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Summary Report: Risk Assessment Forum Technical Workshop on Population-level Ecological Risk Assessment

Office of the Science Advisor
Risk Assessment Forum

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

NOTICE

The statements in this report reflect the individual expert views and opinions of the workshop attendees, together with summary observations and recommendations of an Agency technical panel. They do not represent analyses or positions of the Risk Assessment Forum or of the U.S. Environmental Protection Agency.

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Preface

In June 2008, the Environmental Protection Agency's (EPA) Risk Assessment Forum convened a technical workshop on population-level ecological risk assessment to consider whether the current state of knowledge about this subject was sufficiently mature to develop guidance, and if so, to help to identify key actions needed to produce such guidance. The purpose of this document is to communicate the findings of that workshop.

In 1998, EPA's Risk Assessment Forum developed its *Guidelines for Ecological Risk Assessment* (U.S. EPA 1998) to help guide Agency programs and practitioners in the performance of ecological risk assessments. Public comment associated with publication of the *Guidelines* indicated a need for additional guidance for assessing effects at the population, community and ecosystem levels of ecological organization to serve as more substantive guidance on protecting populations of animals and plants. A survey of EPA ecological risk assessors at that time ranked effects at higher levels of biological organization, along with assessment endpoints and measures of effect, as having the highest priority for development of additional guidance. The call for guidance has been repeated in recent international efforts addressing population-level ecological risk assessment (e.g., Barnthouse et al. 2008; Forbes et al. 2009). In particular, Barnthouse et al. (2008) recommended development of guidance to assist risk assessors, risk managers and stakeholders in selecting, applying, interpreting and communicating population-level ecological risk assessment procedures and analysis tools to cover a range of environmental management contexts. Guidance of this nature does not exist at this time, although Barnthouse et al. (2008) felt that the state-of-the-science was sufficiently mature to produce it.

The primary goal of this document is to inform EPA in its decisions regarding development of additional guidelines or best practice descriptions for planning, implementing and interpreting ecological risk assessments that involve population-level assessment endpoints. It communicates the individual opinions and insights of scientific experts in the fields of population ecology and ecological risk assessment as offered during the workshop. It also communicates the recommendations of an Agency Technical Panel concerning development of guidelines or best practice descriptions for population-level ecological risk assessment, and the actions that can be taken to facilitate development of such guidance. This document does not provide technical guidance for population-level ecological risk assessment, nor does it address the policy issues attendant with performing or interpreting such assessments. This report was prepared by a Technical Panel and Workshop Steering Committee under the auspices of EPA's Risk Assessment Forum, and the Risk Assessment Forum is its primary intended audience.

The Risk Assessment Forum was established to promote scientific consensus on risk assessment issues and to incorporate this consensus into appropriate risk assessment guidance. To accomplish this, the Forum assembles experts from throughout EPA in a formal process to study and report on these issues from an Agency-wide perspective. Technical experts from outside the Agency often contribute to this process as part of workshops and other issue-oriented mechanisms. This document, and the workshop it describes, reflects the Forum's long-standing commitment to advancing the concepts and practice of ecological risk assessment.

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Acronyms

ABM	agent-based model
ALMaSS	Animal, Landscape and Man Simulation System
AQUATOX	a general fate and effects model for aquatic ecosystems
ATLSS	Across Trophic Level System Simulation
BASS	Bioaccumulation and Aquatic System Simulator
CADDIS	Causal Analysis/Diagnosis Decision Information System
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CREM	U.S. EPA Council for Regulatory Environmental Modeling
D4EM	Data for Environmental Modeling
EC_x	concentration causing an effect level of x
EMAP	Environmental Monitoring and Assessment Program
EPA	Environmental Protection Agency
ERA	ecological risk assessment
ERAF	U.S. EPA Ecological Risk Assessment Forum
EU	European Union
I&E	impingement and entrainment
IUCN	International Union for Conservation of Nature
LC_x	concentration causing a lethal response of x
LTRE	life table response experiment
LOAEL	lowest observed adverse effect level
NBII	National Biological Information Infrastructure
NOAEL	no observable adverse effect level
OPP	U.S. EPA Office of Pesticide Programs
ORD	U.S. EPA Office of Research and Development

ORNL	Oak Ridge National Laboratory
OST	U.S. EPA Office of Science and Technology
OSWER	U.S. EPA Office of Solid Waste and Emergency Response
PATCH	Program to Assist in Tracking Critical Habitat, also called HEXSIM
PATH	Plan for Analyzing and Testing Hypotheses
QA	quality assurance
RAF	U.S. EPA Risk Assessment Forum
RAMAS	a family of commercially available software for population risk and other analyses
RCRA	Resource Conservation and Recovery Act
REMAP	Regional Environmental Monitoring and Assessment Program
RI/FS	Remedial Investigation/Feasibility Study
SAB	U.S. EPA Science Advisory Board
SETAC	Society of Environmental Toxicology and Chemistry
SSD	species sensitivity distribution
TMDL	total daily maximum load
ULM	Unified Life Models
USACE	U.S. Army Corps of Engineers
USFWS	U.S. Fish and Wildlife Service

Executive Summary

E.1 Background

The U.S. Environmental Protection Agency (EPA, or the Agency) has adopted risk assessment as a primary tool supporting environmental decision making. To help maximize the value of ecological risk assessment (ERA) to Agency programs, EPA's Risk Assessment Forum (RAF) produced the landmark *Guidelines for Ecological Risk Assessment* (U.S. EPA 1998) which describe a general strategy and framework for planning, executing and interpreting ERAs. The 1998 *Guidelines* recommend a planning dialogue among risk managers, risk assessors and other interested parties as a critical first step toward initiating an ERA. This dialogue is intended to produce agreement on and understanding of management goals and the types of decisions that the assessment will support. It also establishes the scope, complexity and focus of the risk assessment to be conducted. Depending upon their context, planning agreements might be established as a matter of policy, or might be made on an *ad hoc* basis to inform situation-specific management decisions. Regardless, these agreements lead to selection, during the problem formulation phase of the assessment, of the endpoints to be evaluated during the risk assessment. Assessment endpoints are selected to describe valued ecological entities and their attributes at levels of ecological organization that are relevant and applicable to the decisions being made, and in combination can encompass single or multiple levels of ecological organization in a single assessment.

The choice of ecological organization levels to be evaluated in regulatory ERAs can be a challenging one. Although the enabling legislation of many of EPA's programs either explicitly or implicitly identify protection of ecological populations as management goals, most ERAs conducted for chemicals by EPA, and indeed by most organizations worldwide, focus on organism-level entities and attributes (e.g., rainbow trout survival, growth or reproduction) as assessment endpoints. These endpoints are practical because they often can be estimated through toxicological testing and other means, and are expedient because they are commonly presumed to provide protection of population-level attributes (e.g., abundance and persistence). Further, methods and practice are well established for assessing risk to organism-level assessment endpoints, but documentation of consensus methods for population-level ecological risk assessment is lacking. Consequently, risk to populations has only occasionally been evaluated directly by EPA (e.g., trout populations of Adirondack lakes in the National Acid Precipitation Assessment). This situation results from several factors affecting assessment planning, including the perceived relationships between assessment endpoints and environmental management goals, historical precedence, and importantly, the lack of recognized consensus and guidance about how such assessments should be performed.

The RAF conducted a colloquium in 1999 to help identify the nature and scope of projects that would advance development of ecological risk assessment guidance in three broad areas: 1) effects at higher levels of biological organization, including landscape-level effects; 2) assessment endpoints and measures of effect[2]; and 3) risk characterization techniques. A broad theme emerging from discussion of the first area was a focus on methods for assessing risks to populations and interpreting the results obtained by those methods. During the colloquium, the needs of "on-the-ground" risk assessors and risk managers led to identification of several developmental projects (organized by assessment phase in Table 1) related to population-level ecological risk assessment and approaches to implement them. These approaches reflected a number of considerations, including the perceived state-of-the-science, the types of intermediate products deemed useful and the needs of the Agency.

[2] The RAF published guidance for *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment* (EPA/630/P-02/004f) in 2003 (www.epa.gov/raf/publications/geae.htm).

In 2005, the RAF formed a Technical Panel to explore a number of issues associated with population-level ecological risk assessment. Consisting of representatives of EPA Program Offices, Regions and the Office of Research and Development (ORD), this working group initially identified three broad actions intended to enhance the Agency's understanding of approaches for assessing risks to populations. These actions are:

1. <u>Expand training in population-level ecological risk assessment</u> – Since the publication of the *Guidelines*, ORD has received a number of requests for formal training and educational exchanges addressing topics related to population-level ecological risk assessment. To help meet this need, EPA's Risk Assessment Forum sponsored the vendor-supplied "Population Modeling Training Workshop," conducted at Region 5's offices in Chicago, Illinois in late 2004. This training was coordinated through the Ecological Risk Assessment Forum (ERAF) and was attended primarily by regional risk assessors who support hazardous waste assessments under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA).

   In response to the positive reception of the Chicago training workshop, the RAF Technical Panel identified additional training opportunities, open to all interested Agency personnel, as a near-term mechanism to enhance familiarity by Program Offices and Regions with population-level ecological risk assessment concepts and methods. Additionally, such training could facilitate identification of issues requiring enhanced guidance. Progress in this first action was made in October 2006 when the RAF sponsored a vendor-supplied "Population Ecological Risk Assessment Training Workshop" in Crystal City, Virginia.

2. <u>Convene a technical workshop on approaches for population-level ecological risk assessment</u> – As an action to be completed in the mid-term, the Technical Panel identified a multiple-day technical discussion of the states of the science and practice of population-level ecological risk assessment to help inform the Agency in decisions concerning development of additional guidance supplemental to the 1998 *Guidelines*. Such an event would bring together Agency and external experts in population ecology and ecological risk assessment in part to build upon the previous discussions of this nature (e.g., Barnthouse et al. 2008). This workshop was held in June 2008 and is the primary subject of this report.

3. <u>Develop best practices guidance for population-level ecological risk assessment</u> – Development of best practices guidance was envisioned by the Technical Panel as a long-term (2-4 year) activity. The specific projects and actions needed to produce such guidance would be informed by the workshop, by input received from various training events and by other developmental activities as needed. The guidance would be developed by a cross-program Technical Panel of the RAF to supplement the 1998 *Guidelines*, and would be responsive to the needs of Agency Programs and Regions in their performance of population-level assessments that inform regulatory decisions. Technical Panel recommendations for developing this guidance are offered in Section 5 of this report.

E.2 Workshop Objectives

The RAF Technical Panel organized this technical workshop to achieve three specific objectives:

1. Identify the approaches, methods and tools currently available for performing population-level ecological risk assessment in support of EPA programmatic and regional decision making.

2. Identify the strengths, current limitations, tradeoffs and outstanding research needs associated with specific methods and

tools currently available for performing population-level ecological risk assessment in support of EPA programmatic and regional decision making.

3. Identify areas of need with respect to development of written guidance for performing population-level ecological risk assessment to supplement the *Guidelines for Ecological Risk Assessment*, and the additional steps that can facilitate development of such guidance.

These objectives were derived from the recommendations of the 1999 colloquium and the desires of practitioners, risk managers and stakeholders for guidance in performing and interpreting population-level ecological risk assessment. The focus of the workshop was on the technical matters of conducting, and the state-of-the-science supporting, population-level ecological risk assessment, and not on the policy issue of levels of ecological organization appropriate for environmental decision making. The individual insights and opinions exspressed during the workshop were intended to inform future RAF projects and potential development of guidance. The workshop itself did not produce guidance or policy for any agency, nor did it develop consensus opinions or group recommendations for consideration by EPA.

The Workshop on Population-Level Ecological Risk Assessment was convened on June 16-18, 2008 in Crystal City, Virginia. Thirty-two experts in population ecology, ecological risk assessment and risk management were invited from EPA Programs and Regions, the U.S. Army Corps of Engineers, academia and the private sector to reflect a range of perspectives (Appendix A). A small number of non-participating observers, exclusively from EPA, were present on the first day of the workshop.

The workshop's format included both plenary interactions and breakout group conversations intended to facilitate information exchange. The final workshop agenda is provided as Appendix B. Plenary presentations and discussions during the first day of the workshop were structured to establish context and a common basis of understanding by summarizing past efforts and providing broad overviews from the perspectives of EPA and other users of population risk information. These presentations covered a wide range of topics, and included descriptions of the needs and approaches of individual Program Offices and Regions, the perspectives of another federal agency (the U.S. Army Corps of Engineers, a long-time partner in population risk research), case study illustrations of how population-level assessments were used to inform decisions, and insights from experiences in other countries. An evening poster session on the first day of the workshop provided the opportunity to explore case studies and assessment approaches in greater detail. Summaries of these presentations are offered in Section 2 of this report.

Three primary approaches for obtaining information about the population-level consequences of human activity—observational, empirical and modeling—provided the structure of breakout groups charged primarily with characterizing the states-of-science and practice of techniques, methods and tools of each approach. In this regard:

<u>Observational approaches</u> include those that obtain data by monitoring the responses of populations in the field to pollutants or other anthropogenic stressors, and to natural variables. The analysis of such data is sometimes called "ecoepidemiology." These approaches can be used to:

- Describe the condition of an assessment population and determine the causes of spatial and temporal variation in population attributes
- Generate exposure-response relationships directly from observational data
- Provide data to parameterize process-based models
- Provide data to test specific risk hypotheses and the predictions of process-based models

<u>Experimental approaches</u> involve controlled experiments (e.g., toxicity tests) that expose organisms or populations of organisms to varying levels of chemical, physical and biological agents to evaluate population response. Experiments can be performed in a laboratory, field or semi-field system. These approaches can be used to:

- Derive understanding of population responses directly from the data (e.g.,

population growth rate, equilibrium abundance)
- Provide data to parameterize process-based models
- Provide data to test specific risk hypotheses and the predictions of process-based models

Modeling approaches involve application of process-based population models to general and specific risk problems to evaluate population response to varying levels of chemical, physical and biological agents, and to natural variables. Process-based models are mathematical constructs that estimate properties of biological populations such as growth rate or time to extinction, and are based on estimates of underlying biological processes (such as survival rates) and environmental change. These approaches can be used to:

- Project or forecast population-level consequences of changes in stressors and other environmental conditions associated with different management scenarios
- Evaluate the population-level consequences of changes in individual-level attributes observed or measured using observational and experimental approaches
- Evaluate distributions of population outcomes through time and across space
- Inform the design of observational and experimental approaches for assessing population risk

The three breakout groups met throughout the second day of the workshop to consider questions relevant to workshop objectives (see Appendix C) from the perspective of each individual's expertise. Two breakout group leads, one from the Workshop Steering Committee, the other invited from outside of this committee, facilitated the discussions and the expression of individual opinions. No attempts were made to seek consensus among breakout group members on any point or issue; rather, the intention was to capture the diversity of expert opinions and perspectives in each group relative to their charge. Group membership consisted primarily of experts with respect to the specific approach to population-level ecological risk assessment being considered. Two mechanisms were used to help ensure a healthy level of cross-fertilization in the discussions: 1) each group was "seeded" with experts in the other two approaches, and 2) the workshop chair, workshop facilitator and RAF liaison each circulated among breakout groups to communicate issues from the other groups. Each group had a note taker to capture conversations.

The individual perspectives and opinions of participants in the three breakout groups were reported and summarized in plenary on the third day of the workshop to address the workshop's three primary objectives. Facilitated discussions following the breakout group reports provided yet another opportunity for the exchange of perspectives and ideas.

E.3 Summary of Expert Opinions

The summaries provided in Section 3 communicate the breadth of opinions and input expressed by workshop attendees during breakout group conversations. Section 4 communicates additional observations, issues and suggestions that were expressed during plenary discussions. Although no attempts were made to seek consensus on any particular issue or topic, certain commonalities emerged over the course of breakout and plenary interactions. Key opinions with respect to workshop objectives are summarized here.

E.3.1 Experimental Approaches

Participants generally felt that the methods employed to provide data for input to population-level ecological risk assessments are sufficiently well developed and informative to warrant development of guidelines or best practices descriptions. Several experimental methods are available, and sometimes even standardized, that can measure the responses of experimental populations to stressors directly, or that provide data that can be extrapolated to the population level of biological organization. Even so, additional design considerations might be required to help ensure that key hypotheses regarding mechanisms of effect and other important ecological processes can be evaluated as needed to inform environmental decision making. In this regard, some experimental designs likely have limited ability to incorporate processes and interactions that can have important population consequences, such as competition and other forms of species interactions. Careful planning during problem formulation of the assessment will help to ensure use of experimental designs and methods that provide the information needed to quantify decision-relevant risk.

Because experiments inherently are abstractions of nature and therefore cannot include all aspects that might have ecological relevance, additional research and development might be needed to improve the value of experimental approaches to population-level ecological risk assessment. For example, the issue of cross-species extrapolation was highlighted. Many species are not particularly amenable to experimental manipulation, and when assessment goals focus specifically on populations of such species, their responses to stressors will need to be extrapolated from those of surrogates. Some progress could be made toward resolving this issue by focusing upon mechanisms of action and their ecological analogs, but there likely will always continue to be meaningful uncertainty whenever cross-species extrapolations are required. Extrapolation of organism-level measures to characterize risk to populations might be less worrisome, because a variety of modeling approaches are available that can accommodate organism-level attributes to project population dynamics. Even so, attention is needed to help ensure that experimental data are collected in the forms and temporal frames required by extrapolation models.

Other areas of valuable research include development of approaches and data that can link certain types of measures—namely biomarkers and organism dose concentrations—more directly to the key demographic rates of reproduction and survivorship that determine population dynamics. In a similar vein, there might be opportunities within the evolving technologies of genomics and proteomics to develop approaches that link data derived from these techniques to population response. Advancements in this area could produce efficiencies in the collection of information for assessing population risk. Finally, discussions emphasized the potential value to be derived from combining experimental methods (including more tightly coupled laboratory and field experiments) with modeling and observations, as these approaches provide complementary and supplemental information about risks to populations.

Several activities were identified that could support communication of best practices. Included are case study analyses, both comparing the informational value of population-level measurement endpoints versus organism-level measurement endpoints when assessments include populations as environmental values to be protected, and evaluating the efficacy of population-level assessments with respect to the outcomes of decisions based upon them. Associated with this was a sense that descriptions of experimental designs that promote use of the resulting data in modeling evaluations, and of how experimental data can best be used in modeling applications, should be developed to help focus experiments on generating the most critical information needed. Included were specific guidelines for performance of life table response experiments (LTREs), bucket tests and so on. Guidance about how experimental results should be interpreted and communicated with respect to population risk was also identified.

E.3.2 Observational Approaches

Workshop participants generally agreed that observational methods are well established in the fields of ecology and conservation biology, and that approaches based upon them have unique advantages in reflecting realism with respect to population responses to stressors in the environment. In this regard, information obtained through direct observation reflects the effects of multiple stressors and influences of compensatory mechanisms (e.g., density dependence), but the relative contributions of various effects and processes usually are difficult to tease apart. Additionally, the variability inherent to natural systems could at times mask detection of some important stressor effects. Observational approaches were thought to be applicable to all tiers within a tiered assessment protocol. Many noted, however, that the utility of observational approaches might be limited with respect to prospective assessments due to imperfect transferability of study results beyond the conditions and context within which they were obtained. They also have limited value for helping to evaluate decision alternatives, because the information they produce reflects only the specific circumstances in which they were conducted. Data from observational studies can, however, help to inform reassessments of past management decisions. It was noted that new methods are coming on line that can help to guide decisions about the inferences that can be made using observational data.

Developmental activities that were identified to promote best practices included compilations of case study examples of the use of observational approaches to assess population risk, examples of when such approaches failed to provide the information needed to assess population risk, and how observational studies influenced decisions. Workshop participants highlighted the value of catalogues and annotated descriptions of available methods and observational data sets and sources. Guidance in the form of decision trees was suggested as being particularly helpful with respect to assessment planning and interpretation of observational study results. Participants also noted that acceptance of the use of observational approaches by decision makers could be facilitated and enhanced through development of best practices descriptions for effective communication.

E.3.3 Modeling Approaches

Contributors to the workshop expressed the opinion that population models and the approaches to deploy them within population-level risk assessment are well established, and noted several compilations of model descriptions and use considerations in the recent literature. Opinion was expressed that the stressors under evaluation, and especially the decision context, influence which models and approaches provide the most valuable information. It generally was believed that population models can be used to advantage in any level within a tiered assessment protocol, and that they are important integrators of data and knowledge gained through observational and experiment approaches. Important drawbacks to modeling approaches, however, include the skepticism often expressed by decision makers about the degree of realism captured by models and the accuracy of their outputs, and concerns about assessment transparency when stakeholder and decision maker understanding of modeling is limited. A lively plenary discussion centered around perceived inconsistencies in the level of acceptance of population models relative to chemical fate and transport models (of which acceptance is high). Associated with this was continuation of the ongoing debate centered around the meanings and desirability of model verification, validation and evaluation.

In spite of the generally high regard held by most workshop participants for population models, certain developmental issues were highlighted as important. Among these was advancement in coupling population models more directly to exposure models, particularly with respect to physiological-based dose-response models. Additional exploration of modeling philosophy and approaches addressing the effects of multiple stressors would enhance model realism and likely, accuracy. Issues associated with the form and strength of density dependence as important determinants of population response to stressor exposure, although not directly ones of modeling per se, might influence model realism and the accuracy of assessment conclusions. Several participants expressed the opinion that density dependence might not be as important an issue as some believe. Additional attention to developing accessible implementation software and packages also was highlighted as a need, although some software is available commercially or as freeware.

A number of activities were identified that would foster acceptance of good practices in the use of modeling approaches in population-level ecological risk assessment. Important among these were:

- Development of a decision framework for model selection
- Development of best practices guidelines for interpreting modeling results
- Identification of best practices for

facilitating communication directly with decision makers and stakeholders

- Documentation to guide design of experimental and observational studies performed in conjunction with modeling approaches to ensure modeling compatibility with data accessibility
- Development of guidelines for approaches that extrapolate effects reflected in toxicity data through time

E.3.4 Commonalities Across Approaches

Several considerations expressed during the workshop cut across assessment approaches, and reflected the general sentiments of many of the participants. Most importantly, in relation to workshop objectives, was the sense that the science underlying population-level ecological risk assessment is sufficiently mature to support further development of best practice guidelines. Although the various approaches have perceived benefits and limitations relative to different decision contexts, and attention to certain developmental needs is desirable, opportunities for applying existing techniques to inform decisions were identified within almost all of EPA's regulatory programs. Participants often articulated the opinion that the three assessment approaches should best be treated as interdependent and complementary, and that the power and value of population-level ecological risk assessment as a decision-informing tool are enhanced when approaches are used in combination. Also expressed was the sentiment that a primary advantage of focusing attention more explicitly on measurement endpoints and analysis techniques that address population attributes directly is an assessment more relevant to decisions involving protection of populations. Most workshop participants promoted greater use of population-level ecological risk assessment as a tool to inform environmental decision making.

Documentation, communication and training were felt to be components critical to credible performance, advancement and acceptance of population-level ecological risk assessment by practitioners, decision makers and the public. Important in this will be articulation of a framework uniquely oriented toward planning, implementing and interpreting results of population-level ecological risk assessments. This framework could include considerations leading to selection of assessment approaches (i.e., combinations of experimental, observational and modeling techniques) appropriate to the decision and its context, potentially organized in the form of a decision tree. Compilations and catalogues of existing techniques, models, designs and data could be linked to the decision tree to aid assessment planning and performance. Programs could be developed to help ensure that practitioners are appropriately trained in relevant techniques and models. Specific best practices guidelines would help to direct interpretation of data and results, focused on the decision they intend to inform. These guidelines might summarize key aspects of ecological theory and link to compilations of case studies as illustrations of sound interpretation approaches. Additional guidelines could support communication of assessment results and their meaning to the end-users of the assessment. And throughout, materials and information should be oriented toward or tailored to the unique decisions and contexts of EPA's programs.

Several cross-cutting issues will require attention if guidelines are to be developed. Key among these are considerations associated with pragmatic definitions of *assessment population* in various decision contexts. Although reasonable approaches to address this particular issue exist, definition of the assessment population has been problematic for Superfund and certain other programs. Somewhat related to this are considerations about spatial scale and context, and time horizons appropriate to various management goals and decisions. Attention also is needed for identifying those measurement endpoints most relevant to population assessment endpoints and the nature of risks being evaluated. And finally, all acknowledged that assessment populations do not exist in isolation from other populations. Species interactions can have important and substantial influences on population performance and the risks associated with anthropogenic stressors. Some of the techniques explored during the workshop (especially observational approaches) reflect or accommodate species interactions more realistically than do others. Even so, the importance of species interactions to assessment results, and the uncertainties created when species interactions are ignored, will require careful consideration as the science of population-level ecological risk assessment is employed.

E.4 Technical Panel Recommendations

The resounding sentiment of the experts assembled in this workshop was that EPA and ecological risk assessment practitioners alike would benefit from guidelines or best practices documentation concerning population-level ecological risk assessment. The science underlying such assessments is sufficiently well developed that guidelines could be created to promote best practices with the understanding that such guidelines would be updated on a regular basis as the state-of-the-science and practice of population level ecological risk assessment improves over time. Based in large part on the opinions of these experts, but also based on our individual and collective professional perspectives, the RAF Technical Panel recommends that the Forum proceed with an effort to develop best practices guidelines for population-level ecological risk assessment. This section describes some of the options and outputs that could be pursued in such a project. Suggestions are offered only generally about how best to accomplish individual activities and the overall project. It is suggested, however, that a phased implementation with multiple intermediate products is likely to be most successful.

The Technical Panel recommends a phased approach to producing guidelines. Initial issue-oriented white papers and summaries would help to document the current states of science and practice of technologies supporting population-level ecological risk assessment, and could suggest how EPA programs would benefit from a more explicit focus on risk to populations. Opinion statements would help to visualize how regulatory programs could use information directly communicating population risk to facilitate understanding of the advantages and limitations with respect to program mandates. Supporting white papers could summarize EPA program policy with respect to management goals, and how a more explicit focus on population-level measures could support the decisions to meet those goals. Additional opinion papers, summarizing current knowledge, could focus on inferences drawn about risks to populations, and on projecting future Agency practices that would be more inclusive of population risk.

Development of best practice guidelines likely will require directed conversations involving ecologists, practitioners and users of assessment results. Workshops that enable such interactions likely will be important steps to developing best practices guidelines. Topics for deliberation include detailed evaluations of methods, best approaches for combining methods in relationship to decision contexts, and the decision criteria and processes that could lead to a planning and implementation framework specifically for population-level ecological risk assessment. Equally important is development of guidelines for interpreting results and assessment outcomes. Such guidelines could be organized by assessment endpoint attribute, and could describe a nested hierarchy of considerations and conclusions for interpreting lines of evidence generated by multiple assessment approaches.

Retrospective analyses of cases in which risks to populations were assessed would provide both examples for future assessments, and opportunities to evaluate the efficacy of various approaches. Either as part of this or as a separate effort, considerations of the informative value to environmental decision making of population-level ecological risk assessment and the approaches used would provide additional insights supporting best practices guidelines. Case study evaluations could be commissioned from groups of experts, or could be conducted in focused workshop settings.

In a related vein, assembly of information describing the methods, models and data sources would help to improve the accessibility of these tools to risk assessment practitioners. Compilations could include annotations describing acknowledged advantages and limitations of methods and models with respect to various risk problems, environmental settings, stressors and decision contexts. Catalogues pointing to key sources of toxicological data, demographic and life history information and extrapolation relationships would facilitate access to critical information and would help to promote the quality of future assessments.

Attention to education, communication and outreach will be critical to the success of an RAF project that develops best practices guidelines for population-level ecological risk assessment. Although past Forum efforts to provide general training in this area have been quite successful, further development of training modules to focus specifically on key topics and methods likely would improve their value to practitioners. Modules communicating best practices for using population risk information would support understanding, and perhaps further adoption, of population-level ecological risk assessment by EPA programs.

Recognition of the roles and contributions of stakeholder groups and the general public in environmental decision making will be important as education and outreach materials are developed.

The Technical Panel believes that each of the activities described above will be important as the project moves forward. It is also suggested that a successful approach to supplementing existing RAF guidelines will be to release products in a phased manner as they are developed, rather than to focus solely on a single major contribution at the conclusion of the project. Such an approach is likely to have several advantages, namely a more rapid release of valuable information and guidelines, an enhanced ability to incorporate advancements in science and practice through time, and a more timely and flexible responsiveness to evolving Forum and Agency priorities.

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1.0
Introduction

1.1 Background and Context

The U.S. Environmental Protection Agency (EPA, or the Agency) has adopted risk assessment as a primary tool supporting environmental decision making. To help maximize the value of ecological risk assessment (ERA) to Agency programs, EPA's Risk Assessment Forum (RAF) produced its landmark *Guidelines for Ecological Risk Assessment* (U.S. EPA 1998) which describe a general strategy and framework for planning, executing and interpreting ERAs. The 1998 *Guidelines* recommend a planning dialogue among risk managers, risk assessors and other interested parties as a critical first step toward initiating an ERA. This dialogue is intended to produce agreement on and understanding of management goals and the types of decisions that the assessment will support. It also establishes the scope, complexity and focus of the risk assessment to be conducted. Depending upon their context, planning agreements might be established as a matter of policy, or might be made on an *ad hoc* basis to inform situation-specific management decisions. Regardless, these agreements lead to selection, during the problem formulation phase of the assessment, of the endpoints to be evaluated during the risk assessment. Assessment endpoints are selected to describe valued ecological entities and their attributes at levels of ecological organization that are relevant and applicable to the decisions being made, and in combination can encompass single or multiple levels of ecological organization in a single assessment.

The choice of ecological organization levels to be evaluated in regulatory ERAs can be a challenging one. Although the enabling legislation of many of EPA's programs either explicitly or implicitly identify protection of ecological populations as management goals, most ERAs conducted for chemicals by EPA, and indeed by most organizations worldwide, focus on organism-level entities and attributes (e.g., rainbow trout survival, growth or reproduction) as assessment endpoints. These endpoints are practical because they often can be estimated through toxicological testing and other means, and are expedient because they are commonly presumed to provide protection of population-level attributes (e.g., abundance and persistence). Further, methods and practice are well established for assessing risk to organism-level assessment endpoints, but documentation of consensus methods for population-level ecological risk assessment is lacking. Consequently, risk to populations has only occasionally been evaluated directly by EPA (e.g., trout populations of Adirondack lakes in the National Acid Precipitation Assessment). This situation results from several factors affecting assessment planning, including the perceived relationships between assessment endpoints and environmental management goals, historical precedence, and importantly, the lack of recognized consensus and guidance[3] about how such assessments should be performed.

Public comment prior to publication by EPA of the *Guidelines* in 1998 indicated a desire by some stakeholders for additional guidance on assessing effects at the population, community and ecosystem levels of ecological organization, and more substantive guidance on protecting populations of animals and plants. Also at that time, a survey of EPA ecological risk assessors ranked effects at higher levels of biological organization, along with assessment endpoints and measures of effect, as having the highest priority for development of additional guidance. The call for guidance has been repeated in recent international efforts addressing population-level ecological risk assessment (e.g., Barnthouse et al. 2008, Forbes et al. 2009). In particular, Barnthouse et al. (2008) recommend development of guidance to assist risk assessors, risk managers and stakeholders in selecting, applying, interpreting and communicating

[3] Throughout this report, the terms "guidance" and "best practice description" are used generically and interchangeably to mean the documentation of technically credible and generally accepted approaches and methods. No policy implications are intended through their use.

population-level ecological risk assessment procedures and analysis tools to cover a range of environmental management contexts.

The RAF conducted a colloquium in 1999 to help identify the nature and scope of projects that would advance development of ecological risk assessment guidance in three broad areas: 1) effects at higher levels of biological organization, including landscape-level effects; emerging from discussion of the first area was a focus on methods for assessing risks to populations and interpreting the results obtained by those methods. During the colloquium, the needs of "on-the-ground" risk assessors and risk managers led to identification of several developmental projects (organized by assessment phase in Table 1) related to population-level ecological risk assessment and approaches to implement

Table 1. Developmental projects recommended for population-level ecological risk assessment from an earlier RAF colloquium

Assessment Phase	Focus of Recommended Project	Approach*
Problem Formulation	Selection of assessment endpoints – sensitivity of response vs. level of organization	1. Workshop 2. Guidelines
	Conceptual model development • consideration of scalar issues • consideration of multiple stressors • incorporation of multiple assessment endpoints • delineation of scope, approach and boundaries	No recommendation
Analysis	Ecological models • basic principles underlying development and use • rules for model selection and application • procedures for model evaluation • integration with other assessment tools	1. Annotated bibliography 2. Application guidelines
	Extrapolation • across levels of ecological organization • through time and across space	1. Issue paper
Risk Characterization	Interpretation of assessment results • relative to unstressed conditions • in context of natural variation • significance of changes in population attributes	No recommendation

** For some projects, multiple steps in approach were recommended. For others, no specific approach was recommended.*

2) assessment endpoints and measures of effect[4]; and 3) risk characterization techniques. A broad theme them. These approaches reflected a number of considerations, including the perceived state-of-the science, the types of intermediate products deemed useful and the needs of the Agency.

In 2005, the RAF formed a Technical Panel to explore a number of issues associated with population-level ecological risk assessment. Consisting of representatives of EPA Program Offices, Regions and the Office of Research and Development (ORD), this working group initially identified three broad actions intended to enhance the Agency's understanding of approaches for assessing risks to populations. These actions are:

1. Expand training in population-level ecological risk assessment – Since the publication of the *Guidelines*, ORD has received a number of requests for formal training and educational exchanges addressing topics related to population-level ecological risk assessment (see text box). To help meet this need, ORD's Office of Science Policy sponsored the vendor-supplied "Population Modeling Training Workshop," conducted at Region 5's offices in Chicago, Illinois in late 2004. This training was coordinated through the Ecological Risk Assessment Forum (ERAF) and was attended primarily by regional risk assessors who support hazardous waste assessments under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA).

   In response to the positive reception of the Chicago training workshop, the RAF Technical Panel identified additional training opportunities, open to all interested Agency personnel, as a near-term mechanism to enhance familiarity by Program Offices and Regions with population-level ecological risk assessment

[4] The RAF published guidance for *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment* (EPA/630/P-02/004f) in 2003 (http://www.epa.gov/raf/publications/geae.htm).

Examples of Previous Requests for Training and Educational Exchange

2001 – W. Munns and M. Mitro presented an overview entitled "Population Modeling to Estimate Risks of Chemical and Other Stressors to Wildlife and Aquatic Populations" as part of the ORD/OPPTS Seminar Series in Washington, DC.

2002 – EPA's Regional Risk Assessors requested "Assessing Risks to Populations at Superfund Sites – Characterizing Effects on Populations" (W. Munns and M. Mitro) at their 2002 annual meeting in Philadelphia, PA.

2003 – The Ecological Risk Assessment Forum (ERAF) requested an introductory training course entitled "Assessing Risks to Populations – Population Modeling" (W. Munns and A. Fairbrother) in Washington, DC.

2004 – Region 1's Biological Technical Advisory Committee requested a presentation entitled "Population-Level Risk Assessment" (W. Munns) in Boston, MA.

2004 – A request from Region 9 through the ERAF to ORD's Ecological Risk Assessment Support Center (ERASC) lead to development of "Assessing Risks to Populations at Superfund and RCRA Sites – Characterizing Effects on Populations" (Munns and Mitro 2004), which describes population concepts and approaches for evaluating risk to populations at hazardous waste sites.

2004 – The Office of Pesticide Programs requested a presentation entitled "Population Modeling to Support Ecological Risk Assessment: An Example Using Mysid Toxicity Test Data" (J. Grear) in Crystal City, VA.

2004 – The Office of Water requested a presentation entitled "Population Modeling to Support Ecological Risk Assessment: An Example Using Mysid Toxicity Test Data" (J. Grear) in Washington, DC.

2004 – The ERAF requested a presentation entitled "Assessing Population-Level Risk at Hazardous Waste Sites" (W. Munns) at the annual Regional Risk Assessors meeting in Boston, MA.

2005 – The Office of Pesticides Programs requested a presentation entitled, "A Primer on Matrix Population Modeling" (G. Thursby) in Arlington, VA.

concepts and methods. Additionally, such training could facilitate identification of issues requiring enhanced guidance. Progress in this first action was made in October 2006 when the RAF sponsored a vendor-supplied "Population Ecological Risk Assessment Training Workshop" in Crystal City, Virginia.

2. <u>Convene a technical workshop on approaches for population-level ecological risk assessment</u> – As an action to be completed in the mid-term, the Technical Panel identified a multiple-day technical discussion of the states of the science and practice of population-level ecological risk assessment to help inform the Agency in decisions concerning development of additional guidance supplemental to the 1998 *Guidelines*. Such an event would bring together Agency and external experts in population ecology and ecological risk assessment in part to build upon the previous discussions of this nature (e.g., Barnthouse et al. 2008). This workshop was held in June 2008 and is the primary subject of this report.

3. <u>Develop best practices guidance for population-level ecological risk assessment</u> – Development of best practices guidance was envisioned by the Technical Panel as a long-term (2-4 year) activity. The specific projects and actions needed to produce such guidance would be informed by the workshop, by input received from various training events and by other developmental activities as needed. The guidance would be developed by a cross-program Technical Panel of the RAF to supplement the 1998 *Guidelines*, and would be responsive to the needs of Agency Programs and Regions in their performance of population-level assessments that inform regulatory decisions. Technical Panel recommendations for developing this guidance are offered in Section 5 of this report.

1.2 Workshop Objectives

The RAF Technical Panel organized this technical workshop to achieve three specific objectives:

1. Identify the approaches, methods and tools currently available for performing population-level ecological risk assessment in support of EPA programmatic and regional decision making.

2. Identify the strengths, current limitations, tradeoffs and outstanding research needs associated with specific methods and tools currently available for performing population-level ecological risk assessment in support of EPA programmatic and regional decision making.

3. Identify areas of need with respect to development of written guidance for performing population-level ecological risk assessment to supplement the *Guidelines for Ecological Risk Assessment*, and the additional steps that can facilitate development of such guidance.

These objectives derive from the recommendations of the 1999 colloquium and the desires of practitioners, risk managers and stakeholders for guidance in performing and interpreting population-level ecological risk assessment. The focus of the workshop was on the technical matters of conducting, and state-of-the-science supporting, population-level ecological risk assessment, and not on the policy issue of levels of ecological organization appropriate for environmental decision making. The individual insights and opinions expressed during the workshop were intended to inform future RAF projects and potential development of guidance. The workshop itself did not produce guidance or policy for any agency, nor did it develop consensus opinions or group recommendations for consideration by EPA.

1.3 Workshop Format

The Workshop on Population-Level Ecological Risk Assessment was convened on June 16-18, 2008 in Crystal City, VA. Thirty-two experts in population ecology, ecological risk assessment and risk management were invited from EPA Programs and Regions, the U.S. Army Corps of Engineers, academia and the private sector to reflect a range of perspectives (Appendix A). A small number of non-participating observers, exclusively from EPA, were present on the first day of the workshop.

The workshop's format included both plenary interactions and breakout group conversations intended to facilitate information exchange. The final workshop agenda is provided as Appendix B. Plenary presentations and discussions during the first day of the workshop were structured to establish context and a common basis of understanding by summarizing past efforts and providing broad overviews from the perspectives of EPA and other users of population risk information. These presentations covered a wide range of topics, and included descriptions of the needs and approaches of individual Program Offices and Regions, the perspectives of another federal agency (the U.S. Army Corps of Engineers, a long-time partner in population risk research), case study illustrations of how population-level assessments were used to inform decisions, and insights from experiences in other countries. An evening poster session on the first day of the workshop provided the opportunity to explore case studies and assessment approaches in greater detail. Summaries of these presentations are offered in Section 2 of this report.

Three primary approaches for obtaining information about the population-level consequences of human activity—observational, experimental and modeling—provided the structure of breakout groups charged primarily with characterizing the states-of-science and practice of techniques, methods and tools of each approach. In this regard:

<ins>Observational approaches</ins> include those that obtain data by monitoring the responses of populations in the field to pollutants or other anthropogenic stressors, and to natural variables. The analysis of such data is sometimes called "ecoepidemiology." These approaches can be used to:

- Describe the condition of an assessment population and determine the causes of spatial and temporal variation in population attributes
- Generate exposure-response relationships directly from observational data
- Provide data to parameterize process-based models
- Provide data to test specific risk hypotheses and the predictions of process-based models

<ins>Experimental approaches</ins> involve controlled experiments (like toxicity tests) that expose organisms or populations of organisms to varying levels of chemical, physical and biological agents to evaluate population response. Experiments can be performed in a laboratory, field or semi-field system. These approaches can be used to:

- Derive understanding of population responses directly from the data (e.g., population growth rate, equilibrium abundance)
- Provide data to parameterize process-based models
- Provide data to test specific risk hypotheses and the predictions of process-based models

<ins>Modeling approaches</ins> involve application of process-based population models to general and specific risk problems to evaluate population response to varying levels of chemical, physical and biological agents, and to natural variables. Process-based models are mathematical constructs that estimate properties of biological populations such as growth rate or time to extinction, and are based on estimates of underlying biological processes (such as survival rates) and environmental change. These approaches can be used to:

- Project or forecast population-level consequences of changes in stressors and other environmental conditions modeled for different management scenarios
- Evaluate the population-level consequences of changes in individual-level attributes observed or measured using observational and experimental approaches
- Evaluate distributions of population outcomes through time and across space

- Inform the design of observational and experimental approaches for assessing population risk

The three breakout groups met throughout the second day of the workshop to consider questions relevant to workshop objectives (see Appendix C) from the perspective of the group's focus. Two breakout group leads, one from the Workshop Steering Committee, the other invited from outside of this committee, facilitated the discussions and the expression of individual opinions. No attempts were made to seek consensus among breakout group members on any point or issue; rather, the intention was to capture the diversity of expert opinions and perspectives in each group relative to their charge. Group membership consisted primarily of experts with respect to the specific approach to population-level ecological risk assessment being considered.

Two mechanisms were used to help ensure a healthy level of cross-fertilization in the discussions: 1) each group was "seeded" with experts in the other two approaches, and 2) the workshop chair, workshop facilitator and RAF liaison each circulated among breakout groups to communicate issues from the other groups. Each group had a note taker to capture conversations.

The individual perspectives and opinions of participants in the three breakout groups were reported and summarized in plenary on the third day of the workshop to address the workshop's three primary objectives. Facilitated discussions following the breakout group reports provided yet another opportunity for the exchange of perspectives and ideas.

2.0 Summary of Opening Remarks and Presentations

The following descriptions summarize briefly the plenary presentations of the first day of the workshop. Copies of all presentation material are available at http://www.epa.gov/raf/population_era_workshop.htm.

2.1 Lee Hofmann, EPA Risk Assessment Forum, Executive Director

Dr. Lee Hofmann opened the workshop by welcoming attendees on behalf of EPA and the RAF. She provided background information regarding the RAF, including its organizational structure, recent successes and current projects. She briefly discussed the current state of ecological risk assessment and the future directions of ERA, including a growing emphasis on population-level endpoints. Dr. Hofmann also explained the workshop goals, processes and desired outcomes. The goal of the workshop was to assess the current state-of-the-science with respect to population-level ecological risk assessment and to solicit individual opinions from workshop attendees regarding the maturity of population assessment methods and tools.

2.2 Wayne Munns, EPA Office of Research and Development, Workshop Chair

Dr. Wayne Munns welcomed and thanked the workshop attendees and observers, and provided additional detail concerning workshop objectives, approach and structure. He observed the current lack of consensus guidance regarding approaches for assessing risk to populations, and noted that although such assessments are becoming more commonplace, they are ad hoc and often contentious in the absence of such guidance. Dr. Munns described the workshop objectives: 1) to identify and discuss approaches, methods and tools available to population-level ecological risk assessment, and in doing so to identify their strengths, limitations and tradeoffs in use; 2) to identify technical needs with respect to developing guidance; and 3) to identify additional steps needed to facilitate the development of guidance for planning, conducting and interpreting the results of population-level ecological risk assessment. He described the opening plenary interaction as an opportunity to review background information, to describe perspectives and needs for information regarding risk to populations, to illustrate case studies and to identify issues that could be addressed in the breakout group discussions of the second day. He emphasized that the intention of the workshop was to define the maturity of science underpinning population-level ecological risk assessment from a technical standpoint by seeking the individual input of attendees, and that the discussions would avoid recommendations of specific approaches and issues of policy. Dr. Munns concluded his overview by describing the products expected from the workshop and their intended uses.

In a presentation immediately following, Dr. Munns described three key precursor activities that helped to establish the context for the current workshop. In the first, the RAF had sponsored a colloquium shortly after publication of the 1998 *Guidelines* to inform future RAF projects regarding selection of assessment endpoints, effects at higher levels of biological organization and risk characterization. The second was a Society of Environmental Toxicology and Chemistry (SETAC) "Pellston Workshop on Population-Level Ecological Risk Assessment," held in Roskilde, Denmark in 2003 (Barnthouse et al. 2008). That workshop focused on advancing the acceptance and practice of population-level ecological risk assessment informing environmental management. The objectives of that workshop were to evaluate policy contexts for assessments, explore technical issues and opportunities, identify appropriate empirical and modeling methods within varying decision contexts, and to develop a framework for conducting population-level ERA to inform risk management decisions. The conclusions drawn from the workshop included: 1) the science is sufficiently mature to develop guidance; 2) specific guidance should be developed for use of models and data within a tiered assessment format; 3) training programs should be developed; and 4) acceptable levels of population risk in different management contexts should be articulated. The third activity, the SETAC "LEMTOX Workshop on Ecological Models in Support of Regulatory Risk Assessments of Pesticides," focused on the role of population models to support pesticide registration (primarily) in the European Union (Forbes et al. 2009). The conclusions identified in this 2007 workshop in Germany included the need to develop guidance for good modeling practice. This group recommended that aspects of such guidance should focus on model development and evaluation, documentation and communication, and analysis and interpretation. Case studies were encouraged to explore the value added to pesticide registration decisions by using models in the assessment process. Dr. Munns concluded that these precursor activities positioned the current workshop to meet its objectives.

2.3 Charles Delos, EPA Office of Water

Dr. Charles Delos offered perspectives of the Office of Science and Technology (OST) of EPA's Office of Water in a presentation entitled "Is There Potential for Using Population Modeling in Aquatic Life Criteria Program?" He described the intention of the aquatic life criteria and standards to define biological goals in terms of community protection, and to protect populations as opposed to individuals within populations. Dr. Delos reflected on considerations by OST and the Agency's Aquatic Life Criteria Guidelines Committee over the past 15 years about how to incorporate population modeling into criteria development, and indicated that population modeling supported derivation of the saltwater dissolved oxygen criterion in 2000. Dr. Delos then described a case study addressing time-variable exposures using population modeling. This study involved a) a kinetic toxicity model to translate between constant exposures used in laboratory tests and the continuously varying concentrations that occur in the field, and b) a stage structured population model to extrapolate measured effects on test organism survival and reproduction to reductions in long-term population abundance and growth rate. Population models took both density-dependent and density-independent forms, and results were compared. Dr. Delos also described use of population models to address assumptions used in criteria development concerning the relative influences of various demographic rates (namely, reproduction and survivorship) on population abundance and growth. He concluded his presentation with the observation that overall the water quality criteria program cannot be said to warmly welcome the additional complexity introduced by population modeling.

2.4 Edward Odenkirchen, EPA Office of Pesticide Programs

Dr. Edward Odenkirchen provided insights of EPA's Office of Pesticide Programs (OPP) in a presentation entitled "Population Modeling in Ecological Risk Assessment – Regulatory Perspective." He emphasized that the regulatory context for incorporating population-level risk into pesticide registration decisions is well established in the United States by law and policy. Currently, however, the program focuses on organism-level attributes (e.g., survival, fecundity and growth) assuming these to provide insight about risks at higher levels of biological organization (e.g., populations). He stated that for many risk management decisions, these endpoints and their inferences about population-level effects are sufficient to inform the decision. Dr. Odenkirchen went on to describe the potential benefits of population modeling to his office's regulatory process in the context of assessment tiering. Such benefits include providing interpretation of screening-level assessment results, supporting refinement of problem formulation for future assessments, allowing consideration of temporal and spatial variability, supporting evaluation of the consequences of pesticide exposure to species of special concern (e.g., threatened or endangered species) and supporting description of pesticide risks and benefits in common units. He then outlined the requirements of population models for use in OPP regulatory programs to include the use of existing effects data sets (as provided through the registration process), and their compatibility with existing organism-level risk assessment tools. Additionally, models should be adapted from other programs or the open scientific literature when practical, with proprietary models being avoided. Communication of model assumptions, uncertainties and limitations should be made explicit, and a number of quality assurance requirements must be met.

Dr. Odenkirchen also expressed the desire that model architecture permit advancement of model complexity and realism, in part to avoid proliferation of tools across levels of assessment refinement. Some challenges faced in use of population models in pesticide regulation include balancing model simplicity, realism and portability across risk problems, and ensuring acceptable levels of output uncertainty. Dr. Odenkirchen concluded his presentation by describing past and ongoing efforts by OPP and ORD to incorporate population-level risk assessment methods into OPP's refined risk assessment processes. These include developmental activities to extract key demographic information from avian reproduction tests to support population model parameterization, construction and evaluation of demographic models for aquatic invertebrates and agricultural birds, and refinement of a spatially-explicit population model for potential use in assessing risks to bird populations in agro-ecosystems.

2.5 David Charters, EPA Office of Solid Waste and Emergency Response

Dr. David Charters presented perspectives from EPA's Superfund Program. He described the roles of ecological risk assessment in this program as: 1) identifying and characterizing the current and potential environmental threats of hazardous waste spills at sites; 2) evaluating the ecological impacts of alternate remedial strategies; and 3) informing identification of cleanup goals for the remedy selected that will protect natural resources. By Office of Solid Waste and Emergency Response (OSWER) directive, ERAs in the Superfund Program utilize organism-level data to postulate risks to populations and communities occurring in specific habitats at hazardous waste sites. Dr. Charters elaborated that the Superfund Program extrapolates toxicity information (including benchmarks) to potential impacts on site populations based upon causal relationships, and that it is not necessary to observe adverse effects onsite to make determinations about ecological risk. Site cleanup goals frequently are based on no or lowest observed adverse effect levels as determined from toxicity testing, or on toxicological benchmarks established more generally. Dr. Charters went on to describe some of the perceived challenges attendant to assessing population risk at hazardous waste sites, including issues associated with data collection and the time frames allotted for Remedial Investigations/ Feasibility Studies (RI/FS), the need to associate effects with hazardous substance releases and issues surrounding reference comparisons. Jokingly, Dr. Charters noted that Superfund ERAs "are probably weakest in the terrestrial and aquatic areas," implying substantial opportunity for contributions by population-level risk science to the program's assessment of ecological risk at sites. He described useful contributions to include short-term population studies that can be completed in two years or less (consistent with the RI/FS expectations), population metrics that are useful for developing numerical cleanup goals, methods to extrapolate from organism-level effects to population-level response and insights into problems associated with definition of and risk to assessment populations when the organisms onsite are part of more broadly distributed populations. Dr. Charters concluded his presentation by offering insights about how incorporation of population-level ERA approaches and methods into the Superfund Program could be facilitated.

2.6 Bruce Duncan, EPA Region 10

Dr. Bruce Duncan offered additional insights relative to hazardous waste site assessments and states' water quality standards approval processes in a presentation entitled "Regional Perspective: Population-Level ERA." As a regional risk assessor, he expressed a goal common to both programs of evaluating population-level effects associated with chemical stress. He described the needs relative to this goal to include approaches for evaluating risk directly to populations, and those for extrapolating population-level effects from information obtained at lower levels of biological organization (e.g., the organism level). Dr. Duncan elaborated on several issues related to assessing population risk, including those associated with definition of assessment populations relative to the needs of the decision being informed, identification of population attributes best suited to the risk problem, interpretation of assessment results in terms of their ecological significance and the uncertainties attendant to the assessment. Dr. Duncan concluded his presentation by expressing his desire to leave the workshop with specific ideas for facilitating use of population-level ecological risk assessment by regional programs, and with insights into approaches to address some of the issues he had described earlier in his talk.

2.7 Steve Newbold, EPA Office of Policy, Economics and Innovation

Dr. Steve Newbold provided a case study of the use of population-level assessment to support Agency rule making in a presentation entitled “Population Modeling in Economic Analysis.” The case study he described supported benefit-cost analysis of the Clean Water Act Section 316(b) rule developed by the Office of Water. Dr. Newbold introduced this study by linking some ecosystem services to population phenomena, and suggested that economic valuation of the ecological benefits of an Agency action often will require population impacts as inputs. He offered that economic analyses can inform selection of assessment endpoints, and that improvements in risk assessment practices should also help to improve the benefits assessments conducted by the Agency. Dr. Newbold then described Section 316(b) as requiring application of best technology to various aspects of power plant cooling water intake design and construction to minimize impingement and entrainment (I&E) of aquatic organisms, and provided the context for this case study. The benefits of the rule to be quantified included expected increases in commercial and recreational fish harvests. A fisheries yield model was developed originally to evaluate fish biomass foregone through I&E losses, using simplifying assumptions of density-independence and constancy of key model parameters. By allowing feedbacks in the construction of a scalar population dynamics model, Dr. Newbold demonstrated that ignoring density-dependence does not always lead to conservative estimates of risk.

2.8 Todd Bridges, U.S. Army Corps of Engineers

Dr. Todd Bridges described efforts of the U.S. Army Corps of Engineers (USACE) Engineer Research and Development Center, a long-standing partner with ORD in development of population-level ecological risk assessment methods, in a presentation entitled “The Relevance of Populations to USACE.” He introduced the mission of USACE to include management of navigational dredging, hydropower and reservoir management, ecosystem restoration and invasive species management, and provided details about each relevant to the workshop. In particular, Dr. Bridges presented case studies in the development of demographic models to extrapolate toxicity test data to population-level effects to support dredged material assessments responsive to the requirements of the Marine Protection, Research and Sanctuaries Act and Clean Water Act, in addition to research to develop a spatially-explicit exposure model for fish potentially utilizing a historic aquatic disposal site to support selection of remediation (capping) material. He next offered a case study of population-level impacts on fish of hydroelectric dam entrainment mortality which used a stochastic demographic modeling approach with density dependence. Dr. Bridges followed this with descriptions of ecosystem restoration case studies involving metapopulation models, population viability analysis and habitat-based modeling. He described the population-relevant issues pertaining to invasive species management to include quantifying the propensity for and conditions of species invasions, predicting spread and developing effective control strategies. Dr. Bridges concluded his presentation with the articulation of several issues to consider in population-level ecological risk assessment, including: 1) ensuring assessment relevance to the decision being made; 2) quantifying and using information about uncertainty and establishing confidence in the use of population models; 3) distinguishing the influences of multiple factors on assessment results;

4) defining the temporal limits of population projections; 5) considering spatial aspects and reflecting behavior and movement appropriately; and 6) using descriptions of synthetic populations as analogs of real populations to simplify risk assumptions and characterizations.

2.9 Jill Awkerman, EPA Office of Research and Development

Dr. Jill Awkerman offered a case study from the field of conservation biology in a presentation entitled "Risks of Fishery Mortality to a Seabird Population and Conservation Implications," focusing on the risks of fishery-induced mortality of waved albatross (*Phoebastria irrorata*) in South America. She explained that while many albatross populations are declining in part because of incidental longline bycatch, intentional waved albatross capture in artisanal fisheries was reported at an alarming rate. Dr. Awkerman described parameterization of a three-stage stochastic matrix model to evaluate albatross population growth using current estimates of survival and fecundity and discussed extinction risk under different assumptions of additional mortality. She also presented analyses of factors potentially influencing differential mortality between sexes including chick survival, foraging behavior and susceptibility to fisheries capture. The results of these analyses prompted creation of an Action Plan for Waved Albatross conservation.

2.10 Richard Sibly, University of Reading, U.K.

Dr. Richard Sibly, a population ecologist who has supported numerous population-level ERA initiatives in the European Union (EU) and internationally, provided his perspectives on selected issues regarding the state-of-the-science. He noted that compensatory processes within populations, and population dynamics in heterogeneous environments, are two issues requiring additional attention. Dr. Sibly went on to describe novel research from his laboratory that has addressed variation in carrying capacity as influenced by environmental stressors, illustrating with a contour plot the relationship of population growth rate to experimental chemical concentration and initial population density. He used a similar approach to explore the natural distribution of a daphnid by characterizing its ecological niche in terms of pH and calcium concentration. Dr. Sibly touched briefly on some potential roles that microarray technology might play in helping to quantify demographic rates of reproduction and survivorship, and concluded his presentation with highlights from a workshop held in 2004 in York, England. That workshop focused on approaches to assess risk to populations of birds and mammals associated with pesticide use. Dr. Sibly described an agent-based modeling approach that he felt holds great promise for population-level assessments, indicating that it illustrates that population dynamics emerge as a result of local interactions between organisms and their landscapes.

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3.0 Breakout Group Reports

Breakout groups reflecting different approaches to population-level ecological risk assessment—observational, experimental and modeling—were asked to address three broad questions from the perspective of each group's analytical approach and set of tools:

1. What specific approaches, methods and tools are available currently for performing population-level ecological risk assessment? To what types of environmental decisions, risk problems and environmental situations do they apply?

2. Identify the strengths, current limitations and tradeoffs associated with specific methods and tools currently available for performing population-level ecological risk assessment in support of EPA programmatic and regional decision making. What technical issues currently limit the usefulness to environmental decision makers of information developed using the methods of this approach for population-level ecological risk assessment? With what priority should these issues be addressed to improve population-level ecological risk assessment?

3. Is the current state-of-the-science and practice sufficient to support development of guidance for performing population-level ecological risk assessment? Up to what point can that guidance be developed (e.g., only broadly, detailed with respect to certain (specified) tools, etc.)?

Issues considered when addressing these questions are elaborated in Appendix C.

This section communicates the opinions of breakout group participants as summarized initially by the leads for each group. Individual group reports are not intended to be comprehensive literature reviews or syntheses, but rather provide a sense of how the questions above were approached and answered in group discussions. In some instances, group summaries have been restructured and edited for clarity and to address the charge questions more directly. The original group notes and group lead summaries have been retained to ensure minimal loss of information, but are not presented as part of this report. When appropriate, strongly expressed opinions alternative to those held by many in the breakout group are captured as text boxes.

3.1 Observational Approaches

As a prelude to more specific deliberation of observational approaches to population-level ecological risk assessment, several breakout group members reflected that problem formulation, and the types of hypotheses developed in the problem formulation, are critical to the success of any approach taken to assess risks to populations. With respect to observational approaches in particular, studies need to be designed to generate sufficient amounts of information over appropriate time horizons, so that they provide the data needed to address the risk problem adequately. A power analysis is appropriate in this regard, and there would be value to shifting designs away from the standard null hypothesis approach to an alternative inference approach to support a more comprehensive evaluation of population-level impacts using multiple hypotheses. A thorough problem formulation is required to identify the approaches and methods that are needed to inform the environmental decisions to be made.

3.1.1 Methods, Tools and Applications

Observational approaches breakout group discussions identified a number of tools that are available for population-level assessments (including mark/recapture methods, nest boxes or nest monitoring approaches, telemetry/remote sensing techniques, and a broad range of field study designs and data interpretation methods), together with well developed supporting information to guide planning and performance of observational studies. In doing so, they acknowledged that different types of assessment approaches have different needs and uses with respect to these tools. Two broad categories of approach were identified:

- General observational studies that identify and document status and trends in the environment (e.g., EPA's Environmental Monitoring and Assessment Program (EMAP) and similar monitoring efforts, the US Geological Survey's North American Breeding Bird Survey, harvest databases and others). They can be used to identify problems and associations that are suggestive of causation.

- Targeted observational studies that provide information to help resolve a specific environmental problem. Three types of targeted studies were identified: 1) those that characterize an impairment but not its cause (e.g., application of biocriteria); 2) those that relate an impairment to a cause of concern (e.g., relating impairments to a waste site, a spill or a new pesticide); and 3) those that evaluate an impairment in the context of multiple candidate causes to identify the one most likely (e.g., using EPA's Causal Analysis/Diagnosis Decision Information System (CADDIS) to inform total daily maximum load (TMDL) calculations).

In breakout group discussions, consideration focused primarily on three general types of environmental decisions: 1) hazardous waste site remediation; 2) pesticide and new product registration; and 3) development of national/regional/local criteria protective of the environment. More broadly, however, Table 2 illustrates the views of at least one breakout group member relating the types of observational studies that can be conducted within a range of decision contexts. A listing of population-level attributes (Table 3.1 in Barnthouse et al. 2008; reproduced here as Table 3) provided additional context for group discussions.

In a general discussion of observational approaches available to hazardous waste site decisions, the breakout group noted that there are a number of proven wildlife estimation methods that can support determinations of population status within sites, but that some require a fair amount of resources to implement. The environmental decision to be made will inform the level of expenditure warranted in applying these methods. The group also noted the existence of several sources of pre-existing data that can support or augment targeted observational studies, including:

- EPA's EMAP/REMAP
- State of the environment reports
- TMDL programs
- Fisheries and wildlife management harvest data sets
- Integrated Natural Resource Management Plans required by military bases
- Threatened and endangered species databases maintained by USFWS and state departments of natural resources

3.1.2 Strengths and Limitations

The breakout group identified a number of advantages that observational approaches have generally relative to experimental and modeling approaches. Among these, observational approaches:

- Are easy to understand by most managers and the public because they are more credible reflections of population dynamics in real situations. For example, people can identify with actual living beings more directly than they can with model outputs.

- Rely on readily available methods that have a long history of use in ecology.

- Can be performed in multiple ways to identify population impairments, including:
    - Comparing population status to those at local reference sites (e.g., contaminated sites versus uncontaminated sites)
    - Evaluating population status against regional information

(distribution of attributes in the region)
    - Comparing population status to expectations
    - Incorporating population models to evaluate observations (do the demographic parameters imply a population decline?)
    - Evaluating population status across gradients (do population attributes change along a gradient of contamination?), which does not require a reference location

- Inherently account for density dependence and compensatory mechanisms in the observations made, and as such require no assumptions about the importance and mechanisms of the processes at work.

- Are amenable to methods that assist in the evaluation of multiple stressors (e.g., habitat suitability indices along with the population measures).

Despite these relative strengths, the breakout group identified a number of technical issues associated with observational methods that either present challenges to their use in population-level ecological risk assessment, or limit their usefulness in this context. Among these are:

- The magnitude of changes that should be detected in observational studies to support decision making is as yet unspecified. Interpretive guidelines might be valuable in this regard.

- Depending upon the circumstances of the assessment, observational approaches can be more costly to conduct than modeling or experimental approaches. The financial resources available to the assessment often determine the design employed.

- Inherent variability of some parameter measurements adversely affects analyses of the significance of observed responses, and often requires that other approaches be included as part of the assessment.

- The potential effects of multiple stressors are difficult to tease apart, rendering critical the identification and use of an appropriate study design.

- Risk conclusions drawn from field observation tend to be situation-dependent, and cannot be extrapolated to other situations readily.

- Observational approaches are limited in their ability to support prospective assessments of risk (such as is needed for pesticide registration, for example). In this regard, prospective assessments must rely on experimental and modeling techniques to provide information needed to inform decisions.

3.1.3 Sufficiency of Science for Development of Guidelines

Breakout group discussions of the maturity of the science supporting observational approaches to population-level ecological risk assessment focused largely on four methods and issues: 1) demographic surveys; 2) biomarkers; 3) study design; and 4) drawing inferences from observational studies. A summary of opinions about these approaches and issues includes the following and is consolidated in Table 2:

- Demographic surveys – Methods for counting and characterizing organisms in populations are well developed and accessible, and they have a long history of acceptance for various uses, including in ERA. They are transparent and easy to communicate. There are numerous methods being used in ecology and conservation biology that may or may not have current uses in ERA. Some issues remain incompletely resolved, however, and could form the basis of additional guideline development, including how “population” should be defined in different contexts (although to some extent, this issue was addressed in U.S. EPA 2002), and how much impact a population can sustain without adverse effect.

- Biomarkers and body burdens – These organism-level measures are potentially important for determining exposure and whether observed differences can be related to a toxic mechanism in observational studies. There are many techniques and tools readily available in the literature, but standardization is lacking. Additionally, little guidance is available for utilizing such information in decision making. Consideration is needed of how biomarkers, body burdens and external stressor concentrations relate to exposure of individuals in populations.

- Design of studies – Consideration of spatial and temporal contexts are extremely important when designing observational studies; guidelines clarifying considerations in this regard would be valuable. Population-level ecological risk assessment also would benefit from additional consideration of: supporting information that should be collected when applying observational approaches (e.g., habitat quality and distribution, spatial distribution of stressors, etc.); designs for estimating risk as opposed to testing hypotheses; and designs that support model development and parameterization. The group noted that adequate guidelines for selecting assessment and measurement endpoints exist, but that some expansion specifically focused on population-level endpoints relevant to decision makers would be valuable. A decision tree could provide insights into data collection and analysis activities to evaluate risks.

- Drawing inferences – Some methods for making inferences from the data are accepted, but other methods for are far less standard or straightforward, and clarity in this regard would be beneficial. Elaboration of basic decision considerations regarding interpretation of changes in measurement endpoints also would be helpful (e.g., for changes in age structure).

The breakout group also discussed the desirability of long-term educational efforts to aid stakeholders in understanding that science is not going to be the sole element informing decision making. Guidance may be needed to enhance assessment transparency and risk communication, and its development may require involvement by social scientists.

3.2 Experimental Approaches

The experimental approaches breakout group considered the contributions to population-level ecological risk assessment of information gathered from controlled manipulations in laboratory and field settings, and in a combination of both. They noted that numerical experiments—simulations involving manipulation of models—potentially could be another type of experimental approach, and one likely to be considered perhaps more appropriately as a modeling approach. Even so, many of the issues concerning experimental design, interpretation and usefulness addressed in discussions of experimental approaches might be relevant to numerical experiments.

3.2.1 Methods, Tools and Applications

Members of the breakout group noted that controlled laboratory studies often are designed to provide direct evidence of cause and effect or to characterize stressor-response relationships. Standardized toxicity tests have been applied in many broad and site-specific regulatory decision contexts, including regulation of chemicals and assessments of risks of site-specific environmental media associated with waste disposal and hazardous waste sites. Historically, toxicity tests have used a limited suite of species as biological models to assess the toxicity of single chemicals, tested in isolation from other stressors. There is a large, accessible database of such information; full stressor-response information would be more useful for population modeling input.

Table 2. Observational methods and decision contexts

	General Observational Approach			
Decision Context	General observational data (existing databases; secondary use when applied to Superfund site)	Targeted observational design (ID a problem without ID of cause)	Targeted observational design (ID a problem with one cause - limited use of data if no problem identified)	Targeted observational design (ID a problem with multiple alternative causes)
Estimate risk	Possible, but most of the time no	Yes*	Yes*	Yes*
Develop cleanup levels	Possible, but most of the time no	Yes*	Yes*	Yes*
Evaluate cleanup alternatives	Possible, but most of the time no	Yes*	Yes*	Yes*
Prioritize sites in a region	Possible, but most of the time no	Yes*	Yes*	Yes*
Validate (or not) toxicity thresholds and related decisions	Possible, but most of the time no	Yes*	Yes*	Yes*
Evaluate species distribution, viability and habitat	Possible, but most of the time no	Yes*	Yes*	Yes*
Evaluate resource services	Possible, but most of the time no	Yes*	Yes*	Yes*
Diagnose causes of observed impacts	Possible, but most of the time no	No	Only limited to single cause*	Yes*
Plan restoration projects	Possible, but most of the time no	Yes*	Yes*	Yes*
Develop regional/ national criteria	Possible, but most of the time no	Yes*	Yes*	Yes*
Evaluate specific disposal sites	Possible, but most of the time no	Yes*	Yes*	Yes*
Detect whether perturbations are meaningful	Possible, but most of the time no	Yes*	Yes*	Yes*
Feed into/inform models	Possible, but most of the time no	Yes*	Yes*	Yes*
Detect unexpected problems	Possible	Yes*	Yes*	Yes*
Evaluate pesticides for Registration or Special Review	Not likely	Not really	Not really	Not really

*Ability of observational method to address the issue is critically related to design considerations in problem formation.

Table 3. Attributes of populations in assessment endpoints (from Barnthouse et al. 2008)

Attributes of organisms	Attributes of populations
Demographics of individuals • Mortality (e.g., living or dead) • Reproductive state and output (e.g., fecundity. births per female, potential seeds) • Development rate (e.g., time for larval development, time to maturity, weaning, ripening)	**Abundance** • Population size (number or biomass) • Population density • Equilibrium (steady-state) abundance • Carrying capacity **Extinction and recovery** • Probability of extinction • Time to extinction • Quasi-extinction • Minimum viable population **Recovery time (from disturbance)**
Physiologic characteristics • Individual growth rate • Respiration rate • Ingestion rate • Metabolism and excretion	**Population growth rate** • Intrinsic rate of natural increase • Finite rate of population increase • Birth, death, immigration, and emigration rates
Demographics of individuals (continued) • Age • Size • Sex • Locations and "home range" or dispersal of an individual	**Population structure** • Age class distribution • Size class distribution • Sex ratios • Spatial distribution of the population an individual
Genetic characteristics • Individual genotypes • Presence of particular alleles • Heterozygosity	**Genetic structure and variation** • Genotypic frequencies • Heterozygosity • Genetic diversity
Organism "health" or condition • Condition factors (weight/length relationships) • Morbidity • Deformities • Tumors and other histopathologic anomalies	**Incidence (frequency, percent, or fraction) of the population or distribution thereof with respect to** • Specified conditions • Morbidity • Effects (e.g., percent killed), and/) or exposures to stressors
Ecology, behavior, and exposure • Life history for an individual • Habitat/food "preference" or location in space • Locomotion, dispersal, migration (e.g., range), and spatial extent of activity (e.g., home ranges) for an individual • Individual environmental exposure	**Spatial distribution and habitat** • Spatial distribution across available habitat (may involve distributions of age and/or size classes as well as influences on genetic composition) • Critical patch size • Habitat requirements (quantity, quality, fragmentation)

Toxicity tests were designed to rank the toxic potency of chemicals under idealized, standardized conditions, and generally not to provide realistic assessment of contaminant effects on populations under varied or complex environments. Nor were they designed to inform population models directly. Several examples of studies that use toxicity test data to parameterize models that project population responses are available (see, for example, Akçakaya et al. 2008). A variety of simple to more complex methods have been used to translate toxicity test responses into input for population models, often required because of mismatches between test data and model input needs (such as test versus lifecycle stage duration). Some translations can be accomplished using empirical relationships, such as estimating chronic survival from acute survival (e.g., Mayer et al. 1994). More specific methods have also been described, such as when activities that strongly affect vital rates are simply missing from current testing. For example, seasonal reproduction must be projected based on effects when parental behavior is not considered explicitly in the experimental design (Bennett and Etterson 2007).

Laboratory studies that have been designed to collect information on the effects of stressors (including chemicals) at the population level include life table response experiments (LTREs), in which information is summarized across individuals, and so-called *bucket tests* which collect information about groups of organisms. There is a body of literature, particularly with respect to pesticide effects on target/non-target species, that provides examples of studies using these methods. Studies designed to capture population endpoints have been used more extensively in the EU than in the United States, and it may be useful for EPA to review examples where these have been used in decision making. Some EU-based organizations recognize the usefulness of these approaches, but procedures have yet to be fully standardized.

Information from controlled laboratory studies has also been used to provide demographic information to population models. However, the performance of laboratory populations reflects the "unnatural" conditions of laboratory settings (e.g., excess food, ideal environmental conditions, no predation, etc.). Some examples demonstrate differences in dynamics of populations under laboratory conditions relative to dynamics in the field, and highlight the artifactual nature of laboratory responses. While laboratory-based studies provide opportunity to gather data on stressor effects at high resolution and fine-scale detail, more realistic effects and more natural population dynamics might be observed in field-based studies.

Field experiments have progressed historically from massive and largely unreplicated studies to smaller, replicated studies. They provide important opportunities to gather "real-world" data but are limited in their interpretability and portability to alternate contexts, and often are prohibitively costly. While some of these studies may not have been designed to quantify stressor effects, they have provided valuable information on life history, abundance and habitat requirements of local fauna, and might continue to serve this function. "Semi-field" studies, such as mesocosm experiments, can provide more feasible (and more controlled) options to acquire realistic information about the effects of stressors. For example, stream-side studies (i.e., literally conducted beside streams in mobile laboratories) provide realistic exposure regimes in aquatic studies. Importantly, semi-field experiments provide the opportunity to assess the effectiveness of management alternatives at small scales.

While few examples are currently available of population-level ecological risk assessments, studies designed with integrated laboratory and field components can provide site-specific information, or can facilitate tests of laboratory-based predictions of field effects. Some examples show that laboratory-based projections are not coherent with field realities, but these inconsistencies provide the opportunity to reexamine conditional needs for specific population model complexities. Because of their potential to produce unique site-specific information, field studies are potentially important in "hot spot" (e.g., Superfund) assessments. It is particularly advantageous to link laboratory and field components early on in the assessment process (i.e., during problem formulation), because field studies are more complex, customized and (typically) take longer to perform than do laboratory studies. When results are clearly linked to decision outcomes, the cost and time required for integrated laboratory and field experiments (sometimes requiring two or more years to complete) may be justified. For some important chemicals of concern, critical body residue studies may be useful to link laboratory and field studies.

3.2.2 Strengths and Limitations

In considering the strength and current limitations of experimental approaches, the breakout group identified various strategies to make information from experimental studies more useful to population-level risk ecological assessment, including:

- Simplified controlled laboratory systems provide clear and easily understood linkages between stressor exposure and effects. They typically are inexpensive, quick and easy. But, a population perspective invites examination of complexity, and the use of experimental information to address issues associated with multiple stressors, cumulative effects and real-world population dynamics. Some important issues to consider are factors regulating populations, such as disease and predation, and combinations (and interactions among) chemical and non-chemical stressors. There was also recognition that background conditions may be need to taken into account that reflect real-world exposure to multiple stressors for comparisons involving background/reference populations. Modeling approaches might provide a framework directing the design of experiments to do so.

- In the short term, currently standardized tests with organism-level endpoints might be appropriated for use in assessments of population risk. For example, Bennett and Etterson (2007) provide an example of a modeling approach to translate avian reproduction test data, collected to support pesticides risk assessments, to enhance projections of population-level effects. The best toxicity test designs for input to population-level ecological risk assessment remain to be identified; whole/partial lifecycle tests show promise, but additional methods and validation of their usefulness for this purpose are required. Standardization of or best practices documentation for existing tests (e.g., LTREs) will add to their utility immediately. Dialogue with modelers can contribute to modifications to current test designs so that the resulting data better reflect the needs of population models. First generation toxicity tests were designed to capture toxicological variation among species; next generation population-level tests should try to capture demographic variation among species as well.

- Experimental methods can contribute valuable information to other approaches to population-level ecological risk assessment. For example, experiments can provide data needed to parameterize population models. But, experimental studies also can contribute to an understanding of mechanisms and processes that affect population dynamics and risk of stressors, information valuable to decision making.

- Experimental approaches almost always utilize species amenable to experimental manipulation. Unless the test species is sufficiently representative of the assessment population, or indeed is the same species as the assessment population, some degree of extrapolation of test and assessment results will be required. The breakout group did not address this potential limitation in detail, other than to acknowledge that extrapolation methods are available for certain circumstances. It is likely that population-level ecological risk assessment would benefit from additional research attention on extrapolation approaches.

3.2.3 Sufficiency of Science for Development of Guidelines

Despite the limitations previously noted, members of the experimental approaches breakout group felt that the science underlying toxicity testing, LTREs and some field and semi-field experimental designs are sufficiently well developed to move forward with documentation of best practices for their use in population-level ecological risk assessment. Several of these methods have been standardized with respect to their intended uses for toxicity evaluations and so on, but not necessarily for assessing population responses. The group identified efforts that could advance development of guidelines for population-level ecological risk assessment (some of which are not limited to experimental approaches):

- A synthesis of existing literature (including conservation and gray literature) describing cases in which population assessments have been used in decision making could illuminate best practices and limiting considerations. Such a synthesis should consider the types of decisions (e.g., setting a cleanup goal, determining unacceptable exposure concentration, etc.) informed by the experiment approach employed, describe how the test information was used, and to the extent possible, evaluate whether the decision was appropriate to meet management goals.

- A second activity could evaluate the efficacy of population-level ecological risk assessment to describe risk through case studies. For example, past assessments conducted without consideration of population assessment endpoints could be performed anew with population-level endpoints, with the results being compared against post-decisional data sets (e.g., after-action monitoring data) that describe the outcomes of decisions based on those earlier assessments. Potential candidates for this type of evaluation include certain pesticide usage decisions (together with their 5-year reviews) and water quality criteria.

- A summary or catalogue of experimental tools and data available to population-level risk assessment could be very useful to practitioners.

3.3 Modeling Approaches

Population models can be applied to a wide variety of environmental management problems. In predictive risk assessment, an advantage of population modeling is that it provides the ability to integrate multiple stressors and multiple endpoints in a consistent fashion. Population modeling is not only a practical approach, but it directly addresses the (stated or implied) intent of regulatory statutes to protect species populations as natural resources. Population modeling might serve as a practical compromise between simpler assessments mainly based on organism-level endpoints and more complex assessments based on fully integrated ecological-economic models. The organism-level approach is relatively easy to conduct but may be overly simplistic and may leave many important questions unanswered. Fully integrated ecological-economic modeling can address many more important questions in principle, but in practice it often will require more time, data and other resources than are typically available for most risk assessments.

3.3.1 Methods, Tools and Applications

A wide range of population models is available for use in EPA programs, including some that can be accessed through EPA's Council for Regulatory Environmental Modeling (CREM) Web site (e.g., BASS (Bioaccumulation and Aquatic System Simulator) and PATCH (Program to Assist in Tracking Critical Habitat, also called HEXSIM); see http://cfpub.epa.gov/crem/knowledge_base/knowbase.cfm). The modeling approaches breakout group considered uses of population models in a number of decision contexts, including: 1) developing risk estimates, cleanup levels or evaluating alternative management actions (e.g., at a hazardous waste site or a dredged material disposal site); 2) evaluating ecological risks of pesticides or other chemicals; 3) evaluating species distributions, population viability and habitat; 4) determining resource services and land use actions;

5) diagnosing causes of observed population or habitat impacts; 6) developing criteria; and 7) evaluating the spread of invasive species. Table 4 relates classes or types of population models to applications in these and other environmental management contexts. Formulations range from simple models that aggregate across individuals and space (i.e., unstructured models) to complex agent-based models (ABMs) that are spatially explicit and follow individual organisms through a set of behavioral rules and in some cases physiological processes. In ABMs and other individual-based models, integrating across the pool of individuals in a computer simulation creates the dynamics of the population. Regardless of the basic approach, spatial structure can be an important part of population modeling, such as in metapopulation models that include two or more subpopulations located in different habitat patches at the same time and that are linked by immigration and emigration. Chapters 2, 3 and 9 of Barnthouse et al. (2008) illustrate specific examples of management decisions and related model applications. Pastorok et al. (2002) and Akçakaya et al. (2008) provide compilations of specific applications of population models used in toxic chemical risk assessment and other contexts (e.g., conservation biology, resource harvest management).

Specific guidance is lacking for matching a modeling approach to a particular risk problem. Some ecologists apply unstructured models to lower trophic levels (e.g., phytoplankton, zooplankton), structured models to mid-trophic levels (e.g., some fish, birds and mammals) and individual-based models to higher trophic levels (e.g., other fish, birds and mammals). This approach was taken in the Across Trophic Level System Simulation (ATLSS) modeling system (http://atlss.org) applied to the Everglades Restoration Program. With respect to model selection, a member of the breakout group asked: "Can we characterize the decision context in terms of endpoints of interest, species of interest, degree of detail needed and the relevant spatial and temporal extents and scales (resolutions), and then let those characteristics dictate the type of population model that would be most useful?" The group identified the need to develop a decision framework for selecting and applying population models in EPA programs (see Section 3.3.3 below).

Key points made by members of the modeling approaches breakout group in response to Charge Question 1 include the following:

- In principle, any type of model can be used within any tier of an ecological risk assessment, but in practice, development of complex models typically will be restricted to higher tiers (i.e., later phases of an assessment requiring more detailed evaluations).

- Models to evaluate products (e.g., pesticides) or develop national or regional criteria need to be more flexible and generic (and therefore likely more simplistic) than site-specific models. Some group members thought only scalar and biologically structured models could be used for pesticide registrations. Others thought metapopulation and individual-based models also could be useful.

- When evaluating specific sites with a population modeling approach, two analyses may be useful. First, treat the individuals on the site as an independent population, and then treat the site as one unit of a metapopulation that includes other sites that may be linked to the target site by immigration and emigration.

- Population models can be used in a reverse-mode risk assessment to estimate media cleanup levels required to meet pre-defined levels of acceptable risk. What defines acceptable risk in terms of population endpoints has not been clearly identified for EPA programs, but general approaches and specific metrics used in conservation biology may be relevant.

- A useful reference for EPA programs involving land use decisions is the Akçakaya et al. (2004) compilation of case studies of applications of population modeling to issues in species conservation and management.

- Models can be helpful in evaluating the relative importance of alternative causes of observed population impacts (i.e., using models in a diagnostic mode). However, in conservation biology and similar applications, models cannot be used by themselves to determine the cause of past declines. Historical data also are needed. The multi-agency Plan for Analyzing and Testing Hypotheses (PATH) project, which used population models to evaluate alternative hypotheses concerning causes of declines in abundance of Snake River Basin salmonid populations (Barnthouse et al. 2000; Peters and Marmorek 2001) illustrates the use of population models to evaluate causes of species population decline.

Table 4. Applications of population models in environmental management contexts

	Class of Model				
Decision Context	Unstructured (scalar)	Biologically structured	Individual based	Metapopulation (occupancy)	Metapopulation spatially explicit
Estimate risk	X	X	X	X	X
Develop cleanup level	X	X			Potential (evaluate source/ sink dynamics)
Evaluate cleanup alternatives	X	X	Estimating exposures by modeling behavior		X
Prioritize sites in region			X		X
Evaluate pesticides for Registration	Generic life histories	Generic life histories			
Evaluate pesticides for Special Review		X	X		X
Verify toxicity thresholds and related decisions	Generic	Generic			
Evaluate species distribution, viability and habitat			X	X	X
Evaluate resource services	X	X	X	X	X
Diagnose causes of observed impacts	X	X	X	X	X
Plan restoration projects	X	X	X	X	X
Develop permit criteria	X	X			
Evaluate specific disposal sites		X	X		X
Evaluate spread of invasive species			X		X

- Population models can be applied to organisms and stressor effects in any kind of environment, including terrestrial, aquatic, aerial, wetland, etc.

Recognizing that a key strength of population models is their ability to integrate multiple endpoints and multiple stressors, the modeling approaches breakout group offered the following observations:

- Integration of multiple stressor effects is straightforward if stressor exposure-response functions are (or are assumed to be) independent. Accounting for dependencies between stressor effects requires more data and more sophisticated models.

- Physiologically-based population models (Kooijman and Metz 1984; Kooijman 2000) can deal with bioaccumulation and toxicity as well as illustrating population dynamics. One such model already used by EPA is the BASS model (Barber 2008).

- Some types of models are better than are others for certain types of stressors. All model types can evaluate risks of chemical stressors. Habitat-related stressors are more difficult to assess with some model types (namely, spatially aggregated models).

The attributes of populations potentially evaluated by modeling approaches are listed in Table 5. By implication, the types of population-level effects potentially evaluated using models are reflected in changes in these attributes. Most of these population-level effects can be expressed as probabilistic outputs from software to implement models.

3.3.2 Strengths and Limitations

Table 6, developed initially by R. Akçakaya, and modified by the modeling approaches breakout group, lists specific models types and gives examples of their advantages and disadvantages for use in population-level ecological risk assessment, as well as specific software implementations developed to date. Ferson (2002), Carroll (2002), Regan (2002) and Akçakaya and Regan (2002) provide detailed evaluations of strengths, current limitations and tradeoffs of various specific population models (also see Table 9.1 of Barnthouse et al. 2008).

Technical issues that are likely to arise in applying models to EPA regulatory programs include:

- The relative scarcity of models that link exposure to stressors, stressor-response relationships, and demography.

- Stressor-response data (e.g., toxicity data) that are not measured or reported in a format useful for population modeling.

- Uncertainty about the values of demographic parameters for certain species.

- Limited knowledge of the strength of density-dependence and its interaction with toxicity or other stressors.

Few population models include exposure, toxicity stressor-response relationships and demographic processes as part of their current structure (Ferson 2002, Carroll 2002, Regan 2002, Akçakaya and Regan 2002). Software implementations for population modeling could use improvement in this aspect.

Table 5. Attributes of populations that can be evaluated using population models, and data requirements of population models

Modeled Attributes of Populations	Population-level Effects Potentially Modeled	Key Data Inputs to Models*
Population abundance (size and density)	Change in abundance or population growth rate	Knowledge of the general life history of the target species, such as life span, length of life stages, generation time, habitat distribution, etc.
Population growth rate	Change in age/stage structure	Intrinsic rate of population growth
Population viability/extinction probability/expected time to extinction	Change in population biomass or production	Carrying capacity
Rates of birth, death, immigration and emigration	Change in recruitment	Fecundity and survivorship rates at key ages or stages
Age/stage structure	Reproductive failure	Body size or weight at each age/stage category
Sex ratio	Change in viability/extinction probability/expected time to extinction	Immigration and emigration rates
Spatial distribution	Fragmentation of population	Individual behavior
Genetic structure (e.g., genotypic frequencies, heterozygosity, genetic diversity)	Spread of unwanted species	Knowledge of stressor-effect relationships for one or more of the parameters above
Recovery time after disturbance	Increased variability of abundance	
	Change in sex ratio	
	Change in genetic structure of population	

* Not all of these data are needed for each population model and some of the listed parameters may be outputs from some models and inputs for other models. The specific kinds of data needed depend on the type of model. Simple population models, such as the Malthusian model or the Leslie matrix may require only readily available data or data that can be easily obtained from a stressor-response test in the laboratory (e.g., a toxicity test), at least for some species.

Some stressor-response data are not in the correct units (e.g., a critical tissue residue value is reported when a concentration in abiotic media is needed, which also reflects a problem of mismatched endpoints) or relevant to the time scales of attention for population modeling. Full stressor-response data often are not available, especially for toxic chemical effects on vertebrates. Reported toxicity information sometimes includes summary statistics (e.g., an LC_{50},

Table 6. Types of models, their advantages and disadvantages and specific software implementations. Additional discussion is needed to populate this table completely

Model Type	Examples	Advantages	Disadvantages	Best for/when/if	Software Implementation	Research Needs
Scalar (spatially and demographically unstructured)	• Malthusian • Logistic model • Ricker model • Beverton/Holt • Equilibrium exposure model (Hallam et al. 1983)	• Simple • Few data required	• Simplistic • May overestimate risk	• Tier 1 and data-poor	• RAMAS Metapop	None
Demographically structured models	• Caswell (2001) • Life table • Leslie matrix • Generalized stage	• More realistic • Impacts can be specific to life-history stages • Many applications	• Requires demographic data	• Demography or impact depends on age/stage and • Sufficient demographic data and • No spatial heterogeneity • Applied to vertebrates, plants and some invertebrates	• RAMAS Metapop • RAMAS EcoRisk* • ULM	
Metapopulation-occupancy	• Incidence function (Hanski 1994)	• No demographic data needed	• Difficult to model ecotoxicological impacts • No population dynamics	• Equilibrium metapopulations with large number of patches and high rate of local extinction and recolonization and • Limited demographic data • Usually applied to small, short-lived organisms (e.g., butterflies)		
Metapopulation-demographically structured	• Grid based • Habitat patch-based	• Realistic • Impacts can be specific to life-history stages • Spatial heterogeneity in impact considered • Both small and large populations • Many applications	• Requires spatial and demographic data	• Demography or impact depends on age/stage and/or location (i.e., spatial heterogeneity in demography or toxicant distribution) and • Sufficient demographic data • Applied to vertebrates, plants and some invertebrates	• RAMAS Metapop • RAMAS GIS • Vortex	
Individual-based	• Physiological-based • Agent-based	• Realistic • Genetics can be modeled	• Very data-intensive • No user-friendly and practical software • Difficult to model large populations	• Modeling behavior and movement to estimate exposure, bioaccumulation, genetic effects and/or dispersal rates • Very small populations with abundant demographic and behavioral data • Usually applied to vertebrates	• DEBtox • Vortex • PATCH • ALMaSS	Incorporate behavior to estimate individual-level exposure, dose, dispersal

NOAELs or LOAELs), but the underlying data needed for population modeling (relationships between demographic parameters and exposure) might not be reported and can be difficult to obtain.

It was noted that uncertainty about the values of demographic parameters (e.g., lack of data for portions of a population, particularly for the younger ages/stages) is typically lower than uncertainty about exposure-response relationships and the strength of toxicity effects (Barnthouse et al. 1990). Reducing uncertainty associated with toxicity effects is an important area for research and development (one group member disagreed with this position and felt that that the real issue is whether population modelers effectively use the available toxicity information; see text box). The uncertainty associated with toxicity data comes from several sources. Within-test variability is often represented by confidence intervals about a statistical endpoint (e.g., LC_{50}); however, there also is uncertainty associated with variability from similar tests conducted at different times or in different laboratories (among-test variability). Often, only short-term toxicity data will be available for estimating long-term exposure effects. There also is a significant source of uncertainty associated with toxicity data if extrapolation between species is needed (for example, see Barnthouse et al. 1990). It may be difficult to reduce these sources of uncertainty. However, use of stochastic population models provides an opportunity to reflect this uncertainty in information provided to decision makers.

Clearly, density-dependence is important for most natural populations, but some members of the modeling approaches breakout group questioned whether or under what conditions the inclusion of density-dependence in population modeling would change the qualitative conclusions of modeling. Also, the level of density-dependence that matters in a decision-making context for most species of interest is unknown. Typical issues encountered when incorporating density-dependence into a population model for toxic chemical effects are: What is the strength of density-dependence? How does the relationship between vital rates and population density change with different chemical exposure levels? How sensitive are risk assessment results to assumptions about the form and strength of density-dependence?

An Alternate Opinion Regarding Toxicity Data

One breakout group member did not agree with all the shortcomings of toxicity data suggested by other group members. He felt that the overarching issue is whether population modeling adds value to a good toxicity assessment. If few exposure-toxicity test data exist, then the toxicity assessment is inadequate and cannot be used define a safe concentration, with or without population modeling.

This breakout group member did not agree that toxicity data are in the wrong format or the wrong units. He did caveat this opinion by stating that specifying survival sensitivity of older life stages of fish or aquatic invertebrates (and probably terrestrial animals) can require some digging for appropriate data, and may require some assumptions. Because young organisms generally are assumed to be more sensitive, chronic toxicity tests focus on the early life stages.

At least for the fish class of vertebrates, he felt that the data reporting deficiencies were not critical. Although acute testing customarily reports only the LC50, for chronic tests it is customary to publish the raw data. EPA likes to see the complete concentration-response curve data. Where not published, EPA technical staff can contact the original investigators to obtain it.

Several members of the modeling approaches breakout group thought that one of the key issues that limits application of population modeling to regulatory decision making is the lack of clarity of management objectives. If decision criteria are vague, it is more difficult to develop or select an appropriate type of model. Some members of this breakout group thought that this issue was more important than are any of the outstanding technical issues, suggesting that the technical difficulties associated with gathering data, and developing and applying population models, are less severe than are the communication difficulties between modelers and decision makers.

One member of the group suggested that analysts should select or propose decision criteria in the course of the analysis if the risk manager had not provided clear criteria in planning discussions prior to the assessment. For example, the EPA aquatic-life criteria program's use of Species Sensitivity Distributions (SSDs) did not develop in response to a management objective to protect 95% of species. Rather, it was EPA risk assessors who wanted to use the SSD approach that suggested the level-of-protection objective.

The modeling approaches breakout group identified several research and development needs that are critical for improving the value of population modeling in ecological risk assessment, including:

- Development of toxicity databases with population modeling and population-level ecological risk assessment in mind:
    - One example approach to database development is Data for Environmental Modeling (D4EM). D4EM is a set of open source software tools that obtains and processes data for models. These data include land use/land cover, water bodies and networks, major roads, and political boundaries (http://www.epa.gov/ttn/chief/conference/ei16/poster/brandmeyer.pdf).
    - For existing toxicity data, it is important to ensure that all measurement units are consistent and that any time scale differences between the experiments and the model simulation are reconciled. Furthermore, impacts on survival as represented by EC_x or LC_x statistics may not be completely independent (or perfectly correlated) across time, so it will be important to ensure that all assumptions used to parameterize the population model are explained as transparently as possible and that sensitivity analyses are conducted as appropriate.
    - Some older data are available from experiments that were conducted over longer periods of time than are current testing regimes. The Oak Ridge National Laboratory (ORNL) work on linking acute and full life lifecycle toxicity test data to fish population models (Barnthouse et al. 1987; 1990) needs to be accessed.
    - One member of this breakout group suggested that research is needed to evaluate whether (or when) to use an individual effect dose versus a hazard modeling (stochastic) approach to incorporating the effects of exposure to contaminants. Under the former, a modeled population might evolve tolerance to a contaminant. Under the latter it would not. Newman and McCloskey (2000) concluded that: "neither hypothesis alone was the sole or dominant explanation for the lognormal (probit) model."
- Development of a database of population parameters for species that have been studied in the field or the laboratory. It also would be valuable to consider developing a set of "representative life histories," or "demographic guilds," that can serve as modeling surrogates for groups of similar species when detailed species-specific data are not available. It is important to develop information on fecundity and other reproductive parameters in real populations, and on how toxicity and other stressors affect these variables. The National Biological Information Infrastructure (NBII), a network of partners representing the spectrum of governmental and nongovernmental sectors, may have some relevant information (http://www.nbii.gov/portal/server.pt). The aquatic ecosystem model AQUATOX (supported by EPA: http://cfpub.epa.gov/crem/knowledge_base/crem_report.cfm?deid=74876) may have some information that would be useful to population modelers.

- Compilation of information on variation of demographic parameters over time for representative species.

- Sensitivity analyses to identify data needs for model parameters for specific models as case studies. There is a need to use modeling in designing experiments (and by implication, observational studies) for ecological risk assessment and for parameterizing models. Simulations can be conducted to evaluate various model components and their relative importance to population dynamics and spatial distribution.

- Development of model structures and software implementations that link toxic chemical (or other stressor) effects to demographic parameters in exposure-response functions based on observational and experimental data. Some early research on this issue suggests that the slopes of exposure-response functions for toxic chemicals may not vary much across species, especially if the mode of action of those chemicals is similar, but the locations of the curves on the chemical concentration axis do. Consequently, if estimates of LC_{50}s for different species are available, then the analyst can characterize the rest of the exposure-response curve with the common slope for the group of species.

- More individual-based exposure models are needed, together with linkages between these (or other exposure models) and population-level effects models (e.g., Bennett and Etterson 2007).

- Development of information on the interactions of multiple stressors in eliciting effects. For population modeling exercises, a range of assumptions between pairs of stressors may be plausible, including: 1) independence (correlation = 0); 2) positive dependence (sensitive individuals are the same individuals for all stressor types; correlation > 0); or 3) negative dependence (different individuals are affected by different stressors; correlation < 0). The RAF has guidance on how to model effects of mixtures of chemicals that could be expanded to address issues relevant to population modeling.

- Guidance on model validation is clearly needed as part of the overall process of guidance development for population-level ecological risk assessment[5]. There is relatively little common understanding among modelers, and especially between modelers and decision makers, about what model "validation" or "verification" means. These terms have been used to refer to a wide variety of activities, from confirming the mathematical derivation of the model structure or debugging the computer model code, to sophisticated statistical comparisons of model predictions to observed outcomes. Standardized methods and guidance regarding model validation would be useful for practitioners, and improved communication between modelers and decision makers on this issue is needed. Modelers should strive to help decision makers to understand what verification or validation of a population model means. Validation of most *types* of population models is *not* needed. Unstructured, structured and metapopulation models can be thought of as "accounting frameworks" (e.g., net growth rate equals birth rate minus death rate). These modeling frameworks have been used extensively and are credible. However, specific applications of these modeling frameworks might need to be validated. Also, some verification or validation of ABMs and other individual-based models is needed.

- Validation may be defined generally as a comparison of model outputs to observations of the system being modeled,

[5] Although not discussed during the workshop, this need is partially met by EPA's Council for Regulatory Environmental Modeling (CREM) *Guidance on the Development, Evaluation and Application of Environmental Models*, available at http://www.epa.gov/crem/model-evaluation.html.

for the purpose of evaluating the credibility that should be accorded to results derived from model applications. It has long been understood that all models are approximations to reality, so that no model can be expected to provide accurate and precise predictions under all circumstances (Levins 1966; Mankin et al. 1975). The purpose of validation is to identify the specific circumstances under which the model can be considered reliable. The process may involve validating model components (individual parameters and functions) and software quality assurance (QA), rather than validation of the model structure itself. Recent literature emphasizes the construction of alternative models of the same population, applying the alternatives to the same set of empirical data, and then using statistical methods such as Bayesian inference to identify the model that is most consistent with the data (Hilborn and Mangel 1997; Peters and Marmorek 2001).

- Development of a toxicological front-end for RAMAS (family of commercially available software for population risk and other analyses) or a similar modeling system to characterize the shapes of stressor-response functions for a large number of toxicants (or other stressors) for various species and their life stages. The initial version of such a front-end for RAMAS is now under development (funded by the US Army Corps of Engineers) and will be available freely online by spring 2009. The biggest research and development need is to have data to characterize the sensitivity of species, entire stressor-response curves, and life stages that are affected, while translating the original time scale of the stressor exposure-response test to other time scales relevant for modeling. One member expressed the opinion that there is a need for the distribution of open-source, public-domain software linking a toxicity model to a structured population model.

3.3.3 Sufficiency of Science for Development of Guidelines

The current state-of-the-science is sufficient to develop guidelines to support use of population modeling in EPA risk assessments. There is a high degree of scientific acceptance of population models and their application to environmental management. Basic demographic models and their structures are standardized. The biggest issues lie in increasing understanding of the usefulness of population-level ecological risk assessment and facilitating acceptance by decision makers within EPA. Modelers or model users need to learn how to speak the decision maker's language to increase transparency and understanding of model use.

Population modeling is a tool that is useful for evaluating effects on many different endpoints. There are accepted ways to perform assessments of population-level endpoints. However, there is no scientific consensus on a specific short list of model endpoints because the nature of the endpoints and related risk expressions depend on the specific management question and the related risk assessment objectives. Guidance is needed to help managers work with population biologists to develop risk expressions relevant to management decisions and the criteria for interpreting results of population model outputs.

Harmonization of best modeling practices across EPA programs may be a desirable goal. It might be possible to adapt existing standards and guidance from the literature on constructing and implementing other types of models (e.g., within EPA programs, and the International Union for Conservation of Nature (IUCN)). Also, available guidance such as "Mistakes to avoid in population modeling" (RAMAS.com/mistakes.htm) could be incorporated into future EPA best practices guidelines on population modeling.

Software for population models and analytical techniques is generally available in the academic community, but user-friendly software is limited. It was recognized that if EPA adopts proprietary software, strategies would be needed to make the modeling process, tools and results transparent and available to the public. Adobe Acrobat, a read-only version of which is available free to the public, may serve as a business model for adopting proprietary software without inconveniencing the public.

The modeling approaches breakout group identified several actions as being critically needed to advance development of guidelines or best practice descriptions to support population-level ecological risk assessment, including:

- Creation of an RAF subgroup or team to develop population modeling guidance for risk assessment. Population modeling should be viewed as an integral part of population-level ecological risk assessment.

- Development of a decision framework (e.g., decision tree) for using population ecology assessment tools and developing scenarios is needed.

- Convening of a workshop in the near future to develop and review population-level ecological risk assessment guidance.

- Development of case studies documentation. Case studies can be compiled readily from available books and other literature, but the demonstration of relevance to decision making needs to be carefully documented.

- Communication to managers. A document on applying population-level ecological risk assessment to management decisions in a "weight of evidence" framework should be helpful. Application of population models to inform management decisions and the value added by using them needs to be demonstrated to increase confidence in ecological models.

- The need to convince managers that population-level ecological risk assessment is an important line of evidence to enhance ecological risk assessment could be addressed by commissioning an EPA Science Advisory Board (SAB) review of the issue.

- Development of guidelines for extrapolation of toxicity data over time.

- Development of guidelines for linking exposure models and population ecology models. One member also stated that EPA could use existing software for population-level risk assessment (e.g., PATCH, RAMAS) or develop additional tools throughout the process. Guidelines would be most effective with facilitated access to modeling tools and active training in their use.

Summarizing the deliberations of this breakout group, the state-of-the-science of population modeling is sufficiently well developed to use such models in ecological risk assessments informing EPA programs. Several population modeling approaches are applicable to a wide range of environmental management issues. Although several technical issues arise in applying models, these issues can be overcome. The most important issue likely is to be one of communicating the general usefulness and specific applicability of population modeling to EPA decision makers and project managers. The practice of population modeling is sufficiently developed to support EPA's preparation of guidelines for population-level ecological risk assessment that includes population modeling approaches.

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4.0 Summary of Expert Opinions

The summaries provided in Section 3 communicate the breadth of opinions and input expressed by workshop attendees during breakout group conversations. Additional observations, issues and suggestions were expressed during plenary discussions. Although no attempts were made to seek consensus on any particular issue or topic, certain commonalities emerged over the course of breakout and plenary interactions. Key opinions with respect to workshop objectives are summarized in this section.

4.1 Observational Approaches

Workshop participants generally agreed that observational methods are well established in the fields of ecology and conservation biology, and that approaches based upon them have unique advantages in reflecting realism with respect to population responses to stressors in the environment. In this regard, information obtained through direct observation reflects the effects of multiple stressors and influences of compensatory mechanisms (e.g., density dependence), but the relative contributions of various effects and processes usually are difficult to tease apart. Additionally, the variability inherent to natural systems could at times mask detection of some important stressor effects. Observational approaches were thought to be applicable to all tiers within a tiered assessment protocol. Many noted, however, that the utility of observational approaches might be limited with respect to prospective assessments due to imperfect transferability of study results beyond the conditions and context within which they were obtained. They also have limited value for helping to evaluate decision alternatives, because the information they produce reflects only the specific circumstances in which they were conducted. Data from observational studies can, however, help to inform reassessments of past management decisions. It was noted that new methods are coming on line that can help to guide decisions about the inferences that can be made using observational data.

Developmental activities that were identified to promote best practices included compilations of case study examples of the use of observational approaches to assess population risk, examples of when such approaches failed to provide the information needed to assess population risk, and how observational studies influenced decisions. Workshop participants highlighted the value of catalogues and annotated descriptions of available methods and observational data sets and sources. Guidance in the form of decision trees was suggested as being particularly helpful with respect to assessment planning and interpretation of observational study results. Participants also noted that acceptance of the use of observational approaches by decision makers could be facilitated and enhanced through development of best practices descriptions for effective communication.

4.2 Experimental Approaches

Participants generally felt that the methods employed to provide data for and input to population-level ecological risk assessment are sufficiently well developed and informative to warrant development guidelines or best practices descriptions. Several experimental methods are available, and sometimes even standardized, that can measure the responses of experimental populations to stressors directly, or that provide data that can be extrapolated to the population level of biological organization. Even so, additional design considerations might be required to help ensure that key hypotheses regarding mechanisms of effect and other important ecological processes can be evaluated as needed to inform environmental decision making. In this regard, some experimental designs likely have limited ability to incorporate processes and interactions that can have important population consequences, such as interspecific competition and other forms of species interactions. Careful planning during problem formulation of the assessment will help to ensure use of experimental designs and methods that provide the information needed to quantify decision-relevant risk.

Because experiments inherently are abstractions of nature and therefore cannot include all ecologically relevant processes, additional research and development might be needed to improve the value of experimental approaches to population-level ecological risk assessment. Highlighted was the issue of cross-species extrapolation. Many species are not particularly amenable to experimental manipulation, and when assessment goals focus specifically on populations of that species, their responses to stressors will need to be extrapolated from those of surrogates. Some progress could be made toward resolving this issue by focusing upon mechanisms of action and their ecological analogs, but there likely will always continue to be meaningful uncertainty whenever cross-species extrapolations are required. Extrapolation of organism-level measures to characterize risk to populations might be less worrisome, because a variety of modeling approaches are available that can accommodate organism-level attributes to project population dynamics. Even so, attention is needed to help ensure that experimental data are collected in the forms and temporal frames required by extrapolation models.

Other areas of valuable research include development of approaches and data that can link certain types of measures—namely biomarkers and organism dose concentrations—more directly to the key demographic rates determining population dynamics. In a similar vein, there might be opportunities within the evolving technologies of genomics and proteomics to develop approaches that link data derived from these techniques to population response. Advancements in this area could produce efficiencies in the collection of information for assessing population risk. Finally, discussions emphasized the potential value to be derived from combining experimental methods (including more tightly coupled laboratory and field experiments) with modeling and observations, as these approaches provide complimentary and supplemental information about risks to populations.

Several activities were identified that could support communication of best practices. Included are case study analyses, both comparing the informational value of population-level measurement endpoints versus organism-level measurement endpoints when assessments include populations as environmental values to be protected, and evaluating the efficacy of population-level assessments with respect to the outcomes of decisions based upon them. Associated with this was a sense that descriptions of experimental designs that promote use of the resulting data in modeling evaluations, and of how experimental data can best be used in modeling applications, should be developed to help focus experiments on generating the most critical information needed. Included were specific guidelines for performance of LTREs, bucket tests, and so on. Also identified was guidance about how experimental results should be interpreted and communicated with respect to population risk.

4.3 Modeling Approaches

Contributors to the workshop expressed the opinion that population models and the approaches to deploy them within population-level risk assessment are well established, and noted several compilations of model descriptions and considerations for their application to risk assessment in the recent literature. Opinion was expressed that the stressors under evaluation—and especially the decision context—influence which models and approaches provide the most valuable information. It generally was believed that population models can be used advantageously in any level within a tiered assessment protocol, and that they are important integrators of data and knowledge gained through observational and experiment approaches. Important drawbacks to modeling approaches, however, include the skepticism often expressed by decision makers about the degree of realism captured by models and the accuracy of their outputs, and concerns about assessment transparency when stakeholder and decision maker understanding of modeling is limited. A lively plenary discussion centered around perceived inconsistencies in the level of acceptance of population models relative to chemical fate and transport models (of which acceptance is high). Associated with this was continuation of the ongoing debate centered on the meanings and desirability of model verification, validation and evaluation.

In spite of the generally high regard held by most workshop participants for population models, certain developmental issues were highlighted as important. Among these was advancement in coupling population models more directly to exposure models, particularly with respect to physiological-based dose-response models. Additional exploration of modeling philosophy and approaches addressing the effects of multiple stressors would enhance model realism and likely accuracy. Issues associated with the form and strength of density dependence as important determinants of population response to stressor exposure, although not directly ones of modeling per se, might influence model realism and the accuracy of assessment conclusions. Several participants expressed the opinion that density dependence might not be as important an issue as some believe. Additional attention to developing accessible implementation software and packages also was highlighted as a need, although some software is available commercially or as freeware.

A number of activities were identified that would foster acceptance of good practices in the use of modeling approaches in population-level ecological risk assessment. Important among these were development of a decision framework for model selection, and best practices guidelines for applying models and interpreting modeling results. Identification of best practices for facilitating communication directly with decision makers and stakeholders could help to establish confidence in the use of population models to inform decision making. Documentation developed to guide design of experimental and observational studies performed in conjunction with modeling approaches would help to ensure compatibility with modeling needs in the form and accessibility of the data those studies generate. Some participants also expressed a need for guidelines to approaches for extrapolating the effects reflected in toxicity data through time.

4.4 Commonalities Across Approaches

Several considerations expressed during the workshop cut across assessment approaches and reflected the general sentiments of many of the participants. Most importantly in relation to workshop objectives was the sense that the science underlying population-level ecological risk assessment is sufficiently mature to support furtherance of best practices guidelines. Although the various approaches have perceived benefits and limitations relative to different decision contexts, and attention to certain developmental needs is desirable, opportunities for applying existing techniques to inform decisions were identified within almost all of EPA's regulatory programs. Participants often articulated the opinion that the three assessment approaches should best be treated as interdependent and complementary, and that the power and value of population-level ecological risk assessment as a decision-informing tool are enhanced when approaches are used in combination. Also expressed was the sentiment that a primary advantage of focusing attention more explicitly on measurement endpoints and analysis techniques that address population attributes directly is an assessment more relevant to decisions involving protection of populations. Most workshop participants promoted greater use of population-level ecological risk assessment as a tool to inform environmental decision making.

Documentation, communication and training were felt to be components critical to credible performance, advancement and acceptance of population-level ecological risk assessment by practitioners, decision makers and the public. Articulation of a framework uniquely oriented toward planning, implementing and interpreting results of population-level ecological risk assessments is especially important. This framework could include considerations leading to selection of assessment approaches (combinations of experimental, observational and modeling techniques) appropriate to the decision and its context, perhaps organized in the form of a decision tree. Compilations and catalogues of existing techniques, models, designs and data could be linked to the decision tree to aid assessment planning and performance. Programs could be developed to help ensure that practitioners are appropriately trained in relevant techniques and models. Specific best practices guidelines could help to direct interpretation of data and results, again with an eye toward the nature of the decision they intend to inform. These might summarize key aspects of ecological theory and link to compilations of case studies as illustrations of sound interpretation approaches. Additional guidelines could support communication of assessment results and their meaning to the end-users of the assessment. And throughout, materials and information should consider, be oriented toward or tailored to the unique decisions and contexts of EPA's programs.

Several cross-cutting issues will require attention if guidelines are to be developed. Key among these are considerations associated with pragmatic definitions of *assessment population* in various decision contexts. Although reasonable approaches to address this particular issue exist, definition of the assessment population has been problematic for Superfund and certain other programs. Somewhat related to this are considerations about spatial scale and context, and time horizons appropriate to various management goals and decisions. Attention also is needed for identifying those measurement endpoints most relevant to population assessment endpoints and the nature of risks being evaluated. And finally, all acknowledge that assessment populations do not exist in isolation from other populations. Species interactions can have important and substantial influences on population performance and the risks associated with anthropogenic stressors. Some of the techniques explored during the workshop (especially observational approaches) reflect or accommodate species interactions more realistically than do others. Even so, the importance of species interactions to assessment results, and the uncertainties created when species interactions are ignored, will require careful consideration as the science of population-level ecological risk assessment is applied to EPA programs.

5.0 Technical Panel Recommendations for Future Progress

The resounding sentiment of the experts assembled in this workshop was that EPA and ecological risk assessment practitioners alike would benefit from guidelines or best practices documentation concerning population-level ecological risk assessment. The science underlying such assessments is sufficiently well developed that guidelines could be developed soon to promote best practices with the understanding that such guidelines would be updated on a regular basis as the state-of-the-science and practice of population level ecological risk assessment improves over time. Based in large part on the opinions of these experts, but also based on our individual and collective professional perspectives, the RAF Technical Panel recommends that the Forum proceed with an effort to develop best practices guidelines for population-level ecological risk assessment. This section describes some of the options and outputs that could be pursued in such a project. Suggestions are offered only generally about how to accomplish individual efforts and the overall project. We do suggest, however, that a phased implementation with multiple intermediate products is likely to be successful.

The Technical Panel recommends a phased approach to producing guidelines. Initial issue-oriented white papers and summaries would help to document the current states of science and practice of technologies supporting population-level ecological risk assessment, and could suggest how EPA programs would benefit from a more explicit focus on risk to populations. Opinion statements would help to visualize how regulatory programs could utilize information directly communicating population risk to facilitate understanding of the advantages and limitations with respect to program mandates. Supporting white papers could summarize EPA program policy with respect to management goals, and how a more explicit focus on population-level measures could support the decisions to meet those goals. Additional opinion papers that summarize current knowledge could focus on inferences drawn about risks to populations, and projecting future practices that would be more inclusive of population risk.

Development of best practice guidelines likely will require directed conversations involving ecologists, practitioners and users of assessment results. Workshops that enable such interaction likely will be important steps to developing best practices guidelines. Topics for deliberation include detailed evaluations of methods, best approaches for combining methods in relationship to decision contexts, and the decision criteria and processes that could lead to a planning and implementation framework specifically for population-level ecological risk assessment. Equally important is development of guidelines for interpreting results and assessment outcomes. Such guidelines could be organized by assessment endpoint attribute, and could describe a nested hierarchy of considerations and conclusions for interpreting lines of evidence generated by multiple assessment approaches.

Retrospective analyses of cases in which risks to populations were assessed would provide both examples for future assessments, and opportunities to evaluate the efficacy of various approaches. Either as part of this or as a separate effort, considerations of the informative value to environmental decision making of population-level ecological risk assessment and the approaches used would provide additional insights supporting best practices guidelines. Case study evaluations could be commissioned from groups of experts, or could be conducted in focused workshop settings.

In a related vein, assembly of information describing the methods, models and data sources would help to improve the accessibility of these tools to risk assessment practitioners. Compilations could include annotations describing acknowledged advantages and limitations of methods and models with respect to various risk problems, environmental settings, stressors and decision contexts. Catalogues pointing to key sources of toxicological data, demographic and life history information and extrapolation relationships would facilitate access to critical information and would help to promote the quality of future assessments.

Attention to education, communication and outreach will be critical to the success of a RAF project to develop best practices guidelines for population-level ecological risk assessment. Although past Forum efforts to provide general training in this area have been quite successful, further development of training modules to focus specifically on key topics and methods likely would improve their value to practitioners. Modules communicating best practices for using population risk information would support understanding, and perhaps further adoption, of population-level ecological risk assessment by EPA programs. Recognition of the roles and contributions of stakeholder groups and the general public in environmental decision making will be important as education and outreach materials are developed.

The Technical Panel believes that each of the activities described will be important as the project moves forward. It also suggests that a successful approach to supplementing existing RAF guidelines will be to release products in a phased manner as they are developed, rather than to focus solely on a single major contribution at the conclusion of the project. Such an approach is likely to have several advantages, including perhaps a more rapid release of valuable information and guidelines, an enhanced ability to incorporate advancements in science and practice through time, and a more timely and flexible responsiveness to evolving Forum and Agency priorities.

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Appendix A.
Workshop Attendees

<u>Observational Breakout Group</u>

MEMBER	AFFILIATION	EMAIL	PHONE
Glenn Suter *Working Group Lead*	EPA Office of Research & Development	suter.glenn@epa.gov	513-569-7808
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Charlie Menzie	Exponent, Inc.	camenzie@exponent.com	571-214-3648 (cell)
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Jill Awkerman	EPA Office of Research & Development	awkerman.jill@epa.gov	850-934-9230

Observational approaches include those that obtain data by monitoring the responses of populations in the field to pollutants or other anthropogenic stressors, and to natural variables. The analysis of such data is sometimes called “ecoepidemiology.” These approaches can be used to:

- Describe the condition of an assessment population and determine the causes of spatial and temporal variation in population attributes
- Generate exposure-response relationships directly from observational data
- Provide data to parameterize process-based models
- Provide data to test specific risk hypotheses and the predictions of process-based models

<u>Experimental Breakout Group</u>

MEMBER	AFFILIATION	EMAIL	PHONE
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Experimental approaches involve controlled experiments (like toxicity tests) that expose organisms or populations of organisms to varying levels of chemical, physical and biological agents to evaluate population response. Experiments can be performed in a laboratory, field or semi-field system. These approaches can be used to:

- Derive understanding of population responses directly from the data (e.g., population growth rate, equilibrium abundance)
- Provide data to parameterize process-based models
- Provide data to test specific risk hypotheses and the predictions of process-based models

Modeling Breakout Group

MEMBER	AFFILIATION	EMAIL	PHONE
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Modeling approaches involve application of process-based population models to general and specific risk problems to evaluate population response to varying levels of chemical, physical and biological agents, and to natural variables. Process-based models are mathematical constructs that estimate properties of biological populations such as growth rate or time to extinction, and are based on estimates of underlying biological processes (such as survival rates) and environmental change. These approaches can be used to:

- Project or forecast population-level consequences of changes in stressors and other environmental conditions modeled for different management scenarios
- Evaluate the population-level consequences of changes in individual-level attributes observed or measured using observational and experimental approaches
- Evaluate distributions of population outcomes through time and across space
- Inform the design of observational and experimental approaches for assessing population risk

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Appendix B.
Workshop Agenda

Workshop on Population-Level Ecological Risk Assessment
Crystal City Marriott, Crystal City, VA
16-18 June 2008

Agenda

16 June – Opening Plenary

9:00	Welcome	Lee Hofmann Executive Director, Risk Assessment Forum
9:15	Workshop Overview Objectives Workshop approach Planned output of workshop	Wayne Munns Workshop Chair
9:45	Review of Relevant Past Activities EPA SETAC Pellston Workshop Other	Wayne Munns
10:15	Break	
10:30	EPA Programmatic & Regional Needs and Case Studies	
	Office of Water	Charles Delos
	OPPTS	Ed Odenkirchen
	OSWER	David Charters
12:00	Lunch (on your own)	
1:00	EPA Programmatic & Regional Needs and Case Studies (cont.)	
	Region 10	Bruce Duncan
2:00	Other Needs and Case Studies	
	EPA OPEI	Steve Newbold
	USACE	Todd Bridges
	A Conversation Case Study	Jill Awkerman
	A European Union Perspective	Richard Sibly
4:30	Charge & Instructions for Breakout Group Discussions	Jerry Cura & Wayne Munns
5:00	Dinner (on your own)	
7:00	Poster Session (tentative) Case studies and uses of population-level ERA in environmental decision making, and examples of observational, experimental and modeling tools used in estimating assessment population response to anthropogenic and natural stressors (posters will remain up throughout the workshop).	Bruce Duncan

17 June – Breakout Groups

9:00	Last Minute Issues	Seema Schappelle & Jerry Cura
9:15	Breakout Groups	
	Observational Approaches	Glenn Suter & Mary Sorensen
	Experimental Approaches	Tom Forbes & Diane Nacci
	Modeling Approaches	Steve Newbold & Rob Pastorok

(timing of lunch and breaks optional for each group)

1:30	Questions & Issues in Plenary	Seema Schappelle & Jerry Cura
2:30	Breakout Groups continue (as needed)	

18 June– Group Report Outs and Summary

8:30	Breakout Group Presentations	
	Observational Approaches	
	Experimental Approaches	
	Modeling Approaches	
10:00	Break	
10:15	Summary Discussion	Jerry Cura
	Commonalities, and relative strengths and limitations of the three approaches	
	Answers to the three breakout questions	
12:00	Working Lunch	
1:00	Summary continues	
2:30	Final Observations & Next Steps	Wayne Munns & Seema Schappelle
3:00	Workshop Adjourns	

Appendix C.
Breakout Group Charge

Workshop on Population-Level Ecological Risk Assessment
Breakout Group Charge

Workshop participants have been assigned to one of the three breakout groups prior to the workshop. Each breakout group consists of 10-15 population-level ecological risk assessment experts and stakeholders, and two co-leads. Support will be provided to each group to capture salient issues, information and discussion points on flip charts. This material will be used to support breakout group plenary presentations on the last day of the workshop. The workshop co-chairs and potentially others will be moving among groups over the course of the day to facilitate discussions and to address concerns.

We ask that the deliberations and plenary presentations of each group be structured to answer the following three questions, each with specific issues to consider. These questions should be answered from the perspectives of your group's analytical approach and set of tools (observational, experimental, or modeling). Breakout group report outs (~20 minutes each) should focus on the answers to each question.

Breakout Group Questions

From the perspective of your group's analytical approach and set of tools (observational, experimental, or modeling):

1. What specific approaches, methods and tools are available currently for performing population-level ecological risk assessment? To what types of environmental decisions, risk problems and environmental situations[6] do they apply? Specific issues to consider include:
   - nature and types of decisions potentially informed by the methods and tools employed in this approach
   - types of stressors that can be addressed by the methods and tools employed in this approach
   - nature of population-level effects that can be evaluated by the methods and tools employed in this approach
   - attributes of populations that can be characterized by the methods and tools employed in this approach

[6] Specific decisions, problems and situations to consider include:
- hazardous waste site remediation decisions at sites ranging from small to large & complex
- registration of new products (e.g., pesticides)
- land use decisions at a variety of spatial scales
- development of national, regional and local environmental criteria
- resource protection decisions
- resource extraction decisions
- waste (e.g., dredged material, industrial wastes) disposal decisions

- environmental contexts within which the methods and tools employed in this approach can be used

2. Identify the strengths, current limitations and tradeoffs associated with specific methods and tools currently available for performing population-level ecological risk assessment in support of EPA programmatic and regional decision making. What technical issues currently limit the usefulness to environmental decision makers of information developed using the methods of this approach for population-level ecological risk assessment? With what priority should these issues be addressed to improve population-level ecological risk assessment? Specific issues to consider include:
    - availability and accessibility of analysis techniques and methods
    - data and information requirements, and their availability
    - applicability to different tiers of assessment (ranging from screening to refined)
    - ability to characterize cause and effect relationships, and to partition causes of effect among multiple potential stressors
    - availability of methods to account for temporal and spatial scalar issues
    - availability of methods to account for stochasticity, compensation and other forms of potential uncertainty
    - transferability of analysis results among stressors, species, ecosystems and environmental situations
    - degree to which analysis techniques and methods have been evaluated
    - critical research and development needs addressing key scientific uncertainties

3. Is the current state-of-the-science and practice sufficient to support development of guidance for performing population-level ecological risk assessment? Up to what point can that guidance be developed (e.g., only broadly, detailed with respect to certain (specified) tools, etc.)? Specific issues to consider include:

- degree of scientific acceptance of current techniques, methods and tools
- degree of standardization of existing techniques, methods and tools
- degree of scientific acceptance in interpretation of resulting information
- extent of existing documentation
- degree of transparency and understandability of approach by decision makers and stakeholders
- accessibility of analysis techniques and other necessary information
- critical actions needed to facilitate development of guidance

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