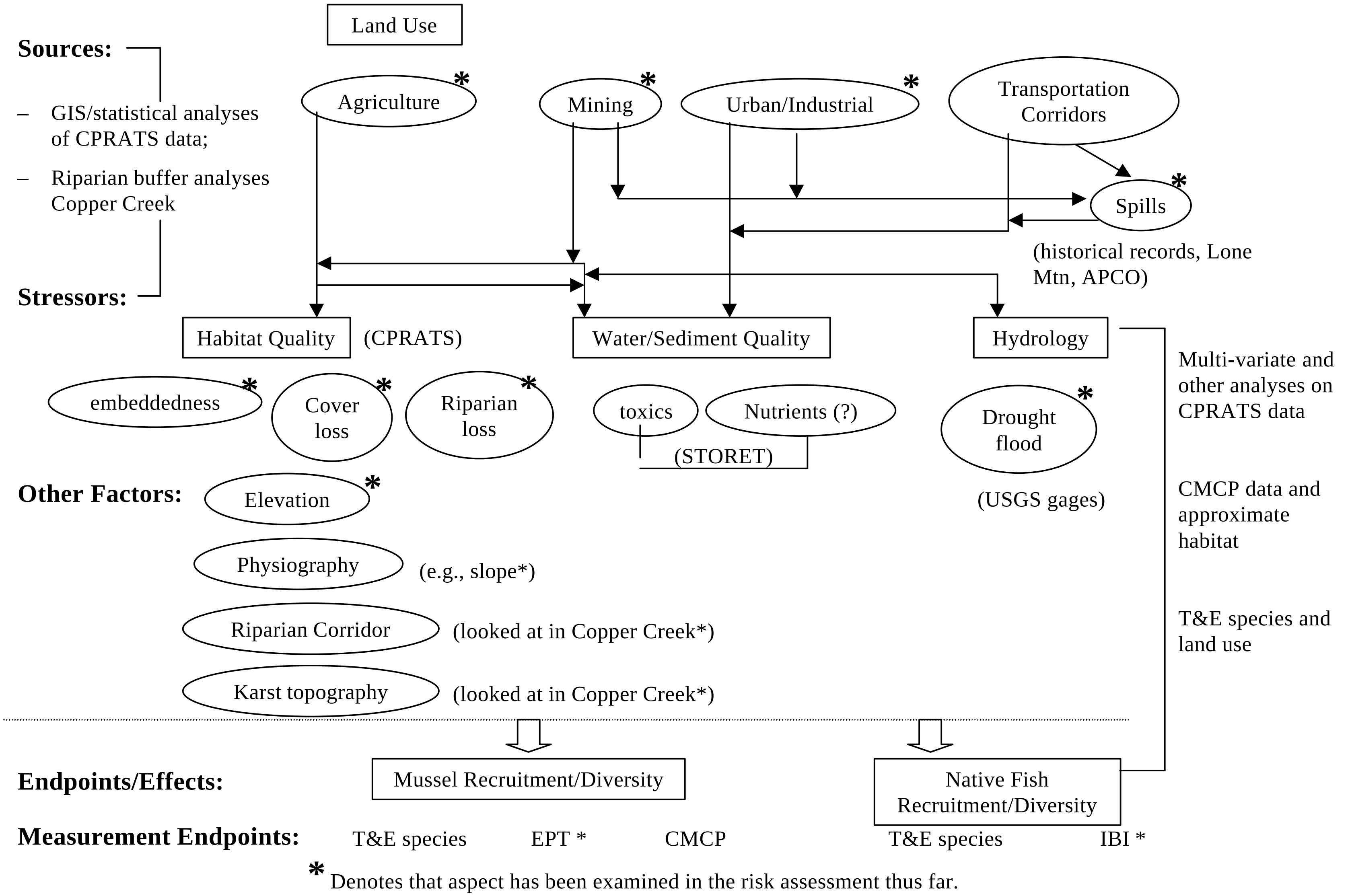
- Distinguish between qualitative uncertainties (e.g., is there a cause-and-effect relationship?) and quantitative uncertainties (e.g., what does the stressor-response curve look like?). Address uncertainties quantitatively when possible, but avoid conducting more quantitative uncertainty analysis than is genuinely necessary. The quantitative uncertainty evaluation (including references to standard tests, metrics, etc.) should be explicitly presented, but may be included in an appendix.

CHARGE QUESTION: What are the best ways to address and present the integration of qualitative and quantitative lines of evidence for a) an individual assessment endpoint and b) drawing overall conclusions?

<u>Use visuals</u>

- Many participants favored the format used in the Snake River assessment (see Table 2-1). An advantage of this format is that it can summarize both qualitative and quantitative lines of evidence. Such a table can be supplemented with a narrative text that refers the reader to

Conceptual Model for Clinch EcoRisk and Assessment Approaches Used
(Not meant to be an exhaustive model, rather for purposes of the Analysis Plan)



* Denotes that aspect has been examined in the risk assessment thus far.

Figure 2-1. Clinch Valley Case Study: Conceptual Model for Clinch Eco-risk and Assessment Approaches Used.

other sections of the report for supporting information, and the very detailed data can be moved to appendices. It was also suggested that such a table include citations to technical references, or in cases where conclusions are based on best professional judgment, identify the scientist(s) drawing the conclusion.

- Maps and map overlays may be helpful in illustrating stressors and impacts.

Use rankings

- Qualitative lines of evidence should be considered and could be ranked as having a high, medium, or low level of importance or confidence. Risk assessor's need to use professional judgement to sort qualitative aspects of issues such as degree of adversity, strength of association, level of confidence, importance to endpoint, etc. into some coarse categories. Addressing the ranked issues in order of importance avoids being overwhelmed because there is never enough data to address all concerns and avioids getting into a never-ending analysis of all the potential uncertainties.

- Several participants recommended avoiding techniques that numerically rank or weight various lines of evidence; others recommended that such techniques only be used with great caution; and still others considered such techniques to be extremely useful. The concern with weighting qualitative data, lines of evidence, or measures of strength of association was that it introduces an additional source of uncertainty.

Presentation style

- As each assessment endpoint is discussed, keep the presentation format relatively constant to enhance continuity of the text.

- Any contradictions between the various lines of evidence should be explained.

CHARGE QUESTION: How should the degree of adversity of predicted or observed effects in watersheds be described (e.g., considering nature and intensity of effects, spatial and temporal scale, and the potential for recovery)?

Use visuals

- The table in the Snake River assessment (reproduced as Table 2-1 for this report) and the map showing degree of impairment for various life stages along the stream reach (see Figure 2-2) are a useful format for illustrating observed effects and predictions for recovery. Such visuals should be accompanied by narrative descriptions.

Consider the historical context

- Trend assessment and comparison with historical data (including historical maps or photos) can be useful. However, caution is warranted because historical data may be of poor or unknown quality, and because historical trends are not always predictive of future trends.

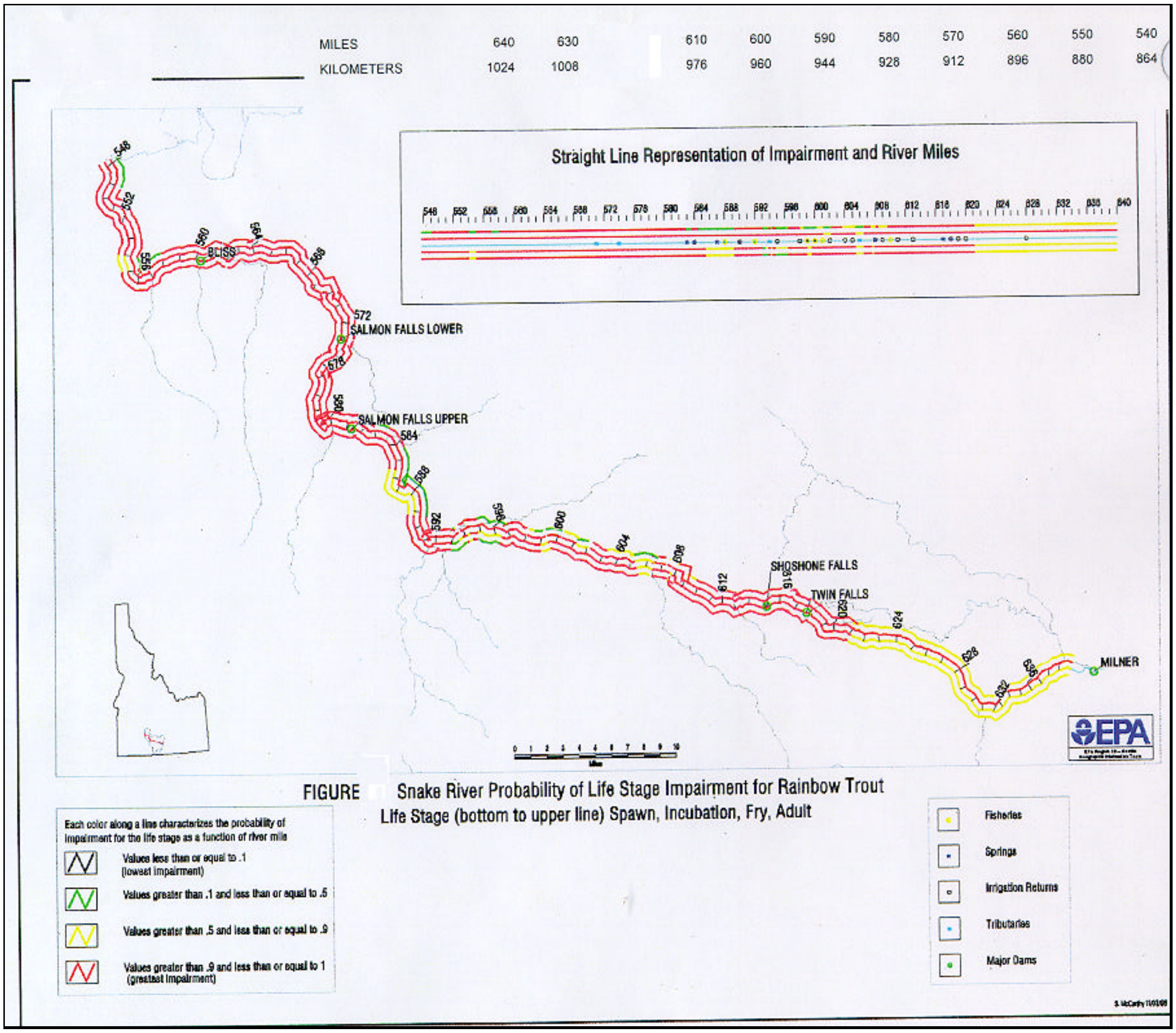


Figure 2-2. Middle Snake River Case Study: Map of Snake River Showing Probability of Life Stage Impairment for Rainbow Trout

Additional Considerations

- Discussions of recovery should include a clear statement of the recovery goal (including whether recovery is to be natural or "assisted") and the potential impact of natural and anthropogenic factors, including ecosystem interactions.

- If an adverse effect has a substantial probability, the risk assessor should explore the potential for secondary adverse effects (e.g., loss of mussel species following loss of fish host species).

CHARGE QUESTION: How are alternative management options selected to have their risks characterized and how is management informed of the consequences?

Interactions with risk managers

- Most participants who expressed an opinion felt that regular consultation with risk managers and stakeholders is necessary throughout the process, especially when alternative management options will be evaluated. A few mentioned that this suggestion should be added to the *Guidelines*. It was recognized that such ongoing involvement has the potential to change the direction of a study.

- One participant noted that only rarely will an individual or distinct committee have complete responsibility for making a risk management decision. It is more likely (as in the five case studies in this pilot project) that the "risk managers" will include landowners, local officials, state officials, environmental groups, news media, and many others. In order to be useful for decision making in these situations, the risk characterization should reflect close adherence to a collaboratively designed problem formulation and analysis plan.

- A few participants and presenters felt it was not appropriate to consider management alternatives in the risk assessment itself, and view risk assessment and evaluation of management alternatives as separate activities.

- Ideally, if management alternatives are to be considered in the risk assessment, they should be introduced by risk managers and discussed in the problem formulation phase. However, it should be recognized that if management alternatives are crystallized too early in the process, the risk assessment may eventually show that some of the favored alternatives are not feasible or that some good alternatives were overlooked. In addition, it was pointed out that some management options may be "discovered" during the risk assessment process itself.
- Many believed the risk characterization section should cover both the current situation and reasonable "what if" scenarios supplied by risk managers. "What to include" and "where to stop" are affected by the type of management information needed (e.g., to determine if there is a problem or if action is needed, to identify priority areas for action, or to determine the best action to take). The risk characterization itself, however, was seen as a summary of the science that explains the probability of an adverse effect on endpoints.

- Recognize that many individuals and organizations may need to be involved when a variety of managers and agencies have authority over subsets of the watershed, stressors, and ecological endpoints.

Examples

- The approach being used in Waquoit Bay is to have the managers decide “how much is too much” (i.e., “How much eelgrass loss is acceptable?”). Researchers are using models to estimate the stressor load (in this case nitrogen) necessary to meet the goal and to evaluate the effectiveness of specific management alternatives (see Figure 2-3).

- A “click-on” web site can be developed to allow planners to conduct “what if” scenarios to evaluate various habitat and landscape feature management options for themselves.

CHARGE QUESTION: How should ecological risk be communicated to the manager and the public (journal articles, computer programs, presentations, town meetings, Internet, fact-sheets)?

Packaging the product

- There was considerable discussion during the workshop concerning who constitutes the audience for the risk characterization. One primary audience is the risk manager(s) who needs to be informed about the scientific basis for the conclusion in the risk assessment. The stakeholders also represent an important audience. Stakeholders may be a diverse audience depending on whether they are directly affected by management decisions or are more interested in the technical, regulatory, or political aspects of the assessment. Length, detail and style of the report should be tailored to meet the needs of the intended audience.

- Many participants agreed that the risk characterization should be a technical, stand-alone document. Yet, many others considered it acceptable to have separate versions of the risk characterization report targeted for various audiences. One option many participants favored was to have a single scientific report with “executive summary” and “relevant findings” sections in “plain language” geared toward managers. An alternative suggestion was for the risk characterization to be written in straight-forward language understandable by lay persons, with technical appendices prepared for scientists to explain the studies, lines of evidence, etc., mentioned in the risk characterization report. A third alternative that several seemed to favor was to have three reports: an executive summary for risk managers, a scientific report for staff and scientists, and a colorful brochure-type product for the public. One participant recommended that EPA consider field-testing targeted communication products to determine which report format options were most effective.

- One participant expressed an opinion that there should only be one risk characterization report and that multiple versions were undesirable for decision-making on policy issues.

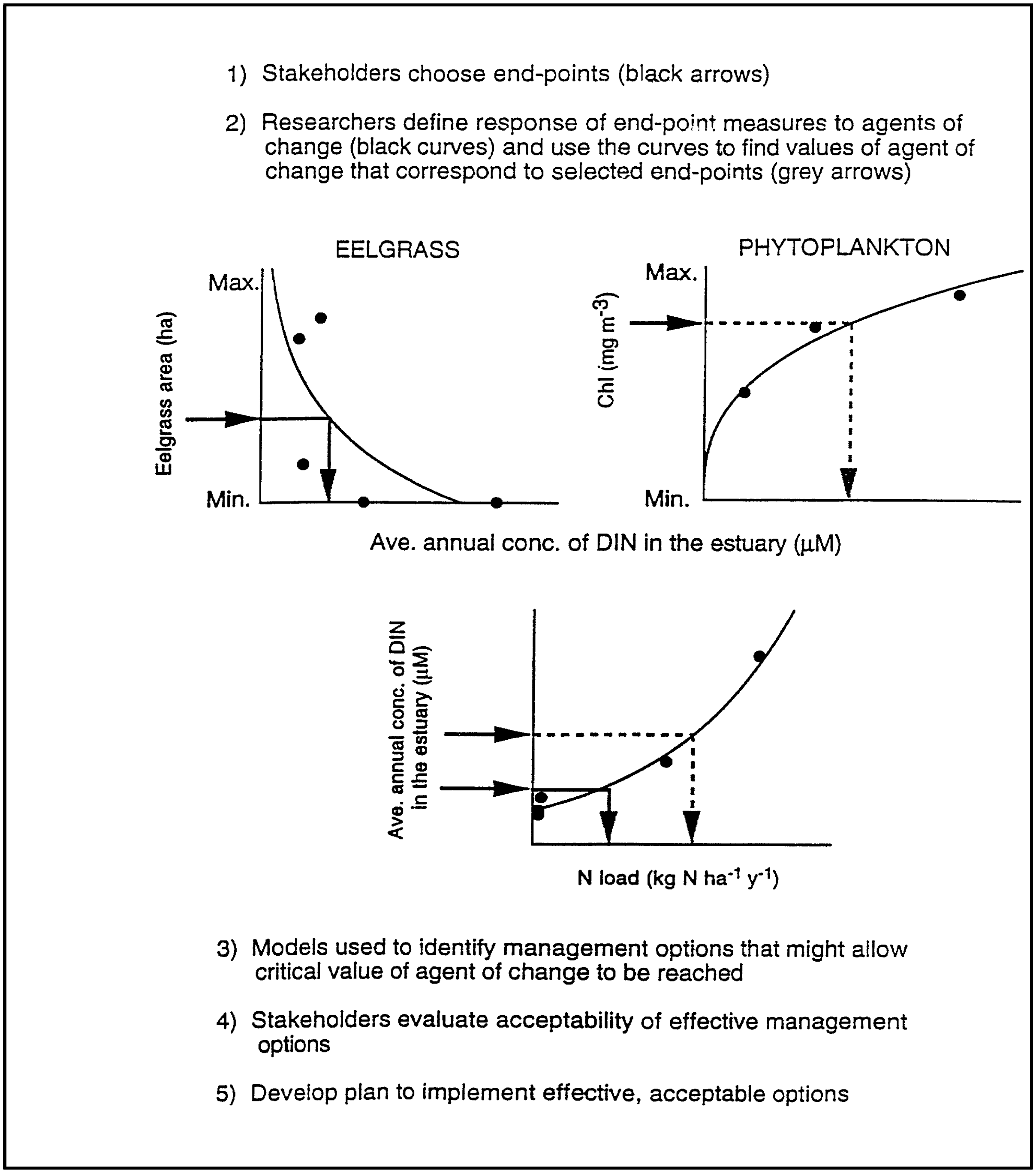


Figure 2-3. Waquoit Bay Case Study: Management Decision Process for Waquoit Bay Assessment

- A few individuals suggested that non-technical stakeholders should be the primary target audience. One participant pointed out that if the problem formulation incorporates significant stakeholder involvement and reflects the values of the affected public, then the characterization should respond to stakeholder information needs.

- Progress and sample reports are very helpful. For instance, during the Clinch case study, drafts of the report with preliminary findings were developed as progress reports to determine how to best present and how technical the writing the final risk characterization should be for the resource managers.

- Some though not all, thought that the first time a technical term is used in the report, it may be helpful to highlight the word using a bold font, and then either define the term on that page or put the term in a glossary. If a term is a central concept and will be used repeatedly, an expanded definition (i.e., a paragraph or more) may be appropriate.

- Consider other options to paper products (e.g., the Internet, an interactive what-if scenario).

<u>Use visuals</u>

- Tables such as the one in the Snake River report (reproduced as Table 2-1 for this report) are a good way to present the lines of evidence in one place.

- Color can be effective if used well, but the writer needs to take into consideration that some readers will be color-blind. A good example of maps created to accommodate color blindness can be found in Pickle, et al., 1996.

- Help decision makers see the connection between human activities in a watershed and achievement of the goals set for the assessment endpoints. This can be accomplished by referring back to the conceptual model diagram developed during the problem formulation. The context in which decisions are being made should also be considered since the linkages between natural and social systems are so strong that risk assessors cannot ignore them. We must deal with all the compartments of the natural, land use, and socio-economic systems and drivers affecting resource endpoints.

<u>Communicating with the public</u>

- Besides the standard written report information can be disseminated via the Internet, videos, print media, public meetings, school programs, fair exhibits, and public radio.

- In the Clinch case study, for the public, a more lay-version executive summary of the report was prepared with input from the entire working group prior to distribution. Feedback from public meetings was used to evaluate the effectiveness of the Executive Summary and to determine whether other presentation materials were advisable.

<u>General communication principles</u>

- Clearly state why the risk assessment was done (e.g., to support a particular management decision or to explain an observed effect).

- Communicate early, often, and in a straightforward manner. The vast majority strongly felt that regular interactions with risk managers were key to the success of the assessment. Some felt that this should also apply to stakeholders, though others did not. One of the lessons learned in the Middle Platte study was that it is critical to have the risk assessors and risk managers in constant touch and that risk assessors need to be aware of local socioeconomic and political concerns. Recognize that individuals and organizations are more apt to participate or view the assessment differently when they may be directly affected by management options under consideration.

- Consider presenting the assessment as an opportunity to help stakeholders develop tools to manage their watershed, as opposed to having EPA doing it for them.

- Follow the seven cardinal rules of communication (plan carefully; coordinate and collaborate with other sources; involve the public; listen to the public; be honest, frank, and open; speak clearly and with compassion; and meet the needs of the media) and "TCCR" (transparency, clarity, consistency, and reasonableness) as outlined in Text Box 6-2 and Text Box 5-9, respectively, in the 1998 EPA *Guidelines*.

- Recognize that multiple stressors and large-scale, place-based efforts may make it necessary to involve multiple resource management authorities.

SECTION THREE
SUMMARY OF OPENING PRESENTATIONS

This section presents a summary of the opening remarks and background information presented during the first session of the workshop.

3.1 WELCOME AND INTRODUCTORY COMMENTS ON PLACE-BASED ECOLOGICAL ASSESSMENTS
Mike Slimak, Associate Director for Ecology, NCEA

In the early days of the risk assessment process, risk assessment was separate from risk management. Emphasis then was on human health assessments, and cancer was the main endpoint of concern. While health assessors never debated the "so what" question for cancer, it has become a frequently-asked question in the realm of ecological risk assessment. It is therefore necessary to integrate risk assessment and risk management from the very beginning of an ecological risk assessment. Dialog during problem formulation is very important to ensure that risk assessors and risk managers are thinking along the same lines. Selecting assessment endpoints that the risk manager understands is crucial for successful risk characterization, which in turn is the key to an effective risk management decision.

The purpose of this workshop is to learn from the experience the participants have in conducting watershed-scale and place-based ecological risk assessments and to incorporate that knowledge into improving EPA's ecological risk assessment guideline products. Ecological risk assessments are evolving from single species to multiple species, single stressors to multiple stressors, chemicals to all stressors, and now, place-based assessments. The place-based approach takes risk assessment to the next level, moving beyond the command-and-control approach of the past.

EPA has a major commitment to place-based assessments. Places represent the real world where exposure to multiple stressors occurs with effects on multiple species in the context of real ecosystems. Stakeholder involvement is integral to this approach and adds a sense of ownership not seen with chemical-based risk assessments. Building and maintaining effective relationships with stakeholders is crucial when working in these complex situations, and methods for creating positive relationships with stakeholders is an area worthy of research. The scale issue is another area worthy of research as the place-based approach is developed. Watersheds range in size from small (e.g., Waquoit Bay) to mid-sized (e.g., Big Darby Creek) to very large (e.g., Mid-Atlantic Integrated Assessment, or Environmental Monitoring and Assessment Program western pilot).

The ecological risk assessment process consists of problem formulation, characterizing exposure and effects in an analysis phase, and integrating those data in the risk characterization phase. Risk characterization, which is the focus of this workshop, is the final phase of the risk assessment and is the culmination of the planning, problem formulation, and analysis. However, risk characterization actually begins during the characterization of ecological effects in the analysis phase of the assessment. The characterization of ecological effects consists of three primary elements that lead to derivation of the stressor-response curve:

- Plausibility that effects may occur as a result of exposure to stressors

- Relationship between stressor levels and ecological effects

- Linkages between measurable ecological effects and assessment endpoints when the latter cannot be directly measured

Derivation of a dose-response curve is not an easy task for complex systems with differing stakeholder values. Derivation of the curve can be a "nested" process, as in the Waquoit Bay case study:

- risks to estuarine fauna as a function of submerged aquatic plants;
- submerged aquatic plants as a function of water clarity;
- water clarity as a function of algal blooms;
- algal blooms as a function of nutrient levels;
- nutrient levels as a function of nitrogen input; and finally,
- nitrogen input as a function of the density of septic systems.

Interpretation and presentation of the exposure and effects must contain a clear explanation of the lines of evidence leading to the conclusions, including a description of the uncertainties, assumptions, and qualifiers in the risk assessment. A compelling, well-communicated risk characterization will allow risk managers to make a decision instead of asking, "So what?"

3.2 WORKSHOP GOALS AND APPROACH
Vic Serveiss, NCEA Environmental Scientist and Workshop Manager

Participants were invited to the workshop because of their experience in ecological risk assessment, watershed management, or regional-scale assessment. The goal is to use the collective wisdom of attendees to further develop and document a process for conducting watershed ecological risk characterization.

The *Framework for Ecological Risk Assessment* (EPA/630/R-92/001) was developed in 1992. In 1993, EPA's Office of Research and Development (ORD) and Office of Water (OW) selected five demonstration sites to further develop, demonstrate and test the ecological risk assessment paradigm by applying it to real world situations with multiple stressors. The five sites were selected based on several factors including availability of data, willingness of organizations to participate, and the existence of multiple stressors. In addition, the study sites came from a variety of geographic regions, ecoregions, and EPA regions. The watershed assessment sites chosen were:

- Big Darby Creek, Ohio;
- Clinch Valley, Virginia;
- Waquoit Bay, Massachusetts;
- the middle segment of the Platte River, Nebraska; and,
- the middle segment of the Snake River, Idaho.

The plan is to complete individual draft assessment reports for each of these five sites between fall 1999 and December 2000, send the assessment reports out for peer review, and then publish them as individual EPA reports.

Many of the attendees have been involved in these assessments. As the five assessments approached the risk characterization phase, several participants, also at this workshop, noted that there was no specific guidance available on how to develop and present a watershed-scale ecological risk characterization. The current guidance that is available, though predominantly focused on single stressors and endpoints, includes:

- *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998)
- EPA's draft *Risk Characterization Handbook* (U.S. EPA, 1999)
- *Improving Risk Communication* (National Research Council, 1989)

Such guidance is helpful, and participants had some ideas of their own on how to proceed, but were also enthusiastic to get additional suggestions. Hence, a workshop seemed appropriate to develop and document additional guidance for watershed and place-based ecological risk characterization. To focus workshop discussions, several charge questions were developed that address the issues of greatest concern for characterizing risk at the watershed scale. It is expected that the workshop proceedings will develop answers to seven selected charge questions. These "answers" will be used to format recommendations to supplement the existing body of literature on risk characterization and will provide guidance to place-based risk assessors and managers.

Draft watershed risk characterizations for the Clinch Valley and Mid-Snake assessments were provided as background materials to participants. These documents should serve as helpful references as responses to the charge questions are developed. A second anticipated benefit of this workshop is to provide information and general guidance to help complete and improve the five demonstration watershed-scale assessments. A draft report on the workshop will be prepared with the help of the TVA and will be sent out for review by workshop attendees. Following a peer review the final workshop products will be an EPA report and a journal article.

3.3 RISK CHARACTERIZATION SUMMARY
Bill van der Schalie, Ecologist and Guidelines Author, NCEA

Ecological risk assessment is a process in which all the elements build on each other. The risk characterization phase of the process consists of risk estimation and risk description, followed by presentation of the risk characterization findings, as shown in Figure 3-1.

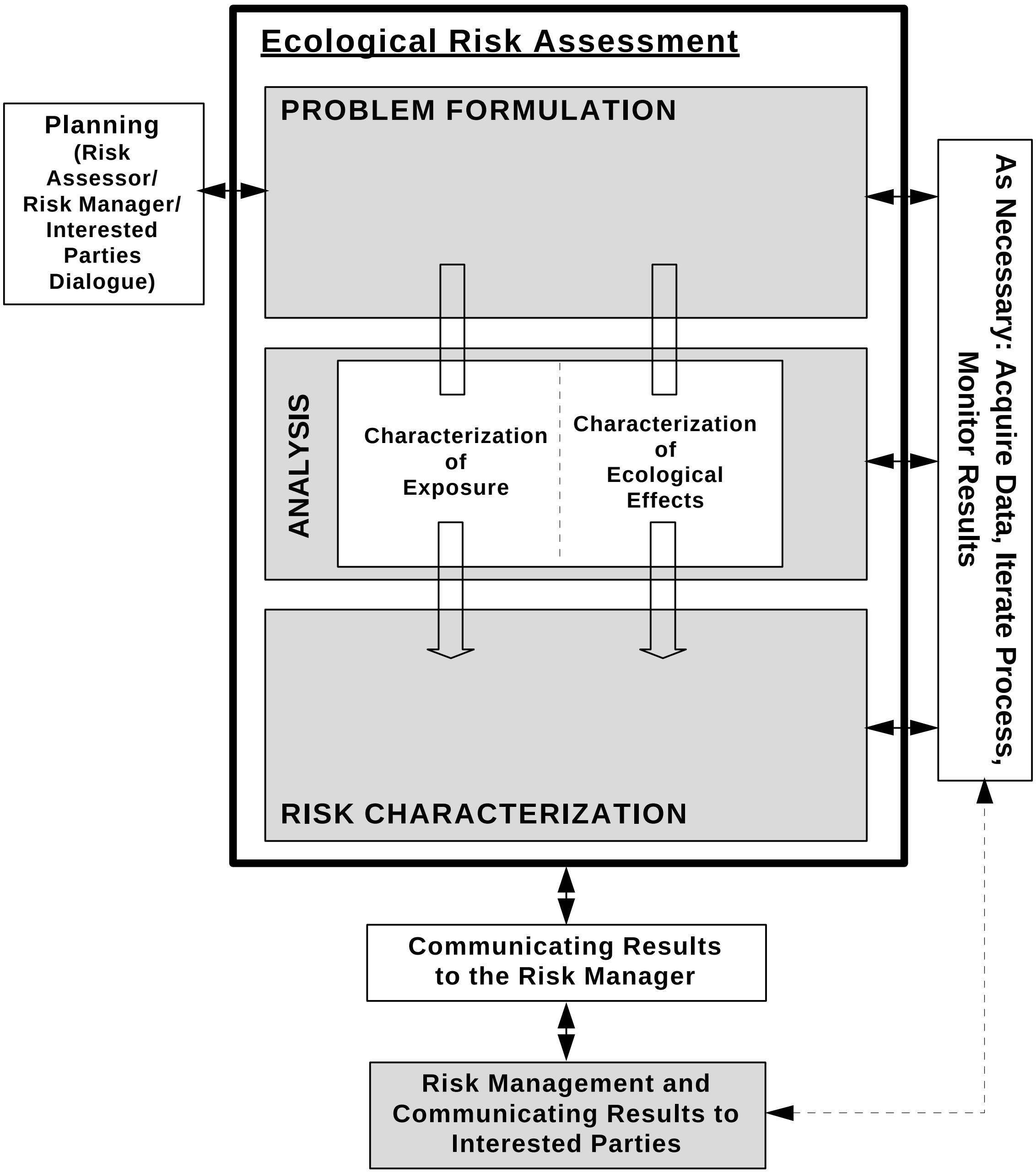


Figure 3-1. Framework for Ecological Risk Assessment.

Risk estimation integrates the exposure and effects information. The *Ecological Risk Assessment Guidelines* (U.S. EPA, 1998) reviewed a number of approaches that can be used, depending on the situation and available data:

- ***Categories and rankings*** - Categories and rankings are a qualitative means of estimating risk. This method is useful in complex situations with little available data. Expert judgment is required and should be documented. Categories and rankings are useful for stressor prioritization, as in the Waquoit Bay problem formulation.

- ***Single point comparisons*** - Single point comparisons use the quotient method. This is a good screening tool that is simple to use; however, it is not quantitative, does not cover indirect effects, and does not consider uncertainty.

- ***Methods incorporating variability in exposure and effects*** - The incorporation of variability can be accomplished using stressor-response curves or toxicity distributions. Advantages of these methods are that quantitative measures show the magnitude of change in response to a stressor and allow uncertainty to be addressed. However, this method does not consider indirect effects and can address only some of the uncertainties.

- ***Process models*** - Mechanistic process models can be used to integrate exposure and effects. These models incorporate indirect effects, and are useful for scenario analyses. Disadvantages are that validation is not always possible, and underlying assumptions may be hidden (i.e., not transparent).

- ***Field observational studies*** - Field observational studies are advantageous because they include direct measurement of exposure and effects, and they can take into account multiple stressors and relationships. Disadvantages can include poor statistical power, lack of replication, and difficulty in establishing causality.

It is clear that each of these methods of risk estimation has both strengths and weaknesses. Because no tool is perfect, the best option may be to use a combination of these approaches to provide different lines of evidence.

Development of the risk description follows risk estimation in the risk characterization process. A risk description interprets the significance of ecological risk by evaluating the available lines of evidence and by determining the ecological adversity (the “so what” question). Interpretation and discussion of lines of evidence should include data quality considerations, uncertainty considerations, and relationships to assessment endpoints and risk hypotheses. Ecological adversity considerations include the nature and intensity of effects, spatial scales, temporal scales, and the potential for recovery.

The risk description should:

- Describe risks to assessment endpoints;
- Revisit critical problem formulation choices;
- Address the risk manager’s needs;

- Use varying lines of evidence; and
- Highlight critical assumptions and uncertainties, while avoiding a laundry list of all potential uncertainties.

Effective presentation of the risk characterization is the key to an effective management decision. The principles of 'TCCR' described in the EPA draft *Risk Characterization Handbook* (U.S. EPA, 1999) are important to a successful risk characterization report and can be summarized as follows:

- ***Transparency*** - Making the process open and frank helps achieve full disclosure of assumptions and uncertainties and permits ready identification of default or policy-driven assumptions. Key elements are to highlight the critical assumptions and uncertainties and their effects on the results; separate science from policy (example - protection of 95 percent of the organisms is policy); acknowledge any conflicting scientific interpretation of major issues; and describe the level of confidence in major risk conclusions.

- ***Clarity*** - Making the product clear makes the assessment complete and understandable. Key elements are that the level of writing should be appropriate for the audience; major risk conclusions should be clearly stated; and graphs and diagrams should be simple and straightforward.

- ***Consistency*** - Consistency provides a context for the reader by ensuring the assessment uses an approach similar to other assessments (or offers an explanation if the approach or findings differ). Key elements are to follow Agency-wide ecological risk assessment guidelines, if appropriate; define and explain the risk assessment purpose and level of effort; and consider results of other similar risk assessments.

- ***Reasonableness*** - The findings should be reasonable within the context of the best-available science, the default assumptions, and the policy choices made. Key elements include ensuring the risk characterization is based on the best scientific information available; using generally accepted scientific knowledge in the assessment; making sure policy judgments use common sense in light of statutory requirements and agency guidance; and presenting plausible alternative risk estimates for the various management options under consideration.

In conclusion, risk characterizations should be prepared using principles from the *Guidelines* (U.S. EPA, 1998) and the EPA draft *Risk Characterization Handbook*, which is scheduled for release in 2000. The major risk characterization challenges in place-based assessments include complexity and multiple stressors, lack of data and large uncertainties, and providing clear information in a usable format to risk managers.

3.4 TRADITIONS OF ENVIRONMENTAL MANAGEMENT AND THEIR IMPLICATIONS

Sue Norton, Ecologist and Guidelines Author, NCEA

Risk characterization is the phase of risk assessment during which the results and conclusions of the risk assessment are reached and summarized in a way that is useful for managers. Risk managers are defined as individuals and organizations who have the responsibility or authority to take action or to require action to be taken (U.S. EPA, 1998). This definition encompasses a broad spectrum from senior managers in regulatory agencies to the farmer who decides to build a fence to limit livestock access to a stream.

The linkage between risk characterization and the decision to be made (i.e., the link between science and management) varies from one guidance document to another:

- *Understanding Risk* (NRC, 1996) - National Research Council (NRC) principles for risk characterization iteratively link the characterization with the decision, beginning in the problem formulation phase. It requires a broad understanding of harms and consequences and is an outcome of on-going interactions between the scientific analysis and the societal deliberation.

- *Risk Assessment and Risk Management in Regulatory Decision-Making* (The Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997) - The framework diagram in this document shows no management interaction until near the end of the process at decision-making time.

- *Ecological Risk Assessment Guidelines* (U.S. EPA, 1998) - Management options are mentioned in the planning phase, but not in risk characterization.

- draft *Risk Characterization Handbook* (U.S. EPA, 1999) - Risk characterizations are written in a generic way to support a variety of decisions. The document makes no mention of the specific decisions the risk characterization is intended to support.

There is no consistent guidance on the interface between risk assessment and risk management. As a consequence, some characterizations appear to be decision-driven, while others appear to be a more generic presentation of information.

Insights into effective ways to link science with decisions can be found by thoughtfully examining the variety of environmental management processes for place-based ecological assessments, including:

- Biological assessment
- Watershed approach
- Community-based environmental protection
- Watershed management
- Adaptive environmental assessment
- Adaptive management

- Regional vulnerability analysis
- Ecosystem management
- Decision analysis
- Natural resource damage assessment
- Risk Assessment for Superfund (includes the no action alternative and comparison of remedial alternatives)

These approaches all seek to bring science into decision making, and have the common goal of making a difference that will result in environmental improvement. Most are also geared toward a specific decision. There are also ways in which the approaches differ. They may have different starting points (e.g., effects, scenario, source, stressor); they may emphasize prospective or retrospective points of view; they may build on different academic fields, traditions, and tools; and they involve varying degrees of interaction with stakeholders.

However, the two most important ways in which the approaches differ are: 1) the degree of dispersion of risk management authority, and 2) the proximity of management authority to on-the-ground action. Decision making or management authority for different types of assessments may be concentrated in one individual or management chain (e.g., Superfund assessments, environmental impact assessments, biological assessments, decision analysis). Alternatively, management authority may be more dispersed, as is the case with the watershed protection approach, ecosystem management, futures analysis, and community-based environmental protection.

The full spectrum in the proximity of management to on-the-ground action can be represented by the list of considerations and associated activities shown in Figure 3-2.

The implications of this discussion for watershed risk characterizations are that the five ongoing watershed assessments support all these types of decisions, and may have a dispersed management audience. As a result, watershed risk characterizations may have different formats. Although there is currently little written guidance that is directly applicable to watershed risk characterization, the variety of environmental management approaches discussed above provides a wide range of styles and formats to build on.

As we develop recommendations for conducting watershed ecological risk characterization and for improving the five assessments underway, the following questions should be considered:

- Where are the case studies on the decision continuum toward taking action on the ground? (The five case studies appear to be at the point of prioritizing issues/risks and deciding if action is required. Waquoit Bay is further along and now involves considering different management options.)

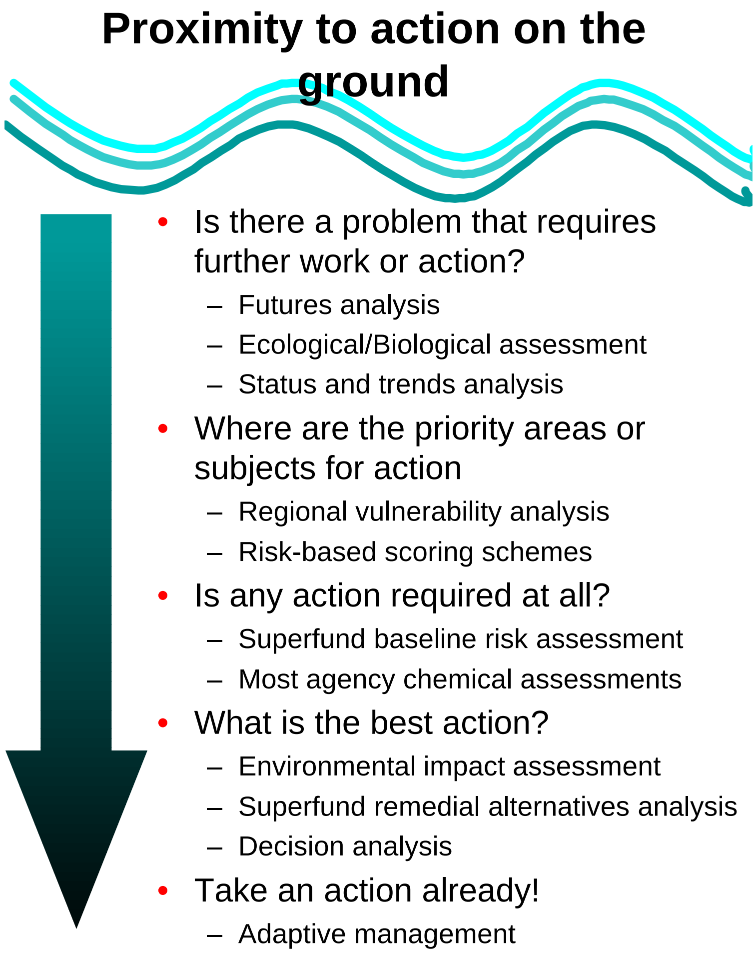


Figure 3-2. Proximity of Management to Action on the Ground

- How dispersed are the people who will be making decisions based on our analysis?

- What type of decisions are our risk characterizations expected to support?

- How can we present our risk characterizations in a way that facilitates decision making?

One workshop participant suggested that the degree to which risk assessment information is feeding into and impacting management decisions provides an indirect measure of success in addressing the last of these four questions.

SECTION FOUR
WATERSHED CASE STUDY PRESENTATIONS

This section provides summaries of the presentations made by chairs of the five EPA-sponsored watershed ecological risk assessments. Each presentation included an overview of the case study with emphasis on the risk characterization phase. Any discussion related to answering the charge question, “How can the watershed assessment draft or plan be improved?” is included in this section.

4.1 BIG DARBY CREEK
Susan Cormier, EPA NERL, Big Darby Creek Assessment Co-chair

The Big Darby Creek watershed is located west of Columbus, Ohio, in the Eastern Corn Belt Plains ecoregion. The drainage area of 1440 km^2 (557 mi^2) is predominately row crop agriculture with forests along the stream. There are several small towns, but the area is relatively unimpaired by urban and industrial use. The stream is both a Federal and State Scenic River and still has high species diversity; however, there has been a 20 to 25 percent decline in aquatic diversity since the 1970s, and the area is in danger of losing additional species.

Based largely on stakeholder input solicited during the first year of the project, the following management goal was developed for Big Darby Creek: “Protect and maintain native stream communities of the Big Darby Creek ecosystem.” The approach to achieving this goal has been to let the stakeholders know the assessment team was there to *help* them take care of the watershed *themselves*, not to do it *for* them. A primary task of the assessment team has been to develop new tools for conducting the assessment and identifying interrelationships among stressors and endpoints.

One of the lessons learned in this case study is that the risk assessor should be able to show exposure pathways and effects and explain them clearly to stakeholders. This helps the risk assessor build personal and professional credibility in the eyes of the stakeholders. The conceptual model has been helpful for this type of communication.

Risk characterization to date has been mostly through presentations to stakeholders and at scientific meetings. These presentations identified and explained key risks and protective factors using some of the following specific methods and techniques:

- Box plots of Index of Biotic Integrity (IBI) metrics showing source signatures (see Figure 4-1).

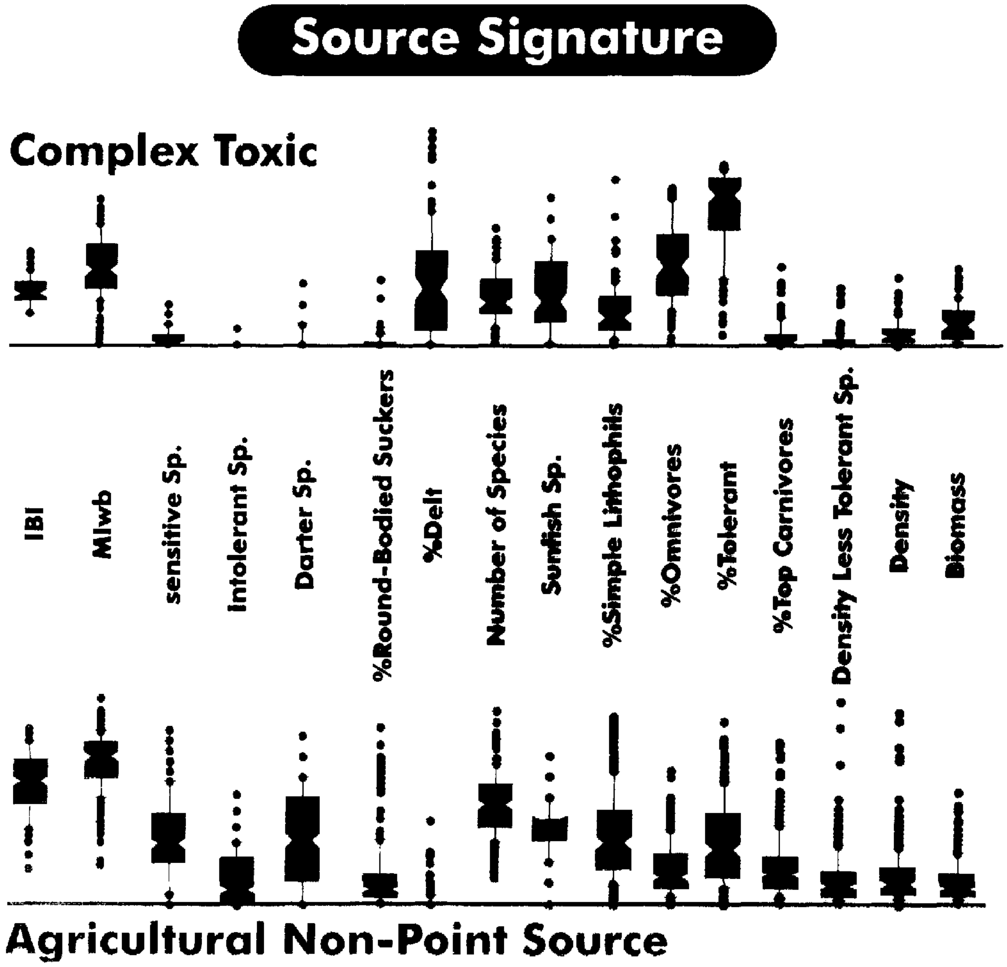


Figure 4-1. Big Darby Creek Case Study: Sample Box Plots of IBI Metrics Showing Source Signatures

- IBI scores plotted on a map using different colors for categories of scores (although a problem was noted with showing temporal variability and measurement uncertainty) (see Figure 4-2).

- Plot of Invertebrate Community Index (ICI) versus river mile (see Figure 4-3).

- Trend analysis of response variables (IBI and ICI scores from 1970 to the present) using radar plots (see Figure 4-4).

- Map showing erosion potential based on model predictions (see Figure 4-5).

- Trends in stressors using radar plots (see Figure 4-6).

- Longitudinal plots of stressors versus river mile showing variability and trend of medians (see Figure 4-7).

The study team identified *protective factors* (e.g., steep gradient, presence of refugia**,** forested streambanks, etc.) and *key risks* (e.g., livestock, housing developments, etc.). The results suggested that useful management approaches would focus on the good stream segments by protecting springs and groundwater, and preventing problem spots from impacting the good stream segments.

The presentations have been successful in prompting stakeholders to take action to improve water quality. Actions taken to date include: removal of lowhead dams (with subsequent improvement in fish communities); landowner action in response to erosion potential models; a proposal by the U.S. Fish and Wildlife Service to designate a Darby Prairie National Wildlife Refuge (which would protect approximately one-tenth of the study area, including the areas with the best aquatic biological conditions and the recharge area); and use of the risk assessment results by the Natural Resources Conservation Service to re-target their erosion control efforts.

Additional technical risk characterization and management options will be considered later as new tools are developed and better data become available. These actions may include development of a “click-on” web site (Ohio Watersheds Modeling Project) with models that allow planners to conduct “what if?” scenarios to evaluate various habitat and landscape feature management options (e.g., if a development of a given size goes in at a location, what impact will that have on endpoint measures?). The models would be based on empirical relationships that link IBI scores to “what if” questions associated with land use, wastewater discharges, etc.

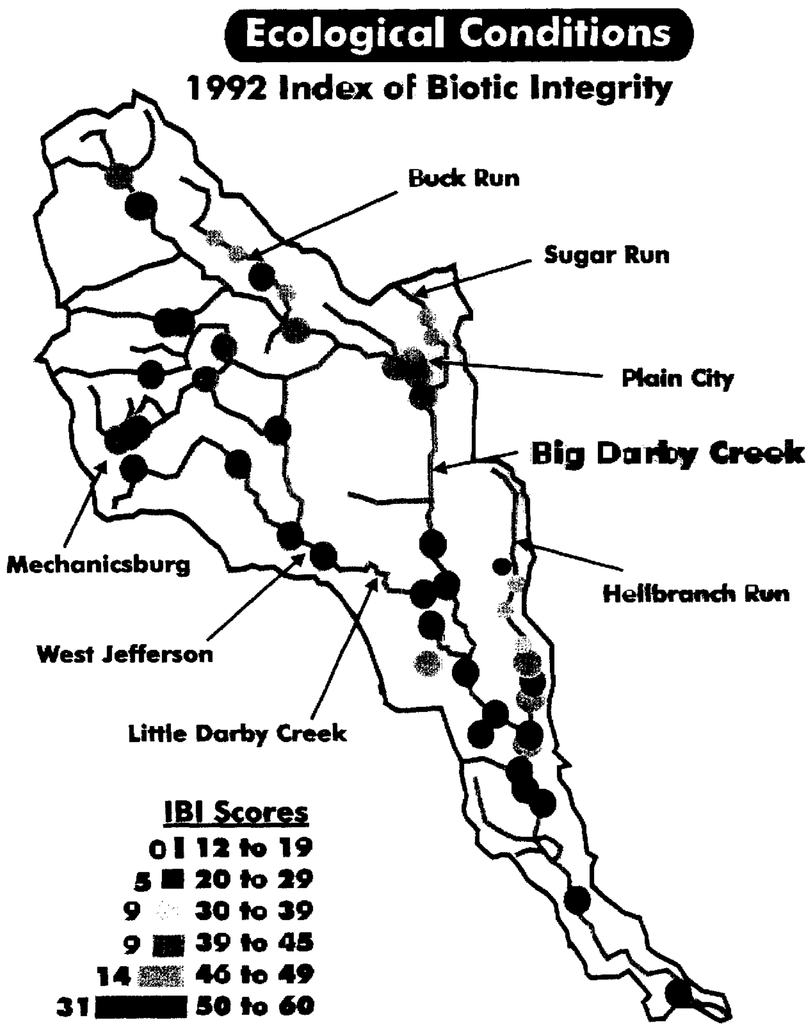


Figure 4-2. Big Darby Creek Case Study: Map Showing IBI Scores By Location

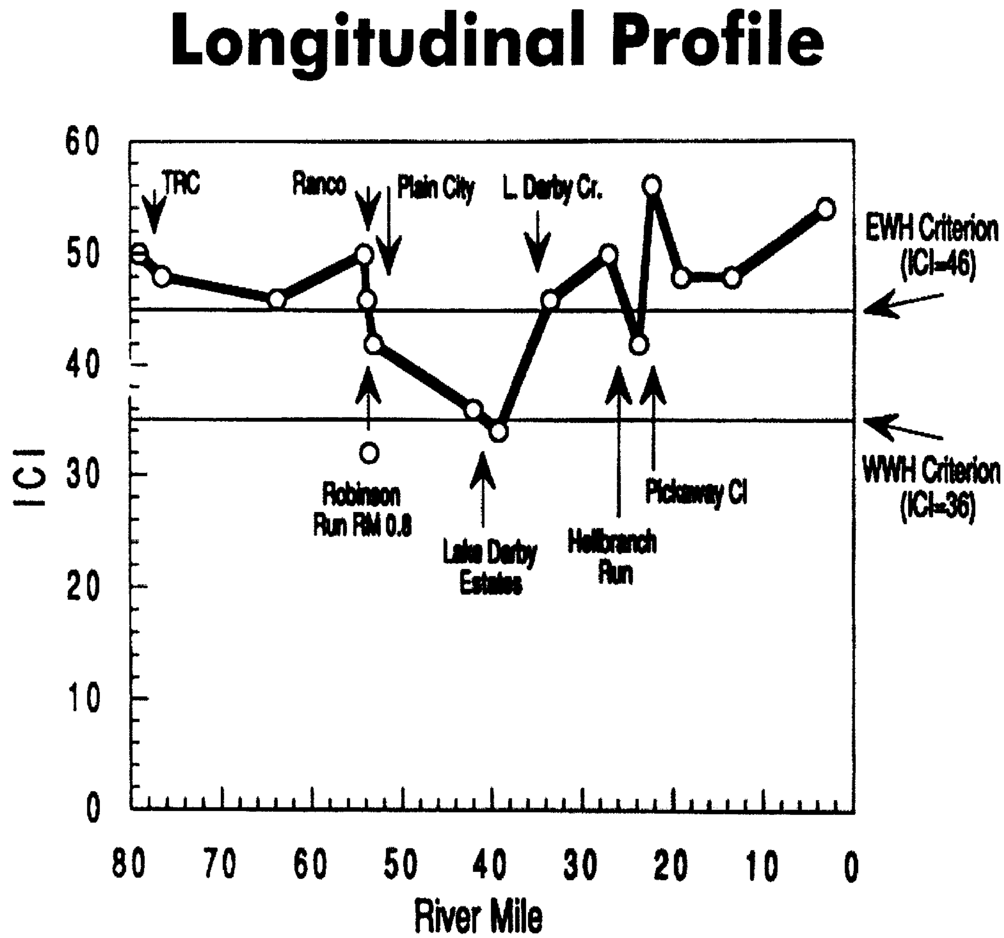


Figure 4-3. Big Darby Creek Case Study: Sample Plots of ICI Versus River Mile

Trend Analysis

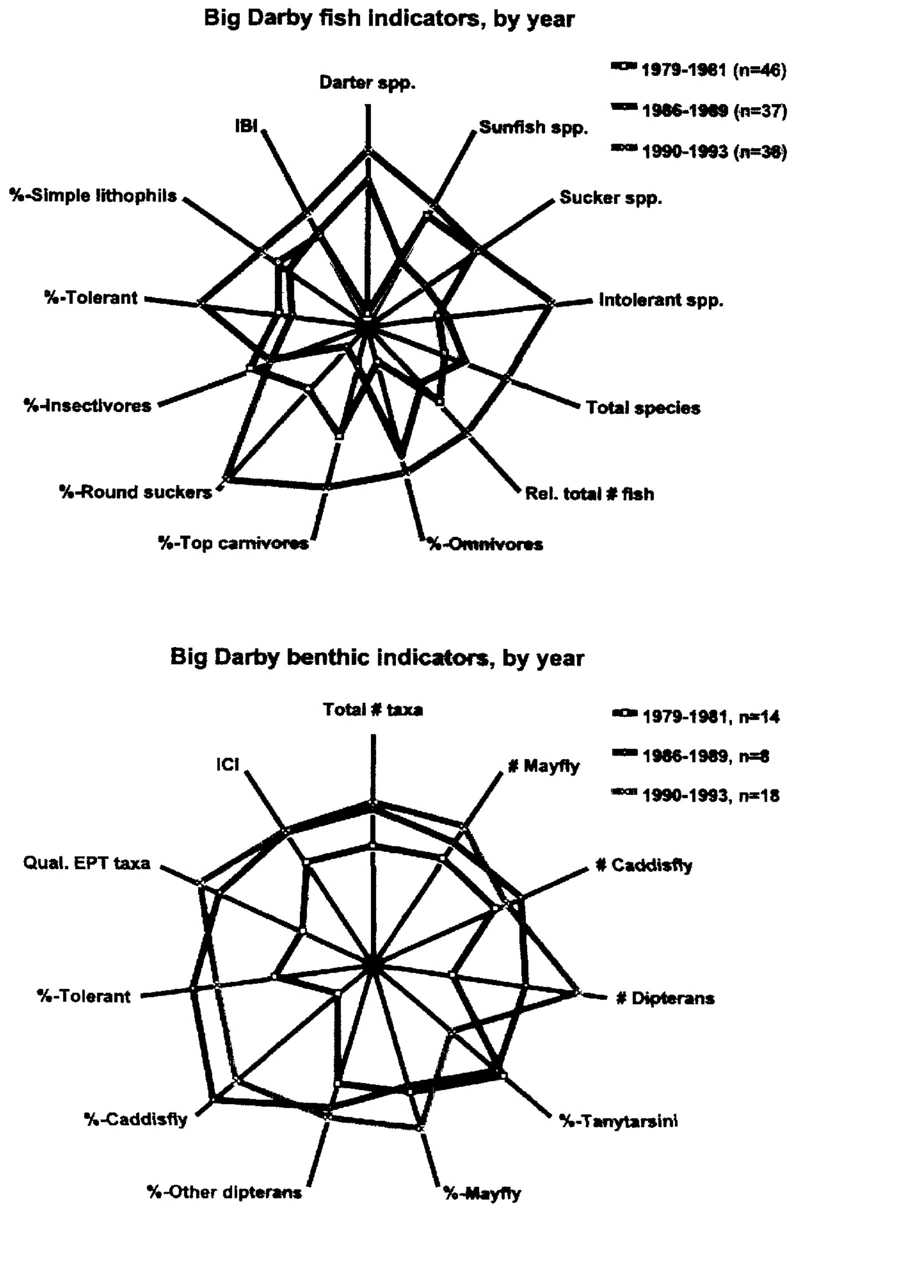
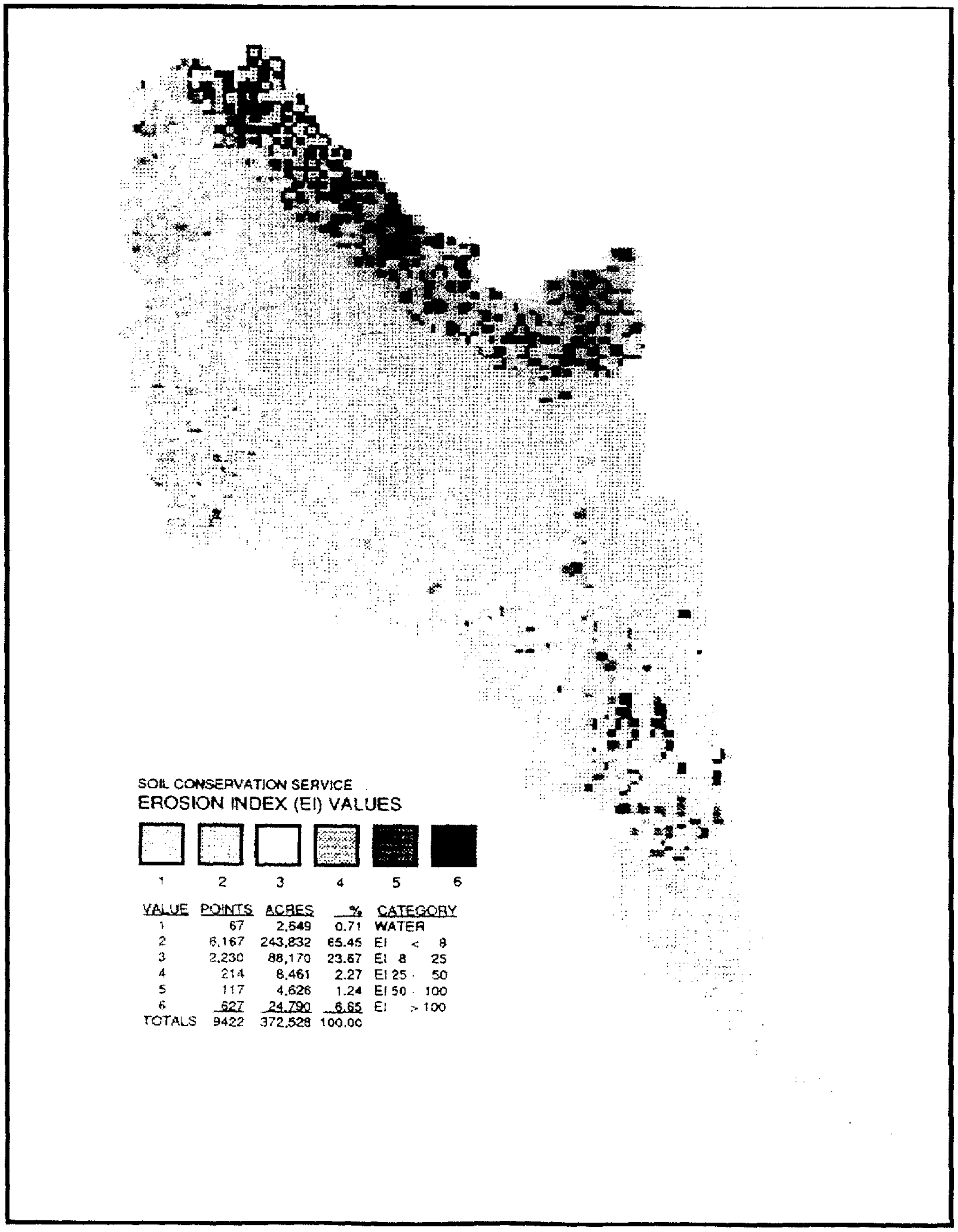
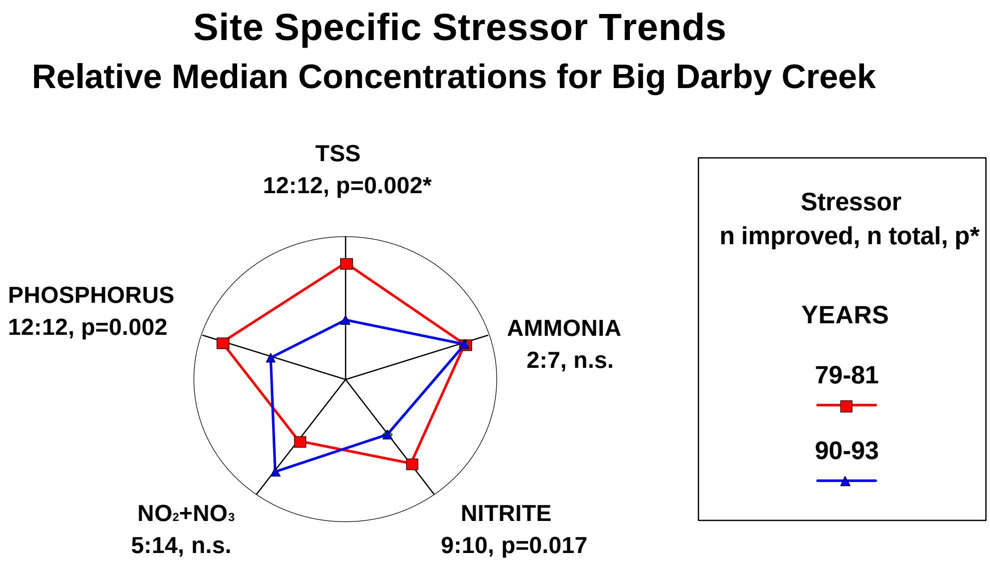


Figure 4-4. Big Darby Creek Case Study: Sample Radar Plot of Trend Analysis of Response Variables



VALUE	POINTS	ACRES	%	CATEGORY
1	67	2,649	0.71	WATER
2	6,167	243,832	65.45	EI < 8
3	2,230	88,170	23.67	EI 8 25
4	214	8,461	2.27	EI 25 - 50
5	117	4,626	1.24	EI 50 - 100
6	627	24,790	6.65	EI > 100
TOTALS	9422	372,528	100.00	

Figure 4-5. Big Darby Creek Case Study: Map Showing Erosion Potential Based on Model Predictions



* one-tailed sign tests

Figure 4-6. Big Darby Creek Case Study Trends in Stressors Using Radar Plots

Figure 4-6. Big Darby Creek Case Study: Trends in Stressors Using Radar Plots

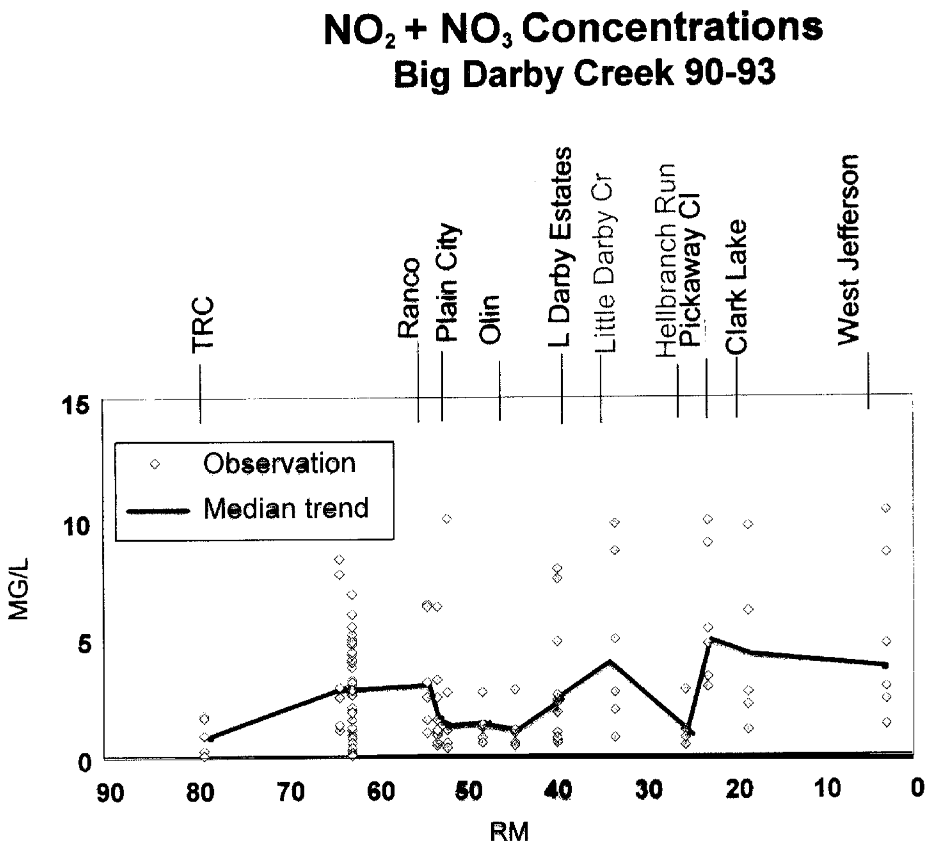


Figure 4-7. Big Darby Creek Case Study: Longitudinal Plot of Stressor Versus River Mile

4.2 MIDDLE PLATTE

Bob Fenemore, EPA Region 7, Middle Platte Assessment Chair, and
Marla Downing, EPA Region 7, Former Middle Platte Assessment Chair

The Middle Platte study area encompasses 5,000 square miles, making it the largest of the five case studies. The stream reach in the study area is 165 miles long. The watershed is 99 percent agriculture and in private ownership. There are approximately 200,000 people living in the area, and there are seven major communities, ranging in population from 1,500 to 42,000.

The Middle Platte is a highly appropriated river system with intense competition for water. Stakeholders in the area have a history of competition rather than cooperation, with little communication. Key issues causing divisiveness included a dam and its operation, water flow rights, and use impairments identified in a Clean Water Act Section 303(d) report.

When the 1996 draft of the planning and problem formulation phase of the risk assessment was issued, the stakeholders were observed to be less concerned with *what* the risk assessment said than with *who* said it. One of the panel members pointed out that this demonstrates how the personal credibility of the risk assessor is critical to how the message is received by stakeholders.

A key issue for this case study was how best to communicate a risk characterization to such a diffuse, diverse, divisive, and untrusting group. Among the lessons learned were that it is critical to have the risk assessors and risk managers in constant touch, and that risk assessors need to be aware of local socio-political “hot buttons.” It is also important to know stakeholders on a personal basis and to understand local communication styles. The chair of this assessment team visited the affected Natural Resource Districts, municipalities, developers, environmental groups, etc., several times a month to develop a trusting relationship with these stakeholders.

EPA was particularly disliked by some stakeholders in the region, so it was important to separate the risk assessment from any regulatory role. Local stakeholders were concerned that information from the risk assessment could later be used in enforcement actions. However, even if that should happen at some point in the future, stakeholders will have been involved throughout the process so that findings will be representative of their concerns and should not come as a shock.

One panelist noted that it might help to clearly separate the management decisions from the science. The speaker commented that close coordination between risk assessment and risk management is necessary to be able to present the risk characterization in a palatable manner, although as a scientist she agrees that they should be separate. It was also suggested that because EPA is held in such low regard by some stakeholders in the region, it might be helpful to present the assessment as an opportunity for the stakeholders to help develop the tools to manage their own watershed, rather than having EPA develop tools to “regulate” them.

4.3 WAQUOIT BAY

Patti Tyler, EPA Region 1, Waquoit Bay Assessment Co-chair, and
Maggie Geist, Waquoit Bay NERR, Waquoit Bay Assessment Co-chair

The Waquoit Bay watershed covers 21 square miles on the southeast coast of Cape Cod, Massachusetts. Initially valued for the hunting, farming, and fishing opportunities it provided, 20 percent of the land is now used for residential purposes. There are seven subwatersheds with different population densities. With sandy soils and low permeability, the watershed hydrology is entirely groundwater driven, and groundwater quality is being impacted by the profusion of on-site septic systems and by contaminated groundwater plumes from the Massachusetts Military Reservation (MMR). Nonetheless, biological resources are many and varied. There are a number of critical habitats including eelgrass beds, coastal-plain, pond-shore communities, anadromous fish runs, salt marshes, shellfish habitats, and barrier beaches. There is a great diversity of shellfish and finfish species. The area is along the Atlantic coast flyway, and there are numerous shorebird species. Several federal and state listed birds and plants occur in the area. As a result, Waquoit Bay has a variety of special considerations and designations, including being a National Estuarine Research Reserve, a U.S. Fish and Wildlife Refuge, a Land Margin Ecosystem Research Site, and a state-designated “Area of Critical Environmental Concern.”

Early in the assessment, the watershed stakeholder community was asked what they wanted to protect and what they thought the stressors were in Waquoit Bay. This stakeholder input was used to help develop a management goal for the risk assessment. A comparative risk analysis was conducted to define which stressors and endpoints needed to be examined further. “Fuzzy Set” decision analysis was used to rank stressors according to their relative contribution to risk to the endpoints. Results of the decision matrix showed excess nutrient loading was the principal stressor that was preventing attainment of the management goal for the watershed and that the effect of nutrient loading on eelgrass beds was the primary stressor/assessment endpoint relationship that needed to be investigated.

The team is now developing a model to relate the response of eelgrass coverage to nutrient loading within Waquoit Bay and eventually to predict future loadings under different development scenarios (e.g., density of septic systems, which are the primary source of the nutrients). The plan is to provide resource managers with the information needed to develop guidelines that would protect estuarine resources.

Exposure (i.e., nitrogen loading) was estimated using two models. The Nitrogen Loading Model (NLM) was used to predict the nitrogen load from various sources based on assumptions about landscape features, atmospheric deposition, groundwater movement, etc. This model tracked nitrogen delivery to the water’s edge. The Estuarine Loading Model (ELM) was then used to estimate the load of nitrogen in the estuary that was available to producers (i.e., the effect of nitrogen load on algal growth).

Risk managers must first decide “how much is too much” (e.g., How much eelgrass loss is acceptable?). Researchers can then use the models to estimate the N load necessary to meet the goal selected by the managers and to evaluate the effectiveness of various management alternatives. A description of how this will be accomplished was shown above in Figure 2-3.

4.4 MIDDLE SNAKE

Patricia Cirone, EPA Region 10, Middle Snake Assessment Chair and Guidelines Author

The Snake River study area is only a portion (a 160 km stretch of the total 1,000 km river) of the watershed. A travelogue slide presentation along the Middle Snake River pointed out that 85 percent of the Idaho population lives on this stretch of the river, and 90 percent of the trout served in U.S. restaurants are from aquaculture operations along this stretch of the river.

This assessment began in 1987, and analysis began in 1994. The Snake River Team is made up of federal and state agencies, county and local governments, private organizations, and academia. Major stressors identified by the team include: flow diversion for irrigation and water supply, flow alteration by impoundments, sediment and nutrient inputs from trout hatcheries, municipal wastewater discharge, cattle grazing, feedlots, and returns from irrigated land.

Much of the native fisheries resource has been lost. Five species of snails are endangered and several others already extinct. Management goals were developed to address these and other water quality related problems, as well as stakeholder interests related to recreational use of the river. The goals included attaining state water quality goals, establishing Total Maximum Daily Loads (TMDLs) for water quality-limited stretches, recovering threatened and endangered species, sustaining economic activity, and increasing tourism and river use.

The assessment endpoints drove the decisions for “what are we going to analyze?” In this case the endpoints selected were growth and survival of cold water biota (Mountain Whitefish, White Sturgeon, Trout); growth, survival, and diversity of molluscs; and growth of aquatic macrophytes and algae (which drove most of the public interest). Measures of effect selected for analysis were water quality criteria (dissolved oxygen, temperature, ammonia, total phosphorus and nitrogen); Habitat Suitability Indices; and presence, absence, and abundance of flora and fauna.

Risk estimation was based on four lines of evidence. These were:

- Field observations and studies (empirical models)
- Literature (field and best professional judgment)
- Stochastic or probabilistic estimates for habitat suitability and water quality criteria
- Process models for eutrophication

Estimates of the likelihood of recovery were also developed and presented using both figures and tables in the case study report (see Figure 4-8 and Table 2-1 of this report). Recovery is an endpoint that is important to stakeholders and is easily understood. While there was much praise for these figures and table, one comment to improve the table was to include citations to technical references or, in the cases where best professional judgment was used, identify the scientist(s) drawing the conclusion.

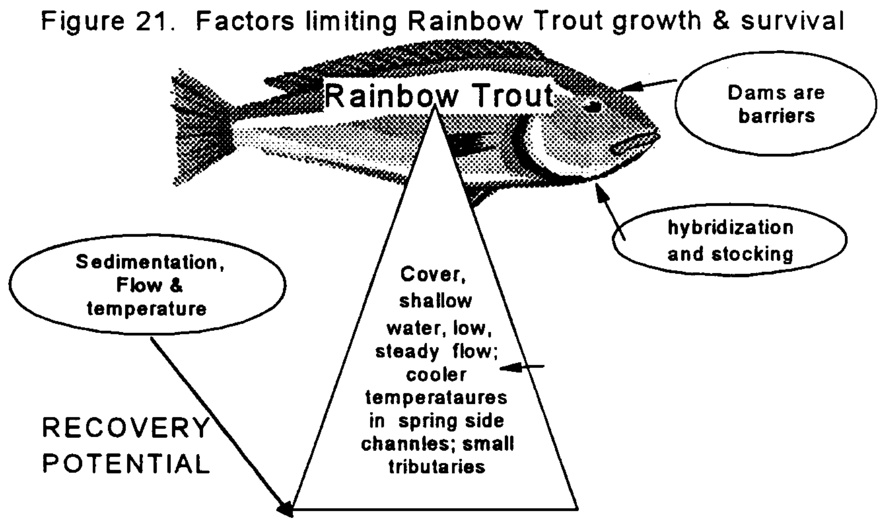


Figure 4-8. Middle Snake River Case Study: Illustration Linking Stressors to Recovery Potential for Rainbow Trout

It is anticipated that the information in the ecological risk assessment can be used to help establish total maximum daily loads (TMDLs) for river sections suffering water quality impairment; used in the review of permits for stream-affecting activities; and used to help evaluate management options for identification and control of nonpoint source pollution.

4.5 CLINCH VALLEY

Jerry Diamond, Tetra Tech, Inc., Clinch Valley Assessment Principal Investigator

The study area for the Clinch Valley assessment case study is in the unimpounded portion of the basin in Virginia. There has been an enormous decline in the fish and mussel species diversity. Stressor sources include dams, logging, some crops, diminished riparian corridor, mining, spills, and livestock pastures.

The management goal developed for the Clinch Valley ecological risk assessment was to maintain or restore the biological diversity of the Clinch-Powell watershed surface and subsurface aquatic ecosystem. Assessment endpoints selected for evaluation were native mussels, native fish and cave-dwelling species. (Ultimately, cave-dwelling species were not considered as part of this assessment due to lack of data.)

The Clinch Valley assessment is analyzing:

- The upland and riparian land use and its relationship to in-stream habitat quality and mussel distribution and abundance;
- Riparian vegetation, connectivity, and width in relation to measures of in-stream resource quality;
- Temporal trends of water quality and mussels; and,
- Water quality, land use, and riparian corridor characteristics in relation to distributions of mussels and native fish.

Scale issues were paramount. The primary question for land use was, “What scale of information is related to the biological endpoint measurement?”

Preliminary conclusions to date include:

- Cumulative impacts appear to be responsible for the decline in species richness and distributions. A stressor index was developed to indicate cumulative impacts based on proximity (> or <2 km) to pasture/cropland, urban areas, mining, and major transportation routes.
- As the number of stressors identified in an area increased (0, 1, 2, or 3), the maximum number of mussel species present declined.

- Percent forest cover is not necessarily an accurate indicator of in-stream conditions due to effects of other factors, especially close proximity to mining.

- A relatively large riparian area upstream of a site can have substantial effects on in-stream habitat quality and distribution of mussels and fish. The best fit (predictor) between biological endpoint measures and riparian zone size was with an area 100 m wide on each side of the river that also extended 1,000-1,500 m upstream of the site. In narrow floodplains or areas of higher gradient, a larger upstream reach needs to be considered.

- Relationships which were found to be significant included cropland (over 3 percent) versus sedimentation, pasture versus riparian vegetation integrity, and urban/barren versus quality of in-stream cover.

- Fish IBI was a better predictor of mussel populations than was EPT (sum of Ephemeroptera, Plecoptera, and Trichoptera taxa in a sample of benthic macroinvertebrates).

The major stressors for mussels were found to be proximity to mining (<1km), proximity to transportation routes (spill sources <1km), percentages of urban area (>10 %), and percentages of cropland (>19 %).

Uncertainties:

- Limitations of the Data - Habitat data were qualitative and not always available from the same sites as biological data; taxonomy for EPT was based on family-level taxonomy (genus may have yielded more conclusive results); water quality data were sparse; flow data were sparse and difficult to relate to the risk assessment.

- Sources of Uncertainty - Differences in sampling sites for mussels, fish and EPT; scales used for calculating land use percentages may not be transferable from stream to stream; and given that not all land uses co-occur everywhere, apparent correlations with a source may actually be due to presence or absence of other sources of stress.

SECTION FIVE
FACILITATOR PRESENTATIONS

5.1 Jack Gentile, Center for Marine and Environmental Analysis, University of Miami"Large-scale Assessment and Risk Characterization - The South Florida Regional Assessment as an Example"

The South Florida Regional Assessment and Restoration Strategy for the area of Florida south of Lake Okeechobee (including The Everglades), is a risk assessment that combines both retrospective and prospective elements in understanding the future risks associated with specific restoration actions.

Restoration goals were developed by the Governor's Commission for a Sustainable South Florida. This commission met quarterly and was tasked with developing the societal and environmental goals for the restoration. The scale and complexity of this activity have tremendous associated uncertainty; consequently, a decision was made to construct conceptual models for the whole system. The first technical problem facing investigators was how to partition an area as large as this (i.e., approximately 3,000 mi^2). Ultimately, the study area was characterized as a mosaic of 13 areas with distinct hydrology, habitat assemblages, and habitats. Alternatively, the assessment could have labeled several habitats, each occurring in one or more areas.

Conceptual models developed for each of these landscape units allowed the development of hypotheses that described the causal basis for the current state of the ecosystem as well as for future recovery. These 13 landscape units became the focus of the South Florida Restoration Strategy to recover south Florida and the Everglades.

The assessment was a tool for managers who needed a method for seeing how "what if" scenarios affected the various endpoints of concern to them. The stress-response relationships developed were the engines driving the analysis. The risk characterization involved building dynamic visualization tools.

In the analysis phase, a 2- by 2-km hydrodynamic model was used to develop exposure information based on a 30-year record of precipitation data. Model outputs of stage height, duration, and flow were generated for various climate scenarios. Stressor-response curves were developed for relationships between percent cover types and hydrologic parameters.

The effects that optimizing hydrology would have on other endpoints (e.g., wading birds, panthers, threatened and endangered species) became a major issue. The model indicated that it was desirable to flood certain areas, but flooding would have had significant social effects (Native Americans now own the area) and ecological effects (habitat of the endangered Cape sparrow would have been eliminated, although the species did not occur in this area until the land was drained by the historical diversion of water). The difficult management decisions have not yet been made.

Information on the assessment has been relayed via area-wide public meetings of the governor's commission. The group has also prepared technical reports, had pieces in publications, and developed brochures and fact sheets several times during the process.

The South Florida case study illustrates the full application of the ecological risk assessment paradigm. Problem formulation was used in a retrospective or deductive manner to identify the sources of the problem as well as to characterize the current state of the system and understand how it got to be where it is today. Hypotheses were developed for actions that, based upon several lines of evidence (e.g., historic, baseline monitoring), would lead to recovery. The Analysis Phase or inductive/prospective component of the guidelines included the examination of a variety of scenarios with sensitivity analyses to identify the most important variables in the system. In the Risk Characterization Phase, the outcomes were examined again, using multiple lines of evidence and often weight of evidence to help optimize the recovery in different landscape units. While numerical models played an important part in forecasting recovery, expert judgment was equally important. And, in fact, the latter often had a much higher degree of confidence than the former.

5.2 William Smith, Yale School of Environment and Forestry Studies, Yale University

The watershed concept has utility in that it is universal, allows for examining effects on different scales, allows for hypothesis testing, and is useful as an environmental management unit. Three goals of regional or watershed-scale risk assessments are to explain observed effects, evaluate actions with regional implications, and evaluate the status of key endpoints.

Successfully meeting these challenges involves developing good conceptual models with source-stressor-effects linkages, and comprehensively including what we know to be important. Clarity on the purpose of the risk assessment (e.g., whether the assessment is being done to answer a scientific question or to support a management decision) is also critical.

Ecological risk assessors should move away from the term "uncertainty" and think in terms of "degree of confidence." But while risk assessors should strive to be honest and clear about uncertainties in the assessment, they should also avoid being hamstrung or silenced by those uncertainties. Most major risk management decisions have a political context, and decision makers do not usually need the 95 percent confidence level that scientists strive for. In the real world, risk management decisions will continue to be made even in the face of great uncertainty.

Several panelists pointed out that the perceived need for certainty increases when risk management decisions involve the expenditure of large sums of money or an attempt to change ingrained land management practices. Another panelist commented that the perceived need for certainty may decrease when it is very expensive to collect and analyze the data to increase the level of confidence, or when the level of uncertainty ceases to be significant relative to the specific endpoint of interest.

Focusing specifically on the charge questions for the risk assessment case studies, Dr. Smith offered the following suggestions:

- Clearly state why the risk assessment was done (e.g., to support a particular management decision or to explain an observed effect). This should be repeated in the risk characterization even though it was stated initially in the problem formulation.

- Consider the potential benefits of a ranking or weighting system based on relative importance when dealing with qualitative lines of evidence and focus first on those judged most important. A ranking approach would also be useful in discussing the degree of adversity of predicted or observed effects in a watershed.

- When appropriate, include and develop qualitative lines of evidence. Sometimes both qualitative and quantitative lines of evidence are required to "tell the story" effectively.

- Keep risk assessment and evaluation of management options as two separate activities.

- Risk assessment reports should be polished, highly readable, professional-looking communication products. They should include a high quality executive summary targeted to decision makers.

5.3 Patrick Bourgeron, INSTAAR University of Colorado, Colorado State University

The linkages between natural and social systems are so strong that risk assessors cannot ignore them. We must deal with all the compartments of the natural, land use and socio-economic systems and drivers affecting resource endpoints. Too often, there is a disconnect between the system components considered by landscape ecologists and those considered by land or regional planners.

Selecting appropriate data for the scale examined is a crucial decision in assessing risk. In general, moving toward more conceptual viewpoints of the landscape (i.e., going from the real landscape, to spatial representation in mapping, to including temporal and dynamic features, to the strategic level of considering scenarios) necessitates a movement from high levels of precision to more general probabilities. In addition, as the domain under consideration enlarges (i.e., from local, to sub-region, to watershed, to regional), the "grain" of data changes from fine, to medium, to coarse. Use of finer or coarser data than is appropriate for a scale will cause serious problems in the ability to discern exposure-response relationships, interpret results, and define uncertainty.

There are typically several spatial areas to be considered in developing large-scale assessments. Ideally, the areas are one and the same, but this situation rarely occurs. The areas to consider are:

- Assessment area (the area over which data are available or will be collected)

- Analysis area (the area over which analyses are conducted)

- Planning area (the area over which community planning will occur)

- Response units (the lowest level on which you can expect a response)

- Cumulative impact areas (the area that management or land use activities will affect)

- Reporting Units (the area on which the risk assessor is reporting)

Tables presenting accuracy/precision versus cost are one method to communicate key information about the level of uncertainty. The information may be expressed as simply as low, medium, or high ranges. This information can be used in discussion of the appropriate level of effort in minimizing uncertainty.

One panelist commented that it might be useful to include an accuracy/precision versus cost table in the risk assessment to help communicate the justification for accepting a particular level of uncertainty. He also noted that there should be consideration of whether the increased cost of achieving a higher level of confidence produced a comparable value-add in decision quality.

SECTION SIX
BREAKOUT SESSION SUMMARIES

This section presents a summary of each team discussion during the breakout session.

6.1 BREAKOUT TEAM 1
Jack Gentile, Facilitator

CHARGE QUESTION: How should exposure and effects data be integrated in a watershed context to generate a risk estimate?

- There is value in using a "process diagram" similar to that used in the Clinch Valley presentation (see Figure 2-1) to summarize what could or could not be addressed with the available data. To be effective, such a diagram need not be a complete reproduction of the detailed conceptual model, but rather should provide an "in a nutshell" review of what was addressed and what the key issues are. The approach would be especially useful in situations where the risk characterization focuses on a single assessment endpoint within a complex ecosystem. A similar diagram could also be developed to highlight where the major uncertainties lie.

- Stakeholders may only be interested in certain endpoints or certain sub-areas of a complete watershed and the characterization should place greater emphasis on those parameters.

- Although the risk assessor may recognize complex interrelationships between stressors, or between a single stressor and multiple effect endpoints, models tend to approach such relationships linearly and one at a time. A potential approach to writing a risk characterization within this framework of complexity begins with a reiteration of the goals of the analysis and the linkage between those goals and the assessment endpoints. The second step would be presentation of a simplified version of the conceptual model and a summary of why the assessment focuses on selected endpoints within a fabric of cumulative effects. From this point, the risk characterization would proceed into a summary of the cause-and-effect relationships or benchmarks that will be used to evaluate exposure data.

CHARGE QUESTION: How should uncertainty be addressed and presented (e.g., incomplete data or analyses, qualitative estimates, data at different spatial and organizational levels)?

- Discussions of uncertainty should focus on the *key* uncertainties (i.e., those that could change the decision) rather than simply reciting a "laundry list" of all possible uncertainties.

- When uncertainties are due to a gap in the available data, the risk characterization should make recommendations for filling in the data gaps. The text might preface the recommendation with a statement such as: "If 'X' data were available, the probability of this response could be predicted with 'Y' degree of confidence."

- When the data are not adequate to develop a stressor-response curve, the risk characterization should assess the strength of the association between putative stressor and effect. The references on biological inference cited in the *Guidelines for Ecological Risk Assessment* (e.g., Fox [1991], Hill [1965], Susser [1986], and Suter [1993]) were identified as providing a useful conceptual framework for this analysis.

- When conclusions are based on comparison of data with benchmarks (such as water quality criteria), the uncertainties inherent in the development of the benchmarks should be acknowledged.

- The group discussed the differences in how risk assessors and risk managers might view uncertainty in the analysis. For example, a risk manager might choose to act based on a potential for an adverse effect, even if there is no conclusive evidence of causality. Discussing the degree of confidence in the results is a critical step in developing a credible risk characterization even if the uncertainties are only a minor consideration in the risk management decision making process.

- As scientists, we tend to demand a high degree of confidence before we present results. However, much of the uncertainty in ecological risk assessment cannot be captured in terms of standard statistics, even in those cases where quantitative information on the variability of exposure or endpoint data is available. Nonetheless, a qualitative, semi-intuitive estimate of confidence can usually be made based on best professional judgment, and this estimate of confidence may be adequate for the risk manager.

CHARGE QUESTION: What are the best ways to address and present the integration of qualitative and quantitative lines of evidence for a) an individual assessment endpoint and b) drawing overall conclusions?

- The group liked Table 17 on page 99 (see Table 2-1) of the Middle Snake River report as a way of displaying and summarizing multiple stressors and lines of evidence. The addition of a "references cited" column on the right-hand side of the table was identified as a potential improvement in the format. The group suggested that a table of this type, if used, should be supplemented by a narrative treatment of the various lines of evidence.

- Any contradictions between the various lines of evidence should be explored and, if possible, explained. The text should address whether the contradictory lines of evidence nullify the risk assessment process or whether it is reasonable to proceed with the risk characterization.

- The agreement or concordance of various lines of evidence, which individually may have a high degree of uncertainty, can strengthen confidence in the conclusion.

- One participant noted that EPA's Office of Research and Development and Office of Water are presently developing a document that addresses stressor identification and evaluation within the context of defining causal relationships.

- The group cautioned against numerically weighting qualitative data.

CHARGE QUESTION: How should the degree of adversity of predicted or observed effects in watersheds be described (e.g., considering nature and intensity of effects, spatial and temporal scale, and the potential for recovery)?

- A variety of qualifying and modifying factors should be addressed in a description of adversity, including:
  - spatial scale
  - temporal scale
  - biological scale (i.e., are adverse effects apparent on an individual organism scale or on a population scale?)
  - functional redundancy in the ecosystem that may obscure or limit apparent adverse ecological effects (e.g., species composition may change, but primary production rates may not).

- If the potential for recovery is an important part of determining the degree of adversity, address the following:
  - probability of recovery
  - spatial and temporal scale of recovery expected (including alerting the risk manager to any potential "quick successes")
  - whether recovery will be natural or "assisted" (e.g., species reintroductions, population supplementation by stocking)
  - what other factors (natural and anthropogenic) might limit recovery when the primary stressor is reduced or eliminated.

CHARGE QUESTION: How are alternative management options selected to have their risks characterized and how is management informed of the consequences?

- A question was raised about whether it was "heresy" to address management alternatives in a risk assessment (based on the separation of risk assessment from risk management in the NRC analytical deliberative paradigm).

- Depending on the purpose of the risk assessment (e.g., characterizing ecosystem dynamics versus supporting informed decisions by risk managers), evaluation of management alternatives may or may not be an integral part of the effort. If it is the goal of the risk assessment to evaluate management alternatives, this should be clearly reflected in the problem formulation. However, the group noted that even if the ultimate purpose is to support evaluation of management alternatives, the suite of alternatives may be developed through an iterative process that involves bringing stakeholders into the process.

CHARGE QUESTION: How should ecological risk be communicated to the manager and the public (journal articles, computer programs, presentations, town meetings, Internet, fact-sheets)?

- Set the stage for clear communication in the risk characterization by briefly reiterating the goal(s) of the risk assessment (e.g., characterizing a complex system; providing the information to support a specific management decision).

- Ecological risk communication should follow the "7 cardinal rules of communication" as listed in Text Box 6-2 of the 1998 Guidelines for Ecological Risk Assessment.

- The risk characterization should strive for TCCR as discussed in Text Box 5-9 of the 1998 *Guidelines for Ecological Risk Assessment*.

- The risk characterization presentation style should be tailored for the intended audience. The potential audiences are diverse and range from other environmental professionals to congressional representatives to land owners. At a minimum, there should be a scientifically credible, reasonably detailed and technical version that summarizes and documents the results of the assessment for the technical reader. Depending on the goal(s) of the assessment, it may be desirable to prepare a relatively nontechnical executive summary suitable for a broad audience. The executive summary should be tightly focused, and possibly arranged in a "bulleted" format.

6.2 BREAKOUT TEAM 2
William Smith, Facilitator

CHARGE QUESTION: How should exposure and effects data be integrated in a watershed context to generate a risk estimate?

- Output from mathematical models comprised a large portion of the case study presentations, and the breakout group was surprised at the limited use of mapping overlays to summarize results. Although several presentations used mapping overlays, there was a feeling that there were many additional opportunities to use the technique. When used effectively, mapping overlays can make the data more user friendly and aid the scientist in understanding it. For example, in the Clinch Valley case study, maps of endpoint measurement data and stressor data were effectively used to portray relationships and linkages (see Figure 6-1).

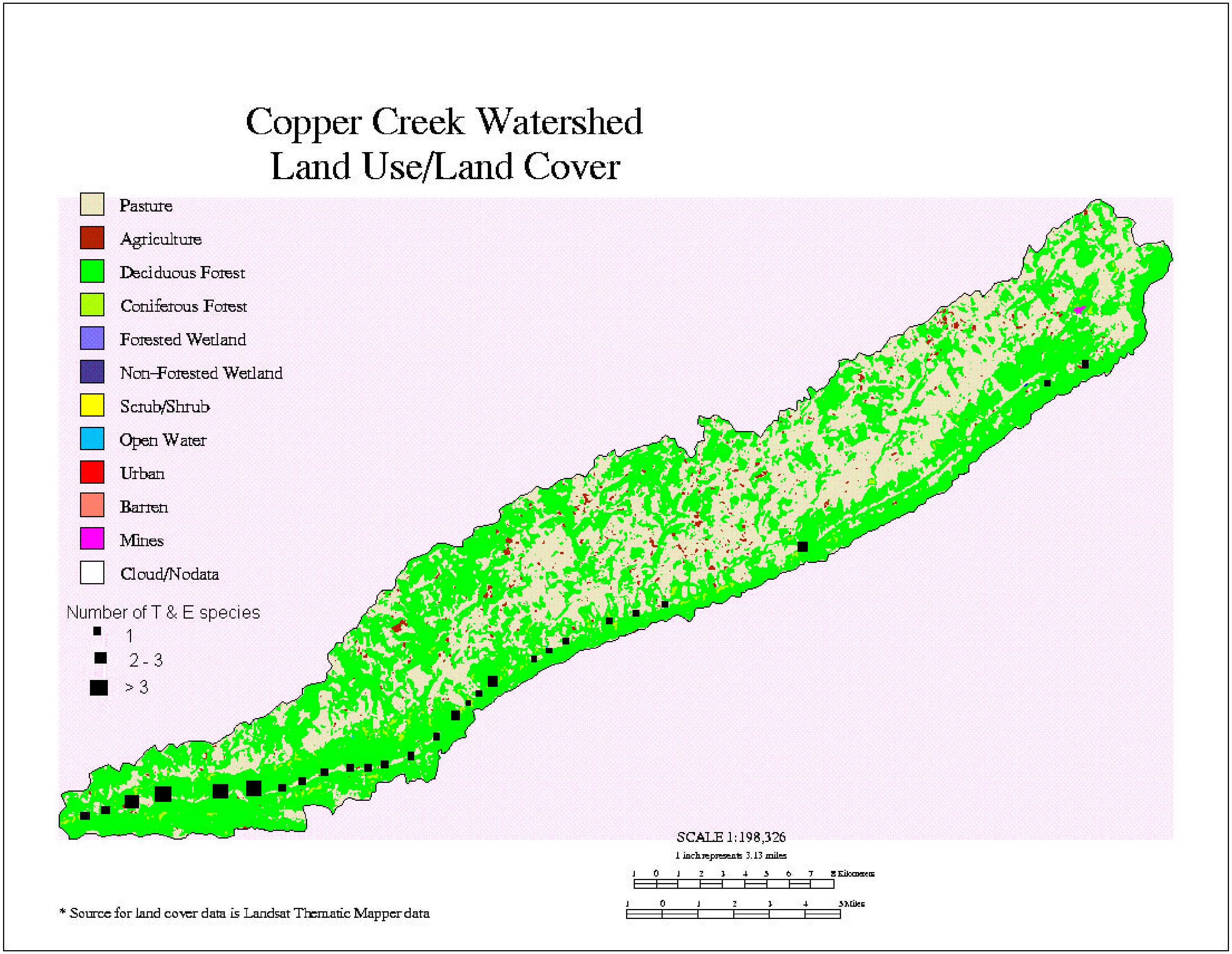


Figure 6-1. Clinch Valley Case Study: Map Showing Land Use Versus Threatened & Endangered Species

- The group felt that examining small subwatersheds was an effective way to decrease complexity of analysis and presentation, and to focus on the effects of individual stressors. Subsequently (as in the Clinch Valley case study), the analysis can be re-expanded (with assumptions clearly identified) to evaluate the cumulative impacts of stressors. One participant noted that the Big Darby investigators had used an analogous approach by sorting out the stressors using Principal Components Analysis (PCA) and then developing a multivariate model that "reassembled" the effects.

- Ranking techniques and development of stressor indices (but not weighting) for the watershed were considered reasonable methods of assembling the data into usable information. (There was no detailed discussion on either of these approaches.)

- The picture charts and tables relating stressors (see Figure 4-8 and Table 2-1, respectively), lines of evidence, description of risk, uncertainty, assumptions and recovery potential from the Snake River case materials in the workshop handout binder were considered to be the best examples of integrating and presenting information.

CHARGE QUESTION: How should uncertainty be addressed and presented (e.g., incomplete data or analyses, qualitative estimates, data at different spatial and organizational levels)?

- Discussion began with the level of comfort of risk assessors in addressing uncertainty, and the participants warned against being paralyzed by "uncertainty block."

- Risk assessments are likely to be questioned at some point, and one group member remarked on the fear that a risk assessment might be challenged in court. Another participant noted that in the NEPA arena courts tend to find for the initial investigator rather than the challenger as long as the investigator has conducted and documented a "reasonable" scientific approach to assessing the magnitude and likelihood of impacts. It is generally sufficient to show that the issue has been considered, the investigator has used a reasonable scientific process to reach conclusions (conducting studies, developing conceptual linkages and consolidating lines of evidence), and the degree of uncertainty has been identified. "Sins of omission" (e.g., leaving out an important stressor or endpoint) are worse than "sins of inaccuracy."

- Paying due respect to gaps in conceptual models is critical.

- The levels of confidence needed for scientist and managers differs. Risk managers make many decisions with levels of uncertainty that are considered high for the risk assessor. The confidence level needed may be affected by the management decision to be made (e.g., it may be correlated with capital involved and political context). In public policy decisions, the uncertainty about effects from economics or cultural issues that influence decisions may be far greater than the uncertainty associated with factors in the risk assessment. This does not, however, let the investigator off the hook: uncertainty should be clearly addressed with good science and judgment.

- Uncertainty can be captured either quantitatively or qualitatively, depending on what is most appropriate for the data or information being considered. Quantitative data should be used whenever possible, but in many cases, uncertainty may simply be characterized as “high,” “medium” or “low.” The appropriate level of uncertainty analysis may be non-quantitative for some data or lines of evidence.

- The objectives should be to lay out the degree of uncertainty with clarity, honesty and openness; and to be as comprehensive as possible in your "uncertainty" inventory.

- It is often helpful to reference standards, tests, and accepted metrics (e.g., IBI) in support of level of uncertainty.

CHARGE QUESTION: What are the best ways to address and present the integration of qualitative and quantitative lines of evidence for a) an individual assessment endpoint and b) drawing overall conclusions?

- For the technical audience, use an approach similar to that of the Snake River presentation was good (see Table 2-1). The advantage of a tabular presentation was that the information regarding the lines of evidence (e.g., model, field observations, similar sites comparison, etc.) could be seen in one place. Use of qualitative categories (high, medium or low) was both appropriate and useful in some instances. The addition of numeric references at the side of the table was suggested as a useful change in format.

CHARGE QUESTION: How should the degree of adversity of predicted or observed effects in watersheds be described (e.g., considering nature and intensity of effects, spatial and temporal scale, and the potential for recovery)?

- The Snake River table (see Table 2-1 above) in conjunction with the maps showing degree of impairment for various life stages along the stream reach (see Figure 2-2 above) are good formats to follow.

- Temporal scale analyses and presentations should indicate trends for stressors and endpoints. Participants noted the need for caution about making subjective judgments.

CHARGE QUESTION: How are alternative management options selected to have their risks characterized, and how is management informed of the consequences?

- Management decision making goes on throughout the risk assessment and continues after it is completed, yet risk assessments need closure.

- Management options and issues should be identified to the extent possible in the planning/problem formulation stage, but risk managers (whether urban planners or farmers) should be involved along with the risk assessor in the iterative development of risk scenarios during the risk assessment process.

- The risk characterization section should cover both the current situation and reasonable "what if" scenarios supplied by risk managers. "What to include" and "where to stop" are affected by the type of management information needed (e.g., to determine if there is a problem or if action is needed, to identify priority areas for action, or to determine the best action to take). The risk characterization itself, however, is seen as a summary of the science that explains the probability of an adverse effect on an endpoint.

- The risk assessor should not feel obligated to go further than covering the management options that were identified in the planning/problem formulation stage.

- When considering management options, recognize that many individuals may need to be involved because different managers and agencies may have authority over subsets of the spatial scale, stressors, and ecological endpoints.

CHARGE QUESTION: How should ecological risk be communicated to the manager and the public (journal articles, computer programs, presentations, town meetings, Internet, fact-sheets)?

- There is a strong need for continued communications to "bring the public along all the way." This is especially true when considering management options.

- Although somewhat simpler in presentation, executive summaries should have enough "meat" to give the reader the full understanding of major risks, stressors, and impacts to important endpoints identified in early stakeholder discussions.

- Other routes for sharing risk assessment information that were either done in the course of the demonstration risk assessments or were thought to be good ideas include: exhibits at a county fair, school audiences, use of print media and development of "slicks" for the public as well as a technical report for the scientific community. Full text versions of risk assessments should be made available on web sites.

- Recognition of your audience was a major point of discussion. A key question is, "Do you know who your audience is?" There were three basic audiences identified: risk managers, the public, and other scientists. To be maximally effective, correct identification of the management audience was thought to be critical. Reports should be appropriate for 1) scientific review; 2) risk management utility; and 3) public access and readability.

- Tables such as the one in the Snake River report (see Table 2-1 above) are a good way to present the lines of evidence in one place. Using qualitative categories (high, medium, or low) can be useful sometimes. The addition of numeric references at the side of the table was suggested as a useful change in format.

6.3 BREAKOUT TEAM 3
Pat Bourgeron, Facilitator, and

Patti Tyler, Report-Back Volunteer

CHARGE QUESTION: How should exposure and effects data be integrated in a watershed context to generate a risk estimate?

- The dose-response curve format is useful for a single stressor dose-response (e.g., using eelgrass as an assessment endpoint for nutrients in the Waquoit Bay assessment).

- Multivariate analysis can be used in a system with multiple stressors to help determine which stressor is having the greatest impact.

- The group liked Table 17 on page 99 of the Snake River report (reproduced as Table 2-1 for this report) as a way to display and summarize the impact of multiple stressors and lines of evidence. A table of this type can capture both quantitative and qualitative evaluations.

- Evidence of exposure, evidence of effects, magnitude of effects, confidence, and risk potential can all be ranked as high, medium, or low. This qualitative evaluation can be quite useful. For example, if there is medium confidence of low risk, it is unlikely that additional data would change the conclusion that the risk is low.

- Sometimes it may be best to use best professional judgment rather than to try to quantify. For instance, better information may be derived from the best professional judgment of a local biologist than from an in-depth study of limited data.

- The group discussed the scale issue and how to extrapolate from subwatersheds to entire watersheds. Applying specific subwatershed relationships to entire watersheds works better if the entire watershed is similar in nature. It is possible to develop templates for different habitats which may then be extrapolated to similar locations rather than the whole watershed. In the Clinch Valley Assessment, data from study stations were used to define trends based on water quality data, land use, habitat, etc., which were then extrapolated to specific sites with mussels to help explain existing conditions or help predict future recovery.

- It may not always be appropriate to manage a stressor for the whole watershed if only a small or specific area needs to be protected.

- It is also good to be able to present risk estimates at different scales. Data should be used for an appropriate area and reported for an appropriate area.

- The relationship between exposure and effects must be communicated so that the manager can understand all the links between the stressor and the endpoint. Plugging data into the conceptual model is one way to demonstrate effects, and it is best if it can be shown at different spatial scales.

CHARGE QUESTION: How should uncertainty be addressed and presented (e.g., incomplete data or analyses, qualitative estimates, data at different spatial and organizational levels)?

- Be aware that users of the report aren't as interested in uncertainty as are scientists.

- Nutrient modeling is an example of where a model can demonstrate variability. Confidence in predictive numbers, limitations of model output, standard deviations, standard errors, etc., can be determined.

- When it is not possible to describe uncertainty quantitatively, references to the literature may help support a conclusion.

- One participant commented that variability cannot be reduced, but that the associated uncertainty can be defined/reduced through use of probabilistic analysis to reach a quantitative estimate of uncertainty. Uncertainty factors may also be useful in some situations to account for uncertainties associated with extrapolation.

- Describe how uncertainty is based on available data and analysis. For example, in the Clinch Valley Assessment a less than optimal taxonomic level was used for the benthic macroinvertebrate analysis. Investigators questioned whether a benthic macroinvertebrate index could serve as a surrogate for mussels in their study. The fish IBI had a much stronger correlation with the mussels than did the EPT index in that study, possibly because taxonomic data below the family level was unavailable.

- At the end of the process the risk assessor should address which uncertainties have the most impact on the conclusion. Uncertainties should be ranked for the risk manager.

- The degree of uncertainty should be addressed as the degree of confidence in discussions with the public. While it is better to present what we are confident about, uncertainties in some exposures will still have to be explained. Example: A certain degree of change in an exposure may not predict with certainty that recovery will occur because of uncertainties in the exposure.

- Risk characterization should consider the risk management context. For example, reducing all uncertainties in data may be meaningless if there are no feasible management alternatives.

CHARGE QUESTION: What are the best ways to address and present the integration of qualitative and quantitative lines of evidence for a) an individual assessment endpoint and b) drawing overall conclusions?

- The team recommended that conclusions be presented in a summary table with references to the location of in-depth data. Table 17 on page 99 of the Snake River report (reproduced for this report as Table 2-1) is a good example. One participant noted that a similar approach is described in a report from the Society for Environmental Toxicology and Chemistry

(SETAC) Pellston Workshop on Multiple Stressors in Ecological Risk and Impact Assessment (*Pellston Workshop Report is now available. See Foran and Ferenc, 1999*). The Pellston approach uses a series of matrices to 1) show stressor/risk rankings which provide managers with relative rankings of stressors within each scenario, including uncertainty information; 2) show information about the magnitude, duration, and spatial extent of a stressor and the probability the effect will be expressed, including uncertainty information; and 3) allow development of a set of management scenarios with associated sets of stressors and management options.

- The team agreed that maps showing stressors and assessment endpoints are excellent tools for presentation; however, it was pointed out that people often don't realize there are uncertainties involved (accuracy and confidence associated with points on the map) when viewing map presentations. Web sites with maps were also suggested.

- Multiple stressors and multiple endpoints often make it difficult to concisely state a conclusion. Use of a matrix, summary table, or the conceptual model may help in presentation of the results and conclusions.

CHARGE QUESTION: How should the degree of adversity of predicted or observed effects in watersheds be described (e.g., considering nature and intensity of effects, spatial and temporal scale, and the potential for recovery)?

- The Snake River case study is an example where it is easy to illustrate present versus historical conditions using photographs and maps.

- Maps showing individual stressors help explain the overall situation, especially if there is some ranking or scoring system.

- Recovery potential is included in Tables 17 and 19 on pages 99 and 101 of the Snake River report (see Table 2-1 above).

- Refer to the literature on similar situations to give best professional judgment about what might happen. Sometimes the predicted recovery does not occur. In the Clinch Valley some improved areas which now provide a suitable habitat still do not have mussels. Another example is areas where stocking of salmon and habitat improvement have not resulted in restored populations.

    - Temporal scales for recovery vary for different species (e.g., earthworms versus bear), thus making recovery difficult to estimate. Spatial considerations should be appropriate for the assessment.

    - Units of adversity, such as percent mortality, may be more useful than rankings if they are understood by the public and directly relate to something the public cares about.

CHARGE QUESTION: How are alternative management options selected to have their risks characterized and how is management informed of the consequences?

- Ideally, management options should be discussed during planning or problem formulation; however, after some findings are available later in the process, additional discussions with management may be needed because some options may no longer be realistic and new alternatives must be considered. At the beginning of an assessment it may not be known whether recovery is possible, so it may not be clear what alternatives should be considered. If management options are not discussed throughout the process, the risk assessment may not produce meaningful findings.

- Later in a study, the assessor may be able to determine subsections of a study area that need different management options to achieve management goals.

- A meeting with the stakeholders following the analysis phase was advised to plug in different scenarios based on stakeholder input. In addition, periodic meetings with stakeholders should be held to discuss management options and to receive other viewpoints that might help explain data.

- When stakeholders are included throughout the process, they understand the process and have buy-in from the beginning. When conclusions are reached, the stakeholders are more likely to understand them, and the process does not have to be explained from the beginning. The stakeholders were a part of the entire assessment.

- A recommendation for more extensive involvement and consultation with risk managers and stakeholders during the analysis phase should be added to the guidelines. Such involvement could change the direction of a study.

  - Public advisory committees are a forum to exchange information and meet regularly. Public meetings with stakeholders should always be scheduled in advance, and scientists and investigators should be available for questions and discussions.

CHARGE QUESTION: How should ecological risk be communicated to the manager and the public (journal articles, computer programs, presentations, town meetings, Internet, fact-sheets)?

- In risk communication, a few participants felt writers should apply the "teenager rule" (i.e., the report should be explainable to a teenager) or use writing at a seventh-grade level. For example, say "no dissolved oxygen," rather than "anoxia."

- Several members of the team felt the risk characterization should be written at the level of the technical literacy of the risk manager. Any version of the risk characterization should be written as appropriate for the target audience.

- Many felt the risk characterization should be a scientific report, but it should have a “relevant findings” section for the manager.

- Alternatively a “plain language” watershed plan/risk characterization could be written with technical appendices. This is in agreement with the approach provided in the *Guidelines* and *Handbook*.

- Terms not in the dictionary should be briefly defined in the text or in a glossary. If a term is a central concept that will be used repeatedly, it may need even more definition (possibly expanded to a paragraph or two). Words that are contained in the glossary should be in bold type the first time they appear in the text.

- Technical terms should not be used in the executive summary or the relative findings section of the risk characterization.

- Encourage stakeholders to participate in presentations. It is advantageous if the communicator is part of the audience group or is otherwise considered to be credible by the stakeholders.

- Have open houses for school children.

- Meet the needs of the media.

- Reporting units used for the results should be compatible with the display of other results. Consistency in presentation is helpful for the readers.

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APPENDIX A

LIST OF WORKSHOP PARTICIPANTS

Attendee Name	Organization	Address	Phone	e-mail	Interest in Meeting
USEPA ORD NCEA					
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Attendee Name	Organization	Address	Phone	e-mail	Interest in Meeting
Panel Members continued:					
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Patricia Cirone	US EPA MS PEA/095	Region 10 1200 Sixth Avenue Seattle WA 98101	206-553-1597	CIRONE.PATRICIA@epamail.epa.gov	Middle Snake Assessment Chair & Guidelines Author
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Laura Gabanski	US EPA OW OWOW	4503F, 401 M Street, SW Washington, DC 20460	202-260-5868	Gabanski.Laura@epamail.epa.gov	Former Participant Waquoit Bay Assessment, Developer of Eco Risk & Decision Making Course
Ken Jones	Green Mountain Institute	104 East State Street Montpelier, VT 05602	802-229-6070	kjones@gmied.org	Green Mountain Institute

Attendee Name	Organization	Address	Phone	e-mail	Interest in Meeting
Additional Participants continued:					
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APPENDIX B

WORKSHOP AGENDA

Watershed Ecological Risk Characterization Workshop
July 7-8, 1999

I. Purpose of Workshop: To further develop and document the process for conducting watershed ecological risk characterization.

II. Desired Output: Develop recommendations for how to conduct a watershed ecological risk characterization. Discuss the desirable items to include in such a characterization and how to address common situations.

III. Workshop Approach: We are developing additional guidance for how one should develop the risk characterization phase of a watershed scale ecological risk assessment. We are advancing what is documented in the ecological risk assessment guidelines. While we will attempt to comply with the guidelines, we will also deviate from them if justifiable. Where applicable we may also develop supplemental and deviating guidelines for the analysis phase of risk assessment.

The Agency is also developing a risk characterization handbook. These will be revised based on peer review comments. The peer review comments noted that the document needs to more fully incorporate ecological risk assessment principles. The latest draft does conclude that the risk characterization should summarize the earlier phases of the risk assessment including planning and problem formulation. The current draft also requires the risk characterization to be written in "plain language" and to be concise.

We need an approach that attempts to comply with the Agency ecological risk assessment guidelines and the Agency risk characterization guidelines. To achieve scientific credibility while also using plain language and concise explanations we will develop a scientific risk characterization report that will also include a relevant findings section in plain language. In addition, the executive summary for the entire assessment will also be written to be understandable to an educated non-scientist.

IV. Charge questions to consider when reviewing the provided risk characterizations and other background materials.

A. How can the three submitted watershed assessment drafts (or plans) be improved, especially in regards to the other charge questions listed below?

B. How should exposure and effects data be integrated in a watershed context to generate a risk estimate?

C. How should uncertainty be addressed and presented (e.g., incomplete data or analyses, qualitative estimates, data at different spatial and organizational levels)?

D. What are the best ways to address and present the integration of qualitative and quantitative lines of evidence for (a) an individual assessment endpoint and (b) drawing overall conclusions?

E. How should the degree of adversity of predicted or observed effects in watersheds be described (e.g., considering nature and intensity of effects, spatial and temporal scale, and the potential for recovery)?

F. How are alternative management options selected to have their risks characterized and how is management informed of the consequences?

G. How should ecological risk be communicated to the manager and the public (journal articles, computer programs, presentations, town meetings, Internet, fact-sheets)?

V. Background Documents:

A. Ecological Risk Assessment Guidelines, Section on Risk Characterization

B. Draft Risk Characterization Handbook, Sections 1, 2, & 3

C. Waquoit Bay Risk Characterization Plan

D. Review Comments on Waquoit Bay Risk Characterization Document

E. Draft Middle Snake Watershed Risk Characterization

F. Draft Clinch Valley Watershed Risk Characterization

Agenda
Watershed Risk Characterization Workshop
July 7 & 8 1999

July 7:

8:00	Registration and conversation
8:45	Opening remarks, value of this workshop Mike Slimak, Associate Director for Ecology National Center for Environmental Assessment (NCEA)
9:00	Workshop goals and approach, progress on five case studies, review agenda Vic Serveiss, Environmental Scientist, NCEA
9:15	Introductions
9:25	Risk characterization summary Bill van der Schalie, Environmental Scientist, NCEA
9:50	Different traditions of environmental management and their implications for watershed ecological risk assessment Sue Norton, Ecologist, NCEA
	10:15 Break
10:40	<u>Presentation and discussion of five watershed assessments</u> Present the risk characterization draft or plan. Discuss charge question #1: How can each watershed risk characterization be improved?
10:45	Big Darby Creek, Susan Cormier
11:15	Middle Platte, Dennis Jelinski
11:45	Lunch
12:45	Waquoit Bay, Maggie Geist; Jack Gentile, facilitator
2:00	Middle Snake, Patricia Cirone; Patrick Bourgeron, facilitator
3:15	Break
3:30	Clinch Valley, Jerry Diamond; William Smith, facilitator
4:45	Plan for tomorrow, Vic Serveiss
5:00-6:00	Optional conversation time (Crystal Club Room)

July 8:

8:00	Optional conversation time
	Facilitators present responses to charge questions # 2-7
8:30	Facilitator #1 Jack Gentile
9:00	Facilitator #2 William Smith
9:30	Facilitator #3 Patrick Bourgeron
10:00	Break
10:15	Break-out groups led by facilitators developed recommendations for conducting watershed eco-risk characterization by developing replies to charge questions.

Break-out Session Team 1 - Crystal Club Room
Break-out Session Team 2 - Board Room
Break-out Session Team 3 - Salon F (Main Room)

12:00-1:00	Lunch
2:30	Report back by a volunteer from each group
3:30	Break
4:00	Group synthesis/consensus, led by invited experts
4:45	Closing comments-Serveiss/Norton/van der Schalie
5:00	Adjourn

Break out teams:

Crystal Club Room	Board Room	Salon F
Team 1	**Team 2**	**Team 3**
James Andreasen	Ed Bender	Richard Batiuk
Kay Austin	Bob Fenemore	Joyce Brooks
Patricia Cirone	Jack Fowle	Patrick Bourgeron
Janice Cox	Maggie Geist	Susan Cormier
Marla Downing	Roberta Hylton	Jerry Diamond
Bill Ewald	Lawrence Martin	Susan Ferenc
Laura Gabanski	Robert Murphy	Jennifer Moses
Jack Gentile	Sue Norton	Donald Rodier
Don Gowan	Anne Sergeant	Catriona Rogers
Ken Jones	William Smith	Vic Serveiss
John Miller	Molly Whitworth	Michael Slimak
Margaret Stewart	Dennis Yankee	Barry Tonning
Bill van der Schalie	Bruce Yeager	Patti Tyler
		Michelle Witten

APPENDIX C

ECOLOGICAL RISK ASSESSMENT GUIDELINES
SECTION ON RISK CHARACTERIZATION

5. RISK CHARACTERIZATION

Risk characterization (figure 5-1) is the final phase of ecological risk assessment and is the culmination of the planning, problem formulation, and analysis of predicted or observed adverse ecological effects related to the assessment endpoints. Completing risk characterization allows risk assessors to clarify the relationships between stressors, effects, and ecological entities and to reach conclusions regarding the occurrence of exposure and the adversity of existing or anticipated effects. Here, risk assessors first use the results of the analysis phase to develop an estimate of the risk posed to the ecological entities included in the assessment endpoints identified in problem formulation (section 5.1). After estimating the risk, the assessor describes the risk estimate in the context of the significance of any adverse effects and lines of evidence supporting their likelihood (section 5.2). Finally, the assessor identifies and summarizes the uncertainties, assumptions, and qualifiers in the risk assessment and reports the conclusions to risk managers (section 5.3).

Conclusions presented in the risk characterization should provide clear information to risk managers in order to be useful for environmental decision making (NRC, 1994; see section 6). If the risks are not sufficiently defined to support a management decision, risk managers may elect to proceed with another iteration of one or more phases of the risk assessment process. Reevaluating the conceptual model (and associated risk hypotheses) or conducting additional studies may improve the risk estimate. Alternatively, a monitoring program may help managers evaluate the consequences of a risk management decision.

5.1. RISK ESTIMATION

Risk estimation is the process of integrating exposure and effects data and evaluating any associated uncertainties. The process uses exposure and stressor-response profiles developed according to the analysis plan (section 3.5). Risk estimates can be developed using one or more of the following techniques: (1) field observational studies, (2) categorical rankings, (3) comparisons of single-point exposure and effects estimates, (4) comparisons incorporating the entire stressor-response relationship, (5) incorporation of variability in exposure and/or effects estimates, and (6) process models that rely partially or entirely on theoretical approximations of exposure and effects. These techniques are described in the following sections.

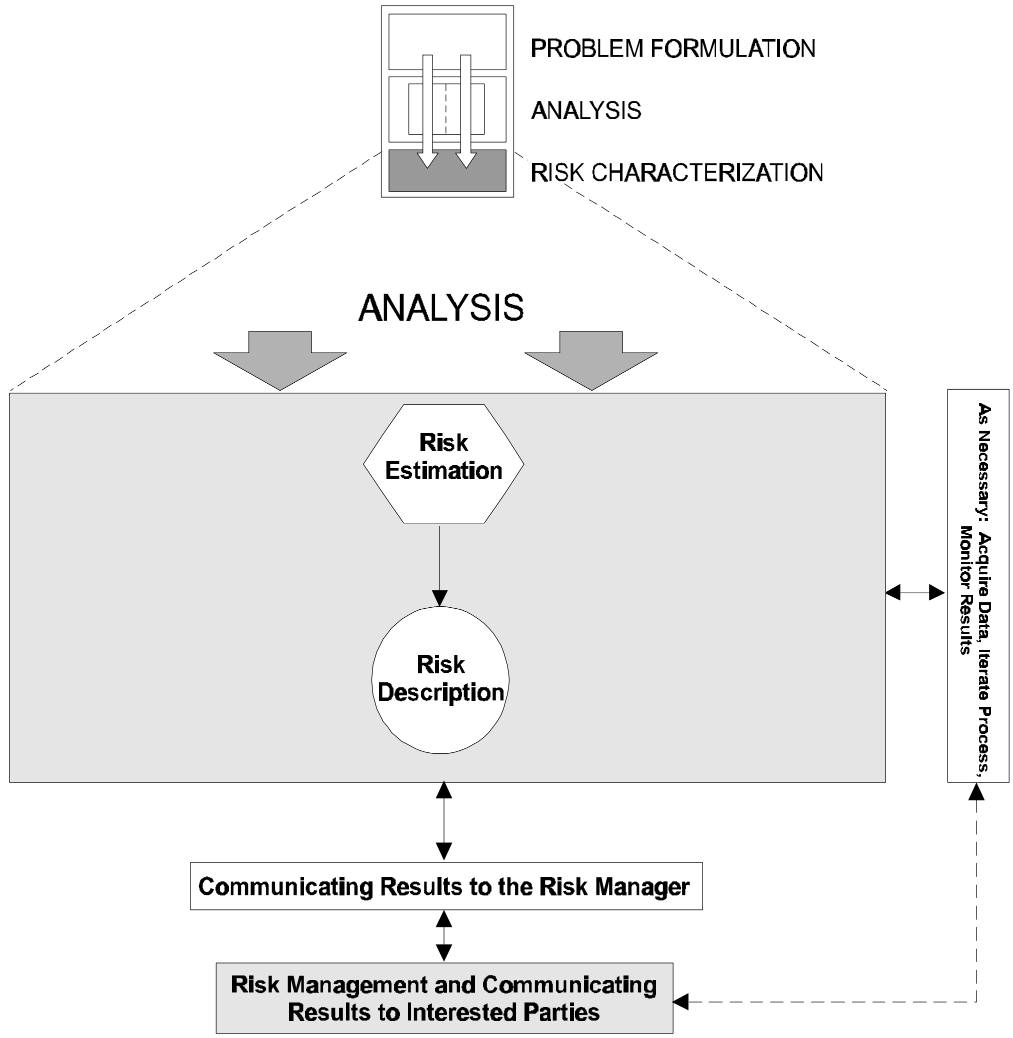

Figure 5-1. Risk characterization.

5.1.1. Results of Field Observational Studies

Field observational studies (surveys) can serve as risk estimation techniques because they provide empirical evidence linking exposure to effects. Field surveys measure biological changes in natural settings through collection of exposure and effects data for ecological entities identified in problem formulation.

A major advantage of field surveys is that they can be used to evaluate multiple stressors and complex ecosystem relationships that cannot be replicated in the laboratory. Field surveys are designed to delineate both exposures and effects (including secondary effects) found in natural systems, whereas estimates generated from laboratory studies generally delineate either exposures or effects under controlled or prescribed conditions (see text box 5-1).

While field studies may best represent reality, as with other kinds of studies they can be limited by (1) a lack of replication, (2) bias in obtaining representative samples, or (3) failure to measure critical components of the system or random variations. Further, a lack of observed effects in a field survey may occur because the measurements lack the sensitivity to detect ecological effects. See section 4.1.1 for additional discussion of the strengths and limitations of different types of data.

Several assumptions or qualifications need to be clearly articulated when describing the results of field surveys. A primary qualification is whether a causal relationship between stressors and effects (section 4.3.1.2) is supported. Unless causal relationships are carefully examined, conclusions about effects that are observed may be inaccurate because the effects are caused by factors unrelated to the stressor(s) of concern. In addition, field surveys taken at one point in time are usually not predictive; they describe effects associated only with exposure scenarios associated with past and existing conditions.

Text Box 5-1. An Example of Field Methods Used for Risk Estimation

Along with quotients comparing field measures of exposure with laboratory acute toxicity data (see Text Box 5-3), EPA evaluated the risks of granular carbofuran to birds based on incidents of bird kills following carbofuran applications. More than 40 incidents involving nearly 30 species of birds were documented. Although reviewers identified problems with individual field studies (e.g., lack of appropriate control sites, lack of data on carcass-search efficiencies, no examination of potential synergistic effects of other pesticides, and lack of consideration of other potential receptors such as small mammals), there was so much evidence of mortality associated with carbofuran application that the study deficiencies did not alter the conclusions of high risk found by the assessment (Houseknecht, 1993).

5.1.2. Categories and Rankings

In some cases, professional judgment or other qualitative evaluation techniques may be used to rank risks using categories, such as low, medium, and high, or yes and no. This approach is most frequently used when exposure and effects data are limited or are not easily expressed in quantitative terms. The U.S. Forest Service risk assessment of pest introduction from importation of logs from Chile used qualitative categories owing to limitations in both the exposure and effects data for the introduced species of concern as well as the resources available for the assessment (see text box 5-2).

> **Text Box 5-2. Using Qualitative Categories to Estimate Risks of an Introduced Species**
>
> The importation of logs from Chile required an assessment of the risks posed by the potential introduction of the bark beetle, *Hylurgus ligniperda* (USDA, 1993). Experts judged the potential for colonization and spread of the species, and their opinions were expressed as high, medium, or low as to the likelihood of establishment (exposure) or consequential effects of the beetle. Uncertainties were similarly expressed. A ranking scheme was then used to sum the individual elements into an overall estimate of risk (high, medium, or low). Narrative explanations of risk accompanied the overall rankings.

Ranking techniques can be used to translate qualitative judgment into a mathematical comparison. These methods are frequently used in comparative risk exercises. For example, Harris et al. (1994) evaluated risk reduction opportunities in Green Bay (Lake Michigan), Wisconsin, employing an expert panel to compare the relative risk of several stressors against their potential effects. Mathematical analysis based on fuzzy set theory was used to rank the risk from each stressor from a number of perspectives, including degree of immediate risk, duration of impacts, and prevention and remediation management. The results served to rank potential environmental risks from stressors based on best professional judgment.

5.1.3. Single-Point Exposure and Effects Comparisons

When sufficient data are available to quantify exposure and effects estimates, the simplest approach for comparing the estimates is a ratio (figure 5-2a). Typically, the ratio (or quotient) is expressed as an exposure concentration divided by an effects concentration. Quotients are commonly used for chemical stressors, where reference or benchmark toxicity values are widely available (see text box 5-3).

The principal advantages of the quotient method are that it is simple and quick to use and risk assessors and managers are familiar with its application. It provides an efficient, inexpensive means of identifying high- or low-risk situations that can allow risk management decisions to be made without the need for further information.

Quotients have also been used to integrate the risks of multiple chemical stressors: quotients for the individual constituents in a mixture are generated by dividing each exposure

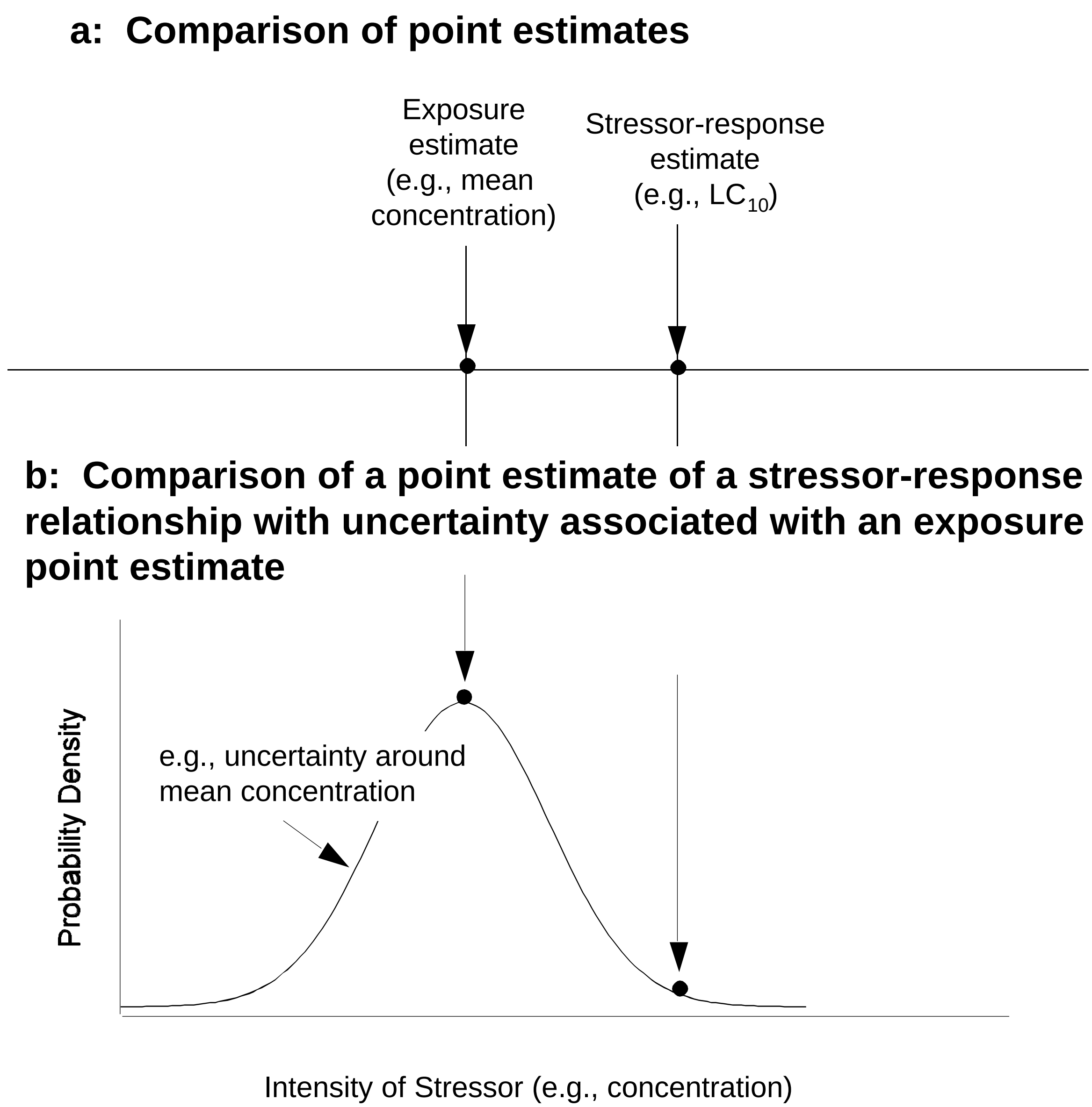

Figure 5-2. Risk estimation techniques. a. Comparison of exposure and stressor-response point estimates. b. Comparison of a point estimate from the stressor-response relationship with uncertainty associated with an exposure point estimate.

level by a corresponding toxicity endpoint (e.g., LC_{50}, EC_{50}, NOAEL). Although the toxicity of a chemical mixture may be greater than or less than predicted from the toxicities of individual constituents of the mixture, a quotient addition approach assumes that toxicities are additive or approximately additive. This assumption may be most applicable when the modes of action of chemicals in a mixture are similar, but there is evidence that even with chemicals having dissimilar modes of action, additive or near-additive interactions are common (Könemann, 1981; Broderius, 1991; Broderius et al., 1995; Hermens et al., 1984a, b; McCarty and Mackay, 1993; Sawyer and

Safe, 1985). However, caution should be used when assuming that chemicals in a mixture act independently of one another, since many of the supporting studies were conducted with aquatic organisms, and so may not be relevant for other endpoints, exposure scenarios, or species. When the modes of action for constituent chemicals are unknown, the assumptions and rationale concerning chemical interactions should be clearly stated.

A number of limitations restrict application of the quotient method (see Smith and Cairns, 1993; Suter, 1993a). While a quotient can be useful in answering whether risks are high or low, it may not be helpful to a risk manager who needs to make a decision requiring an incremental quantification of risks. For example, it is seldom useful to say that a risk mitigation approach will reduce a quotient value from 25 to 12, since this reduction cannot by itself be clearly interpreted in terms of effects on an assessment endpoint.

Text Box 5-3. Applying the Quotient Method

When applying the quotient method to chemical stressors, the effects concentration or dose (e.g., an LC_{50}, LD_{50}, EC_{50}, ED_{50}, NOAEL, or LOAEL) is frequently adjusted by uncertainty factors before division into the exposure number (U.S. EPA, 1984; Nabholz, 1991; Urban and Cook, 1986; see section 4.3.1.3), although EPA used a slightly different approach in estimating the risks to the survival of birds that forage in agricultural areas where the pesticide granular carbofuran is applied (Houseknecht, 1993). In this case, EPA calculated the quotient by dividing the estimated exposure levels of carbofuran granules in surface soils (number/ft^2) by the granules/LD_{50} derived from single-dose avian toxicity tests. The calculation yields values with units of LD_{50}/ft^2. It was assumed that a higher quotient value corresponded to an increased likelihood that a bird would be exposed to lethal levels of granular carbofuran at the soil surface. Minimum and maximum values for LD_{50}/ft^2 were estimated for songbirds, upland game birds, and waterfowl that may forage within or near 10 different agricultural crops.

Other limitations of quotients may be caused by deficiencies in the problem formulation and analysis phases. For example, an LC_{50} derived from a 96-hour laboratory test using constant exposure levels may not be appropriate for an assessment of effects on reproduction resulting from short-term, pulsed exposures.

In addition, the quotient method may not be the most appropriate method for predicting secondary effects (although such effects may be inferred). Interactions and effects beyond what are predicted from the simple quotient may be critical to characterizing the full extent of impacts from exposure to the stressors (e.g., bioaccumulation, eutrophication, loss of prey species, opportunities for invasive species).

Finally, in most cases, the quotient method does not explicitly consider uncertainty (e.g., extrapolation from tested species to the species or community of concern). Some uncertainties, however, can be incorporated into single-point estimates to provide a statement of likelihood that the effects point estimate exceeds the exposure point estimate (figures 5-2b and 5-3). If exposure variability is quantified, then the point estimate of effects can be compared with a cumulative

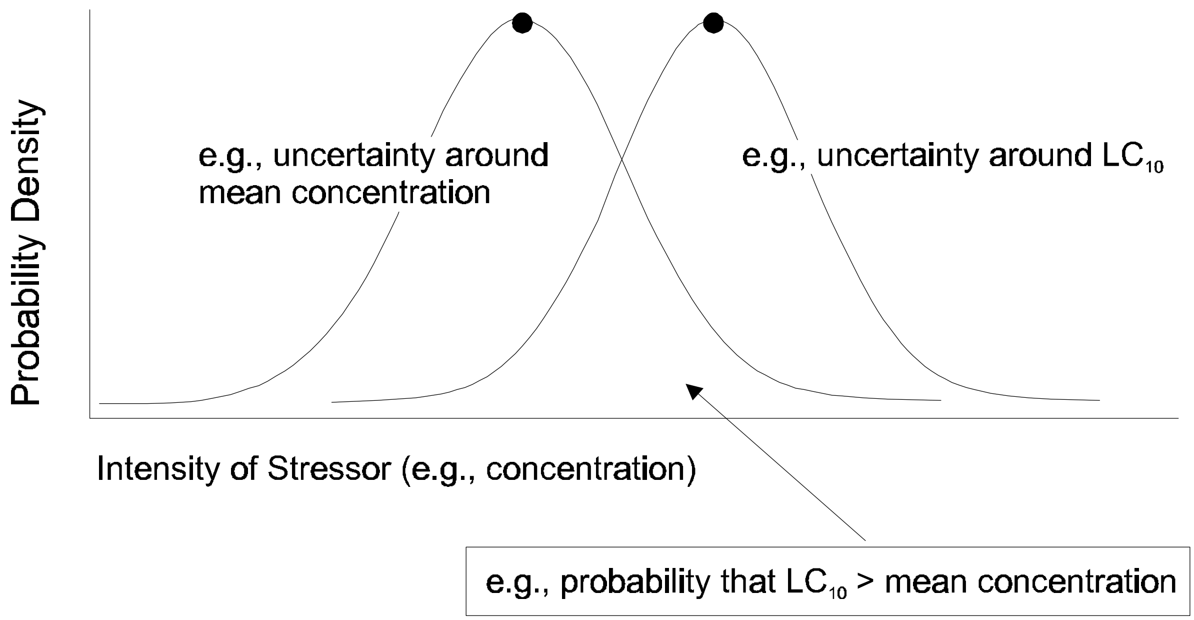

Figure 5-3. Risk estimation techniques: comparison of point estimates with associated uncertainties.

exposure distribution as described in text box 5-4. Further discussion of comparisons between point estimates of effects and distributions of exposure may be found in Suter et al., 1983.

In view of the advantages and limitations of the quotient method, it is important for risk assessors to consider the points listed below when evaluating quotient method estimates.

- How does the effect concentration relate to the assessment endpoint?
- What extrapolations are involved?
- How does the point estimate of exposure relate to potential spatial and temporal variability in exposure?
- Are data sufficient to provide confidence intervals on the endpoints?

5.1.4. Comparisons Incorporating the Entire Stressor-Response Relationship

If a curve relating the stressor level to the magnitude of response is available, then risk estimation can examine risks associated with many different levels of exposure (figure 5-4). These estimates are particularly useful when the risk assessment outcome is not based on exceedance of a predetermined decision rule, such as a toxicity benchmark level.

There are advantages and limitations to comparing a stressor-response curve with an exposure distribution. The slope of the effects curve shows the magnitude of change in effects associated with incremental changes in exposure, and the capability to predict changes in the magnitude and likelihood of effects for different exposure scenarios can be used to compare different risk management options. Also, uncertainty can be incorporated by calculating uncertainty bounds on the stressor-response or exposure estimates. Comparing exposure and stressor-response curves provides a predictive ability lacking in the quotient method. Like the quotient method, however, limitations from the problem formulation and analysis phases may limit the utility of the results. These limitations may include not fully considering secondary effects, assuming the exposure pattern used to derive the stressor-response curve is comparable to the environmental exposure pattern, and failure to consider uncertainties, such as extrapolations from tested species to the species or community of concern.

Text Box 5-4. Comparing an Exposure Distribution With a Point Estimate of Effects

The EPA Office of Pollution Prevention and Toxics uses a Probabilistic Dilution Model (PDM3) to generate a distribution of daily average chemical concentrations based on estimated variations in stream flow in a model system. The PDM3 model compares this exposure distribution with an aquatic toxicity test endpoint to estimate how many days in a 1-year period the endpoint concentration is exceeded (Nabholz et al., 1993; U.S. EPA, 1988b). The frequency of exceedance is based on the duration of the toxicity test used to derive the effects endpoint. Thus, if the endpoint was an acute toxicity level of concern, an exceedance would be identified if the level of concern was exceeded for 4 days or more (not necessarily consecutive). The exposure estimates are conservative in that they assume instantaneous mixing of the chemical in the water column and no losses due to physical, chemical, or biodegradation effects.

5.1.5. Comparisons Incorporating Variability in Exposure and/or Effects

If the exposure or stressor-response profiles describe the variability in exposure or effects, then many different risk estimates can be calculated. Variability in exposure can be used to estimate risks to moderately or highly exposed members of a population being investigated, while variability in effects can be used to estimate risks to average or sensitive population

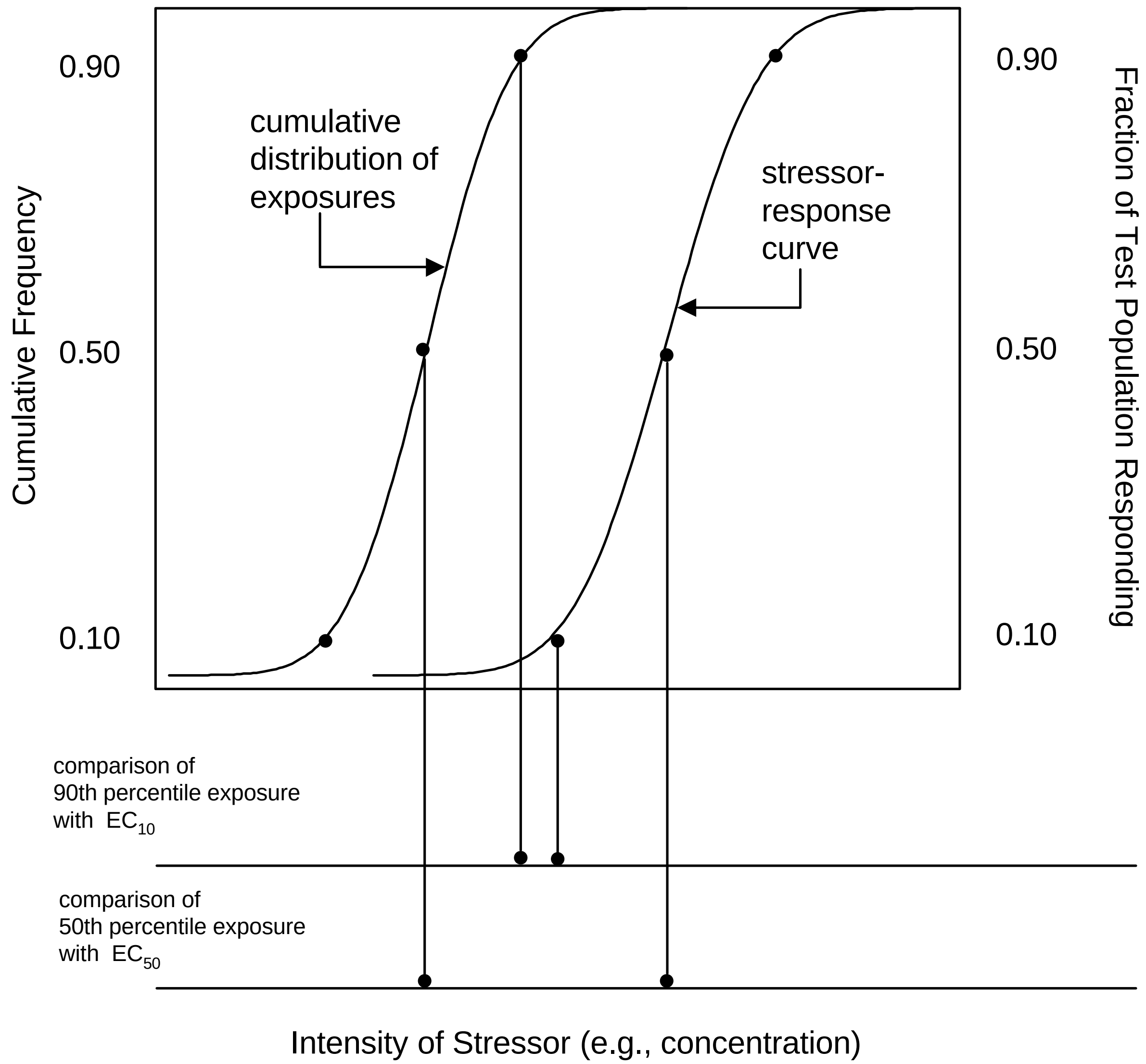

Figure 5-4. Risk estimation techniques: stressor-response curve versus a cumulative distribution of exposures.

members. A major advantage of this approach is its ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios and thus provide a means for comparing different risk management options. As noted above, comparing distributions also allows one to identify and quantify risks to different segments of the population. Limitations include the increased data requirements compared with previously described techniques and the implicit assumption that the full range of variability in the exposure and effects data is adequately

represented. As with the quotient method, secondary effects are not readily evaluated with this technique. Thus, it is desirable to corroborate risks estimated by distributional comparisons with
field studies or other lines of evidence. Text box 5-5 and figure 5-5 illustrate the use of cumulative exposure and effects distributions for estimating risk.

Text Box 5-5. Comparing Cumulative Exposure and Effects Distributions for Chemical Stressors

Exposure distributions for chemical stressors can be compared with effects distributions derived from point estimates of acute or chronic toxicity values for different species (e.g., HCN, 1993; Cardwell et al., 1993; Baker et al., 1994; Solomon et al., 1996). Figure 5-5 shows a distribution of exposure concentrations of an herbicide compared with single-species toxicity data for algae (and one vascular plant species) for the same chemical. The degree of overlap of the curves indicates the likelihood that a certain percentage of species may be adversely affected. For example, figure 5-5 indicates that the 10th centile of algal species' EC_5 values is exceeded less than 10% of the time.

The predictive value of this approach is evident. The degree of risk reduction that could be achieved by changes in exposure associated with proposed risk mitigation options can be readily determined by comparing modified exposure distributions with the effects distribution curve.

When using effects distributions derived from single-species toxicity data, risk assessors should consider the following questions:

- Does the subset of species for which toxicity test data are available represent the range of species present in the environment?
- Are particularly sensitive (or insensitive) groups of organisms represented in the distribution?
- If a criterion level is selected—e.g., protect 95% of species—does the 5% of potentially affected species include organisms of ecological, commercial, or recreational significance?

5.1.6. Application of Process Models

Process models are mathematical expressions that represent our understanding of the mechanistic operation of a system under evaluation. They can be useful tools in both analysis (see section 4.1.2) and risk characterization. For illustrative purposes, it is useful to distinguish between analysis process models, which focus individually on either exposure or effects evaluations, and risk estimation process models, which integrate exposure and effects information (see text box 5-6). The assessment of risks associated with long-term changes in hydrologic conditions in bottomland forest wetlands in Louisiana using the FORFLO model (Appendix D) linked the attributes and placement of levees and corresponding water level measurements (exposure) with changes in forest community structure and wildlife habitat suitability (effects).

A major advantage of using process models for risk estimation is the ability to consider "what if" scenarios and to forecast beyond the limits of observed data that constrain techniques based solely on empirical data. The process model can also consider secondary

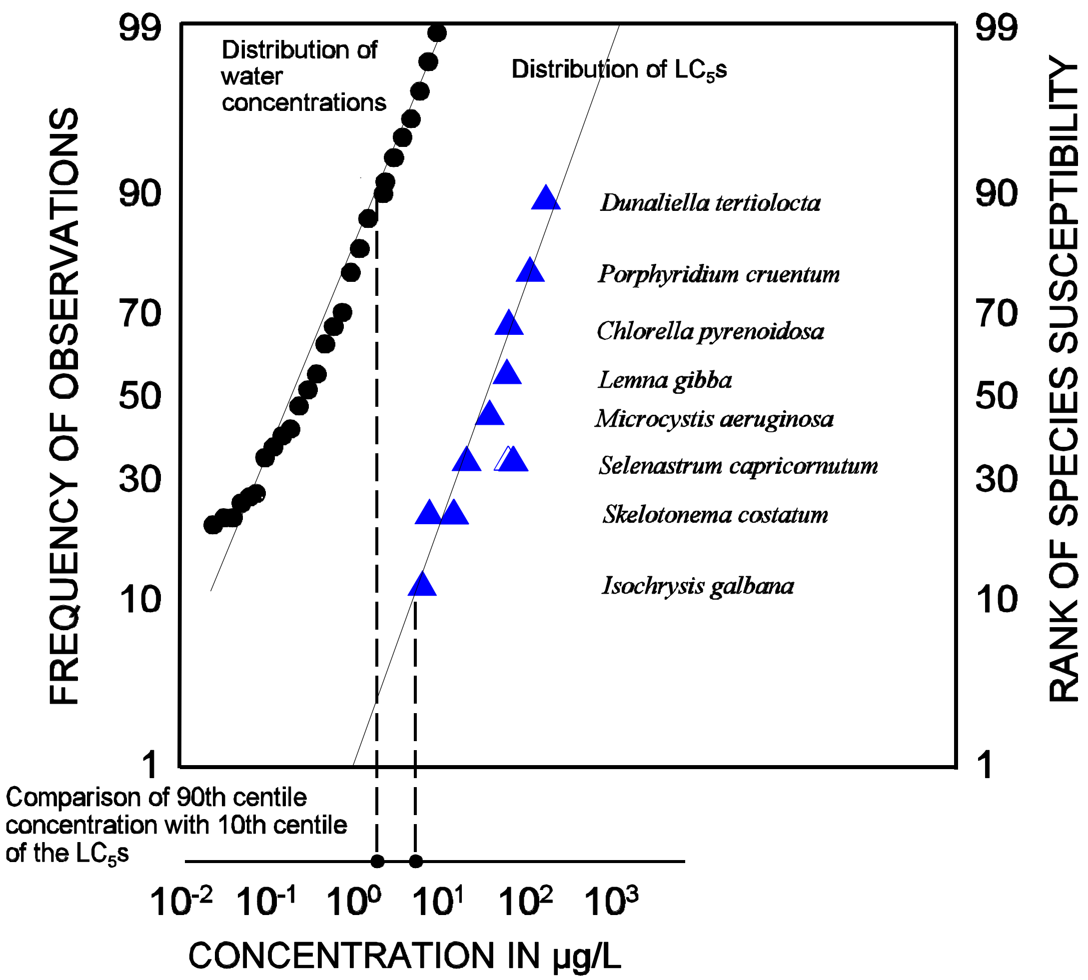

Figure 5-5. Risk estimation techniques: comparison of exposure distribution of an herbicide in surface waters with freshwater single-species toxicity data. See text box 5-4 for further discussion. Redrawn from Baker et al., 1994. (Centile ranks for species LC_5 data were obtained using the formula (100 x *n*/[N+1]), where *n* is the rank number of the LC_5 and *N* is the total number of data points in the set; adapted from Parkhurst et al., 1995).

effects, unlike other risk estimation techniques such as the quotient method or comparisons of exposure and effect distributions. In addition, some process models can forecast the combined effects of multiple stressors, such as the effects of multiple chemicals on fish population sustainability (Barnthouse et al., 1990).

Process model outputs may be point estimates, distributions, or correlations; in all cases, risk assessors should interpret them with care. They may imply a higher level of certainty than is appropriate and are all too often viewed without sufficient attention to underlying assumptions. The lack of knowledge on basic life histories for many species and incomplete knowledge on the structure and function of a particular ecosystem is often lost in the model output. Since process models are only as good as the assumptions on which they are based, they should be treated as hypothetical representations of reality until appropriately tested with empirical data. Comparing model results to field data provides a check on whether our understanding of the system was correct (Johnson, 1995), particularly with respect to the risk hypotheses presented in problem formulation.

Text Box 5-6. Estimating Risk With Process Models

Models that integrate both exposure and effects information can be used to estimate risk. During risk estimation, it is important that both the strengths and limitations of a process model approach be highlighted. Brody et al. (1993; see Appendix D) linked two process models to integrate exposure and effects information and forecast spatial and temporal changes in forest communities and their wildlife habitat value. While the models were useful for projecting long-term effects based on an understanding of the underlying mechanisms of change in forest communities and wildlife habitat, they could not evaluate all possible stressors of concern and were limited in the plant and wildlife species they could consider. Understanding both the strengths and limitations of models is essential for accurately representing the overall confidence in the assessment.

5.2. RISK DESCRIPTION

Following preparation of the risk estimate, risk assessors need to interpret and discuss the available information about risks to the assessment endpoints. Risk description includes an evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the significance of the adverse effects on the assessment endpoints. During the analysis phase, the risk assessor may have established the relationship between the assessment endpoints and measures of effect and associated lines of evidence in quantifiable, easily described terms (section 4.3.1.3). If not, the risk assessor can relate the available lines of evidence to the assessment endpoints using qualitative links. Regardless of the risk estimation technique, the technical narrative supporting the risk estimate is as important as the risk estimate itself.

5.2.1. Lines of Evidence

The development of lines of evidence provides both a process and a framework for reaching a conclusion regarding confidence in the risk estimate. It is not the kind of proof demanded by experimentalists (Fox, 1991), nor is it a rigorous examination of weights of evidence. (Note that the term “weight of evidence” is sometimes used in legal discussions or in other documents, e.g., Urban and Cook, 1986; Menzie et al., 1996.) The phrase *lines of evidence* is used to de-emphasize the balancing of opposing factors based on assignment of quantitative values to reach a conclusion about a “weight” in favor of a more inclusive approach, which evaluates all available information, even evidence that may be qualitative in nature. It is important that risk assessors provide a thorough representation of all lines of evidence developed in the risk assessment rather than simply reduce their interpretation and description of the ecological effects that may result from exposure to stressors to a system of numeric calculations and results.

Confidence in the conclusions of a risk assessment may be increased by using several lines of evidence to interpret and compare risk estimates. These lines of evidence may be derived from different sources or by different techniques relevant to adverse effects on the assessment endpoints, such as quotient estimates, modeling results, or field observational studies.

There are three principal categories of factors for risk assessors to consider when evaluating lines of evidence: (1) adequacy and quality of data, (2) degree and type of uncertainty associated with the evidence, and (3) relationship of the evidence to the risk assessment questions (see also sections 3 and 4).

Data quality directly influences how confident risk assessors can be in the results of a study and conclusions they may draw from it. Specific concerns to consider for individual lines of evidence include whether the experimental design was appropriate for the questions posed in a particular study and whether data quality objectives were clear and adhered to. An evaluation of the scientific understanding of natural variability in the attributes of the ecological entities under consideration is important in determining whether there were sufficient data to satisfy the analyses chosen and to determine if the analyses were sufficiently sensitive and robust to identify stressor-caused perturbations.

Directly related to data quality issues is the evaluation of the relative uncertainties of each line of evidence. One major source of uncertainty comes from extrapolations. The greater the number of extrapolations, the more uncertainty introduced into a study. For example, were extrapolations used to infer effects in one species from another, or from one temporal or spatial scale to another? Were conclusions drawn from extrapolations from laboratory to field effects, or were field effects inferred from limited information, such as chemical structure-activity relationships? Were no-effect or low-effect levels used to address likelihood of effects? Risk assessors should consider these and any other sources of uncertainty when evaluating the relative importance of particular lines of evidence.

Finally, how directly lines of evidence relate to the questions asked in the risk assessment may determine their relative importance in terms of the ecological entity and the attributes of the assessment endpoint. Lines of evidence directly related to the risk hypotheses, and those that establish a cause-and-effect relationship based on a definitive mechanism rather than associations alone, are likely to be of greatest importance.

The evaluation process, however, involves more than just listing the evidence that supports or refutes the risk estimate. The risk assessor should carefully examine each factor and evaluate its contribution in the context of the risk assessment. The importance of lines of evidence is that each and every factor is described and interpreted. Data or study results are often not reported or carried forward in the risk assessment because they are of insufficient quality. If such data or results are eliminated from the evaluation process, however, valuable information may be lost with respect to needed improvements in methodologies or recommendations for further studies.

As a case in point, consider the two lines of evidence described for the carbofuran example (see text boxes 5-1 and 5-3), field studies and quotients. Both approaches are relevant to the assessment endpoint (survival of birds that forage in agricultural areas where carbofuran is applied), and both are relevant to the exposure scenarios described in the conceptual model (see figure D-1). The quotients, however, are limited in their ability to express incremental risks (e.g., how much greater risk is expressed by a quotient of "2" versus a quotient of "4"), while the field studies had some design flaws (see text box 5-1). Nevertheless, because of the strong evidence of causal relationships from the field studies and consistency with the laboratory-derived quotient, confidence in a conclusion of high risk to the assessment endpoint is supported.

Sometimes lines of evidence do not point toward the same conclusion. It is important to investigate possible reasons for any disagreement rather than ignore inconvenient evidence. A starting point is to distinguish between true inconsistencies and those related to differences in statistical powers of detection. For example, a model may predict adverse effects that were not observed in a field survey. The risk assessor should ask whether the experimental design of the field study had sufficient power to detect the predicted difference or whether the endpoints measured were comparable with those used in the model. Conversely, the model may have been unrealistic in its predictions. While iteration of the risk assessment process and collection of additional data may help resolve uncertainties, this option is not always available.

Lines of evidence that are to be evaluated during risk characterization should be defined early in the risk assessment (during problem formulation) through the development of the conceptual model and selection of assessment endpoints. Further, the analysis plan should incorporate measures that will contribute to the interpretation of the lines of evidence, including methods of reviewing, analyzing, and summarizing the uncertainty in the risk assessment.

Also, risk assessments often rely solely on laboratory or in situ bioassays to assess adverse effects that may occur as a result of exposure to stressors. Although they may not be manifested in the field, ecological effects demonstrated in the laboratory should not be discounted as a line of evidence.

5.2.2. Determining Ecological Adversity

At this point in risk characterization, the changes expected in the assessment endpoints have been estimated and the supporting lines of evidence evaluated. The next step is to interpret whether these changes are considered adverse. Adverse ecological effects, in this context, represent changes that are undesirable because they alter valued structural or functional attributes of the ecological entities under consideration. The risk assessor evaluates the degree of adversity, which is often a difficult task and is frequently based on the risk assessor's professional judgment.

When the results of the risk assessment are discussed with the risk manager (section 6), other factors, such as the economic, legal, or social consequences of ecological damage, should be considered. The risk manager will use all of this information to determine whether a particular adverse effect is acceptable and may also find it useful when communicating the risk to interested parties.

The following are criteria for evaluating adverse changes in assessment endpoints:

- Nature of effects and intensity of effects
- Spatial and temporal scale
- Potential for recovery.

The extent to which the criteria are evaluated depends on the scope and complexity of the risk assessment. Understanding the underlying assumptions and science policy judgments, however, is important even in simple cases. For example, when exceedance of a previously established decision rule, such as a benchmark stressor level, is used as evidence of adversity (e.g., see Urban and Cook, 1986, or Nabholz, 1991), the reasons why this is considered adverse should be clearly understood. In addition, any evaluation of adversity should examine all relevant criteria, since none are considered singularly determinative.

To distinguish adverse ecological changes from those within the normal pattern of ecosystem variability or those resulting in little or no significant alteration of biota, it is important to consider the nature and intensity of effects. For example, for an assessment endpoint involving survival, growth, and reproduction of a species, do predicted effects involve survival and reproduction or only growth? If survival of offspring will be affected, by what percentage will it diminish?

It is important for risk assessors to consider both the ecological and statistical contexts of an effect when evaluating intensity. For example, a statistically significant 1% decrease in fish growth (see text box 5-7) may not be relevant to an assessment endpoint of fish population viability, and a 10% decline in reproduction may be worse for a population of slowly reproducing trees than for rapidly reproducing planktonic algae.

Natural ecosystem variation can make it very difficult to observe (detect) stressor-related perturbations. For example, natural fluctuations in marine fish populations are often large, with intra- and interannual variability in population levels covering several orders of magnitude. Furthermore, cyclic events of various periods (e.g., bird migration, tides) are very important in natural systems and may mask or delay stressor-related effects. Predicting the effects of anthropogenic stressors against this background of variation can be very difficult. Thus, a lack of statistically significant effects in a field study does not automatically mean that adverse ecological effects are absent. Rather, risk assessors should then consider other lines of evidence in reaching their conclusions.

It is also important to consider the location of the effect within the biological hierarchy and the mechanisms that may result in ecological changes. The risk assessor may rely on mechanistic explanations to describe complex ecological interactions and the resulting effects that otherwise may be masked by variability in the ecological components.

The boundaries (global, landscape, ecosystem, organism) of the risk assessment are initially identified in the analysis plan prepared during problem formulation. These spatial and temporal scales are further defined in the analysis phase, where specific exposure and effects scenarios are evaluated. The spatial dimension encompasses both the extent and pattern of effect as well as the context of the effect within the landscape. Factors to consider include the absolute area affected, the extent of critical habitats affected compared with a larger area of interest, and the role or use of the affected area within the landscape.

Adverse effects to assessment endpoints vary with the absolute area of the effect. A larger affected area may be (1) subject to a greater number of other stressors, increasing the complications from stressor interactions, (2) more likely to contain sensitive species or habitats, or (3) more susceptible to landscape-level changes because many ecosystems may be altered by the stressors.

Nevertheless, a smaller area of effect is not always associated with lower risk. The function of an area within the landscape may be more important than the absolute area. Destruction of small but unique areas, such as critical wetlands, may have important effects on local and regional wildlife populations. Also, in river systems, both riffle and pool areas provide important microhabitats that maintain the structure and function of the

Text Box 5-7. What Are Statistically Significant Effects?

Statistical testing is the "statistical procedure or decision rule that leads to establishing the truth or falsity of a hypothesis . . ." (Alder and Roessler, 1972). Statistical significance is based on the number of data points, the nature of their distribution, whether intertreatment variance exceeds intratreatment variance in the data, and the a priori significance level (α). The types of statistical tests and the appropriate protocols (e.g., power of test) for these tests should be established as part of the analysis plan during problem formulation.

total river ecosystem. Stressors acting on these microhabitats may result in adverse effects to the entire system.

Spatial factors are important for many species because of the linkages between ecological landscapes and population dynamics. Linkages between landscapes can provide refuge for affected populations, and organisms may require corridors between habitat patches for successful migration.

The temporal scale for ecosystems can vary from seconds (photosynthesis, prokaryotic reproduction) to centuries (global climate change). Changes within a forest ecosystem can occur gradually over decades or centuries and may be affected by slowly changing external factors such as climate. When interpreting adversity, risk assessors should recognize that the time scale of stressor-induced changes operates within the context of multiple natural time scales. In addition, temporal responses for ecosystems may involve intrinsic time lags, so responses to a stressor may be delayed. Thus, it is important to distinguish a stressor's long-term impacts from its immediately visible effects. For example, visible changes resulting from eutrophication of aquatic systems (turbidity, excessive macrophyte growth, population decline) may not become evident for many years after initial increases in nutrient levels.

Considering the temporal scale of adverse effects leads logically to a consideration of recovery. Recovery is the rate and extent of return of a population or community to some aspect of its condition prior to a stressor's introduction. (While this discussion deals with recovery as a result of natural processes, risk mitigation options may include restoration activities to facilitate or speed up the recovery process.) Because ecosystems are dynamic and, even under natural conditions, constantly changing in response to changes in the physical environment (e.g., weather, natural disturbances) or other factors, it is unrealistic to expect that a system will remain static at some level or return to exactly the same state that it was before it was disturbed (Landis et al., 1993). Thus, the attributes of a "recovered" system should be carefully defined. Examples might include productivity declines in a eutrophic system, reestablishment of a species at a particular density, species recolonization of a damaged habitat, or the restoration of health of diseased organisms. The Agency considered the recovery rate of biological communities in streams and rivers from disturbances in setting exceedance frequencies for chemical stressors in waste effluents (U.S. EPA, 1991).

Recovery can be evaluated in spite of the difficulty in predicting events in ecological systems (e.g., Niemi et al., 1990). For example, it is possible to distinguish changes that are usually reversible (e.g., stream recovery from sewage effluent discharge), frequently irreversible (e.g., establishment of introduced species), and always irreversible (e.g., extinction). Risk assessors should consider the potential irreversibility of significant structural or functional changes in ecosystems or ecosystem components when evaluating adversity. Physical alterations such as deforestation in the coastal hills of Venezuela in recent history and in Britain during the Neolithic period, for example, changed soil structure and seed sources such that forests cannot easily grow again (Fisher and Woodmansee, 1994).

The relative rate of recovery can also be estimated. For instance, fish populations in a stream are likely to recover much faster from exposure to a degradable chemical than from habitat alterations resulting from stream channelization. Risk assessors can use knowledge of factors, such as the temporal scales of organisms' life histories, the availability of adequate stock for recruitment, and the interspecific and trophic dynamics of the populations, in evaluating the relative rates of recovery. A fisheries stock or forest might recover in decades, a benthic invertebrate community in years, and a planktonic community in weeks to months.

Risk assessors should note natural disturbance patterns when evaluating the likelihood of recovery from anthropogenic stressors. Alternatively, if an ecosystem has become adapted to a disturbance pattern, it may be affected when the disturbance is removed (e.g., fire-maintained grasslands). The lack of natural analogs makes it difficult to predict recovery from uniquely anthropogenic stressors (e.g., synthetic chemicals).

Appendix E illustrates how the criteria for ecological adversity (nature and intensity of effects, spatial and temporal scales, and recovery) might be used in evaluating two cleanup options for a marine oil spill. This example also shows that recovery of a system depends not only on how quickly a stressor is removed, but also on how the cleanup efforts themselves affect the recovery.

5.3. REPORTING RISKS

When risk characterization is complete, risk assessors should be able to estimate ecological risks, indicate the overall degree of confidence in the risk estimates, cite lines of evidence supporting the risk estimates, and interpret the adversity of ecological effects. Usually this information is included in a risk assessment report (sometimes referred to as a risk characterization report because of the integrative nature of risk characterization). While the breadth of ecological risk assessment precludes providing a detailed outline of reporting elements, the risk assessor should consider the elements listed in text box 5-8 when preparing a risk assessment report.

Like the risk assessment itself, a risk assessment report may be brief or extensive, depending on the nature of and the resources available for the assessment. While it is important to address the elements described in text box 5-8, risk assessors should judge the level of detail required. The report need not be overly complex or lengthy; it is most important that the information required to support a risk management decision be presented clearly and concisely.

To facilitate mutual understanding, it is critical that the risk assessment results are properly presented. Agency policy requires that risk characterizations be prepared "in a manner that is *clear*, *transparent*, *reasonable*, and *consistent* with other risk characterizations of similar scope prepared across programs in the Agency" (U.S. EPA, 1995b). Ways to achieve such characteristics are described in text box 5-9.

After the risk assessment report is prepared, the results are discussed with risk managers. Section 6 provides information on communication between risk assessors and risk managers, describes the use of the risk assessment in a risk management context, and briefly discusses communication of risk assessment results from risk managers to interested parties and the general public.

Text Box 5-8. Possible Risk Assessment Report Elements

- Describe risk assessor/risk manager planning results.
- Review the conceptual model and the assessment endpoints.
- Discuss the major data sources and analytical procedures used.
- Review the stressor-response and exposure profiles.
- Describe risks to the assessment endpoints, including risk estimates and adversity evaluations.
- Review and summarize major areas of uncertainty (as well as their direction) and the approaches used to address them.
  - Discuss the degree of scientific consensus in key areas of uncertainty.
  - Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results.
  - Discuss science policy judgments or default assumptions used to bridge information gaps and the basis for these assumptions.
  - Discuss how the elements of quantitative uncertainty analysis are embedded in the estimate of risk.

Text Box 5-9. Clear, Transparent, Reasonable, and Consistent Risk Characterizations

For clarity:

- Be brief; avoid jargon.
- Make language and organization understandable to risk managers and the informed lay person.
- Fully discuss and explain unusual issues specific to a particular risk assessment.

For transparency:

- Identify the scientific conclusions separately from policy judgments.
- Clearly articulate major differing viewpoints of scientific judgments.
- Define and explain the risk assessment purpose (e.g., regulatory purpose, policy analysis, priority setting).
- Fully explain assumptions and biases (scientific and policy).

For reasonableness:

- Integrate all components into an overall conclusion of risk that is complete, informative, and useful in decision making.
- Acknowledge uncertainties and assumptions in a forthright manner.
- Describe key data as experimental, state-of-the-art, or generally accepted scientific knowledge.
- Identify reasonable alternatives and conclusions that can be derived from the data.
- Define the level of effort (e.g., quick screen, extensive characterization) along with the reason(s) for selecting this level of effort.
- Explain the status of peer review.

For consistency with other risk characterizations:

- Describe how the risks posed by one set of stressors compare with the risks posed by a similar stressor(s) or similar environmental conditions.
- Indicate how the strengths and limitations of the assessment compare with past assessments.

6. RELATING ECOLOGICAL INFORMATION TO RISK MANAGEMENT DECISIONS

After characterizing risks and preparing a risk assessment report (section 5), risk assessors discuss the results with risk managers (figure 5-1). Risk managers use risk assessment results, along with other factors (e.g., economic or legal concerns), in making risk management decisions and as a basis for communicating risks to interested parties and the general public.

Mutual understanding between risk assessors and risk managers regarding risk assessment results can be facilitated if the questions listed in text box 6-1 are addressed. Risk managers need to know the major risks to assessment endpoints and have an idea of whether the conclusions are supported by a large body of data or if there are significant data gaps. Insufficient resources, lack of consensus, or other factors may preclude preparation of a detailed and well-documented risk characterization. If this is the case, the risk assessor should clearly articulate any issues, obstacles, and correctable deficiencies for the risk manager's consideration.

In making decisions regarding ecological risks, risk managers consider other information, such as social, economic, political, or legal issues in combination with risk assessment results. For example, the risk assessment results may be used as part of an ecological cost-benefit analysis, which may require translating resources (identified through the assessment endpoints) into monetary values. Traditional economic considerations may only partially address changes in ecological resources that are not considered commodities, intergenerational resource values, or issues of long-term or irreversible effects (U.S. EPA, 1995a; Costanza et al., 1997); however, they may

Text Box 6-1. Questions Regarding Risk Assessment Results (Adapted From U.S. EPA, 1993c)

Questions principally for risk assessors to ask risk managers:

- Are the risks sufficiently well defined (and data gaps small enough) to support a risk management decision?
- Was the right problem analyzed?
- Was the problem adequately characterized?

Questions principally for risk managers to ask risk assessors:

- What effects might occur?
- How adverse are the effects?
- How likely is it that effects will occur?
- When and where do the effects occur?
- How confident are you in the conclusions of the risk assessment?
- What are the critical data gaps, and will information be available in the near future to fill these gaps?
- Are more ecological risk assessment iterations required?
- How could monitoring help evaluate the results of the risk management decision?

provide a means of comparing the results of the risk assessment in commensurate units such as costs. Risk managers may also consider alternative strategies for reducing risks, such as risk mitigation options or substitutions based on relative risk comparisons. For example, risk mitigation techniques, such as buffer strips or lower field application rates, can be used to reduce the exposure (and risk) of a pesticide. Further, by comparing the risk of a new pesticide to other pesticides currently in use during the registration process, lower overall risk may result. Finally, risk managers consider and incorporate public opinion and political demands into their decisions. Collectively, these other factors may render very high risks acceptable or very low risks unacceptable.

Risk characterization provides the basis for communicating ecological risks to interested parties and the general public. This task is usually the responsibility of risk managers, but it may be shared with risk assessors. Although the final risk assessment document (including its risk characterization sections) can be made available to the public, the risk communication process is best served by tailoring information to a particular audience. Irrespective of the specific format, it is important to clearly describe the ecological resources at risk, their value, and the monetary and other costs of protecting (and failing to protect) the resources (U.S. EPA, 1995a).

Managers should clearly describe the sources and causes of risks and the potential adversity of the risks (e.g., nature and intensity, spatial and temporal scale, and recovery potential). The degree of confidence in the risk assessment, the rationale for the risk management decision, and the options for reducing risk are also important (U.S. EPA, 1995a). Other risk communication considerations are provided in text box 6-2.

Text Box 6-2. Risk Communication Considerations for Risk Managers (U.S. EPA, 1995b)

- Plan carefully and evaluate the success of your communication efforts.
- Coordinate and collaborate with other credible sources.
- Accept and involve the public as a legitimate partner.
- Listen to the public's specific concerns.
- Be honest, frank, and open.
- Speak clearly and with compassion.
- Meet the needs of the media.

Along with discussions of risk and communications with the public, it is important for risk managers to consider whether additional follow-on activities are required. Depending on the importance of the assessment, confidence in its results, and available resources, it may be advisable to conduct another iteration of the risk assessment (starting with problem formulation or analysis) in order to support a final management decision. Another option is to proceed with the decision, implement the selected management alternative, and develop a monitoring plan to evaluate the results (see section 1). If the decision is to mitigate risks through exposure reduction, for example, monitoring could help determine whether the desired reduction in exposure (and effects) is achieved.