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February 1992

PEER REVIEW WORKSHOP REPORT

ON A

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

Risk Assessment Forum
U.S. Environmental Protection Agency
Washington, DC 20460

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CONTENTS

APPENDIX A MEETING MATERIALS

APPENDIX B PREMEETING MATERIALS

LIST OF FIGURES

TABLES

ACKNOWLEGEMENTS

Many individuals contributed to this report. James Fava, Lawrence Barnthouse, Mark Harwell, Kenneth Reckhow, and James Falco prepared the chairperson's summary and, prior to the workshop, worked with the U.S. Environmental Protection Agency (EPA) staff to plan the meeting. William van der Schalie, the Risk Assessment Forum coordinator for ecological effects, coordinated all workshop and document development activities with the assistance of William Wood, associate staff director for the Forum. Susan Brager of Eastern Research Group, Inc., an EPA contractor, worked with Dr. van der Schalie, Dr. Wood, and Dr. Fava in all phases of this project, providing administrative and logistical support.

FOREWARD

In 1986, EPA issued five guidelines for health risk assessment (51 Federal Register 33992-34054, September 24, 1986). Based on a 10-year effort, these guidelines set forth risk assessment principles, concepts, and methods for cancer, developmental effects, mutagenic effects, exposure, and chemical mixtures. Since then, EPA has developed guidance in other health risk areas, for a total of nine guidelines for health risk assessment in various phases of development. During this period, individual EPA programs have generated program-specific guidance for ecological effects, but none has been developed for EPA as a whole.

At the behest of the EPA Risk Assessment Council, EPA's Risk Assessment Forum has sponsored three activities related to the development of Agency-wide ecological risk assessment guidelines: (1) compilation of case studies to illustrate the state of the practice in ecological assessments; (2) preparation of a long-term plan for developing ecological risk assessment guidelines; and (3) development of a framework for ecological risk assessments that will offer a simple and flexible structure for conducting and evaluating ecological risk assessments at EPA. The proposed framework also is intended to contribute organizing principles for future ecological risk assessment guidelines and is expected to evolve with experience.

A seven-person EPA workgroup, chaired by Susan Norton, Donald Rodier, and Suzanne Marcy, prepared a draft EPA report entitled "Framework for Ecological Risk Assessment" (framework draft), which incorporates comments from EPA reviewers on earlier drafts. The framework draft also benefitted from insights gained at a February 1991 National Academy of Sciences (NAS) Conference held at the Airlie House in Warrenton, Virginia, and from recommendations of EPA's Science Advisory Board.

Ecologists and ecotoxicologists from academia, consulting firms, and Government (State and Federal) brought expertise in a wide range of relevant disciplines to the Risk Assessment Forum's May 1991 peer review workshop for the framework draft. EPA did not expect to cover all of the many principles, concepts, and methods that are important for ecological risk assessment in this one workshop. Rather, EPA asked for expert opinion on the logic, scientific validity, and utility of the principles proposed in the framework draft as general guidance for EPA risk assessors. EPA expected the workshop participants to develop consensus on some parts of the document and useful recommendations for change on others. Members of the public and EPA scientific staff attended the workshop as observers.

The workshop was highly productive. Most significantly, the 20 peer reviewers, some of whom had participated in the February 1991 NAS workshop and EPA's April 1991 ecological risk strategic planning workshop, agreed during the discussion that the basic elements of the ecological risk assessment process, rather than substantive guidance, should be the focus of the final framework report. Accordingly, the peer reviewers developed information and identified issues to assist EPA in this task.

Dorothy E. Patton, Ph.D.
Chair
Risk Assessment Forum

PREFACE

On May 14, 1991, EPA convened a 3-day workshop in Rockville, Maryland, for discussion and peer review of the draft report "Framework for Ecological Risk Assessment" (56 Federal Register 20223; May 2, 1991). The framework draft and the workshop were part of a new EPA program for developing risk assessment guidelines for ecological effects.

This workshop report highlights issues and recommendations developed at the Rockville Workshop, which was chaired by Dr. James Fava of Roy F. Weston, Inc. The report features the chairperson's summary of the workshop findings and includes a copy of the framework draft that was the subject of the Rockville peer review. Based on the highly constructive and useful suggestions presented in the chairperson's summary, EPA is simplifying and streamlining the framework draft for publication in early 1992 as a step toward future development of EPA guidelines for ecological risk assessment.

1. INTRODUCTION

The U.S. Environmental Protection Agency (EPA) has established a program through its Risk Assessment Forum to develop ecological risk assessment guidelines. As part of this effort, EPA developed a draft technical framework document for ecological risk assessment. The technical framework will provide general guidance and promote consistency within EPA on the basic principles for conducting ecological risk assessments. The proposed framework also is intended to provide organizing principles for future ecological risk assessment guidelines in specific subject areas.

1.1. SCOPE AND ROLE OF THE PEER REVIEW PANEL

In order to improve the technical basis for ecological risk assessment guidelines, EPA requested an independent peer review of the draft "Framework for Ecological Risk Assessment," which was prepared by the Risk Assessment Forum (EPA, 1991). A panel of 20 experts (see table 1) participated in the peer review. These individuals represent expertise in a wide range of disciplines and experience in ecological risk assessment.

1.2. PEER REVIEW PROCESS

The peer review of the draft framework involved three steps. First, the draft framework document was mailed to each reviewer; each reviewer then prepared comments that were distributed to all reviewers. Second, a peer review workshop was held to obtain an independent review of the logic, scientific validity, and utility of the principles that were proposed in the framework document as general guidance on ecological risk assessment. Consensus was reached on some parts of the document, and recommendations for change were made for other parts. Third, a written report was prepared, summarizing the results of the workshop and presenting the panel's recommendations to EPA. This report represents that third step.

EPA's draft "Framework for Ecological Risk Assessment" presents an ecological risk assessment paradigm based on the National Academy of Sciences (NAS) human health risk assessment paradigm, which was published in 1983 (NRC, 1983). The ecological risk assessment paradigm presented in the draft framework consists of four components (figure 1): conceptual framework, hazard assessment, exposure assessment, and risk characterization. One of the panel's recommendations is to use more ecologically relevant terms for three of these components: "problem definition/scoping" replaces "conceptual framework," "characterization of ecological effects" replaces "hazard assessment," and "characterization of stress" replaces "exposure assessment." These suggested terms are used throughout this summary report.

Because the peer reviewers' charge was to conduct an independent review of the draft framework and make suggestions to improve the framework, the panel's comments and recommendations follow the draft framework's organization. The panel's overall recommendations are presented in section 2; comments on the conceptual framework (problem definition/scoping) component are presented in section 3; suggestions on exposure assessment (characterization of stress) and hazard assessment (characterization of ecological effects) are presented in sections 4 and 5; and, finally, comments on the risk characterization component are discussed in section 6.

Table 1. List of Participants

Workshop Chair

- James Fava, Roy F. Weston, Inc.

Workshop Topic Area Leaders

- Lawrence Barnthouse, Oak Ridge National Laboratory
- James Falco, Battelle Pacific Northwest Laboratory
- Mark Harwell, University of Miami
- Kenneth Reckhow, Duke University

Other Participants

- William Adams, ABC Laboratories
- John Bascietto, U.S. Department of Energy
- Raymond Beaumier, Ohio Environmental Protection Agency
- Harold Bergman, University of Wyoming
- Nigel Blakeley, Washington Department of Ecology
- Alyce Fritz, National Oceanic and Atmospheric Administration
- James Gillett, Cornell University
- Michael Harrass, U.S. Food and Drug Administration
- Ronald Kendall, Clemson University
- Wayne Landis, Western Washington University
- Ralph Portier, Louisiana State University
- John Rodgers, University of Mississippi
- Peter Van Voris, Battelle Pacific Northwest Laboratory
- James Weinberg, Woods Hole Oceanographic Institution
- Randall Wentsel, U.S. Army Chemical Research, Development and Engineering Center

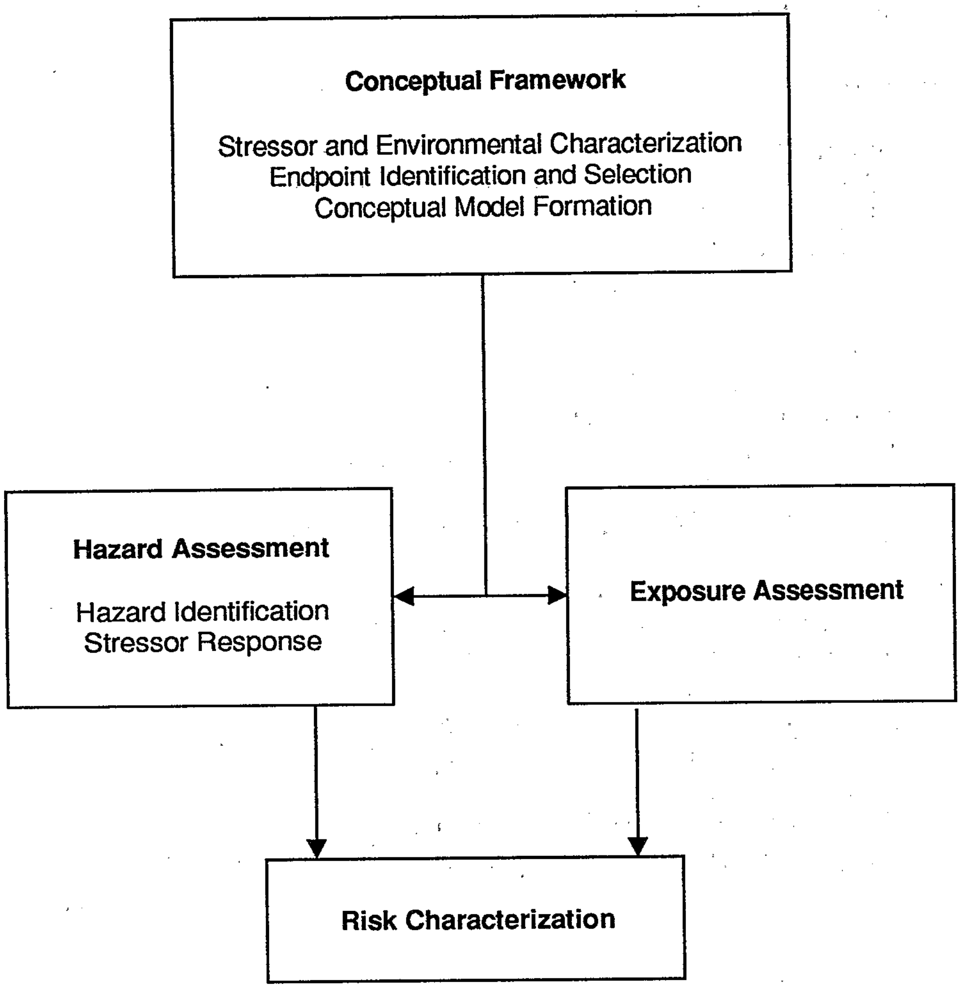


Figure 1. EPA's Draft Ecological Risk Assessment Paradigm

2. OVERALL COMMENTS AND RECOMMENDATIONS

The peer review panel would like to express appreciation for the opportunity to participate in the peer review of the draft "Framework for Ecological Risk Assessment." The panel is pleased to provide assistance in preparing a framework that EPA and the Risk Assessment Forum have indicated will be the underlying foundation from which ecological risk assessment guidelines will be developed. The individuals within EPA who prepared the draft framework should be commended for an excellent job, and the panel would like to recognize the performance of those individuals at EPA who prepared the draft document for review.

While the panel was mostly positive about the draft framework document, members were in consensus that there are issues associated with ecological risk assessment that can only be addressed more broadly throughout EPA. These issues and the panel's recommendations are presented below.

2.1. OVERALL RECOMMENDATIONS

EPA's management structure and approach to ecological risk assessment should be examined. During the workshop, there was considerable discussion about the importance of conducting ecological risk assessments in an integrated fashion. Because of the importance of effectively using interdisciplinary teams to perform ecological risk assessments, the panel believes that the current EPA organization should be critically examined to identify ways to foster and facilitate the effective implementation of consistent and comprehensive ecological risk assessments. For example, the current separation of the exposure and hazard assessment technical staffs in different branches, which might inhibit such integration, should be carefully considered.

Ecological risk assessment terminology should be standardized throughout EPA. A terminology workgroup should be formed to provide Agency-wide consistency. Once EPA produces the framework, strategic plans, and guidelines documents, the terminology for ecological risk assessment used by other agencies will probably follow EPA's lead.

2.2. SPECIFIC RECOMMENDATIONS TO IMPROVE THE ECOLOGICAL RISK ASSESSMENT PARADIGM

One of the first and major areas of discussion by the panel was the draft ecological risk assessment paradigm developed by EPA. The panel agreed that, while using the National Academy of Sciences (NAS) human health risk assessment paradigm as a basis was a good idea, that model should not be adopted directly. There are many important differences between ecological and human health risk assessment. For example, ecological risk assessment must include consideration of stressors other than chemicals for evaluation. Also, ecological risk assessment concerns multiple species, populations, communities, and ecosystem levels, while human health risk assessments focus on one species.

EPA should develop a paradigm for ecological risk assessment and then, if desired, reference how the NAS human health risk assessment is similar to or is related to the ecological risk assessment. Consistent with this recommendation, the panel strongly believes that the definitions for the components of the ecological risk assessment paradigm should be ecologically based, not human health based. Also, the panel recommends that EPA refer to the ecological risk assessment paradigm as a framework. Throughout the remainder of this report, the panel will refer to the overall ecological risk assessment paradigm as the ecological risk assessment framework.

After much discussion, ***the panel developed a modified ecological risk assessment framework.*** The modified framework is based on the one developed by EPA (see figure 1). Because the panel recognizes EPA's desire to maintain similarity with the NAS human health risk assessment framework, the modified framework presented here (figure 2) should be viewed as an evolution of the NAS framework, recognizing distinct differences between human health and ecological risk assessment. The panel would like to emphasize that the modified framework is presented to EPA for review and consideration. As EPA evaluates and develops the Technical Framework for Ecological Risk Assessment, the panel's modified framework should be used as the basis for that development.

Several major distinctions were incorporated into the modified framework. For ecological risk assessment, the framework must be able to incorporate both chemical and nonchemical stressors. Thus, the panel suggests the term "characterization of stress" as a replacement for the term "exposure assessment," which was used in the draft framework. (Exposure assessment is generally perceived as referring to chemical exposure.) Second, ecological risk assessments must be able to incorporate potential effects at various levels of biological organization (e.g., population, community, and ecosystem). The panel recommends that EPA use the term "characterization of ecological effects" rather than "hazard assessment," as used in the draft framework. Using the suggested term will help eliminate the inconsistent use of the term "hazard assessment," which has come to have several different meanings.

Third, while ecological risk assessment must be considered a scientific and technical process, the panel recognizes that policy influences ecological risk assessment. The reviewers believe that policy input would be appropriate for the components of problem definition/scoping and risk characterization. However, the analysis sections of the characterization of stress and ecological effects must be allowed to proceed without policy influence. The panel agrees that risk assessors have the responsibility to present scientific and technical recommendations as a key output of ecological risk assessment. The panel also agrees that the final decision-making and risk management must take other factors into account that are not addressed during the ecological risk assessment. Therefore, the panel supports the need for a risk management component outside the ecological risk assessment framework.

Fourth, the draft framework describes two distinct components for hazard assessment and exposure assessment. The panel believes strongly that these two components are not separate activities that can proceed side by side, but are, in fact, interrelated. The modified framework indicates this interrelationship as such, by including the two within one box with a dotted line between them. The acceptance and recognition of this important element of ecological risk assessment have implications for how the assessments are performed. Along with an understanding of this interrelationship, the panel recommends that for ecological risk assessment to proceed, a team approach with qualified individuals is required.

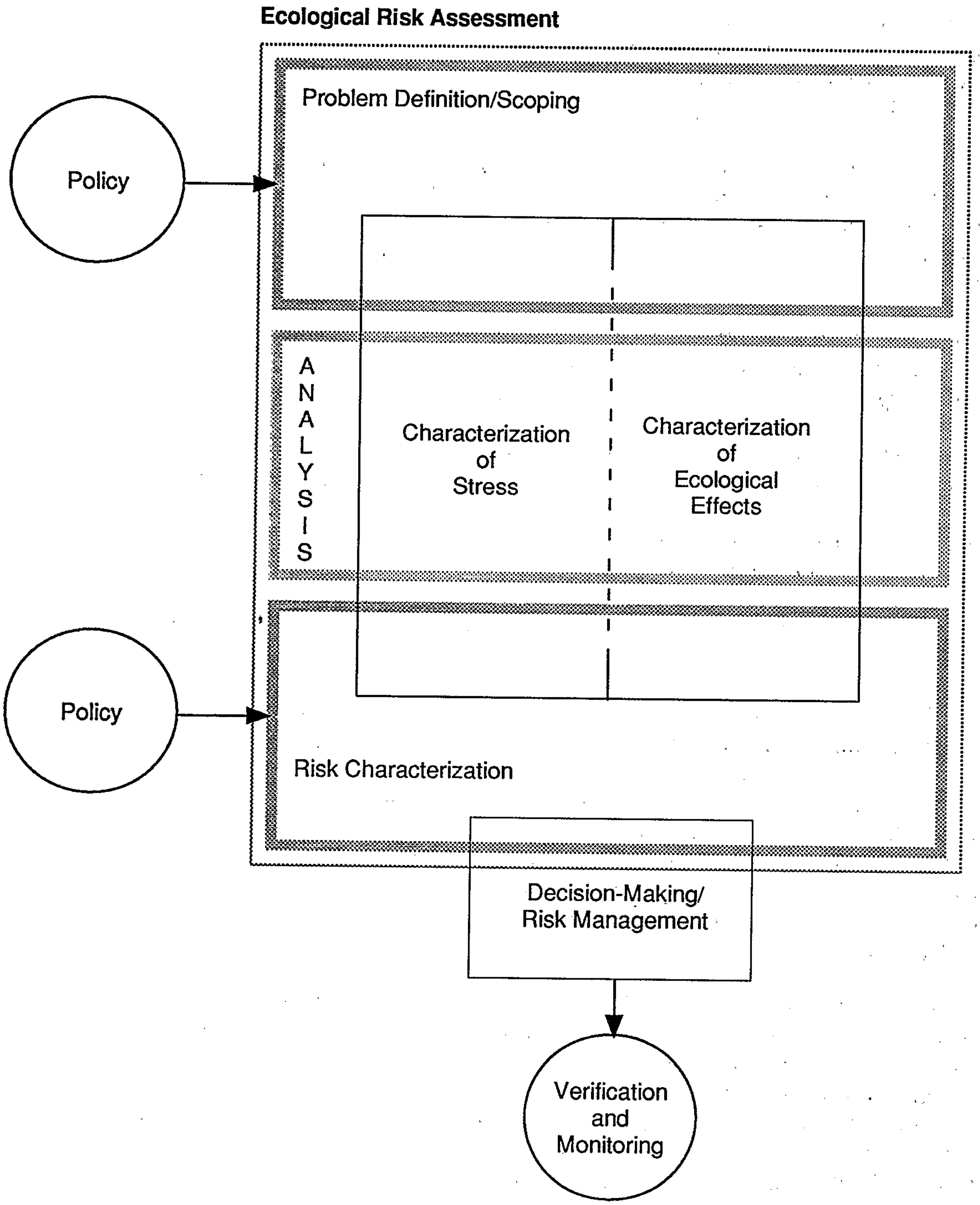


Figure 2. Ecological Risk Assessment Framework

2.3. IMPORTANCE OF VERIFICATION, MONITORING, AND RESEARCH

EPA should adopt a long-term program to verify, monitor, and conduct research to improve ecological risk assessment. The reviewers spent considerable time discussing the importance of using verification, monitoring, and research to improve the framework and tools of ecological risk assessment. The interrelationship among these components is shown in figure 3.

The panel debated whether verification and monitoring should be included within the ecological risk assessment framework. Reviewers strongly agreed that verification and monitoring are essential to (1) determine the overall effectiveness of the ecological risk assessment framework; (2) provide feedback to adjust and improve the framework in future years; (3) provide feedback to evaluate the effectiveness and practicality of current policy and help adjust policy, as necessary; and (4) provide feedback on scientific analysis of the framework to help identify requirements for new or improved scientific tools. The foregoing interrelationships underscore the adaptive nature of ecological risk assessment, which cannot be cast in concrete but, rather, must involve learning about and living with natural systems.

Because overall verification is not included within the ecological risk assessment framework, EPA must develop and perform the necessary verification within its other programs. Whether current efforts for monitoring (e.g., the Environmental Monitoring and Assessment Program [EMAP]) are adequate is unknown. However, the panel believes that other forms of verification (e.g., quality assurance/quality control (QA/QC)) are inadequate to meet the specified needs. Focused efforts are needed to evaluate and verify the effectiveness of the ecological risk assessment framework as it is being applied. For example, in the Superfund program or the Toxic Substances Program, sites and decisions must be revisited and their effectiveness must be determined.

The framework document should discuss the dichotomy between the ideal ecological risk assessment, as outlined in the developed framework, and the practicalities of present assessments by EPA. Clearly the need to balance the framework between ideal and practical considerations is critical to the successful use of the framework. Presenting ecological risk assessment too idealistically, without clarification of what is currently practicable, will establish unrealistic expectations. On the other hand, presenting ecological risk assessment only as it is practiced today will establish expectations that are too low, will reduce the likelihood of scientific advances, and will fail to meet the anticipatory needs of EPA in addressing the priority ecological risks identified by the Science Advisory Board (SAB, 1990).

To fill the gap between the ideal and current risk assessments, EPA should establish a research program that is focused to meet the ideal ecological risk assessment framework. The relationship among research, monitoring and verification, and improved ecological risk assessment tools is presented in figure 3. The panel strongly recommends that EPA use the developed framework as the foundation not only for ecological risk assessment guidelines, but also for focused long-term research, monitoring, and verification programs. Much of ecological risk assessment also requires a more substantial commitment to basic research in both the biological and physical sciences. While there are many documents that discuss the research needs of ecological risk assessment, one document that might be useful to review is "Research Priorities in Environmental Risk Assessments" (SETAC, 1987).

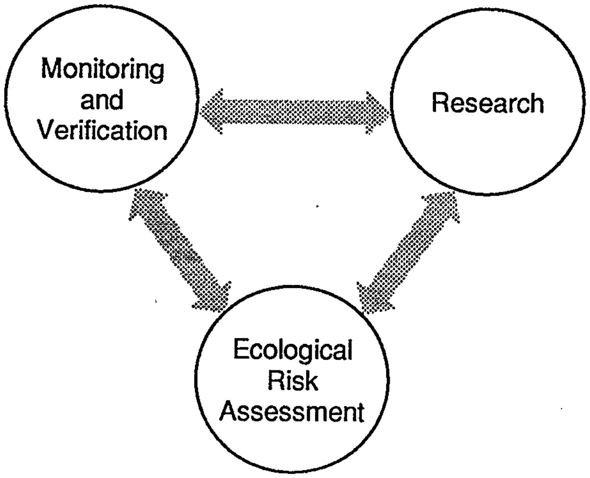


Figure 3. Relationship Among Research, Monitoring and Verification, and Improved Ecological Risk Assessment Tools

2.4. ISSUES RELATED TO OVERALL FRAMEWORK

The framework document should be limited to the discussion of the first and second levels of flowcharts (see figures included in this report). Because of the evolving science and application of ecological risk assessment, more detailed presentations of methods should be included in the guidelines to be developed. A more detailed discussion of the state of the practice also should be part of the various guidelines and technical support documents proposed as part of the ecological risk assessment strategic planning process.

The framework document should provide guidance in addressing ecological risk assessment as a tiered approach. The panel also discussed the use of tiered approaches during the analysis phase of ecological risk assessment. Ecological risk assessments differ in the breadth and depth of the required data collection and analysis. A tiered approach would offer the opportunity to approach ecological risk assessments from basic data sets (e.g., LD_{50} and LC_{50}) or from requirements for more complex data sets (e.g., field studies). Of critical concern are the triggers (or decision points) that would move an ecological risk assessment from a lower case data requirement, to a more sophisticated study, to full-scale field studies providing complex interactive data. Movement through the tiers according to perceived data needs for evaluating certain ecological risks must be carefully considered. Also, field validation using at least one appropriate model system (e.g., stream, lake, cropland, rangeland) should be designed and implemented to test the ecological risk assessment process. In other words, how confident (or how uncertain) are the predictions that a certain chemical or nonchemical stressor might cause an aberration in the environment? Examples of some triggers to more extensive data collection and analysis are the following:

- Specific regulatory requirements.
- Serious consequences associated with potential impacts.
- Lack of adequate data for extrapolations needed to proceed from the measurement endpoints to the assessment endpoints.
- Potential for irreversible consequences.

The state of the practice of ecological risk assessment constitutes an expert judgment process with a range of methodologies, including qualitative and quantitative tools. Another topic of discussion was the use of the quotient method in ecological risk assessment. The panel was concerned about the limitations of the quotient method and strongly recommended that EPA develop or expand its research program to investigate innovative ways to integrate data for making risk characterizations. The quotient method should be used in ecological risk assessment only in the context of wise use of professional judgment and should not exceed professional judgment during decision-making. Another suggestion was the addition of a range of values in the numerator and denominator used in the quotient method.

Given the importance of professional judgment in the final decision-making process, the panel recommended that EPA incorporate language into the final framework document to express the need for qualified environmental scientists and ecologists to participate in ecological risk assessments.

The issues associated with uncertainty should be given much greater attention throughout the framework document. There are many different components of uncertainty, ranging from fundamental lack of understanding about ecological systems and anthropogenic stresses, to measurement error and natural stochasticity. Some aspects are reducible with further research; others are not. Consequently, environmental decision-making must proceed in the presence of uncertainties. The presence of uncertainties must be recognized throughout the ecological risk assessment process, and the types and magnitudes of the various components of uncertainty must be identified at each step in the process.

These discussions should be carefully worded to convey the sense of uncertainties without implying that little or nothing is known about ecological systems and their responses to anthropogenic activities. Discussion of uncertainties should include such issues as the use of sensitivity analyses, availability of qualitative and quantitative methods, precision versus accuracy, and QA/QC requirements.

The framework document should be written to ensure that it will not be outdated quickly, unless research illustrates that the basic framework needs revision. The panel emphasizes that the ecological risk assessment framework document should be conceptually sound in order to be the basis for future ecological risk assessment efforts, including guidelines. The panel strongly agrees that ecological risk assessment performance will improve greatly over the next 5 to 10 years as research enhances understanding of basic ecological processes and improves the tools. The scientific tools will be improved and our basic understanding will be enhanced. Thus, the guidelines, not the framework, will need to be revised.

The framework document should clearly state its objectives, the intended audience, and where the framework fits into the overall ecological risk assessment strategy. The document should be written so that it can be understood by decision-makers and risk assessors. It is recommended that professional editing be used to highlight the important points and terms in the document. One approach that should be considered is having sidebar information that could help communicate critical definitions and concepts without disrupting the flow of the text. Good examples of this approach are found in the policy-makers' summary document produced for the EPA Reports to Congress on global climate change and in the summary document of the Science Advisory Board's "Reducing Risks" report (SAB, 1990).

3. COMMENTS ON THE PROBLEM DEFINITION COMPONENT

The peer review panel decided that the term "problem definition/scoping" better represents the initial component of the framework than does the draft framework document's term "conceptual framework." There is a clear need to examine the nature of the specific environmental problem at hand initially and then to develop a conceptual model of the stress and its ecological response/recovery relationships for affected ecological systems. This is the objective of the problem definition component as recommended by the panel.

The panel recommends adoption of the problem definition component illustrated in figure 4 and recommends that the framework report elaborate on this component in the context of the overall revised ecological risk assessment framework discussed above. The following section suggests issues and concepts for elaboration in the framework document.

3.1. ISSUES RECOMMENDED FOR DISCUSSION IN THE FRAMEWORK DOCUMENT

Ecological risk assessment, unlike human health risk assessment, must address a diverse set of ecological systems, from tropical to arctic environments, deserts to lakes, and estuaries to alpine systems. For each type of ecological system, there is a wide array of specific properties that may be of concern with respect to human activities. These properties may cut across biological organizational levels, from the reproductive viability of a particular population with special ecological or economic importance, to community-level concerns for biodiversity, to ecosystem-level issues such as primary productivity or nutrient processing, and landscape-level issues of maintaining the spatial heterogeneity of a mosaic of ecosystems.

Human activities result in a plethora of environmental stresses, some of which are strictly xenobiotic (e.g., releases of certain pesticides), while others consist of changes in the frequency or intensity of natural physical conditions (e.g., global climate change or increased ultraviolet radiation from stratospheric ozone depletion). Typically, multiple anthropogenic stresses occur simultaneously, with potential interaction among stresses or in the response processes of biological systems. Ecological risk assessment may occur over much wider temporal and spatial scales than those for human health risk assessment.

Because of the great diversity of ecosystems, ecological components, and anthropogenic stresses, ecological risk assessment must be flexible and adaptive, and the specific data needs, analytical methodologies used, and interpretations made will vary considerably for different environmental problems. The initial step in ecological risk assessment, therefore, must be detailed *problem definition*, in which the characteristics of the ecological systems and anthropogenic stresses are sufficiently specified to guide the particular ecological risk assessment.

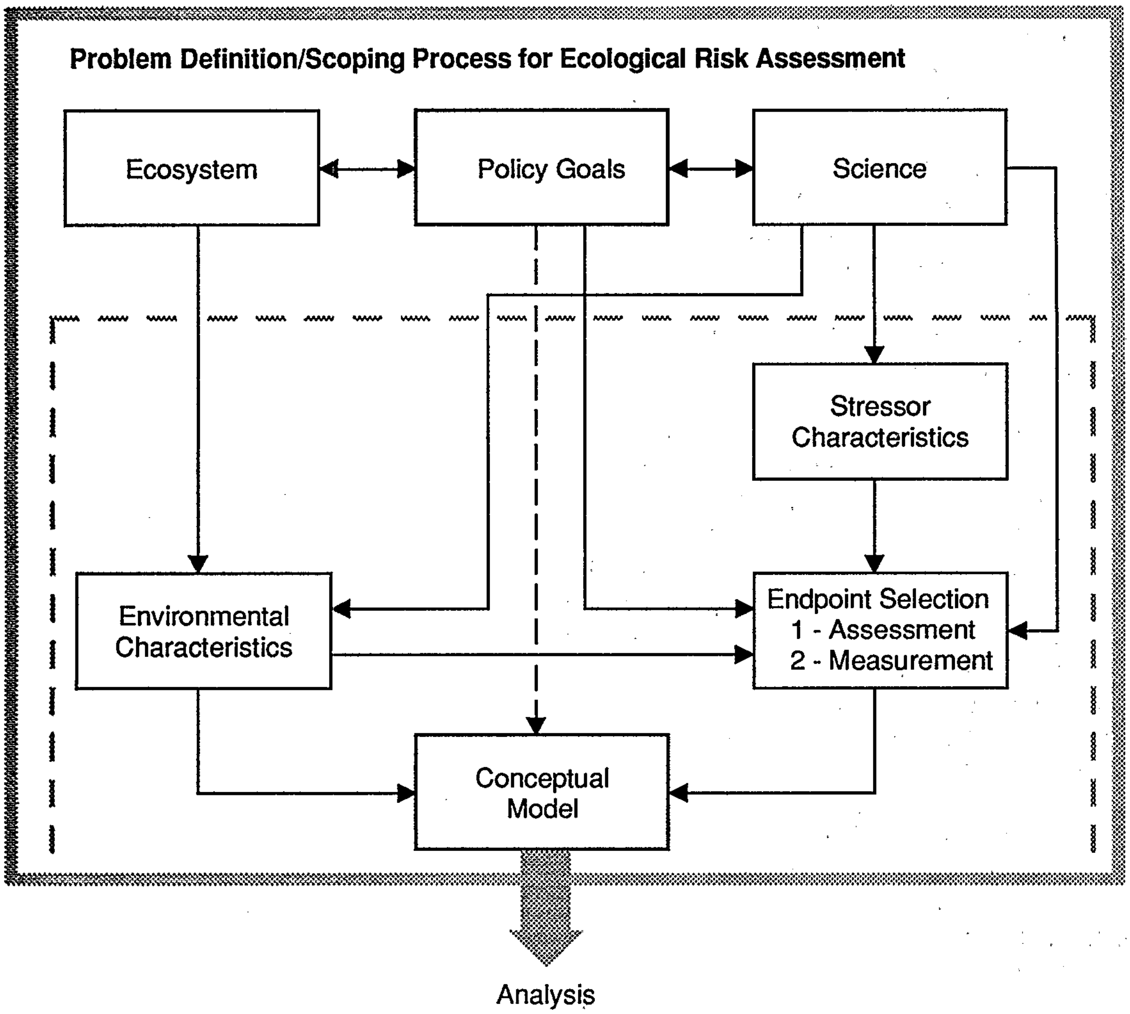


Figure 4. Problem Definition Component

The problem definition/scoping phase of ecological risk assessment is closely linked to the policy context of the environmental problem. The problem may be either stress-specific (such as the risks of a new chemical or of global climate change) or effects-driven (such as when forest damage is observed, and a risk assessment is conducted to explore possible causes). The policy connection comes through identifying the environmental problem of concern and, in some cases, through specification of the regulatory endpoints at issue. Here the term "regulatory endpoint" is defined as the legislative, regulatory, or judicial norm for decision-making (e.g., the Clean Water Act regulatory endpoints of "maintenance of a balanced indigenous population" and "unreasonable degradation of the marine environment").

The problem definition component should identify the particular ecological systems that are at risk from a particular stress. The stress must be examined sufficiently to define its direct and indirect target ecosystems, including consideration of such issues as the spatial extent of the stress, the potential for transport across ecosystem boundaries, the transformations of the stress, and other factors that relate to where in the environment the stress may occur. Using expert judgment with this and similar stresses will identify those ecological systems and ecological components that might be adversely affected by the stress.

Once the ecosystems of concern are specified, the problem definition component should include selection of the appropriate endpoints for conducting the ecological risk assessment. Two types of endpoints are required: *assessment* or *ecological endpoints* (i.e., the specific properties of each ecosystem at risk that are used to evaluate the state or change in state of the ecological system); and *measurement endpoints* or *indicators* (i.e., those aspects of the ecological system that are measured to characterize the assessment endpoints). First the assessment endpoints must be identified, with explicit attention to organizational hierarchy of the ecological system. A suite of assessment endpoints is usually necessary, covering the species-, community-, ecosystem-, and landscape-level concerns for the health of the at-risk ecosystem. The selection of assessment endpoints relates in part to the policy interests (e.g., to specified regulatory endpoints or to public concerns); thus, changes in assessment endpoints must be related ultimately to changes in things about the ecosystem that humans care about (anticipating the *so what?* question). But assessment endpoints are actually characteristics of the ecological systems and, thus, must reflect ecological importance. Changes in the selected endpoints would constitute changes in the health of the ecosystem. Moreover, the assessment endpoints selected are in part a function of the specific stress of concern; for example, a chemical stress suspected of causing avian eggshell thinning would logically have raptor population viability as one ecological assessment endpoint.

Similarly, measurement endpoints or indicators should be specified in the problem definition component. Each selected assessment endpoint should have one or more indicators that can be used to characterize the state or change of state of the endpoint. These are the items that are actually measured in a monitoring scheme or that represent data sought from a historical data base. The indicators may be selected also for relevance to the policy concerns, although that is not necessary. Indicators will be somewhat stress-specific, as is the case for endpoints. The ecological risk assessment guidelines should specify criteria for selecting both assessment endpoints and associated indicators.

The problem definition component should include a conceptual model, in which initial consideration of the stress-specific and ecosystem-specific situation is used to establish a working concept of how the stress might be imposed on the environment (i.e., a conceptual model of the stress regime) and how the ecological systems might respond and recover when exposed to the stress (i.e., a conceptual model of the ecological response/recovery regime). The conceptual model, perhaps comprising a set of testable hypotheses and assumptions, becomes the basis for entering the analysis phase of the ecological risk assessment (see figure 2).

3.2. OTHER RECOMMENDATIONS OF THE PANEL

In addition to the above-described framework for the problem definition component, the panel has several other recommendations for the framework development team. Many of the recommendations apply to the overall framework paradigm, not just the problem definition component.

The problem definition component should include a discussion of uncertainties. As an example, uncertainties about the ecosystems that might be at risk from a particular stress may, through the expert judgment process, result in inclusion of ecosystems with less obvious risks. As experience is gained for a particular stress type, the selection of ecosystems for examination in an ecological risk assessment may eliminate some ecosystems from consideration. Similarly, uncertainties may suggest that additional endpoints or indicators are required for evaluation of ecological risks. The initial conceptual model itself is limited by the uncertainties, and as the ecological risk assessment proceeds, or as experience is gained from similar ecological risk assessments, the conceptual model may be refined and improved. The adaptive aspect of ecological risk assessment must be explicitly recognized in the framework.

The framework document should specify an initial set of criteria for selecting ecological assessment endpoints and measurement indicators for ecological risk assessment. Examples of the criteria that should be specified for endpoints are ecological importance, relevance to regulatory endpoints and/or public concerns, stress-specificity or susceptibility, predictability, and the purpose or needs of the particular risk assessment. Examples of criteria that should be specified for indicators are relevance to the assessment endpoint, signal-to-noise ratio, early-warning ability, stress-specificity, ease or economy of measurement, availability of historical data, and predictability.

The framework document should include crisp examples of a few types of stresses, including at least one xenobiotic chemical example and one nonchemical stress example, such as climate change or habitat alteration. The selected examples should be used throughout the framework document to illustrate what is meant at each stage, from problem definition, endpoint and indicator selection, through stress and recovery regime analyses, to risk characterization.

4. COMMENTS ON THE CHARACTERIZATION OF STRESS COMPONENT

The peer review panel concluded that the term "characterization of stress" was preferred over the term "exposure assessment," because it better incorporates both chemical and nonchemical stressors. The panel developed a flowchart for the characterization of stress component (see figure 5).

Characterization of ecological stress requires consideration of a number of aspects. For chemical stressors, source characterization, which usually results in defined distribution and rates of release of chemical contaminants into the environment, must be considered. For other stressors, biological, chemical, or physical changes that are the causes of ecosystem stress are defined. Modification of the stressor by ecosystems also should be evaluated. For chemical stressors, such phenomena include transformation reactions that these chemicals may undergo and ecosystem conditions such as pH, which may alter reaction rates.

For all stress, ecosystems stressors must be characterized. This must be done in conjunction with ecological effects assessment because of the close relationship between these aspects of ecological risk assessment. Both abiotic and biotic features of ecosystems must be characterized.

Source and ecosystem characteristics are employed in model development, selection, and verification. These models are used to characterize the behavior of chemical stressors in the environment as well as to define the opportunity for exposures to ecosystems. For other stressors, these models are used to predict the extent and severity of the stress and the ecosystem components exposed to the stressors.

Finally, the results of modeling studies are evaluated and organized to establish a stressor profile that can be input to the risk characterization component (see figure 2). It should be emphasized that stressor analysis requires the skills of a multidisciplinary team. Such assessments should be carried out in conjunction with technical staff characterizing ecological effects to ensure that all overlapping aspects are addressed and to minimize duplication of effort.

4.1. RECOMMENDATIONS OF THE PANEL

Stress characterization should include description of scaling phenomena and the definition of heterogeneity of the ecosystem and ecosystem bounds. Both temporal and spatial aspects of scaling should be included. Under scaling phenomena, it should be emphasized that spatial extent as well as a temporal variation in stressor should be characterized. Time frames of interest include the time required to complete a nutrient cycle, the life span of individual species, and the life span of the ecosystem itself.

Characterizing the heterogeneity of the ecosystem should be emphasized. Heterogeneity in ecosystems is a major confounding factor in characterizing the behavior of contaminants and other stressors, and, in many cases, heterogeneity is a major factor in the maintenance or diminution of a species in a particular ecosystem. When migratory species are of interest, characterization of all occupied ecosystems and the role each ecosystem plays in the development of the species should be specified.

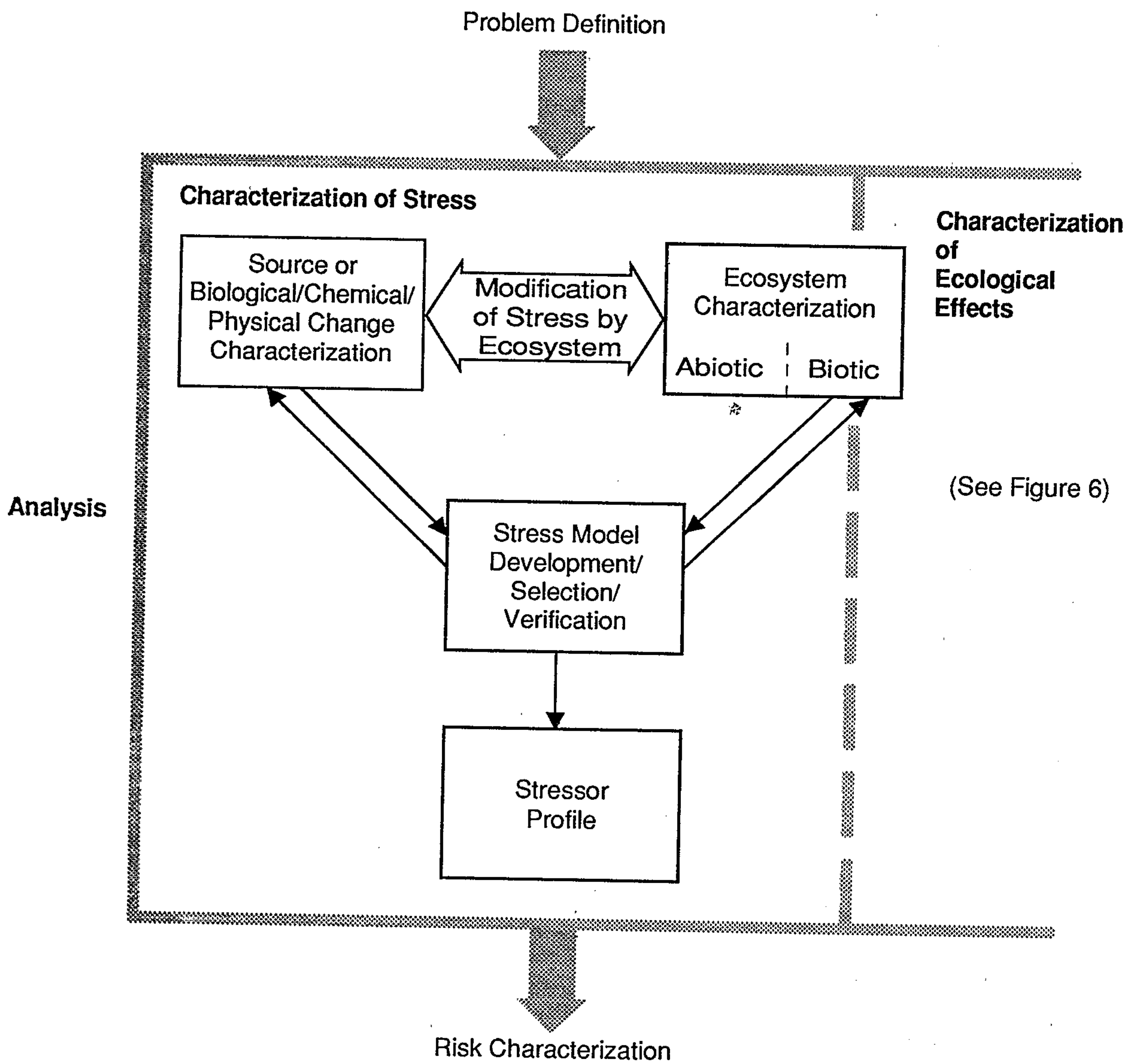


Figure 5. Characterization of Stress Component

A synopsis from EPA's Exposure Guidelines should be included. Summaries of guidance should be included in conjunction with describing the sources of uncertainty and methods for describing these uncertainties, with descriptions of point-of-contact measurements, scenario evaluation, and reconstructive assessment approaches. Given that the role of measurement and modeling of ecosystem stressors is different from measurement and modeling of human exposures, these different roles must be identified.

The adaptation of these approaches to nonchemical stressors should be specified. The meaning of a physical change that is analogous to a source should be described. The role of approaches such as measurement, scenario evaluation, and reconstructive assessment should be presented. The role of measurement techniques, as well as that of scenario evaluation, seems to be straightforward. The role of reconstructive assessment techniques will require the discussion of field studies and biomonitoring techniques.

The framework should state that expert judgment is required to assess most stressors. Expert judgment should be used to formulate assumptions in developing the scenario evaluation approach and analogies from previous assessments when interpreting limited data using measurement and retrospective assessment techniques. The use of simplified techniques, such as estimation of a single exposure value in the quotient method, requires the maximum amount of expert judgment. The framework should clearly state that when such methods are employed, the assessment should include detailed descriptions of the logic and the assumptions made in describing an appropriate exposure value.

The framework should state that gaps in stressor assessment technology exist and should provide a brief description of a commitment to further guidelines development, implementation of better methods, and research in the areas of source characterization, ecosystem characterization, and stress model development and verification. It is clear that EPA has a variety of plans and programs to address these issues. To provide a perspective for the framework, a summary statement of these efforts and the direction that EPA intends to pursue would show how major gaps are expected to be filled.

A stressor uncertainty characterization section should be added. This section should describe the sources of uncertainty in source or physical change characteristics, ecosystem characteristic model assumptions, and resultant stressor profile. The framework should specify that both qualitative and quantitative methods can be used. It would be appropriate to note that when professional judgment is used, qualitative descriptions of uncertainty may be crucially important. In most cases, including those in which professional judgment is used, sensitivity analysis and/or simulation techniques should be included as part of the assessment. For quantitative assessments, precision and accuracy of estimates should be characterized.

The framework should indicate that every assessment should include QA/QC requirements. This can be accomplished through the statement of data quality objectives required of studies conducted within EPA. The framework should incorporate standard language about the scope and intent of those objectives.

4.2. OTHER RECOMMENDATIONS

Because chemical stressors are not all equally available, bioavailability should be considered as an aspect of chemical stressor assessment. For such stressors, this will require consideration of transformations that the chemical undergoes and, for inorganic elements, the species of chemical present. Consideration of bioavailability may require estimation of dosage in some assessments.

Chemical stressor exposure pathways from the source to the organism/system should be defined. For nonchemical stressors, the relationship of a physical or other change should be related to the occurrence of a stressor that affects an organism/system.

5. COMMENTS ON THE CHARACTERIZATION OF ECOLOGICAL EFFECTS COMPONENT

After much discussion, the panel agreed that the term "hazard assessment" in the draft framework should be changed to the term "characterization of ecological effects." This would eliminate concerns about the inconsistent use of the term "hazard assessment," and could more accurately reflect the broader levels of biological organization required in ecological risk assessment. The reviewers developed a proposed flowchart for the characterization of ecological effects component (see figure 6).

Characterization of ecological effects refers to the determination of the relationship between the stressor and the endpoints identified during problem definition. Characterization will involve both observation in the field (biotic/abiotic ecosystem characterization) and experimentation in controlled settings. Both observation and experimentation contribute data and scientific understanding to the development, selection, and verification of simulation models. The relationship between observation/experimentation and model development/testing may be iterative; unsatisfactory model verification may result in additional field or laboratory studies. Once the model is verified, it may be used in stressor-response characterization, which concerns the relationship between the stressor and assessment endpoints. The process of characterizing ecological effects probably also will involve activities concerned with characterization of stress.

The workgroup on characterization of ecological effects developed a series of recommendations that would improve the framework document. These recommendations are summarized in the following paragraphs.

The risk characterization section of the framework document should present a more detailed discussion of uncertainty. The importance of uncertainty analysis in ecological risk assessment was discussed. Even though error calculations may occur in only one step, uncertainty is important in all components of risk assessment. As such, it should be discussed in all sections.

Statements should be added that identify (and reference) statistical issues and methods so that specific guidance is provided in subsequent technical manuals. The discussion of statistical methods, with frequent reference to regression analysis, ignores many difficult questions with regard to selection and application of statistical methods when data are error-contaminated and models are non-normal and/or nonlinear.

Technical guidance and detail should not appear in the framework document unless they are necessary for identification of otherwise unfamiliar methods. Even in those cases, the discussion should be brief. The dilemma concerning avoidance of technical details while maintaining clarity of explanation could be solved by using "boxed-in" examples of statistical methods, applications, etc.

Field confirmation of an effect caused by a stressor should be assessed whenever possible, since it is the field response of the assessment endpoint that is ultimately of consequence. In many instances, experimentation provides strong support for causality, whereas field observation provides evidence of correlation. Both are important, as noted in Hill's criteria. Still, it is important to recognize the limited support for causality that correlation alone provides. The framework document

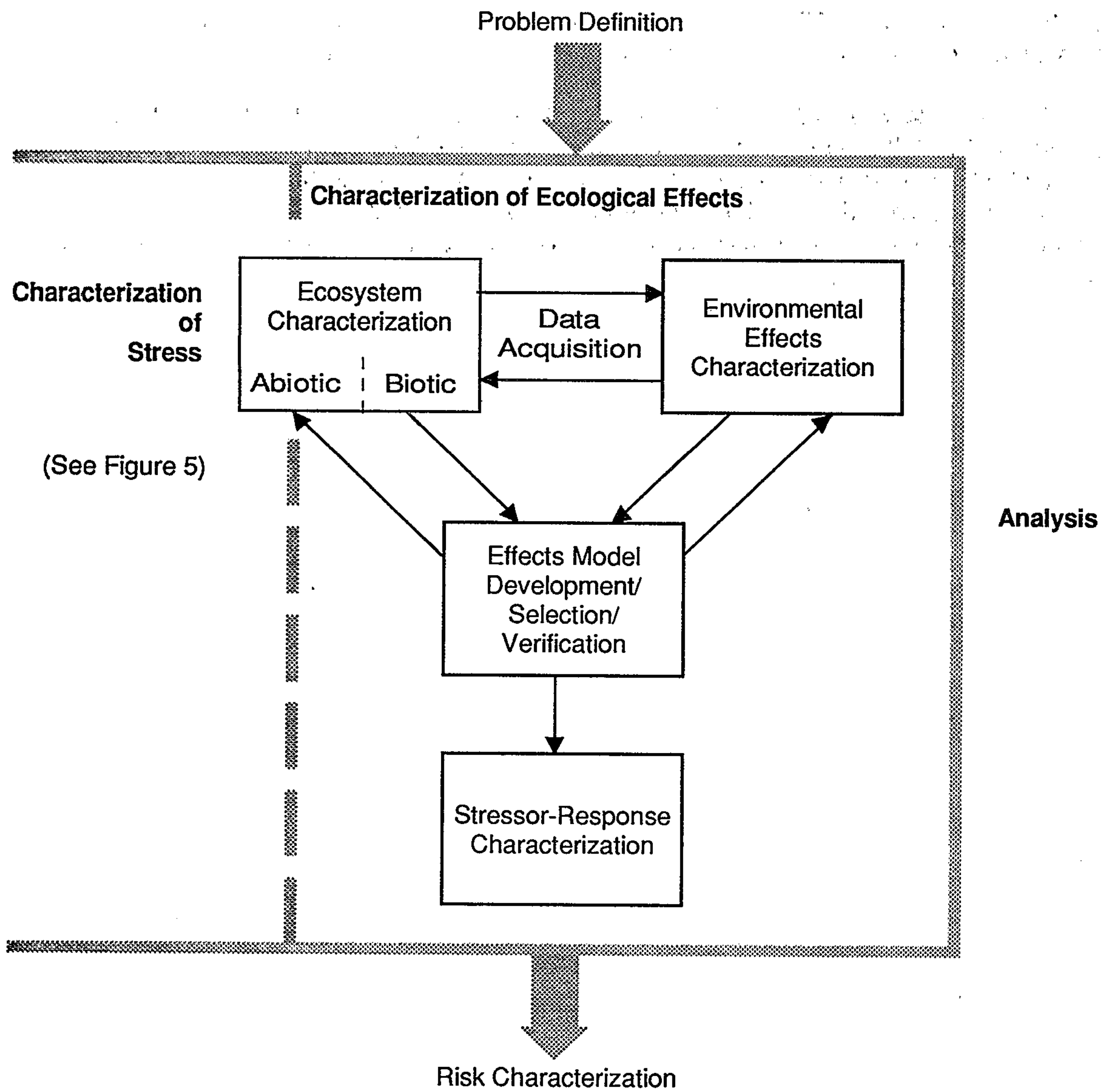


Figure 6. Characterization of Ecological Effects Component

should include a brief discussion of the importance of field verification. A brief discussion also should be added to address laboratory-to-field extrapolation and its role in ecological risk assessment. Additional guidance and discussion on nonchemical stressors are needed.

It is important to build flexibility into the framework to allow for future methods development. Flexibility in the framework would permit consideration of key unresolved issues, such as how multiple stressors with interactions and synergisms should be addressed. The panel believes that the framework should be flexible enough to allow new methods and approaches to be incorporated in the various guidelines and technical documents without requiring alteration of the basic framework itself.

6. COMMENTS ON THE RISK CHARACTERIZATION COMPONENT

The 1983 NAS report, "Risk Assessment in the Federal Government," defines risk characterization as

> ...the process of estimating the incidence of a [health] effect under the various conditions of human exposure described in exposure assessment. It is performed by combining the exposure and dose-response assessments. The summary effects of the uncertainties in the preceding steps are described in this step.

The draft EPA framework document accepts the NAS definition but expands it to include ecological effects and consequences. This definition implies the risk characterization section in the framework document should discuss:

- Integration of exposure and stressor-response information.
- Summarization of uncertainties.
- The relationship between "consequences" and "effects."

In their premeeting comments, a significant number of reviewers suggested that risk communication is inadequately addressed in the draft framework document, and that communication between scientists and managers is an important aspect of risk characterization. In light of these comments, the discussion groups were asked to answer three questions:

- How adequately does the framework document address risk characterization under the stated definition?
- Should the definition be expanded to explicitly include communication to decision-makers or to the public at large?
- If an expanded definition is needed, how should the expansion be addressed in the framework document?

6.1. ADEQUACY OF THE FRAMEWORK DOCUMENT UNDER STATED DEFINITION

Effects and Consequences

There was substantial confusion concerning the meanings of the terms "effect" and "consequence" and the relationships of these terms to "assessment endpoints." The terms "effect" and "consequence" are used nowhere else in the document, and their use in the risk characterization section creates apparent conflicts between different sections.

The conceptual framework development section defines assessment endpoints in terms of immediate relevance to decision-making (e.g., acres of wetland lost, decline in biodiversity). Given this definition, the consequences discussed in the risk characterization section should be synonymous with assessment endpoints. However, the discussion of stressor-response assessment in the hazard assessment section appears to include extrapolation to assessment endpoints. This would imply that effects, as defined in the risk characterization section, are synonymous with assessment endpoints and that consequences are some new and previously undefined type of endpoint.

The discussion groups were unable to resolve this problem. One group suggested substituting the term "occurrence" for "consequence," but later agreed that this change does not solve the problem. The final consensus was that, if "consequence" is retained as the form in which risks are communicated to managers, then consequences should be expressed in terms of assessment endpoints. The hazard assessment and risk characterization sections, which both appear to discuss extrapolation to assessment endpoints, must be reconciled. As stated above, this area was not resolved by the peer review panel. However, we believe it is critical for EPA to reach a consensus on how best to proceed in this area. The comments above are meant to be helpful as EPA proceeds with its considerations.

Uncertainty

The consensus among both risk characterization workgroups was that summarization of uncertainties is a critical component of risk characterization. The value of scientific information in the risk assessment is conveyed in the uncertainty analysis. Scientific uncertainty is present in all risk assessments. It does not prevent management and decision-making; rather, it provides a basis for selecting among alternative actions and for deciding if (and what) additional information (experimentation and/or observation) is needed.

The reviewers recommended recasting the uncertainty discussion in the risk characterization section to include discussion of sources of uncertainty, methods of characterizing uncertainty, methods of propagating uncertainty, and presentation of uncertainty.

Sources of uncertainty. The sources of scientific uncertainty in ecological risk assessment include inadequate scientific knowledge, natural variability, measurement error, and sampling error (e.g., standard error of an estimator). In actual practice, uncertainties that should be addressed specifically include mis-specification of models used (e.g., excessive aggregation of variables and inappropriate assumptions), error in parameter estimates, errors in the specification of initial conditions, and errors in expert judgment.

Methods of characterizing uncertainty. In some situations, uncertainty in an unknown quantity (e.g., a model parameter or a measurement endpoint) may be estimated by means of standard measures of statistical variability. Model errors can sometimes be estimated from a measure of goodness-of-fit (predictions versus observations). In many situations, however, judgmental estimation of uncertainty is the only option. This alternative is acceptable since methods of eliciting uncertainty estimates are available from experts.

Methods of propagating uncertainty. For model-based assessments, e.g., Monte Carlo or Latin Hypercube simulation, first-order error analysis and response-surface analysis often are used to estimate the influence of parameter errors on uncertainty concerning model predictions. Software for performing these analyses is now widely available.

Presentation of uncertainty. The group noted the importance of properly communicating uncertainty to decision-makers but did not offer specific comments on the adequacy of the framework document's treatment of this topic.

Exposure-Response Integration

The consensus of the group was that the risk characterization section places far too much emphasis on the "quotient method." The discussion of integration should be more general, and it should be revised to eliminate the confusing distinctions among responses, effects, and consequences. The material on the quotient method, if retained, should be condensed and put in a box as an example.

6.2. NEED FOR EXPANSION OF THE DEFINITION OF RISK CHARACTERIZATION

Workshop participants all recognized the need for communicating ecological risk information to decision-makers and to the public at large. There was not, however, uniform agreement about the role of risk analysts in this process. During the discussion, the group reached a consensus that communication should be included in the definition of risk characterization, but in a carefully circumscribed way. Risk characterization should include expression of risks in terms of assessment endpoints of direct management relevance and communication to risk managers of the ecological implications of alternative management actions. Communication to the public at large (magnitude and significance of the risks and rationale for actions taken) is the responsibility of the risk manager.

6.3. TREATMENT OF EXPANDED DEFINITION IN THE FRAMEWORK DOCUMENT

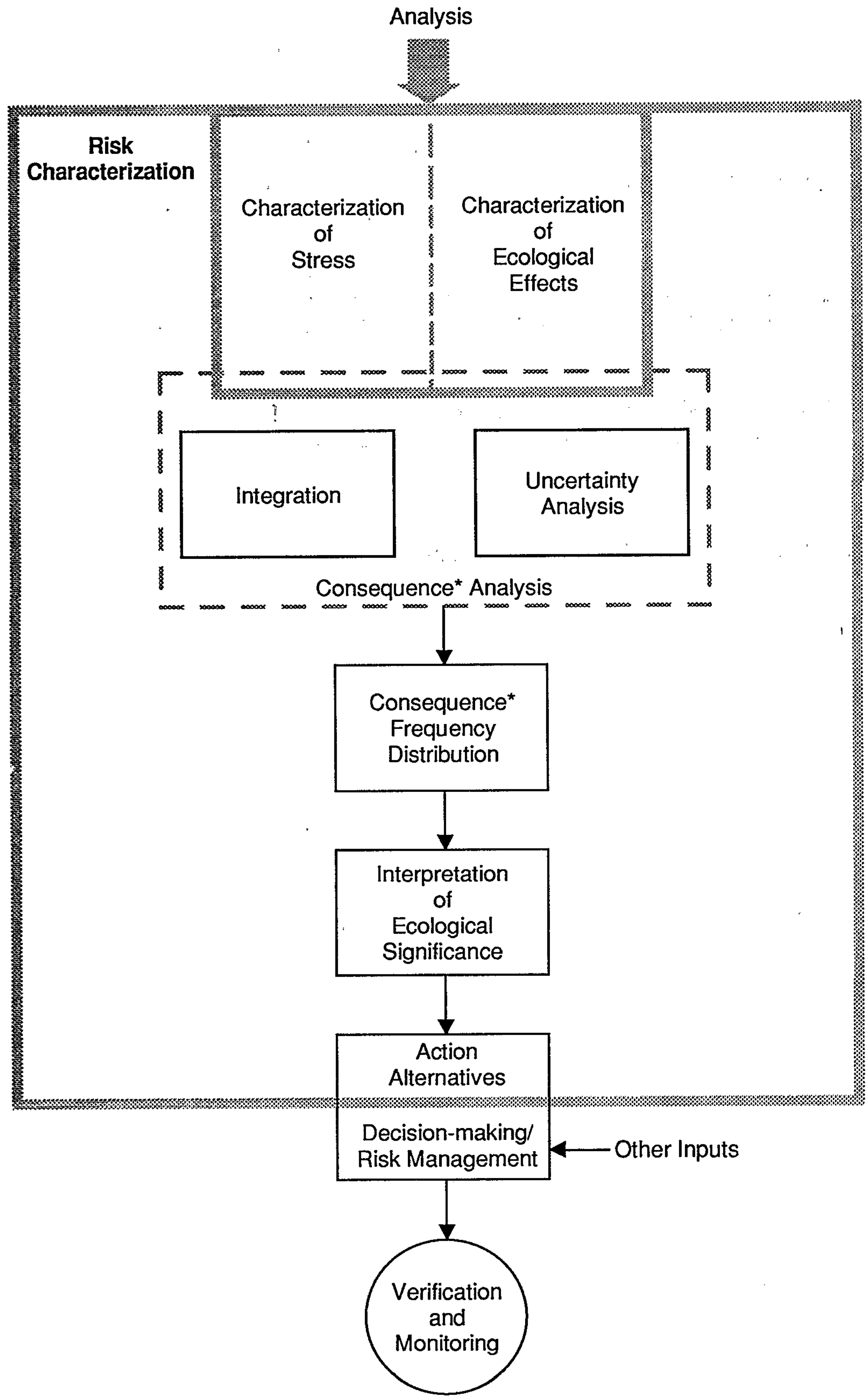
Figure 7 is a flowchart for the risk characterization component of the framework. As envisioned by the group, risk characterization includes several intervening steps between formal exposure/effects integration (termed "Consequence Analysis" in the figure and taken to include quantitative and qualitative uncertainty analysis) and communication to risk managers. These steps are as follows:

1. Expression of the quantitative results as a "consequence distribution," in which the range of possible ecological responses is presented as a function of probability of occurrence (quantitative or qualitative);

2. Interpretation of the ecological significance of the consequences (in narrative form); and

3. Description of the ecological consequences (either quantitative or qualitative) of the action alternatives available to the risk manager.

As appropriate, all three steps would include discussion of uncertainty and weight-of-evidence determinations. After the range of possible consequences and their relationship to both society's risk goals and action alternatives are conveyed to the risk manager, the risk assessor's responsibility ends. The risk manager must integrate relevant non-ecological considerations, make a decision, and then communicate the decision to the public.



*Consequence is used in this figure, even though the peer review panel did not reach a consensus on its use.

Figure 7. Risk Characterization Component

7. REFERENCES

National Research Council (NRC), 1983. *Risk Assessment in the Federal Government: Managing the Process.* National Research Council, National Academy Press, Washington, DC.

Science Advisory Board (SAB), 1990. *Reducing Risks: Setting Priorities and Strategies for Environmental Protection.* U.S. Environmental Protection Agency, Washington, DC.

Society of Environmental Toxicology and Chemistry (SETAC), 1987. *Research Priorities in Environmental Risk Assessment.* Published by SETAC.

U.S. Environmental Protection Agency (EPA), 1991. *Draft Framework for Ecological Risk Assessment.* Prepared by the Risk Assessment Forum.

APPENDIX A

MEETING MATERIALS

AGENDA

U.S. Environmental Protection Agency

ECOLOGICAL RISK ASSESSMENT GUIDELINES: WORKSHOP TO REVIEW FRAMEWORK DOCUMENT

TUESDAY, MAY 14, 1991

8:30 a.m. - 11:30 a.m. OPENING PLENARY SESSION

8:30 a.m. Welcome
Dorothy Patton, Chair, USEPA Risk Assessment Forum

8:45 a.m. Workshop Purpose and Objectives
James Fava, Roy F. Weston, Inc.

9:00 a.m. Ecorisk Activities of the NAS Committee on Risk Assessment Methodology
Lawrence Barnthouse, Oak Ridge National Laboratory

9:15 a.m. EPA's Strategic Planning Workshop for Ecorisk Assessment
Mark Harwell, University of Miami, Rosentiel School of Marine and Atmospheric Science

9:30 a.m. Ecorisk Paradigm: Highlights
Susan Norton, USEPA

9:45 a.m. Ecorisk Paradigm: Issues Presentation
James Fava

10:00 a.m. **BREAK**

10:15 a.m. Ecorisk Paradigm: Discussion
James Fava

11:30 a.m. **LUNCH**

12:30 p.m. - 1:30 p.m. PLENARY SESSION

12:30 p.m. Conceptual Framework Development: Highlights
David Mauriello, USEPA

12:45 p.m. Conceptual Framework Development: Issues Presentation
Mark Harwell

TUESDAY, MAY 14, 1991 (cont.)

1:30 p.m. - 4:30 p.m. **WORKGROUP SESSIONS**

1:30 p.m. Conceptual Framework Development: Discussion (Two Workgroups)
Mark Harwell and Lawrence Barnthouse

3:00 p.m. **BREAK**

3:15 p.m. Conceptual Framework Development: Discussion (cont.)

4:30 p.m. - 5:30 p.m. **PLENARY SESSION**

4:30 p.m. Conceptual Framework Development: Summary
Mark Harwell and Lawrence Barnthouse

5:30 p.m. **ADJOURN**

5:30 p.m. **Reception - Pool Terrace**

WEDNESDAY, MAY 15, 1991

8:30 a.m. - 9:30 a.m. **PLENARY SESSION**

8:30 a.m. Hazard Assessment: Highlights
Donald Rodier, USEPA

8:45 a.m. Hazard Assessment: Issues Presentation
Kenneth Reckhow, Duke University, School of Forestry and Environmental Studies

9:15 a.m. Exposure Assessment: Highlights
Anne Sergeant, USEPA

9:30 a.m. Exposure Assessment: Issues Presentation
James Falco, Battelle Pacific Northwest Laboratory

10:00 a.m. **BREAK**

10:15 a.m. - 12:15 p.m. **WORKGROUP SESSIONS**

10:15 a.m. Hazard Assessment: Discussion
Kenneth Reckhow

Exposure Assessment: Discussion
James Falco

WEDNESDAY, MAY 15, 1991 (cont.)

12:15 p.m. **LUNCH**

1:15 p.m. - 3:15 p.m. PLENARY SESSION

1:15 p.m. Hazard Assessment: Summary
Kenneth Reckhow

1:45 p.m. Exposure Assessment: Summary
James Falco

2:15 p.m. Risk Characterization: Highlights
Michael Brody, USEPA

2:30 p.m. Risk Characterization: Issues Presentation
Lawrence Barnthouse

3:15 p.m. **BREAK**

3:30 p.m. - 5:00 p.m. WORKGROUP SESSIONS

3:30 p.m. Risk Characterization: Discussion (Two Workgroups)
Lawrence Barnthouse and Mark Harwell

5:00 p.m. - 5:30 p.m. PLENARY SESSION

5:00 p.m. Risk Characterization: Summary
Lawrence Barnthouse and Mark Harwell

5:30 p.m. **ADJOURN**

THURSDAY, MAY 16, 1991

8:30 a.m. - 12:00 p.m. CLOSING PLENARY SESSION

8:30 a.m. OBSERVER COMMENTS
James Fava

9:30 a.m. FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT: SUMMARY AND RECOMMENDATIONS

9:30 a.m. Introduction
James Fava

__THURSDAY, MAY 16, 1991__ (cont.)

9:35 a.m.	**Resolved Issues** *Mark Harwell*
10:15 a.m.	**BREAK**
10:30 a.m.	Unresolved Issues *Lawrence Barnthouse*
11:15 a.m.	Recommendations to EPA *James Fava*
12:00 p.m.	**ADJOURN**

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APPENDIX B

PREMEETING MATERIALS

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

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

March 1991

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DRAFT - DO NOT CITE OR QUOTE

TABLE OF CONTENTS

FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT

1. INTRODUCTION

In 1984, the United States Environmental Protection Agency (EPA) organized the Risk Assessment Guidelines program to ensure scientific quality and technical consistency in the Agency's risk assessments. The first group of five guidelines, issued in 1986, focused on evaluating risks to human health. In addition to concerns for human health, there has been an increased awareness in the public, private, and governmental sectors of society regarding ecological issues. These issues include global warming, acid deposition, a decrease in biological diversity, and the ecological impacts of xenobiotic compounds such as pesticides and toxic chemicals. This Framework for Ecological Risk Assessment is the first agency-wide statement of general principles to guide ecological risk assessment. It is intended to foster a consistent Agency approach for conducting ecological risk assessments, help to identify key issues and research needs, and provide operational definitions for terminology. In addition, it will serve as the foundation for future subject-specific guidelines.

1.1. Intended Audience

This guidance is intended for risk assessors in the Agency, and other persons who either perform work under Agency contract or sponsorship or who are subject to Agency regulations[1]. Risk managers in the Agency, other Federal agencies, and state and local agencies may also benefit from this guidance since it clarifies the terminology and methods used by assessors.

1.2. Definition of Ecological Risk Assessment

Ecological risk assessment evaluates the likelihood that undesirable ecological effects may occur or are occurring as a result of exposure to one or more stressors. The term stressor is defined here as any physical, chemical or biological entity that can induce an adverse effect. Adverse ecological effects encompass a wide range of disturbances, ranging from an increase in the normal mortality rate in individual organisms to reductions or deviations from normal ecosystem structure and function.

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[1] It is preferable that scientists with ecological training perform and interpret ecological risk assessments. Those who do not have this background may find the standard texts listed in the references helpful (e.g., Odum, 1983; Krebs, 1985; Ricklefs, 1990; and Pianka, 1988).

Risk is a function of two major elements, hazard and exposure. Hazard refers to the type and magnitude of effect caused by a stressor. It is usually evaluated by identifying levels of a stressor associated with effects observed in laboratory or field studies. Exposure refers to the co-occurrence of a stressor with an ecological component (e.g., individual, population, community, or ecosystem). It is usually determined by measuring or estimating the amount of the stressor in environmental compartments (e.g., air, soil, water). An adverse effect is likely to occur in the field only if exposure approaches or exceeds a levels associated with the adverse effects identified in the hazard assessment. A probabilistic statement about the likelihood of adverse effects can be made when stochastic estimates of the two elements are provided.

The current state of the art in ecological risk assessment permits only limited potential for developing stochastic estimates of both the hazard and exposure elements. Thus, ecological risk assessments often are deterministic in nature and likelihood is expressed as a semi-quantitative comparison of exposure and hazard. In some instances, such as evaluating current or past risks, quantifying hazard and exposure may be difficult, and qualitative risk estimates or opinions are often employed. Even though such estimates may be qualitative, they are still considered to be risk estimates in this document.

1.3. Applications of Ecological Risk Assessment.

Ecological risk assessments play a fundamental and often pivotal role for addressing ecological effects. Ecological risk assessments can be used to define problems, set priorities, and serve as a basis for regulatory actions. The ecological risk assessment process is flexible enough that it can be used to predict future risks or assess adverse effects that are occurring or have already occurred. An example of the former is an evaluation of a new chemical not yet manufactured. Such assessments are often referred to as predictive risk assessments. Examples of the latter include evaluation of hazardous waste sites, eutrophication of aquatic systems, and oil spills. These types of assessments are commonly referred to as retrospective risk assessments. Although the types of data and analyses may differ, the elements of the risk assessment paradigm described in Section 1.6 are used in both types of assessments.

1.4. Document Background and Ancillary Activities

As part of the present effort in ecological risk assessment, meetings were held in the spring and summer of 1990 to review important scientific issues (Gentile et al., in press). Experts in ecology and ecological risk assessment met to discuss the ecological risk assessment paradigm, uncertainty issues in hazard and exposure assessment, and population modeling. Representatives from state and federal agencies described how ecological risk assessments are conducted in their organizations, and the EPA Science Advisory Board provided an informal consultation on the development of ecological risk assessment guidelines.

Based in part upon these meetings as well as extensive discussions with EPA managers and scientists and outside experts, EPA has initiated a three-part program to develop ecological risk assessment guidelines. Two efforts are underway in addition to the framework guidance document:

- Compilation of Ecological Risk Assessment Case Studies. Peer-reviewed case studies illustrating the "state-of-the-practice" in ecological risk assessment are being compiled by six EPA work groups chaired by personnel from the Regions, Environmental Research Laboratories, and Headquarters. Selected case studies represent a wide range of programmatic tasks and ecosystem types. Individual case studies will be compiled into an overall report that will include a description of each study; a "tools" section that will contain a cross-referenced listing of ecological risk methods, models, and assessment schemes used in the case studies; and a discussion of issues related to ecological risk assessment and research needs. The report will provide interim assistance in performing ecological risk assessments until additional specific guidelines can be developed.

- Plans for Future Guidelines. A work group has been formed to create a work plan for long-term (1991-1998) development of ecological risk guidelines. This group will coordinate with other Agency ecological risk assessment activities, including the core research program and the Ecological Monitoring and Assessment Program (EMAP). Based on scientific feasibility and EPA's program priorities, the work group will recommend specific subject areas for future ecological risk assessment guidelines.

1.5. Purpose and Scope of the Framework Document

This framework is intended to convey the general principles of ecological risk assessment and provide a foundation for future subject-specific guidelines. It will also foster a consistent Agency approach for conducting ecological risk assessments, help to identify key issues and research needs, and provide operational definitions for terminology. It is not intended to serve as a detailed instructional guide or set of rules. The principles discussed here apply to ecological risk assessments at the individual, population, community, and ecosystem organizational levels. The need for assessing risks at higher organizational levels (i.e., communities and ecosystems) has been highlighted recently (U.S. EPA, 1990a,b). However, most operational methods assess effects at lower levels of ecological organization (i.e., individuals and populations) and these methods provide most of the examples discussed in this guidance. As methods for assessing risks at higher organizational levels are developed, the Agency will prepare more detailed guidelines.

Risks posed by introduced exotic species are not addressed here because EPA does not have the authority to regulate these organisms. EPA does have the authority to regulate genetically-engineered organisms; although the risk assessment paradigm described in Section 1.6 would conceptually apply to genetically-engineered organisms, methods for evaluating the hazard of and exposure to such organisms are still being investigated. As more experience is gained, guidelines for evaluating the ecological risks of genetically-engineered organisms will eventually be developed.

1.6. The Ecological Risk Paradigm

This guidance represents the first Agency-wide effort to identify and discuss the elements of ecological risk assessment. Figure 1 illustrates the elements of the ecological risk assessment paradigm described in this framework. Figure 2 presents the paradigm in the context of risk management and policy concerns.

The risk assessment paradigm published by the National Academy of Sciences (NRC "red book," 1983) is used as a foundation for the ecological risk assessment paradigm shown in Figure 1. The Academy identified four basic elements of risk assessment: 1) Hazard Identification, 2) Dose-Response Assessment, 3) Exposure Assessment, and 4) Risk Characterization. For the purposes of ecological risk assessment, an additional step, Conceptual Framework Development, is also shown. This is analogous to a preliminary hazard identification that identifies adverse effects associated with the stressor. It is proposed here since ecological risk assessments, unlike human health assessments, must often address the risks of stressors to many species as well as risks to communities and ecosystems. In addition, there may be many ways a stressor can elicit adverse effects (e.g., direct effects on mortality and growth, or indirect effects such as decreased food supply). A systematic planning element helps identify major factors to be considered in a particular assessment in order to

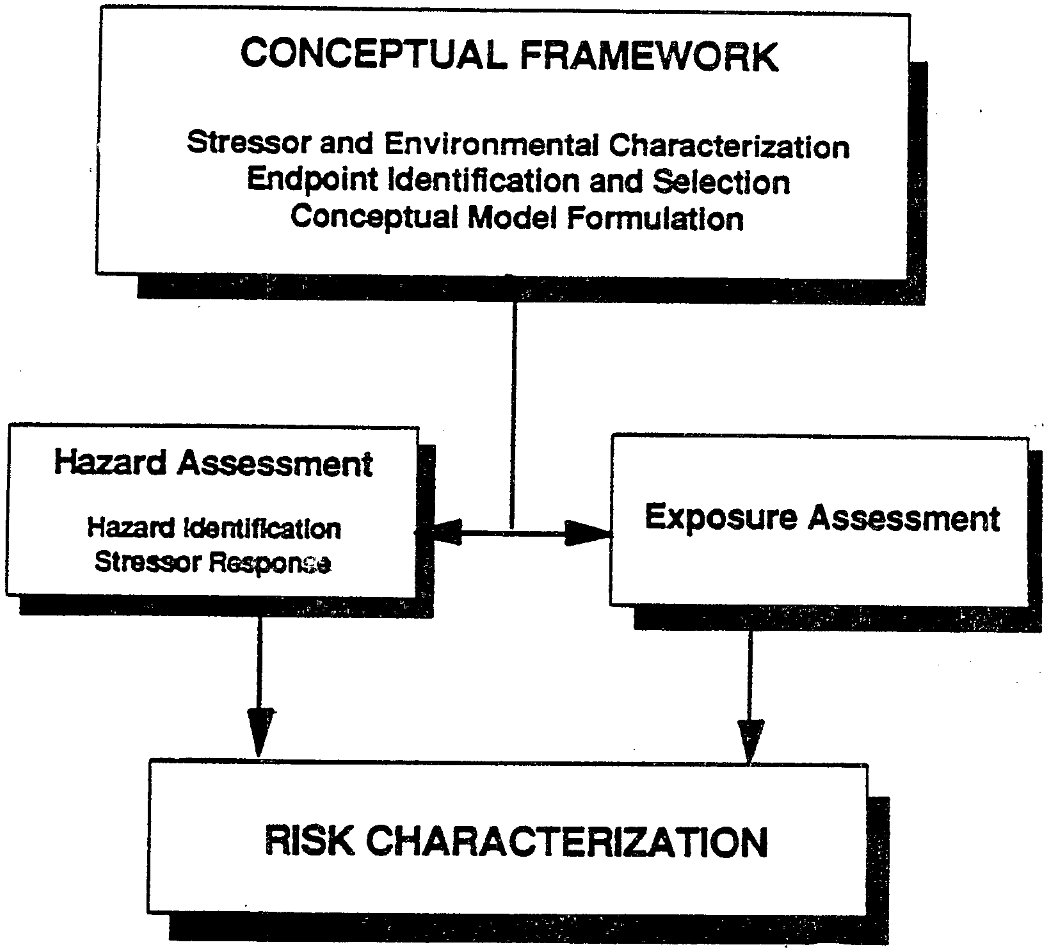

Figure 1: Ecological Risk Assessment Paradigm

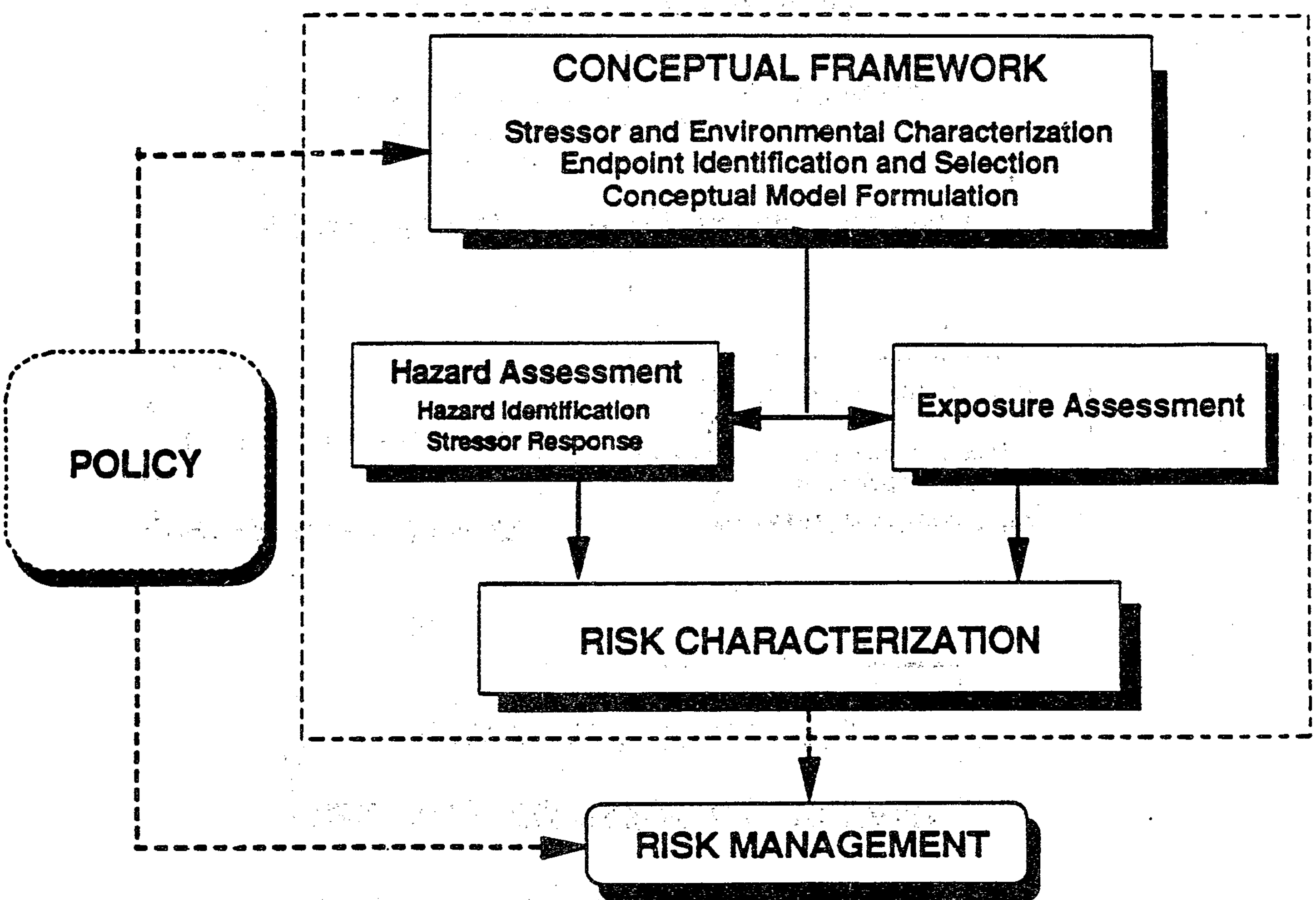

Figure 2 : Activities Associated with Ecological Risk Assessment

produce a scientifically-acceptable ecological risk assessment relevant to risk management decisions.

There are three elements of Conceptual Framework Development. Stressor and Environmental Characterization describes the stressor's potential spatial and temporal distribution and identifies the ecological components that might be exposed to it. Endpoint Identification describes the types of effects that may be elicited by a certain stressor. Conceptual Model Formulation summarizes plausible ways a stressor could cause adverse effects. Section 2 describes these elements in more detail.

The four elements of the NAS paradigm complete the ecological risk assessment paradigm. The term Hazard Identification is used here in a manner similar to NAS (NRC, 1983): "the process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (cancer, birth defect, etc.). This element characterizes the nature and strength of the evidence of causation." Dose-Response Assessment is "the process of characterizing the relationship between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent." The term stressor-response, rather than dose-response, is used in this guidance to include the great number of non-toxicological stressors that impair ecological systems. Like the dose-response assessment described by the NAS (NRC, 1983), stressor-response assessment considers the intensity and pattern of exposure, and other variables (e.g., gender, life-history stage) to evaluate the responses elicited by a particular agent.

In many ecological risk assessments, the hazard identification and stressor-response assessments may be conceptually close to one another. In assessments that rely on laboratory data, the information used for hazard identification (which effects are of concern?) and stressor-response (what is the magnitude of the effect?) may be obtained simultaneously. In other assessments, information linking the stressor with the effect may be obtained separately from the stressor-response assessment. To accommodate both approaches, hazard identification and stressor-response are retained but are treated as one element of the risk assessment paradigm, hazard assessment[2]. This information on hazard is integrated with the exposure assessment to estimate risk.

Exposure assessment is defined by NAS as "the process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment." Ecological exposure assessment considers many of the same concerns; important issues include exposure of multiple organisms, exposure to non-chemical stresses, and the timing of the exposure relative to important life cycle attributes.

Risk characterization is defined by NAS as "the process of estimating the incidence of a health effect under the various conditions of human exposure described in exposure assessment." This definition is applied here to ecological effects, but is expanded to include a discussion, when applicable, of the ecological consequences of observed or estimated adverse effects. For example, a risk assessment demonstrating adverse effects on aquatic invertebrates may also describe the ramifications of these effects on other organisms such as fish. Risk characterization includes a summary of the strengths, limitations and uncertainties of the data and models used to form conclusions.

1.7. Ecological Risk Assessment Issues for Future Consideration

Incomplete information resulting from gaps in scientific theory is common in both ecological and human health risk assessments. The NAS emphasized the need to make necessary judgements and proceed with risk assessments under these conditions (NRC, 1983). At the same time, it is important to identify and address critical scientific issues to fill information gaps and advance the risk assessment process.

Table 1 presents a number of issues of special significance for future ecological risk assessment guidelines. The orientation of this document and the incomplete development of some subjects

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[2] The combination of hazard identification and stress-response assessment is called "hazard assessment" here. Another definition of hazard assessment is a quotient or margin of safety calculated by comparing the toxicological endpoint of interest to an estimate of exposure concentration. The latter definition refers to a combination of stress-response assessment and exposure assessment. This document uses only the former definition.

Table 1: Issues in Ecological Risk Assessment

Conceptual Framework Development

How do endpoints identified for a risk assessment depend on spatial and temporal scale and the type of stressor?

Are there endpoints that are most appropriate for different types of assessment (e.g., priority-setting, initial evaluations of risk, evaluation of remedial alternatives)?

Hazard Assessment

How should different types of evidence be weighed?

What consideration should be given to data obtained from tests conducted with nonstandard procedures or conducted with surrogate species for which there is little information on relative sensitivity?

How should the distribution of individual organism responses to the stressor be taken into account?

What should be the basis for extrapolating among taxa, organizational levels, and functional groups?

What should be the basis for extrapolating the effects of physical perturbations?

What is the nature of the stressor-response function at higher organizational levels (e.g., communities and ecosystems)?

Exposure Assessment

How should temporal and spatial variation in exposure (e.g., transitory vs. resident populations, episodic exposure) be considered?

How should multiple stressors and multiple routes of exposure be considered?

How is exposure influenced by physical, chemical, and biological attributes of the environment?

What are the best attributes of physical disturbance for assessing exposure (e.g., fragmentation, edge)?

Table 1 (continued)

Risk Characterization

How is the potential for recovery factored into risk characterization?

How can critical effects levels be incorporated into risk characterization?

What role should assumptions play in reducing the probability of a false negative (e.g., Type II error)?

How are the overall results of the risk assessment best communicated?

What additional approaches are available for characterizing uncertainty?

How can chemical and non-chemical stressors (e.g., habitat alteration) be combined in the risk characterization process?

What alternatives to the quotient method are available for risk characterization?

General Issues

What is the role of risk management and policy in the risk assessment process?

What information, in addition to the points raised above, is needed for conducting ecological risk assessments:

1. At regional and global scales?
2. At community and ecosystem levels?
3. For non-chemical stressors?

reflect the lack of scientific knowledge in some areas. For example, more methods are currently available for chemical stressors and individual- or population-level effects than for certain non-chemical stressors and community- or ecosystem-level effects. However, risk assessment guideline development is an evolutionary process, so new approaches or methods for dealing with these issues may be incorporated into future guidelines as they become available.

1.8. Organization

The remainder of this document is arranged sequentially. Chapter 2 discusses conceptual framework development; this chapter is particularly important for assessors to consider when endpoints are not determined *a priori* by statute or other authority. Chapter 3 discusses hazard assessment, Chapter 4, exposure assessment and Chapter 5, risk characterization. Chapter 6 contains the glossary.

2. CONCEPTUAL FRAMEWORK DEVELOPMENT

Conceptual framework development establishes the goals, breadth, and focus of the ecological risk assessment. Its product is a conceptual model that describes how a stressor might affect organisms, populations, communities and ecosystems (i.e., ecological components) in the natural environment. This conceptual model is evaluated further in the hazard identification, stressor-response, and exposure assessments.

Conceptual framework development begins with the review of available information on the characteristics of the stressor and the receiving environment, including the organisms, populations, communities, and ecosystems likely to be exposed. It also describes the characteristics of the biological systems that might be affected by exposure to the stressor (i.e., endpoints). Some endpoints are selected for further evaluation based on the purposes of the assessment, ecological relevance, susceptibility, and practical constraints. Selected endpoints and preliminary information on the stressor are then integrated into the conceptual model.

The extent and detail of the development process depend on the purpose of the assessment and the amount of information available on the situation under evaluation. One conceptual model may serve a suite of similar risk assessments (e.g., for new individual chemicals released to water).

2.1. Stressor and Environmental Characterization

Conceptual framework development begins with the identification of a stressor or group of stressors. In some cases, an effect observed in the field or laboratory can be used to identify stressors that can be evaluated further. In other cases, the description of a source helps identify stressors. A preliminary evaluation of the characteristics of the stressor and the receiving environment helps evaluate the spatial and temporal distribution of the stressor and identify the ecological components that may be exposed to it.

The preliminary evaluation of the spatial and temporal distribution of the stressor uses available information on its source and the factors that influence its distribution and fate. This includes information on release rates and patterns, physicochemical properties such as water solubility and volatility, and environmental characteristics such as soil type and climate. The physical and chemical properties of the chemical stressors provide important insight into fate and distribution, which in turn determines which ecological components might be exposed. The components evaluated in ecological risk assessment are discussed below and can include organisms, populations, communities, and ecosystems.

The amount of information available to characterize the temporal and spatial distribution of the stressor and identify potentially exposed ecological components varies greatly among risk assessments. In site-specific assessments (e.g., hazardous waste sites), the physical characteristics are best described using data obtained from site investigations and sampling. A general sense of the expected physical environment and biological community can be provided by using topographic maps, soil maps, remote sensing techniques, and vegetative-cover or ecoregional maps. Expected populations and organisms can be identified by characterizing the habitat at the site. Other stressors that may influence the community should also be identified at this point.

When evaluating stressors released to particular habitats (e.g., pesticides applied to agricultural lands), it is important to consider both exposed and adjacent areas. In addition, the organisms using exposed and adjacent areas may vary in different regions, even though the habitat may be similar.

In other assessments, very little is known about specific potential exposure points, but fate-and-transport data and general release locations can be used to describe generic or representative exposure settings (e.g., aquatic habitats). In these cases, a generic or surrogate community can be defined, and surrogate organisms can be used to represent populations.

2.2. Endpoint Identification and Selection

The second major step in the planning process is the selection of the characteristics of ecological components that can be adversely affected by exposure to a stressor. For the purposes of this document, these characteristics are called endpoints. An endpoint describes the change in the characteristic (e.g., increased mortality), the ecological component that is affected (e.g., trout) (Suter, 1990a), and often the spatial scale (e.g., long-term population viability of a species within its current range).

Assessment and measurement endpoints are often distinguished in ecological risk assessments. Measurement endpoints are the effects that can be measured. As used in this guidance, the definition encompasses both the characteristic that is measured (mortality) and the quantitative summary of those measurements (e.g., an LC_{50})[3].

Effects that are readily measured may not be directly useful in risk management, because the significance of the response is not always evident. Assessment endpoints are useful intermediaries that describe the environmental value to be protected and thus link measurement endpoints to the risk management process. They are the ultimate focus of risk characterization. In the best case, the assessment endpoint can be measured and then the measurement and the assessment endpoint are the same. If an assessment endpoint cannot be directly measured, measurement endpoints are selected that can be related, either qualitatively or quantitatively, to an assessment endpoint.

Measurement and assessment endpoints are often categorized by organizational levels. Organizational levels include individual organisms, populations that include many individuals of the same species, communities comprised of interacting multiple populations, and ecosystems comprised of organisms and their abiotic environment. Multiple units at one organizational level form the next higher level, and changes at one level may influence what occurs at adjacent levels.

Each organizational level has both structural and functional attributes that may serve as endpoints. Structural attributes of ecological systems include, for example, the mass of individuals, the age-class structure of populations, the number and distribution of populations within a community, and the biomass of ecosystems. Functional attributes involve the flow of mass and energy (e.g., respiration rate of individuals, intrinsic rate of increase of populations, primary productivity of communities, and decomposition and nutrient cycling rates of ecosystems). The interaction between structure and function is an area of active research. For example, it is still difficult to map functional attributes onto species assemblages because organisms may perform more than one function, and may perform different functions at different life stages.

3 Alternative terminology distinguishes between the characteristic that is measured (called a response indicator) and the quantitative summary of the results (called a measurement endpoint) (U.S. EPA, 1990b).

Table 2 presents example measurement and assessment endpoints; in practice, an ecological component would also be specified[4]. Endpoints at each organizational level have strengths and limitations. Risk assessments are not confined to one organizational level, and may use a suite of endpoints at multiple levels for different aspects of the assessment. Measurement and assessment endpoints are selected by considering the purpose of the assessment, ecological relevance, susceptibility to the stressor, and practical constraints. These criteria are discussed generally below; more detailed discussions can be found in Suter (1990a), Kelly and Harwell (1990), and U.S. EPA (1990b). Endpoint selection relies on professional judgement; for this reason, the rationale for selection should be clearly documented.

2.2.1. Purpose and Needs of the Assessment

It is important to consider the purpose of the assessment when selecting endpoints. Assessment endpoints vary with program and need within the program, for example, assessment endpoints selected to support a decision under a specific regulation may differ substantially from those used to support a request for further testing. The assessor may wish to consult with the risk manager to identify assessment endpoints for specific regulatory needs. Measurement endpoints also vary with the purpose of the assessment. For example, a measurement endpoint diagnostic of a specific stressor may be preferred when the assessment is based on field observations and this causal evidence is particularly important to the risk management decision.

Assessment endpoints may be selected because they are valued by society (Clements, 1983). Examples include the maintenance of commercially- or recreationally-important populations or the viability of an endangered or threatened species. Other examples are attributes of ecosystems that are valued for functional (e.g., flood water retention by wetlands) or aesthetic reasons (e.g., visibility in the Grand Canyon). In some cases the adverse effect is an increase in undesirable species; the risk assessment may then focus on factors that favor these organisms.

[4] Several areas of active research may provide useful measurement endpoints in the future. These include biomarkers, which measure physiological and biochemical changes, and landscape-level studies and models (e.g., Costanza et al., 1990), which describe distribution patterns of communities and ecosystems. For these measurements to be useful as endpoints, an established relationship with endpoints like those shown in Table 2 is necessary.

Table 2: Recommended Endpoints at Each Level of Ecological Organization#

LEVEL OF ORGANIZATION	ASSESSMENT ENDPOINTS	MEASUREMENT ENDPOINTS
Individual	Organism health	Death* Growth* Reproduction* Morbidity Behavior
Population	Viability	Birth rate Death rate Immigration/Emigration Age-Size-Class Structure* Distribution* Abundance*
Community	Deviation in structure and function from unimpaired community	Species shifts Numbers of species* Species dominance* Trophic shifts
Ecosystem	Deviation in structure and function from unimpaired system	Biomass* Productivity (P/R ratio)* Nutrient dynamics Materials and energy flow*

Generic examples are shown in this table; in practice, an ecological component would also be specified (e.g., mortality in trout; flood retention by wetlands). In addition, the spatial scale of the endpoint is often specified.

* Depending on the goal of the assessment, these measurement endpoints may also serve as assessment endpoints.

When evaluating populations that are valued, it is critical that measurement endpoints include both direct and indirect effects. Direct effects include changes in characteristics of the valued population, such as increased mortality, reduced growth and development, or impaired reproduction. Indirect effects include similar effects on species upon which the valued population depends for food or habitat (see the discussion on ecological relevance, below).

When evaluating valued characteristics of communities and ecosystems, it is important to recognize that measurement endpoints at lower organizational levels may not adequately reflect adverse effects on community structure and function. Endpoints at higher organizational levels are difficult to quantitatively predict using measurement endpoints at lower organizational levels because of characteristics of ecological components that confer resiliency. For example, individuals may be able to tolerate or compensate for a stressor through some physiological mechanism. Communities and ecosystems can continue to function despite changes in components when many components provide similar functions[5]. For these reasons, measurement endpoints at the same organizational level may be the most useful, or, alternatively, a conservative approach may select endpoints on the basis of susceptibility (see the discussion on susceptibility below).

2.2.2. Ecological Relevance

Ideal assessment and measurement endpoints are ecologically relevant. Ecologically-relevant endpoints influence other endpoints, both at the same organizational level and also at other levels. Changes in endpoints at higher organizational levels or at large spatial scales are often ecologically relevant because they can involve large numbers of organisms, populations, communities, and ecosystems.

Changes in endpoints at lower organizational levels can also produce wide-ranging consequences. Changes in organisms and populations that provide important functions in communities may result in indirect effects on other community members. Keystone

[5] While they enable a system to persist despite exposure to a stressor, resistance mechanisms are not without costs. Physiological tolerance mechanisms may require additional energy, and may leave the organism less fit to compete or reproduce. Long-term exposure to a stressor may decrease species or genetic diversity; genotypes or species that compete well in the face of one stress may be more vulnerable to future, different stresses.

species, for example, influence the abundance and distribution of other community members; effects on them may induce changes throughout the community. Community interactions determine the extent to which an effect will be manifested in more than one organizational level. Food-web and trophic relationships are primary characteristics to consider when evaluating indirect effects. In addition, competition for key resources (e.g., food, nesting sites, mates) and important species-to-species interactions (e.g., predator-prey relationships, mutualism, and commensalism) should be considered. A complete risk assessment will account for important ecological relationships during endpoint selection.

2.2.3. Susceptibility

During early or minimal stages of exposure to a stressor, the most susceptible individuals and processes are often the first to be affected[6]. Because ecosystems consist of communities, populations, and individual organisms, if shifts are observed at the ecosystem level, it is likely that significant changes have already occurred at lower organizational levels (Rapport et al., 1985; Bormann, 1985; Kelly and Harwell, 1990; ESA, 1991). However, because of differences in sensitivity within an organizational level, adverse effects can be seen simultaneously at the individual, population, community and ecosystem organizational levels.

Information on relative susceptibility can be used to choose endpoints that are among the first to be affected by exposure to a stressor. Alternatively, this information can be used to select the measurement endpoints that best represent response to a stressor. Risk assessments based on endpoints that are not susceptible will underestimate the risk to more susceptible endpoints. For example, if an organism is tolerant of a stressor, risk assessments based on responses of that organism will underestimate risk to less-tolerant organisms, and may also underestimate risk to a community of more-sensitive or more highly-exposed populations.

Susceptibility to a stressor is a function of both exposure and sensitivity. Relative sensitivity is often stressor-specific, but can also vary with classes of stressors (e.g., narcotic chemicals, pesticides). Data used to evaluate sensitivity can

[6] Low inputs of some stresses (e.g., water, carbon dioxide) can actually result in improvements in health or productivity under some circumstances. This "subsidy effect" is not usually seen with inputs of toxic chemicals (Odum et al., 1979).

include chemical structure-activity relationships (SARs), effects observed in the field, and laboratory stressor-response data. Exposure to multiple stressors may make organisms more sensitive to the particular stressor being assessed (e.g., in populations exposed to habitat loss and harvesting, toxicological impacts may have greater impact on population viability than toxicological studies alone suggest). Although sensitivity directly influences the outcome of the risk assessment, information on relative sensitivity, particularly at higher organizational levels, is often unavailable during the planning process.

The second aspect of susceptibility is exposure. When evaluating endpoints at the individual and population level, it is particularly important to consider life history attributes, since life stage may influence both the sensitivity of the organism and the magnitude of exposure. Organisms may not be present when a stressor is introduced in the environment because they move into an area for short periods to feed, breed, or mate, or they migrate on a diurnal or seasonal basis. These organisms tend to be less exposed than those living continually in the environment if the route of exposure is similar. However, organism use of environmental resources further influences the extent of exposure: some species use resources where exposure will be greatest (e.g., predators at the top of the food web will incur greater exposure to chemicals that bioaccumulate).

When little is known about susceptibility, a group of endpoints is often evaluated in the hazard identification and stressor-response assessment. For example, surrogate species are often chosen to represent different trophic levels or taxonomic groups. No single species is appropriate for every situation, but surrogates can provide useful information with a reasonable commitment of resources. The selection of surrogate species is discussed in U.S. EPA (1980, 1982, 1990c).

2.2.4. Practical Constraints

A number of practical constraints further influence the utility of measurement and assessment endpoints. Ideal assessment endpoints have a clear, unambiguous definition and can be predicted or measured. Ideal measurement endpoints have low natural variability, are easy and inexpensive to measure, have standard protocols, are supported by an existing data series, and produce scientifically defensible results (U.S. DOI, 1987; Suter, 1989).

Endpoints at lower organizational levels are often the most readily measured in controlled laboratory settings. However, community and ecosystem endpoints may be the easiest way to detect effects in field studies. For example, microorganisms that break down organic matter may be adversely affected by a stressor, but the effect may be difficult to recognize at the individual, population, or community level. Inhibition of decomposition can be evaluated at the ecosystem level by predicting or observing the accumulation of leaf litter on a forest floor. In addition, the natural variability in some endpoints at lower organizational levels may be larger than those at higher levels. In these cases it may be easier to detect stressor-related changes at higher organizational levels.

2.3. Presentation of the Conceptual Model and Evaluation Approach

The information gathered on the stressor, the receiving environment and endpoints is integrated into a conceptual model. The conceptual model consists of a series of working hypotheses regarding how the stressor might affect ecological components of the natural environment[7]. The conceptual model summarizes the hypotheses that will be evaluated in the hazard identification, stressor-response, and exposure assessments, and provides a foundation to determine whether the assessment will reflect all logical ways a stressor could cause an adverse response and ensure that important endpoints are considered.

The conceptual model can be presented in narrative or schematic form. An example of a schematic diagram is shown in Figure 3. In this example, decreased birth rate in a hypothetical aquatic population was selected as an assessment endpoint. The diagram illustrates different measurement endpoints that can be used to estimate decreased birth rate. The use of these diagrams is also discussed in Barnthouse et al. (1982) and Rodier (1990).

Many hypotheses may be generated during conceptual framework development; those that are most reasonable and quantifiable are selected for further evaluation. Because of data gaps, some hypotheses will not be carried further in the assessment; it is important that these hypotheses are noted when evaluating uncertainty during Risk Characterization. Professional judgement is needed to select the most appropriate risk hypotheses; the selection rationale should be documented.

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[7] The term hypothesis, as used in this guidance, reflects this preliminary thought process for relating and demonstrating relationships between observed or predicted effects and the stressor under evaluation. The NRC "green book" (1986) also describes development and use of working hypotheses in ecological assessments.

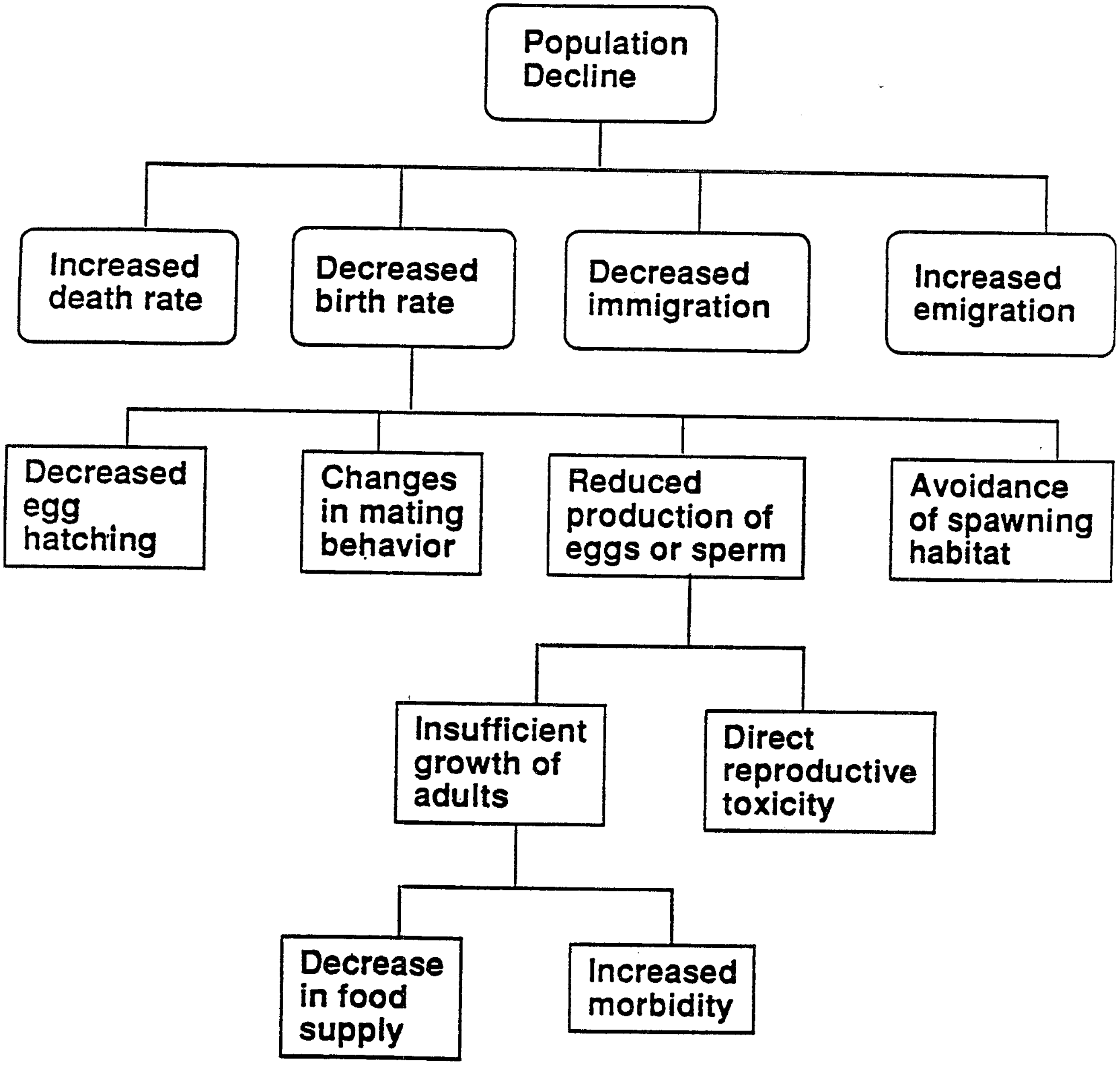

Figure 3: Example flow diagram analysis of decreased birth rate in a population

Data are not always available to support the development of a conceptual model. When data are insufficient for hypothesis development, it cannot be concluded that there is no risk; iterative evaluations are conducted to identify data gaps and ensure that hypotheses are developed.

3. HAZARD ASSESSMENT

Hazard assessment describes the relationship between the stressor and the endpoints identified during conceptual framework development. Hazard identification describes the causal relationship between the stressor and the assessment and measurement endpoints. Stressor-response assessment evaluates the relationships between the stressor and measurement endpoints and quantitatively extrapolates from these to assessment endpoints.

3.1. Hazard Identification

Hazard identification qualitatively evaluates the causal relationship between a stressor and an adverse effect[8]. The information gathered during hazard identification supports and complements the stressor-response assessment. For example, when the stressor-response relationship is based on laboratory studies, the hazard identification might gather data on effects that occur in the field. When stressor-response is based on observational field data (e.g., biomonitoring), hazard identification might focus on causal evidence.

Both controlled tests and observational studies may be used in hazard identification. Where test data are not available (e.g., for chemicals yet to be produced), structure-activity relationships may be helpful (Clements et al., 1988; Auer et al., 1990). Evidence provided by these studies is evaluated by considering the elements of statistical design and analysis, particularly with respect to replication and variability. For example, statistical methods are not very powerful (i.e., they cannot detect small differences) when replication is low and variability is high, such as in many observational studies. And statistical significance does not always reflect biological significance; important biological changes may not be detected by statistical tests. Professional judgement and statistical consultation are both used to evaluate statistical and biological significance.

Controlled laboratory and field tests can provide strong causal evidence linking a stressor with a response, and can also be used to discriminate between multiple stressors. Data from laboratory studies tend to be less variable than those from field studies because many environmental factors can be controlled in the

[8] A causal relationship occurs when an event, condition or characteristic plays an essential role in producing an adverse response (Rothman, 1986).

laboratory. However, because these factors are controlled, responses may differ from those in the natural environment.

Observational field studies provide environmental realism that laboratory studies lack. However, the presence of multiple stressors and other confounding factors (e.g., habitat quality) in the natural environment can make it difficult to attribute observed differences to specific stressors. Confidence in causal relationships can be improved by carefully selecting comparable reference sites, or by evaluating changes along a gradient of the stressor where minimal differences in other environmental factors are apparent. Potential confounding factors must be addressed during the analysis.

Many of the concepts applied to evaluating causal relationships in human epidemiology can be useful for evaluating observational field studies. Hill (1965) suggested that nine aspects of an association be considered when evaluating causality. Rothman (1986) summarized these criteria as follows:

1) **strength**, a high magnitude of effect is associated with exposure to the stressor;

2) **consistency**, the association is repeatedly observed under different circumstances;

3) **specificity**, the effect is diagnostic of a stressor;

4) **temporality**, the stressor preceded the effect in time;

5) **presence of a biological gradient**, a positive correlation between the stressor and response;

6) **a plausible mechanism of action**;

7) **coherence**, the hypothesis does not conflict with knowledge of natural history and biology;

8) **experimental evidence**; and

9) **analogy**, similar stressors cause similar responses.

Not all of these criteria need to be satisfied, but each incrementally reinforces the argument for causality. In addition, negative evidence does not rule out a causal association but may indicate that knowledge of the association is incomplete.

3.2. Stressor-Response Assessment

Stressor-response assessment quantifies the relationship between the amount of the stressor and magnitude of response. Ideally, it quantifies the relationship between the stressor and the assessment endpoint identified during conceptual framework development. When the assessment and measurement endpoint are the same, this analysis is straightforward. When they are different, the relationship between measurement and assessment endpoints is quantified first, and then extrapolations are used to predict changes in the assessment endpoint. In some cases, the quantitative relationship between measurement and assessment endpoints is not known, and qualitative inferences are made during Risk Characterization (see Chapter 5).

3.2.1. Types of Data and Analyses Used in Stressor-Response Assessment

The specific experimental protocols and statistical analyses used to assess stressor-response relationships depend on the assessment objectives and available methods. Since methods change, this discussion addresses the strengths and limitations of general approaches.

Like hazard identification, stressor-response assessments can be based on controlled laboratory and field studies and observational field studies. Stressor-response assessments often progress from short-term, inexpensive tests that measure effects on mortality to longer-term tests that evaluate sublethal effects such as reduced growth, development, or reproduction. Similarly, the test environment may progress from very uniform laboratory conditions to more realistic mesocosm and field trials. The decision for proceeding to a more detailed analysis can be based on stressor-response information alone (e.g., the LC_{50} is at or below a threshold value), or can be based on preliminary risk estimates.

Data from these studies can be used to test specific hypotheses or conduct a regression analysis. Hypothesis testing is most often used to identify a NOEL or LOEL (no-observed-effect and lowest-observed-effect levels, respectively). Hypothesis testing is a commonly-used and accepted approach, but has some important limitations: 1) statistical significance may not correspond to biological significance; and 2) a poor design or testing procedure can reduce the apparent toxicity of the chemical (Barnthouse et al., 1986). When using hypothesis testing, the power of the test to detect differences and the level of statistical significance should both be reported.

Regression analyses can generate stressor-response curves that can evaluate risk at different exposure levels. Regression analyses have been applied to both chemical and physical stressors (for an example of the latter, see Turner's [1977] analysis of the relationship between wetland area and commercial shrimp harvest). For practical reasons, the results of stressor-response curves are often summarized as one reference point, for instance, an LC_{50} or EC_{50} (lethal or effective concentration, respectively, in 50 percent of a test population). Although useful, these values provide no information about the slope or shape of the stressor-response curve. When the entire curve is used, or when many reference points are identified, the difference in magnitude of effect at different exposure levels can be reflected in the risk characterization.

3.2.2. Extrapolation Methods for Stressor-Response Assessments

As discussed above, a stressor-response assessment ideally quantifies the relationship between the amount of the stressor and the magnitude of change in the assessment endpoint. This section describes quantitative methods used to extrapolate between measurement and assessment endpoints. If quantitative methods are not available, measurement and assessment endpoints may be linked qualitatively (see Chapter 5). The rationale for any extrapolations and their associated uncertainty should be clearly explained.

Most quantitative extrapolation methods assess response to chemical exposure at the individual level. The discussion below addresses species-to-species, endpoint-to-endpoint, and laboratory-to-field extrapolations. Much less is known about extrapolating among communities and ecosystems. Models to extrapolate between levels of organization and evaluate indirect effects have rarely been applied. Active research in these areas may provide quantitative extrapolation methods in the future. Because these models are most often used to provide a common framework to describe and compare consequences of adverse effects rather than as predictive extrapolation methods, they are discussed under Risk Characterization (Chapter 5).

Species-to-Species Extrapolations

The difference in response between species is often estimated based on relative differences in other attributes such as physiology, morphology, or life history. The factors that influence response vary from stressor to stressor. If a stressor's mechanism of action is known, it may be easier to identify the characteristics that influence response and perform more confident extrapolations. These general concepts can be applied to physical as well as chemical stressors. For example, interspecies extrapolations for habitat alteration can be qualitatively based on life history characteristics such as resource utilization.

Statistical methods have great utility for species-to-species extrapolations, although most of these focus on evaluating responses of aquatic organisms to chemicals. One approach to species-to-species extrapolations simply calculates concentrations corresponding to a specific endpoint (e.g., an LC_{50}) for a number of species (see Sloof and Canton, 1983; Chapman, 1983; and Mayer et al., 1986 for aquatic examples). Untested species are assumed to fall within the same range (i.e., it is assumed that tested species adequately represent the response of untested species). The response range can be very large, and increases as more species are included in the study. However, the confidence that the response of untested organisms falls within the range also increases with the number of species.

Regression models can be used to reduce the confidence limits and increase the utility of species-to-species extrapolations by correlating taxonomic proximity with variation in response (Kenaga, 1978; Suter et al., 1983, 1986, 1987; Sloof, 1986; von Straalen and Denneman, 1989). These models indicate that taxonomic extrapolations have narrower prediction limits for closely-related species than for distantly-related species. In addition, the prediction limits tend to be narrower for structurally-similar chemicals (and chemicals with similar mechanisms of toxicity). Exceptions may be expected when life-history characteristics or biochemical and physiological processes are very different between closely-related species.

An area of active research is toxicokinetic and toxicodynamic modeling. These models evaluate inter- and intraspecies variation in response to chemicals and may provide a basis for more mechanistic extrapolations in the future.

Endpoint-to-Endpoint Extrapolations

Endpoint-to-endpoint extrapolations are used when short-term endpoints are used to predict long-term or chronic effects (e.g., an LC_{50} used to predict a NOEL). These extrapolations often include temporal and lifestage components and may combine several chronic endpoints. All of these components are integrated in an analysis of acute-to-chronic ratios or a regression analysis. The relationships derived are then applied to other species for which only acute data are available. The implicit assumption here is that the difference between acute and chronic toxicity remains relatively constant between species.

Because of the many sources of uncertainty, this approach often yields very large ranges of acute-to-chronic ratios and wide prediction limits in regression analysis (see, for example, Barnthouse et al., 1990 and Sloof et al., 1986). Endpoint-to-endpoint extrapolations often vary because the degree of response differs between tests. For example, results from an acute test will be expressed as an LD_{50}, whereas results from a chronic test are often expressed as a NOEL or LOEL. One way to reduce the confidence limits and increase the utility of these extrapolations is to correlate endpoints separately and standardize the degree of response (Mayer, 1990; Mayer et al., 1986; Suter et al., 1985).

Laboratory-to-Field Extrapolations

The responses of organisms exposed in the laboratory often differ from those exposed under natural conditions; laboratory-to-field extrapolations evaluate these differences. Laboratory predictions may overestimate field response if they do not account for compensatory or regulatory mechanisms, adaptation to stress, or reduced bioavailability under field conditions (van Straalen and Denneman, 1989; Suter et al., 1985). On the other hand, they may underestimate field response if laboratory conditions do not reflect actual field conditions, account for the ecological cost of adaptation, or identify other interacting stressors.

When possible, factors that influence differences in response between the laboratory and field should be incorporated quantitatively into the stressor-response assessment. For example, some data are available that relate specific habitat characteristics to changes in response to a stressor (e.g., water hardness and metal toxicity). Similarly, some data are available to help predict responses to complex mixtures that are composed of chemicals having the same mechanism of action (see Broderius and Kahl, 1985; McKim et al., 1987).

Laboratory-to-field extrapolations can greatly increase the uncertainty of response estimates, but the direction of any bias is often unclear. If the laboratory-to-field extrapolation appears to be the major component of uncertainty in an assessment, field studies may be warranted.

4. EXPOSURE ASSESSMENT

For the purposes of this document, exposure assessment is defined as the assessment of the spatial and temporal distribution of a stressor and its co-occurrence with components of ecological systems. This definition is somewhat broader than that provided in the Guidelines for Exposure Assessment (U.S. EPA, 1991) which focuses on human exposure to chemicals. The exposure guidelines differentiate between exposure, the contact of a chemical with an organism's outer boundary, and dose, the amount of chemical within the outer boundary of the organism. While these definitions are useful for chemical exposure to organisms, the broader definition better represents exposure assessment for ecological components (i.e., populations, communities, and ecosystems) where the boundary of the system does not serve as a barrier.

Many of the other concepts presented in the Guidelines for Exposure Assessment also apply to ecological exposure assessment. Important aspects of ecological exposure assessment include the following:

- Many different ecological components within a particular environment may be exposed, including organisms, populations, communities and ecosystems.

- The timing of the exposure relative to the life stage and seasonal activity patterns of exposed organisms can greatly influence the occurrence of adverse effects. Even short-term events may be significant if they coincide with critical life stages.

- The perception of, as well as direct contact with, a stressor can cause adverse effects. For example, the perception of degraded spawning habitat may cause animals to avoid spawning areas and decrease reproductive success.

Exposure assessments are most effective when the results of the exposure and stressor-response assessments are comparable. For example, exposure estimates used to evaluate acute effects should be averaged over short periods of time to take into account short-term, pulsed stressor events. Exposure assessments for chronic stressors should account for both long-term, low-level exposure and possible shorter-term, higher-level exposure that may elicit similar adverse chronic effects. Other factors to consider include cumulative effects from continuous or intermittent exposures, the magnitude and frequency of exposure, and the life-history stage of exposed organisms. Particular attention should be given to exposure during periods of reproductive activity, since early life stages are often more sensitive to stressors, and adults may also be more vulnerable during this time.

The description and analysis of uncertainty in exposure assessments is combined with other uncertainty analyses in risk characterization. Sources of uncertainty and methods for describing it are discussed in greater detail in Chapter 5 and in the Guidelines for Exposure Assessment (U.S. EPA, 1991).

4.1. Estimating Exposure

Guidance on specific methodologies for conducting an exposure assessment is beyond the scope of this document. However, the overview of the basic philosophy and concepts of ecological exposure assessment presented below provides a basis for method selection.

There are three approaches used to quantify human exposure to chemicals: point-of-contact measurements, scenario evaluation, and reconstructive assessment (U.S. EPA, 1991). The point-of-contact approach uses monitoring devices to measure the stressor at the actual point of contact while exposure is occurring. Point-of-contact measurements are rarely used in ecological risk assessment because it is difficult to attach monitoring devices to free-ranging organisms. The other two methods (scenario evaluation and reconstructive) are discussed below.

4.1.1. Exposure Scenario Evaluation

The scenario evaluation approach to exposure assessment consists of two basic elements. First, the spatial and temporal distribution of the stressor is measured or estimated. Second, the distribution of the biological component and its characteristics that influence exposure are evaluated. The two are combined to evaluate the co-occurrence of the stressor and the ecological component.

The first element of scenario evaluation measures or estimates the stressor's spatial and temporal distribution. The initial fate and transport evaluation conducted during conceptual framework development should be used to focus measurement and modeling activities. The measurement and modeling of chemical stressors are discussed in detail in the Guidelines for Exposure Assessment (U.S. EPA, 1991). Non-chemical stressors such as increased flooding can be evaluated with techniques from geology, hydrology, engineering, and other relevant fields. Physical alterations can be evaluated by ground reconnaissance, aerial photographs, or satellite imagery, depending on the scale of the disturbance. Quantifying specific attributes of physical alteration (e.g., fragmentation, edge effects) is an area of active research that may yield useful methods in the future.

The presence of one stressor may indicate that others are present. For example, removal of riparian (streamside) vegetation alters habitat structure directly. However, removal can also cause siltation and increase water temperature. In this case the initial stressor (vegetation removal) has additional ramifications (siltation and temperature rise). Similarly, the discovery of one chemical may provide good reason to test for others in the same location.

The second element of scenario evaluation considers the spatial and temporal distribution of the ecological components under evaluation. It should also consider the characteristics of these components that influence their co-occurrence with the stressor, such as habitat, food preferences, and reproductive cycles. Seasonal activities like migration and use of alternate resources may substantially influence exposure and should also be considered.

Exposure scenario evaluations use information routinely obtained by the Agency and are therefore cost-effective for ecological exposure assessments. The assessor should be aware that scenario evaluation implicitly assumes that measured or estimated stressor concentrations accurately represent those at the actual point of contact. In addition, exposure scenario evaluations commonly assess stressors individually, and may under- or overestimate exposure to multiple stressors and mixtures. Scenario evaluation can be performed with little or no data; consequently, the underlying assumptions and uncertainties should be clearly documented.

4.1.2. Reconstructive Exposure Assessment

Reconstructive exposure assessments examine organisms to determine the presence of, or previous exposure to, a stressor. Biochemical or physiological evidence (e.g., biomarkers) may be used to evaluate exposure. This form of exposure assessment is most useful when a chemical or unique metabolite can be detected in the exposed organisms. Changes in certain enzyme systems (such as mixed-function oxidases) must be interpreted carefully because other unrelated stressors may induce similar changes.

Retrospective exposure measurements (including biomarkers) are most useful for risk assessment when 1) they can be quantitatively linked to the amount of stressor contacted by the organism; and 2) the relationship between the measurement and an adverse response can be defined as part of the stressor-response assessment.

5. ECOLOGICAL RISK CHARACTERIZATION

Risk Characterization evaluates the likelihood that an adverse ecological effect could occur as a result of exposure to a stressor, and may also address the significance or consequences of identified risks. It integrates hazard identification, stressor-response assessment, and exposure assessment to evaluate the endpoints selected during conceptual framework development.

As discussed previously, the purpose of the risk characterization determines its sophistication and depth. Before proceeding, the assessor may wish to review the conceptual model and the relationship between measurement and assessment endpoints to evaluate how adequately the data meet the assessment's needs.

The strength of a risk assessment depends on its supporting data. Because there are many interactions between organisms, their environment, and introduced stressors, it may not be possible to answer every question that arises in a particular assessment. Thus, the assessor may need to supplement the analysis with assumptions or models to bridge interpretational or data gaps that arise during risk characterization. Any methods or assumptions used, and the rationale for their application, should be explained. Because ecological risk assessment is an area of current research, methodologies and assumptions evolve and change. Future guidelines may address developing technologies that might be used for ecological risk assessments. In the interim, EPA encourages the assessor to employ state-of-the-art methods and assumptions.

The four basic steps of ecological risk characterization are:

1. Evaluate the likelihood of adverse effects;

2. Describe the consequences of identified adverse effects;

3. Assess the uncertainty associated with the risk assessment and the evidence that supports the conclusions; and

4. Communicate the results of the risk characterization.

These elements are discussed below.

5.1. Assess the Likelihood of Adverse Effects

5.1.1. Basic Concepts

Ecological risk assessment compares predicted or measured environmental concentrations or levels of the stressor with the stressor-response data. Thus, the hazard posed by the stressor is compared with the exposure to the stressor in order to determine the likelihood of effects resulting from a combination of the two.

The degree of quantification in the comparison or integration step depends on the available data. Most ecological risk characterizations for single-chemical stressors are easily quantified because the endpoints used to determine hazard can be measured in a field or laboratory setting, and exposure can be measured or predicted. Characterizations for multiple-chemical stressors are harder to develop because hazard and exposure data are often unavailable and are difficult to determine empirically.

The quality and quantity of stressor-response and exposure assessment data determine how the risk characterization can be presented. When variation in the stressor-response and exposure assessments is quantified, the results can be presented probabilistically (e.g., there is a 50 percent probability of a 10 percent mortality). However, in most situations, data limitations permit only qualitative risk expressions (e.g., the LC_{50} will probably be exceeded).

Although desirable, a quantitative risk characterization is not mandatory (nor may it be achievable) for a successful ecological risk assessment. Qualitative judgements based on the best available data can be very useful. If qualitative categories of risk (e.g., high, medium, low) are used, it is important to define the categories clearly.

State-of-the-practice approaches, which are based on the principle of comparing hazard with exposure, are presented in subsequent sections. Some methods use only a single measurement endpoint such as an LC_{50}. If the results of an assessment are to be used as decision criteria (e.g., determine the need for additional testing), a comparison of single measurement endpoints may be appropriate. On the other hand, if the assessment compares regulatory options for mitigation, it is desirable that the risk characterization compare several stressor levels to obtain a range of values. The latter approach provides better insight into the magnitude or severity of hazard than a single measurement endpoint.

5.1.2. Quotient Method of Ecological Risk Characterization

A commonly-used method of ecological risk characterization is called the Quotient Method (Barnthouse et al, 1986). It compares hazard with exposure and has been used extensively for addressing the risks of pesticides (U.S. EPA, 1986) and industrial chemicals (U.S. EPA, 1990d). The algorithm is given below:

$$\frac{\text{Exposure Value}}{\text{Stressor-Response Value}} = \text{Quotient}$$

Exposure estimates may be measured or estimated, and may need to be adjusted to account for differences in bioavailability between laboratory and field conditions. The frequency and duration of the field exposure and the exposure used in the stressor-response assessment should also be comparable. The Quotient Method implicitly assumes that the predicted or measured exposure duration equals or exceeds that of the toxicological tests used to derive the stressor-response curves.

Stressor-response values commonly used with the Quotient Method include LC_{50}s, EC_{50}s, LOELs, and maximum acceptable toxicant concentrations (MATCs). When needed, stressor-response values should include the extrapolation factors presented in Section 3.2.2. Often, the stressor-response values are adjusted to provide some conservative measure of protection. As an example, one-tenth of an MATC might be used as the stressor-response value (U.S. EPA, 1990d).

Interpretation of the Quotient Method is fairly straightforward. The greater the expected exposure compared to stressor-response values, the larger the quotient and greater the risk (i.e., greater likelihood that the adverse effects described by the stressor-response value will occur). The Quotient Method works best when the ratio is either very low or very high. When the ratio is near 1, the results cannot be interpreted with certainty. Professional judgement should be used in such cases, and additional hazard and exposure data might be sought. The Quotient Method is most often applied by comparing one value from the stressor-response curve to exposure levels. An extension of this method that provides greater insight into the magnitude of expected effects is to compare many stressor-response values.

The Quotient Method has several advantages: It is simple, flexible, and amenable to the data obtained in standard ecotoxicological tests and exposure assessments. Among the disadvantages are that it cannot easily be applied to multiple stressors or cumulative effects, and it cannot predict the magnitude of any effect except that which corresponds to the reference point used in the calculation.

The Quotient Method addresses risks of direct effects that can be quantified; these may or may not be assessment endpoints. For example, a stressor may not be directly toxic to a fish of interest, but may be toxic to the invertebrates it feeds upon. The critical relationship between mortality in aquatic invertebrates and reductions in a fish population may be difficult for a risk manager to recognize unless the assessor links the two and describes the consequences during risk characterization.

5.1.3. Additional Approaches

The basic principle of integrating hazard and exposure can be applied in many ways. For example, exposure assessment models have been used to determine how often a particular stressor-response or other reference value will be exceeded in rivers and streams during a one-year season (U.S. EPA, 1988). Suter et al. (1983) treat reference values, such as an MATC, as probability distributions that are matched against similar exposure distributions to determine the probability of exceeding the reference. Models can combine many different reference values with models of exposure: For example, Pearlstine et al. (1985) combined hydrologic models with stressor-response data relating water level to tree growth to estimate the response of a bottomland hardwood community to different water flow regimes.

5.2. Describing the Consequences of Identified Risks

5.2.1. General Concepts

Many ecological risk assessments evaluate endpoints that can be directly measured or estimated using a closely-related surrogate or quantitative extrapolation methods. In these cases, the need for an evaluation of the consequences is reduced. In other cases, appropriate extrapolation methods relating measurement and assessment endpoints are not available, and an evaluation of the consequences of a measurement endpoints's occurrence is an integral part of the risk characterization process.

Consequences include indirect effects, effects at multiple organizational levels, and effects at greater spatial and temporal scales. Indirect consequences of an adverse effect are evaluated using the logical structure established during conceptual framework development as well as professional judgement. Interspecies relationships (e.g., predation) and resource utilization are considered when evaluating indirect effects. Effects on higher organizational levels depend on the severity of the effect, the number of organisms affected, the role of those organisms in the community or ecosystem, and characteristics that influence resiliency (see Section 2.3.2).

The implications of adverse effects to greater spatial and temporal scales are usually evaluated on a case-by-case basis and are influenced by the spatial and temporal distribution of the stressor. The spatial extent of adverse effects can be compared to the overall extent of the ecological resource. For example, adverse effects to a resource that is small in scale (e.g., acidic bogs) may have a small spatial effect, but represent a significant degradation of the resource due to its overall scarcity. Immigration and emigration patterns can be used to evaluate the implications of a local loss (e.g., destruction of a local heron rookery affects heron abundance over a much larger area). At the ecosystem level, import and export functions are considered (e.g., destroying coastal wetlands can reduce nutrient export to adjoining waterbodies).

The effects of short-term exposure may have long-term impacts. The temporal extent of adverse affects depends in part on the attributes of the exposed systems that influence resiliency and recovery. Ecosystem recovery depends on physiological, life-history, and genetic-adaptation mechanisms[9], and is difficult to predict. However, some useful generalizations can be drawn from recent reviews (Cairns, 1990; Poff and Ward, 1990; Kelly and Harwell, 1990). Recovery depends to a large extent on the existence of a nearby source of organisms to immigrate to an affected system. The source can be refugia within the affected system, or a nearby unaffected area. If some individuals are in a latent or unsusceptible stage during exposure, these individuals can provide a source of immigrants. Organisms immigrating from other areas must be able to reach the affected area; the distance immigrating organisms can travel depends on their mode of transport (e.g., by wind, water, self-propulsion) and the characteristics of the habitat between the two areas. Finally, the success of the immigrants depends on the chemical-physical environmental quality following exposure to the stressor (e.g., presence of persistent chemicals).

In summary, the evaluation of consequences may be critical for certain risk assessments in which the relevance of measurement endpoints is not clear to risk managers. However, not all ecological risk assessments require an evaluation of consequences. In cases where the stressor-response data indicate that direct effects are the main concern and these endpoints can be measured or estimated using quantitative extrapolation methods, further evaluation of consequences may be unnecessary.

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[9] There is some evidence to suggest that these adaptive mechanisms are influenced by historical patterns of temporal and spatial heterogeneity.

5.2.2. Methods for Describing the Consequences of Identified Risks

There are two basic methods for describing the consequences of identified risks: 1) narrative statements and 2) mathematical modeling.

Narrative statements describe the possible consequences if adverse effects occur in the environment. This approach uses the logical structure established during conceptual framework development and supporting information to demonstrate the consequences of concern.

When sufficiently supported, mathematical models can quantitatively describe the consequences of identified risks. Most often, they are used to provide a common framework for comparing the consequences of adverse effects: For example, an assessor may use laboratory data on the stressor's effect on the mortality and reproduction of individual organisms to evaluate its effect on a population. Mathematical models can extrapolate data for individual organisms to effects at the population level.

The applications of mathematical models to ecological risk assessment are not discussed here, but this topic may be addressed in future guidelines. In general, models should be considered in light of how well they make use of available data and support the decision-making process.

No single model is suitable for all risk assessment, and the assessor may want to apply more than one model to a system to cross-check results. The most appropriate model is the one best able to address the assessment endpoints selected during conceptual framework development. Models used to project risks to natural populations and communities can be divided into two main categories:

a) Single-species population (demographic) models can be used to predict direct effects on a single population of concern. These are basically bookkeeping models which balance natality and mortality factors for the population in question.

b) Multispecies models can include both aquatic food web models and terrestrial plant-succession or forest-gap models, and may be used for risk assessments at the population, community, or ecosystem level. Such models can assess both direct and indirect effects of the stressor on the population of interest and effects on the community or ecosystem as a whole. Generally, these are large-scale mechanistic models comprised of a coupled system of difference or differential equations. Both spatial and temporal dynamics can be modeled.

In summary, narrative explanations and mathematical models are equally-valid approaches for describing and evaluating the ecological consequences of an adverse effect. Either approach should present the assumptions made and associated uncertainties.

5.3. Uncertainty in Ecological Risk Characterization

5.3.1. Characterizing Uncertainty

In this step, the assessor describes the sources of uncertainty in each step of the risk assessment and the impact of each on the risk assessment's conclusions. Elements of uncertainty include those associated with particular analyses, methods, and techniques (e.g., fate-and-transport modeling, extrapolations). In addition, the rationale behind any assumptions should be clearly explained.

A useful approach to uncertainty characterization, suggested by Holling (1978), divides uncertainty into three major classes:

1) **Events that can be predetermined, with known effects and known probabilities of occurrence.** This type of uncertainty has also been described as quantitative uncertainty (Suter, 1990b). Examples include natural variability (O'Neill, 1979) and experimental, measurement, and sampling errors.

2) **Events that are partially describable, but have unknown outcomes or probabilities.** This type of uncertainty refers to incomplete characterization of the system in question. In any assessment, some variables are known but excluded by choice, and others are unknown and therefore inadvertently excluded. This category deals primarily with the hypotheses developed to explain the effects of the stressor on the system. Insufficient data and lack of fundamental understanding about ecological processes are examples of this type of uncertainty. Other sources are extrapolations from reference systems, unpredictable perturbations, and indirect effects (Harwell and Harwell, 1989).

3) **Events for which we have no experience or knowledge, or that involve unknown processes of unknown form.** This category includes "true" uncertainties, those for which we lack and cannot acquire information. Such uncertainties may be manifested as inconsistent results from alternative hypotheses or contradictory predictions from alternative models.

5.3.2. Reducing Uncertainty in Ecological Risk Assessments

The approach used to reduce uncertainty in ecological risk assessments varies with the source of the uncertainty and how it influences the assessment.

Quantitative treatments of uncertainty deal primarily with the first category of uncertainty (Finkel, 1990; Suter, 1990b). The effects of this type of error on risk assessments have been described by O'Neill and Gardner (1979). They can be quantified using Monte-Carlo simulation or statistical uncertainty analysis (O'Neill et al., 1982). Probability distributions for parameters and processes enable the assessor to place statistical bounds on the results of the assessment. Measurement errors can be minimized by obtaining data in accordance with accepted methodologies (published guidelines or other validated methods). Computational errors should be minimized by adherence to good laboratory practices and quality assurance procedures. Natural variability can be acknowledged and described, but it normally cannot be controlled or minimized. However, it may be described by appropriate statistical distributions and the quantitative methods described above.

Uncertainty due to data gaps (Category 2 above) is best addressed by collecting additional information. Conceptual uncertainty can be addressed during conceptual model formulation by development of alternative risk hypotheses or alternative predicative process models.

As noted by Suter (1990b), one way to reduce uncertainty is to use a combination of modeling, observation, and experimentation. Where a strong causal relationship has been established, observational or field studies may be the most appropriate for reducing uncertainty, particularly conceptual uncertainty. For example, effects observed in the laboratory can be verified by outdoor studies, which reduce uncertainty about whether the observed effects will occur in the field. Where the cause of observed effects is less certain, controlled laboratory experiments or modeling may help reduce conceptual uncertainty. Once causality is established, appropriate studies can be undertaken to reduce quantitative uncertainty.

5.3.3. Presenting Uncertainty

Quantitative approaches reduce but cannot eliminate the effects of true uncertainty. At best, such approaches place bounds on the risk assessment's conclusions. Differences between predictions from alternative models or hypotheses may result in contradictory or ambiguous conclusions. While such differences may be resolved by further analysis, decisions are often made in spite of remaining uncertainties (Tversky and Kahneman, 1974). Peterman (1990a,b) suggested that risk assessments include an estimate of the statistical power of the analysis, which can be used to determine the probability of rejecting the null hypothesis (concluding that the stressor causes no effect when an effect is indeed present). This analysis is useful for evaluating the results of several alternative models.

There is not always enough information to address all questions that arise during a risk assessment, so the assessor usually makes a number of assumptions based on data from the stressor-response and exposure assessments. Because these assumptions may introduce conceptual uncertainty, they should be carefully explained in the risk characterization.

A weight-of-evidence approach is often used to present information supporting the results and conclusions of the risk characterization. Weight-of-evidence analysis evaluates data quantity and quality as well as supplemental information (U.S. EPA, 1990d) such as that described in Hazard Identification. This can include data from field studies, observations of other adverse effects caused by a particular stressor, and data on observed effects for similar types of stressors (e.g., those with similar mode of action or belonging to the same chemical class).

The uncertainty analysis should present the strengths and weaknesses of each risk assessment element and the impact of associated uncertainties on the risk assessment's conclusions. A clear presentation of how uncertainty could relate to final risk management decisions can provide justification for obtaining or requesting additional information to reduce uncertainty.

5.4. Communicating the Results of the Ecological Risk Assessment

The presentation of an ecological risk assessment is as important as its scientific validity. Ecological risk assessments may focus on endpoints not readily understood by managers unfamiliar with biological or ecological concepts. Whether its conclusion is a simple quotient or a sophisticated simulation, a risk assessment may be misunderstood or misinterpreted if poorly presented. Suggestions for communicating ecological risk assessment results follow:

Clearly establish the relationship between endpoints and consequences.

In many cases the assessment endpoint is not directly affected by a stressor but will be severely impacted because of indirect effects due to loss of essential supporting resources. The assessor should explain the ecological relevance of such risks even if only in a qualitative discussion.

Provide a summary profile of the degrees of risk.

Risk assessments that compare many stressor-response values to exposure estimates provide greater insight into the magnitude of effects. Summaries may be presented in tabular, graphic, or narrative form. When more than one analytical method is employed, all results should be discussed.

Restate the assumptions and uncertainties in the ecological risk characterization.

Although assumptions and uncertainties are identified in each element of ecological risk assessment, those that most influence the conclusions should be repeated when communicating the results of the ecological risk assessment. The weight of evidence supporting the estimates should be clearly summarized.

Often, the data employed to conduct a risk assessment are flawed or incomplete. Data deficiencies should be clearly identified. The assessor should also describe the potential contribution of more accurate or complete data to reducing the uncertainty in the risk estimates.

Place risk in the context of severity, including temporal and spatial attributes.

There is no universally-accepted scale that can be used to compare ecological effects. However, the considerations outlined in Section 2.2 can be used to guide discussion of direct and indirect effects. Discussions of the spatial scale of effects relative to the extent of the resource affected and the time frame of the estimated effects add significantly to the value of a risk assessment.

6. GLOSSARY

Commensalism--A relationship between two species in which one benefits from the association and the other is unaffected.

Community--An aggregate of multiple populations within a specified location in space and time.

Direct Effect--Any adverse effect induced by a stressor that directly affects an ecological component of concern (e.g., individual, population).

Ecological Risk Assessment--The characterization of effects of one or more stressors on biotic components of ecosystems including communities, populations, or individuals.

Ecosystem--The biotic community and abiotic environment within a specified location in space and time.

Endpoint--A characteristic of an ecological system that can be affected by exposure to a stressor.

Endpoint, Assessment--The characteristic of the ecological system that is the focus of the risk assessment.

Endpoint, Measurement--An effect on an ecological component that can be measured and described in some quantitative fashion.

Exposure--The co-occurrence of a stressor (including sensory perception) with one or more ecological components.

Hazard--The intrinsic ability of a substance or other stressor to cause adverse effects under a particular set of circumstances.

Hazard Assessment[10]--The overall process of evaluating the type and magnitude of adverse effects caused by a stressor. Hazard Assessment consists of two steps -1) Hazard Identification and 2) Stressor-Response Assessment. Hazard Identification--the evaluation of the causal relationship between a stressor and an adverse effect.

Indirect Effect--An adverse effect elicited by a stressor to a ecological component via a reduction or change its food supply or other trophic level disturbances such as predator/prey imbalances.

Keystone Species--A species whose function plays a critical role in maintaining a particular community structure.

Lowest Observed Effect Level (LOEL)--The lowest amount or concentration of a stressor for which some effect is observed.

Maximum Acceptable Toxicant Concentration (MATC)--The maximum concentration at which a stressor can be present and not be toxic to the test organism. The MATC is normally calculated as the geometric mean of the lowest concentration for which an adverse effect was observed and the highest concentration that did not yield any adverse effects.

Median Effective Concentration (EC_{50})--The concentration of a stressor in water that is estimated to be effective in producing some response, other than mortality, in 50 percent of the test organisms over a specific time interval (e.g., a 48-hour daphnid EC_{50}).

Median Lethal Concentration (LC_{50})--The concentration of a stressor in water that is estimated to be lethal to 50 percent of the test organisms over a specific time interval (e.g., a 96-hour fish LC_{50}).

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[10] Hazard assessment currently has two commonly-used definitions: The first is the evaluation of the intrinsic potential of a stressor to cause adverse effects under a particular set of circumstances. This definition refers to the combination of hazard identification and stressor-response assessment. The second definition is a quotient or margin of safety calculated by comparing the toxicological endpoint of interest to an estimation of exposure concentration. This definition refers to a combination of stress response and exposure assessment. This document refers only to the first definition, which confines hazard assessment to hazard identification and stressor-response.

Mutualism--A relationship between two species where both benefit from the association and in fact cannot survive separately.

No Observed Effect Level (NOEL)--The amount or concentration of a stressor that does not result in any adverse effect.

Null Hypothesis--A hypothesis that states there is no difference between parameters. The null hypothesis is usually designated as H_o.

Population--An aggregate of interbreeding individuals of a species within a specified location in space and time.

Predictive Ecological Risk Assessment--The characterization of the ecological effects of a stressor prior to its release or occurrence.

Primary Productivity--The production of energy from sunlight by green plants.

Recovery--The ability of a population or community to partially or fully return to a level of equilibrium that existed prior to the introduction of the stressor.

Resiliency--The ability of a population or community to persist or maintain itself in the presence of one or more stressors.

Retrospective Ecological Risk Assessment--The characterization of the ecological effects of a stressor after or during its release or occurrence.

Risk Characterization--The evaluation of the likelihood that adverse ecological effects may occur as a result of exposure to a stressor, including an evaluation of the consequences of these effects.

Statistical Power--Defined as $1-\beta$ where β is the probability of failing to reject the null hypothesis when in fact the null hypothesis is false.

Stressor--Any physical, chemical, or biological entity that can induce an adverse response.

Trophic Level--A functional classification of populations within a community that is based upon feeding relationships (e.g., aquatic and terrestrial green plants comprise the first trophic level and herbivores comprise the second).

Stressor-Response Assessment--A quantifiable relationship between the amount or concentration of stressor and the magnitude of response observed in a test organism or other higher ecological component (e.g., population).

Xenobiotic--A chemical or other stressor that does not occur naturally in the environment. Xenobiotics occur as a result of anthropogenic activities such as the application of pesticides and the discharge of industrial chemicals to air, land, or water.

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Framework Document Workshop

<u>Pre-Meeting Issues Papers</u>

- Ecorisk Paradigm
- Conceptual Framework Development
- Hazard Identification and Stress-Response Assessment
- Exposure Assessment
- Risk Characterization

Pre-Meeting Issue Paper

WORKSHOP TOPIC: ECORISK PARADIGM

GENERAL ISSUE:

The proposed paradigm for ecorisk assessment is modeled after the National Research Council paradigm for human health risk (NRC, 1983). Is the modified paradigm presented in the framework document appropriate for ecorisk assessments, or is another approach preferable?

FRAMEWORK APPROACH AND QUESTIONS:

1. The proposed ecorisk paradigm is quite similar to the NRC health effects paradigm, but it also explicitly provides for an initial planning process in ecorisk assessments.

1a. Comment on whether the elements of the paradigm proposed in the framework document are appropriate. In what situations, if any, would another paradigm be more appropriate?

1b. It has been suggested that the conceptual framework development step be included in an expanded hazard identification section. Please comment on this suggestion.

1c. Comment on the need to include a monitoring step (following risk characterization) in the paradigm.

2. The framework document uses terms such as "risk assessment" and "hazard assessment" that either have no standard meaning or are used inconsistently in the ecotoxicology literature.

2a. Comment on whether terminology related to the paradigm (including "hazard assessment" and "risk assessment") is clearly defined and used consistently throughout the document. Suggest alternate terms or definitions, if appropriate.

2b. Comment on whether the definitions used in the glossary are appropriate and recommend any additional terms that should be added to the glossary.

3. The conceptual framework development section (and the framework document as a whole) emphasizes individual- or population-level effects. While this may reflect the present orientation of the Agency and the state of the science, some scientists feel that there should be more emphasis on community- and ecosystem-level measurements and effects.

3. What should be added or changed in the framework document to place appropriate emphasis on community- and ecosystem-level effects?

4. The proposed ecorisk paradigm maintains a distinction between the process of risk assessment (scientific analysis) and risk management (which may include social, political, legal, and economic/valuation factors). This distinction is also made in human health risk assessments. However, there has been considerable discussion as to the degree that policy or risk management issues should influence the objectives that are established at the outset of an ecorisk assessment. Thus, the relationship between ecorisk assessment and management may need additional clarification in the framework document.

4a. Comment on the roles of risk management in the initial stages of an ecorisk assessment (e.g. establishment of assessment goals and endpoint selection).

4b. What further explanations are needed, if any, of the role of policy considerations in the ecorisk process?

4c. Comment on the role of valuation considerations, in any, in ecorisk assessments. (Valuation concerns the assignment of monetary or societal values to ecological resources).

5. The framework document distinguishes between those areas of ecorisk assessment that are currently used and those areas that are under development or show promise.

5. Comment on whether the distinctions between the present state-of-the-science and future research needs in ecorisk assessment are clearly and appropriately made.

6. Some persons have commented that more examples should be used throughout the document to illustrate points made.

6. Where are additional examples needed? Can you suggest examples that could be used?

7. In the introduction, issues for consideration and future development are listed.

7. What issues, if any, should be added to the list?

Pre-Meeting Issue Paper

WORKSHOP TOPIC: CONCEPTUAL FRAMEWORK DEVELOPMENT

GENERAL ISSUE:

Conceptual framework development is proposed as the first step in an ecorisk assessment. Does this section provide an appropriate description of the process, and are relevant ecorisk issues adequately discussed?

FRAMEWORK APPROACH AND QUESTIONS:

8. The proposed criteria for endpoint selection are (1) purpose and needs of the assessment, (2) ecological relevance, (3) susceptiblity, and (4) practical constraints.

8. Which criteria, if any, should be added (such as type of stressor) or deleted?

9. The framework document distinguishes between "assessment endpoints" (the characteristics of an ecosystem that are the focus of the risk assessment) and "measurement endpoints" (the effects that are actually estimated or measured).

9a. What changes, if any, do you recommend in the terms "measurement endpoint" and "assessment endpoint"?

9b. What changes, if any, do you recommend in the examples shown in Table 2?

10. The conceptual framework development section concludes with the presentation of a conceptual model that is further evaluated in the exposure and hazard assessment sections.

10. Comment on whether the development of a conceptual model is a useful approach for focusing an ecorisk assessment. How should a conceptual model be used?

11.The importance of spatial and temporal scaling factors is mentioned briefly in the conceptual framework development section (2.1.1 - Exposure Settings and Pathways).

11. What additional consideration, if any, should be given to spatial and temporal scales?

12. Some decisions are based only upon preliminary information, similar to that assembled during Conceptual Framework Development. Examples include the decision to consult with the U.S. Department of the Interior on endangered species and the decision to implement an emergency removal.

12. Should the framework document acknowledge that Conceptual Framework Development can be used in this fashion?

Pre-Meeting Issue Paper

WORKSHOP TOPIC: HAZARD IDENTIFICATION AND STRESS-RESPONSE ASSESSMENT

GENERAL ISSUE:

This section includes discussions of the establishment of the causal relationship between stressor and response (hazard identification) and the quantification of that relationship (stress-response). Are the emphasis and level of detail provided for these topics appropriate?

FRAMEWORK APPROACH AND QUESTIONS:

13. The framework document distinguishes between hazard identification and stress-response assessment, as is commonly done in health risk assessments. Hazard identification, which establishes a cause-effect relationship between a stressor and a response, references Hill's criteria.

13a. Comment on the necessity of distinguishing between hazard identification and stress-response assessment.

13b. Discuss the usefulness of Hill's criteria for evaluating cause-effect relationships in ecorisk assessments.

14. The stress-response section describes both extrapolation techniques as well as the uncertainty associated with the extrapolation process. Extrapolation may occur at several levels: across endpoints at a given level of biological organization, across levels of biological organization, from the results of laboratory studies to the prediction of effects in the field, and across temporal and spatial scales.

14a. Are there other currently accepted extrapolation methods that should be added?

14b. Which portions of the extrapolation or uncertainty discussions should be condensed or expanded?

14c. Where should uncertainty be discussed, in this section or under risk characterization? Why?

15. While the framework document recognizes the significance of non-chemical stressors such as habitat alteration, sedimentation, and nutrient loading, there is only minimal guidance provided on these topics as compared with threats associated with toxic chemicals. In addition, there is little information on how to deal with multiple stressors (whether chemical or non-chemical) or cumulative effects.

15a. How should the discussion of non-chemical stressors be expanded?

15b. What additional guidance should be presented concerning the risks of multiple stressors and cumulative effects?

Pre-Meeting Issue Paper

WORKSHOP TOPIC: EXPOSURE ASSESSMENT

GENERAL ISSUE:

Does the discussion in this section adequately cover the major aspects of ecological exposure assessment?

FRAMEWORK APPROACH AND QUESTIONS:

16. Exposure assessment is defined as the evaluation of the temporal and spatial distribution of a stressor and its co-occurence with ecological components. The framework document highlights several aspects of exposure assessment, including the evaluation of multiple kinds of organisms, the importance of the timing of exposure, and the perception of and direct contact with a stress.

16. Are these considerations appropriate? What additional information should be highlighted?

17. Two methods of exposure assessment used in human health assessment were applied to ecorisk exposure assessment.

17. Comment on the usefulness of these two methods. What other methods, if any, should be added?

18. The framework document briefly discusses variables that may modify or complicate exposure assessments, such as the influence of species-specific habitat and behavioral patterns, bioavailability, multiple stressors, time-varying exposures, and multiple exposure routes.

18. Are these topics adequately addressed in view of the objectives and scope of the framework document? If not, what would you expand and how?

19. Methods for assessing uncertainty in exposure assessment are deferred to chapter 5 of the framework document.

19. What additional discussions of uncertainty in exposure assessment should be included in this section or elsewhere, if any?

Pre-Meeting Issue Paper

WORKSHOP TOPIC: RISK CHARACTERIZATION

GENERAL ISSUE:

The risk characterization process is defined to include determination of the likelihood of adverse effects, evaluating the consequences of the adverse effects, assessing uncertainties, and communicating the results of the risk assessment. Does this provide a complete picture of risk characterization as it is applied to ecorisk assessment?

FRAMEWORK APPROACH AND QUESTIONS:

20. The primary approach proposed in the framework document for evaluating the likelihood of adverse effects is the quotient method, which provides a point estimate or a series of point estimates of the ratio between exposure and effect levels. Other methods may be available that provide a more complete picture of risk by using a broader range of the stress-response curve or by considering a variety of different exposure scenarios.

20a. Comment on the clarity and usefulness of the discussion of the quotient and other methods.

20b. What are the alternatives to the quotient method of risk characterization (particularly for higher levels of ecological organization), and how might they be incorporated into the framework document?

21. Risk assessments generally provide an estimate of the probability of an adverse effect. The concept of ecorisk assessment in the framework document has been broadened to include more qualitative estimates of risk, such as might be used for comparative risk assessments or risk ranking exercises.

21. Discuss whether ecorisk assessments should include qualitative as well as quantitative evaluations of risk.

22. The section on uncertainty (5.3) describes general sources of uncertainty and discusses reducing and presenting uncertainty.

22a. Is the discussion of uncertainty clear? What, if anything, should be changed?

22b. What, if anything, should be added to the discussion of weight of evidence?

23. Ecosystem recovery is only mentioned briefly in the framework document (section 5.4 - Describing the Consequences of Identified Risks).

23a. Should more information on ecosystem recovery be included in this document? If so, specifically what should be added?

23b. Should ecosystem recovery be discussed in any other sections?

24. The consequences of effects (e.g. indirect effects, effects at higher levels of organization, and effects at other spatial and temporal scales) are discussed in risk characterization.

24. Is the discussion of ecological consequences appropriately located? Where else in the document should it be included?

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