PLANNING AND SCOPING GUIDE: WITH EMPHASIS ON CUMULATIVE RISK ASSESSMENT

Internal Review Draft
(See note inside for instructions)

August 8, 2000

Request for Comments on the Draft Planning and Scoping Guide

August 8, 2000

EPA Reviewers,

Attached please find a draft copy of the document "Planning and Scoping Guide with Emphasis on Cumulative Risk". We are requesting comments on this version of the guide to make sure the concepts are clear to those who have expressed an interest, before it is offered for review by the Steering Committee of the Science Policy Council (SPC). Your comments and suggestions will be most helpful if they are received before the end of September.

Planning and scoping is a concept which emerged from the ecological risk assessment guidelines. It was developed in the risk characterization workshops and the process is recommended for risk assessment in the risk characterization handbook. This Guide clarifies the 1997 Guidance on Cumulative Risk Assessment, Part 1. Planning and Scoping". The SPC sponsored three practica (1998-1999) to apply the concepts of planning and scoping to agency case studies. From that series, participants recommended that we develop a handbook or guide to describe the planning and scoping process.

For this version, we added information on stakeholders, clarified the problem formulation discussion, and plan to add other examples from program offices to the workshop case studies. We note that planning and scoping is not just for cumulative risk assessments. We maintained a broad definition of cumulative risk, emphasizing that this term must be defined in the context of the risk management problem, therefore, dialog with the risk manager and problem formulation are vital initial steps in the process. We also note that planning and scoping is an iterative process. The conceptual model can be revised and elaborated even after the assessment begins.

We are interested in your suggestions and comments on this draft. We call it a "Guide", because the process is relatively new and the Agency is still gaining experience with it. We use case studies to illustrate the process–Appendix B includes cases from the SPC-sponsored workshops, and other appendices are still developing examples from program offices. In your review of this document, please consider the following questions:

1. Does this guide clarify how the planning and scoping process is performed?

2. Is the relationship between the text and the case studies informative and does it clarify the concepts from the original guidance?

3. Are there sections of this guide which need to be modified (expanded or eliminated)? If so, how would you suggest it be modified?

4. Is there information which is missing or should be referenced? Please be specific.

If you have ideas about other documents, references, or case studies we should cite or abstract, please contact us and provide details about how to obtain the document.

Thanks for your assistance,

Ed Bender
(202) 564-6483
(Mail Stop 8103R)

James Rowe
(202) 564-6488

Nader Elkassabany
(202) 564-6769

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FOREWARD

This document is intended to supplement the "Guidance on Cumulative Risk Assessment. Part one. Planning and Scoping," July 1997, and to be used by EPA/non- EPA individuals who are interested in the application of planning and scoping in cumulative risk assessment. It is NOT intended to provide guidance for analyses of cumulative or other complex risk assessment; guidelines and specific program guidance serves that function. Rather, this guide is intended to illustrate the process and concepts established in the *1997 Guidance*. It is an iterative process for organizing what is considered within a complex risk assessment (including those with cumulative risk aspects), illustrating the planned approach, and explaining the rationale for what is included or excluded. This guide relies on case studies and information collected at three meetings with EPA personnel, as well as on Agency guidelines, program office guidance, and professional experience.

INTRODUCTION

Based on EPA's experience with the four-step NAS risk assessment paradigm (NAS, 1983), it has become clear that the additional step of planning and scoping at the beginning of the risk assessment process will improve and better characterize risk assessment product. The *1997 Guidance* complements EPA's Risk Characterization policy and guide (EPA, 1994; EPA, 2000). In addition, planning and scoping provides a more integrated view of the risk assessment-risk management process that involves the affected and interested parties in environmental decision-making (NRC, 1996; Presidential Report on Risk Assessment and Risk Management, 1997). This guide will help EPA managers and risk assessors implement the requirements of the 1997 Guidance.

Key features of the *1997 Guidance* on planning and scoping include a dialogue among the risk assessor and risk manager, economists, engineers, and other technical experts in planning and formulating the problem for the risk assessment. It also provides details on the nature of the risk assessment planning dialogue and activities that can shape the next generation of integrated risk assessments from Programs and Regions.

Planning and scoping occurs before the risk assessment begins. It is the phase when the purpose and context for the risk assessment is developed. Without this preliminary step, the risk assessment may overlook information and key participants that are critical to inform the risk management decision.

Planning and scoping is not limited to cumulative risk assessment–indeed these concepts apply equally well to plan assessments of hazard, exposure, environmental impact, or other risk assessments. In fact the scientific community has not yet developed a consensus on the definition of cumulative risk assessment. Within the Agency, several program offices are working on aspects of cumulative risk which are discussed in detail in this guide and in case studies in the appendices. Until a broad consensus is developed, we recommend that cumulative risk assessment be defined as "risks considered in the aggregate", with the specifics defined on a case by case basis according to the steps and concepts presented here. Planning and scoping is a dialogue among experts, stakeholders, and decision-makers that precedes the analysis and continues as needed through the risk management decision.

1. THE NEED FOR PLANNING AND SCOPING OF COMPLEX RISK ASSESSMENTS

1.1 Overview Statement

Planning and scoping is a process that sets the stage for conducting a risk assessment. This process begins with a dialogue between the risk assessor and risk manager. The dialogue and problem formulation; first described in the Ecological Risk Assessment Guidelines, was elaborated and highlighted in the Cumulative Risk Assessment Guidance, Part 1. Planning and Scoping (1997) (hereafter referred to as the 1997 Guidance). The dialogue between the risk manager and assessor defines the risk management objective and the purpose for the risk assessment. The assessor and manager work as a team to determine how to obtain technical input, stakeholder comments, and develop a conceptual model and an analysis plan for the risk assessment.

As the 1997 Guidance has been applied and discussed in the planning and scoping workshops, we found that cumulative risk assessment can be improved by using the planning and scoping process. The challenge is to determine how much effort to invest.

This chapter provides some background and rationale for using planning and scoping and the case studies show different approaches.

1.2. What is the purpose of the *1997 Guidance*?

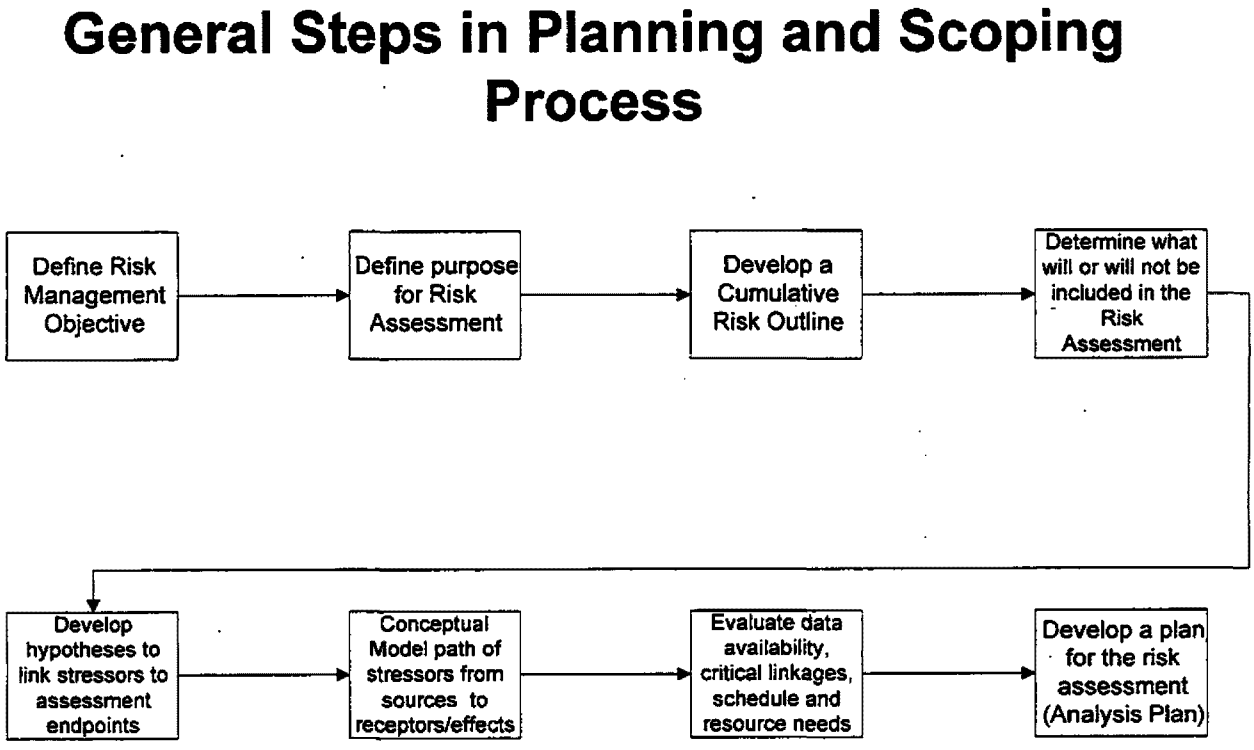
EPA's practice of risk assessment is evolving from a focus on single pollutants within a single medium towards integrated assessments involving multiple pollutants in several media that may cause a variety of adverse effects on humans, plants, animals, or on ecological systems and their processes and functions.

The *1997 Guidance* (see Appendix A)was intended to help EPA plan for cumulative risk assessments and other integrated risk assessments (i.e., those dealing with multiple stressors, sources, pathways, and endpoints of concern). It directed all EPA offices to take into account the combined effects of multiple environmental stressors in planning and scoping major risk assessments, and to integrate multiple sources, effects, pathways, stressors, and populations where data are available. The *1997 Guidance* placed particular importance on opportunities for

citizens and stakeholders to understand EPA's ongoing risk assessments and become involved in the risk management decision-making process.

1.2.1 What does the 1997 Guidance require?

The 1997 Guidance directs each office and region to conduct planning and scoping in major risk assessments, with special emphasis on cumulative risk and the integration of multiple sources, effects, pathways, stressors, and populations. For major assessments,the results of the planning and scoping process should be



described, including the risk management objective, problem formulation, the scope of the assessment, key assumptions and elements to include, technical products (the conceptual model and analysis plan), and participants.

1.2.2 How has the Guidance been implemented within the Agency?

The Science Policy Council's (SPC) Cumulative Risk Working Group (CCRS) (Appendix C), which prepared the *1997 Guidance*, developed a series of workshops

intended to introduce EPA scientists to the concepts of cumulative risk planning and scoping. The practica were designed to offer guidance and training to EPA risk assessors on cumulative risk and to bring EPA risk assessors and managers together to gain experience applying *the 1997 Guidance.* The SPC sponsored workshops to introduce the concepts of planning and scoping for cumulative risk assessment. The first practicum was held in Washington, DC, on July 28-29, 1998, and attracted 54 EPA scientists representing the breadth of EPA programs, research, and several regions. The second practicum was held in Chicago, IL, on November 12-13, 1998. More than 40 EPA, state, and Canadian scientists and risk managers participated. More than 50 participants attended the final workshop in the series, held in Washington, DC, on June 16-18, 1999. Separate summaries were prepared for each of the first two practica and for the entire series (ref.).

Each practicum featured presentations and facilitated discussions in large and small group settings. Drs. Mark Harwell and Jack Gentile, both of the University of Miami's Rosentiel School of Marine and Atmospheric Science, lectured and facilitated the development of the cumulative risk conceptual models and analysis plans through case studies of actual risk assessments going on in the Agency. The cases considered during the series were: Pentachlorophenol; Cumulative Risk Index Analysis of a Concentrated Animal Feeding Operation; and the Chicago Cumulative Risk Initiative. The attached case studies illustrate how the *1997 Guidance* was applied in each of these three instances (see Appendix B).

1.2.2 How does Planning and Scoping relate to other Agency initiatives?

The *1997 Guidance* on planning and scoping complements many of the Agency's initiatives, because cumulative risk assessment covers a wide variety of risk assessment issues including: the role of public involvement; sensitive subpopulations, such as children; and the physical or temporal boundaries of the assessment. Where possible, these issues should be integrated into planning and scoping of major risk assessments. Even when cumulative risk is not involved, planning and scoping is valuable for sorting issues, data, and contributors that must be considered in the risk assessment. For example:

- Planning and scoping accommodates public input and understanding by identifying experts and stakeholders and involving them in the earliest stages of risk assessments (see Section 4).

- As the scope is developed, risk assessors must consider the

characteristics of the population(s) at risk. These include individuals or sensitive subgroups which due to their age, gender, disease history, size or developmental stage, may be highly susceptible to risks from stressors or groups (see Section 5).

- The development of hypothetical stressor-effects relationships and a conceptual model provides a basis to evaluate data that are needed for the assessment and how they may be integrated for the assessment (see Section 6).

There are several other risk issues and concerns (e.g., environmental justice[1]) that the *1997 Guidance* could not address, at this time, but are recognized as important in the risk assessment process. This broader set of issues and concerns relates to social, economic, behavioral or psychological factors that may contribute to adverse health effects. These stressors may include existing health conditions, anxiety, nutritional status, crime, and congestion. The assessment of this broader perspective of risk is very difficult due to : a) major deficiencies in data to establish plausible cause and effect relationships, b) ability to measure exposure to such risks, c) understand their incidence and individual susceptibilities, d) availability of methods for assessing such risks, and e) techniques or approaches to managing the risk.

1.3 What is the first step of Planning and Scoping?

Planning and Scoping usually starts with a dialogue between the risk assessor and risk manager (as shown in Figure 2 below from the *Guidance*). The risk manager describes an objective for risk management (e.g., reducing childhood cancers in agricultural worker families or reducing exposure of city residents to lead). The manager also presents the expectations on timing and available resources. The assessor defines potential cause and effect relationships (e.g., stressors and assessment endpoints to measure the effects). A basic problem is defined, participants are identified (including the appropriate stakeholder groups), and plans are prepared (conceptual model, analysis plan) for the integrated risk assessment. Figure 2 shows that planning and scoping is part of the risk management decision process, separate from the analysis phase of the assessment, and there is extensive interaction among all parts of the process. Also, the risk

[1] EPA has issued *Interim Guidance for Investigating Title VI Administrative Complaints Challenging Permits (Interim Guidance)* which is under review by the Agency's Title VI Implementation Advisory Committee.

assessment is but one of the essential inputs to make an environmental decision. Other inputs include stakeholder input (see Section 4), economic benefits/costs, political science factors, social values and technology assessments. Section 2.3 gives more specific details on steps in the planning and scoping process.

The basic tasks for the risk assessment planning dialogue (see p. 7 of *the 1997 Guidance* for additional discussion) are to:

- *Define the purpose for performing the risk assessment*
- *Define the scope of the risk assessment: what's in, what's out*
- *Define hypotheses relating stressors to assessment endpoints*
- *Document the problem formulation (technical approach): conceptual model, analysis plan*

1.4 What value is added to environmental decision-making from the planning and scoping process? What are the intrinsic limitations of this process?

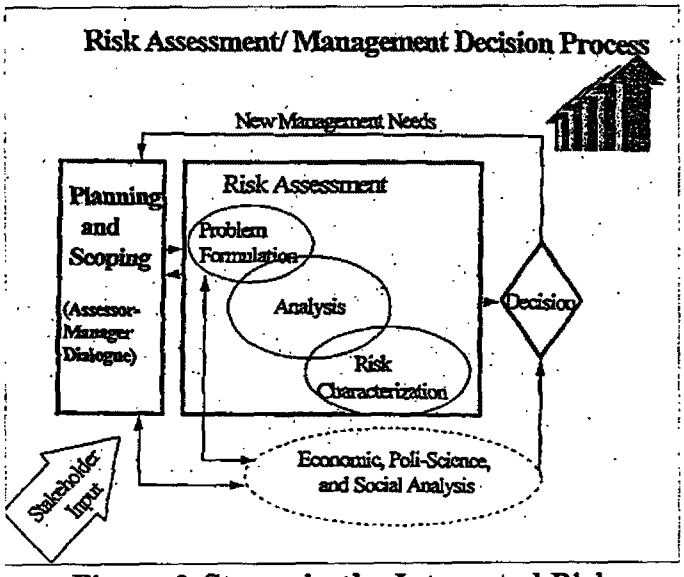


Figure 2. Stages in the Integrated Risk Assessment Process

As discussed in the *SPC Risk Characterization Guide*, "Planning and scoping is an important first step to insure that each risk assessment has a clear purpose, a defined scope, and logical approach. These [attributes] provide a sound foundation for judging the success of the risk assessment and for an effective risk characterization." Further, it formalizes a process that is already used by the Agency's programs on an ad hoc basis, opens up the process (increases transparency) to the public in a structured context, and allows a more clearly defined method of feedback in the risk assessment through the use of the conceptual model and analysis plan. The description of the assumptions and scope of the risk assessment helps participants and stakeholders understand the initial

assumptions and expectations about the risk analysis. Finally, planning and scoping evaluates changes and characterizes the results of the assessment.

The intrinsic limitations of Planning and Scoping are: a) it has the potential to become a protracted process due to public involvement; b) the process can be strongly influenced by the knowledge and judgement of the participants; and c) it may not work for short deadlines. However, the extra time that may be required for planning and scoping generally results in greater credibility in the public's eye for the final decisions made.

The extra time that may be required for planning and scoping may be well rewarded because it generally results in greater credibility in the public's eye for the final decisions made.

1.5 How much effort is involved in developing the planning and scoping products (conceptual model, analysis plan)?

The level of effort for developing planning and scoping products will vary with the complexity of the problem, the number of participants, the risk management objectives, and the experience of the participants. An experienced team of participants, familiar with the problem and data that are available could develop a conceptual model for human health risks within a week, while a complex ecological assessment of a large watershed or regional ecosystem may require several months of work and discussion with experts, stakeholders, and residents.

1.6 How does the terminology used in the *1997 Guidance* relate to the definitions currently used in cumulative, ecological, and human health risk assessment?

The definition of cumulative risk in the *1997 Guidance* is the potential risk presented by aggregating specific multiple stressors. However, the *1997 Guidance* intended that a definition of cumulative risk be developed on a case-by-case basis.

Concepts that Workshop Participants associated with Cumulative Risk

- integrated risk
- total environment
- relationship between risk assessors and risk managers
- multiple compounds, multiple sources, and multiple pathways
- risk over time
- "thinking outside the box"
- difficulties in obtaining good data
- complex interactions and relationships
- uncertainty, unknowns-how to deal with them
- total exposure-sources; similar mechanisms/modes of action of chemicals
- expanding scope to include stakeholders; environmental justice issues
- developing systemic approach
- need framework for scoping and strategies to address overall risk

Participants in the first two practica were encouraged to express their own understanding of "cumulative risk assessment" (see textbox).

The variety of workshop participant responses demonstrates the essence of the problem—everyone has a different initial understanding and emphasis, and nearly everything can be considered. Cumulative risk might implies different things at different times in different cases. To clarify the situation, a SPC Cumulative Risk Subcommittee (CCRS) has recently drafted a set of working definitions (see table below; selected examples are included). The underlying premise of the definitions is that "*All assessments, whether exposure assessments, ecological assessments, aggregate assessments, or cumulative assessments,* ***require specification of the context*** *in terms of agents or stressors being assessed, defining populations being assessed, endpoints being assessed, and routes/pathways/sources being assessed, etc.*" (CCRS, 1999).

WORKING DEFINITIONS FOR CUMULATIVE, ECOLOGICAL AND HUMAN HEALTH RISKS (CCRS, 1999) These are draft definitions.	
Aggregate exposure	The combined exposure of an individual or defined population to a specific agent or stressor via relevant routes, pathways, and sources, e.g., chlorpyrifos exposure to children via dietary /residential use.
Cumulative Risk (FQPA)	Cumulative effects which are the sum of all effects from pesticide chemical residues with the same mechanism of toxicity (e.g., the combination of all organophosphates and carbamates and which inhibit acetylcholinesterase).
Aggregate exposure assessment (FQPA)	An analysis, characterization, and possibly quantification of exposure of an individual or defined population to a specific agent or stressor via relevant routes, pathways, and sources. The Food Quality Protection Act (FQPA) defines aggregate exposure as all anticipated dietary exposures and all other exposures for a single substance. In practice, this includes routes and pathways of exposure for ingestion (food, drinking water, residential scenarios), inhalation (residential pathway) and dermal (residential pathway). Cumulative exposure for FQPA refers to all routes/pathways of exposure to two or more substances that cause toxicity by a common mechanism of toxicity (see Chlorpyrifos Risk Assessment).
Aggregate risk	The risk resulting from aggregate exposure to a single agent or stressor.
Cumulative Risk* (see below)	The combined risks from aggregate exposures to multiple agents or stressors. *Note: the term "cumulative risk" has two major facets. First, it must include multiple agents or stressors. Second, the risks of the agents or stressors must be combined, not just listed separately as might be done in a "multi-chemical" assessment where risks are listed separately*
Cumulative risk assessment	An analysis, characterization, and possibly quantification of the combined risks to health or the environment from multiple agents or stressors.

Total risk	The combined risks resulting from all agents or stressors.
Total risk assessment	An analysis, characterization, and possibly quantification of the combined risks to health or the environment from all agents or stressors.
Stressor	In human and ecological risk assessment the term is defined as a chemical, biological, or physical agent (including radiation) that may produce an adverse effect for an individual, population, sub-population, species, community, ecosystem or environmental process.
Population-based exposures	Exposed populations is a human health term.
Receptors	Receptor is often used in ecology to imply populations, individuals, or more complex entities who are affected by stressors.

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2. THE PLANNING AND SCOPING PROCESS

2.1 Overview Statement

Planning and scoping provides a broad foundation for cumulative and other risk assessment. It allows participants to define the problem that will be addressed and document the rationale for what is included. The process is a "dialogue" between risk assessors and risk managers with significant input from stakeholders. The risk manager should explain why a risk assessment is needed and what questions should be answered. Planning and scoping is an opportunity for the concerns of policy-makers and stakeholders to surface and for determining information needs and participants for planning the assessment. The planning and scoping dialogue should also discuss resources and participant roles.

2.2 What is the purpose of the planning and scoping process? Why is it necessary?

The planning and scoping process promotes discussions between risk managers and risk assessors about the risk management objectives, their roles, and needs for risk assessment. The *1997 Guidance* provides principles that EPA Programs and Regions can follow in the planning, scoping, and problem formulation stages of their risk assessments. Additionally, it applies principles from the Agency's March 1995 Policy for Risk Characterization by providing a clear, transparent, reasonable, and consistent basis for conducting any assessment. Regions and Program offices are strongly encouraged by the Guidance to undertake a formal problem formulation exercise for all risk assessments. In that way, planning and scoping ensures that risk assessment will reflect the principles of the policy.

The planning and scoping process is necessary for complex risk assessments, including cumulative risk assessments, because it promotes a better understanding of risk manager expectations, assessment limitations, and establishes a common purpose for performing the risk assessment. The process helps clarify what will (and can) and what will not (and cannot) be included in the risk assessment. It also identifies who needs to be involved (both from a technical and stakeholder standpoint). Finally, it serves to describe how the risk assessment is expected to proceed and to build consensus.

2.3 What are the Steps in Planning and Scoping for Cumulative Risk Assessments?

During Planning and Scoping, risk assessors, other technical experts such as ecologists, toxicologists, economists, and engineers, and risk managers work together as a team, informed by stakeholder input, to follow generally sequential steps to:

1. Determine the overall purpose and risk management objectives for the risk assessment;

2. Determine the scope, the problem statement, participants, and resources for the assessment;

3. Develop a cumulative risk outline of the risk dimensions and technical elements that may be evaluated in the assessment;

4. Formulate a technical approach including an analysis plan and a conceptual model for conducting the assessment.

2.4 How does planning and scoping affect the scientific integrity of the risk assessment?

The 1983 National Research Council (NRC) report has been interpreted by some as recommending a separation between risk assessment and risk management. A primary concern at that time, was that risk management might unfairly influence the results or analysis of the assessment to support a particular decision or outcome. The *1997 Guidance* recognizes this concern, but it also recognizes that risk assessments (and scientific information) but one of several factors that inform the risk management decision. More recently, the NRC (1996) has recommended dialogue and interaction between the risk assessor, risk manager, and stakeholders throughout the risk assessment-risk management process. In addition, the Agency has discussed the need for dialogue between risk managers and assessors in the risk characterization process (EPA, expected 2000). The development and analysis of the risk assessment should be guided by risk management objectives, input from stakeholders, and other technical information; however, risk assessments must represent unbiased and peer reviewed scientific analysis to maintain scientific integrity.

A written record of the planning and scoping discussion frames decisions on

the risk assessment, its scope and the aspects that will be assessed for the decision-making process. This record may include lists of stakeholders, issues considered and the rationale for including or excluding specific technical elements or data in the cumulative risk assessment. Such information will help all participants evaluate and understand how the Agency addressed the issues. It also distinguishes between policy, science, and compromise positions. This record provides a basis for developing the risk characterization in the assessment phase.

3. DEFINING THE PROBLEM

3.1 Overview statement

There is a logical synergy between risk management and assessment. The risk management problem stimulates the need to conduct the risk assessment. The risk assessment informs the development of risk management options. The risk assessment is guided by the risk management objectives and general nature of the problem. The objectives and scope of the problem help define the participants. Stakeholders also provide key information on concerns and social context. Problem formulation is an iterative process within which the risk assessor develops preliminary hypotheses about why adverse effects might occur or have occurred. It provides the foundation for the assessment and sets the stage for planning how the risk will be analyzed.

3.2 What does "defining the problem" mean for planning and scoping?

Problem formulation or "defining the problem" is a process for generating and evaluating preliminary hypotheses about adverse human health or ecological effects that have occurred or may occur. Risk assessment objectives are refined early in problem formulation (See Figure 4, Section III of Appendix A). Sometimes participants in the planning and scoping process define the problem; other times the problem is defined prior to planning and scoping. Problem definition sets the stage for an evaluation of the nature of the problem, a plan for analyzing data and characterizing risk. The importance of problem formulation has been shown repeatedly in the Agency's analysis of risk assessment case studies and in interactions with senior EPA managers and regional risk assessors (EPA, 1994; EPA, 2000-risk characterization guide). Shortcomings reported from case studies (EPA, 1998) consistently included 1) absence of clearly defined goals, 2) endpoints that are ambiguous and difficult to measure, and 3) failure to identify important risks. By following the planning and scoping process, the shortcomings cited above should be avoided. For the CCRI case study, when the problem was defined, the workshop participants discovered that the problem was focused on hazard and not risk.

3.3 What is the relationship between the risk management objectives, the development of the risk assessment and the risk management options?

Risk management objectives define the condition (i.e., public health and ecological quality) that the public wants to protect and regulatory goals that risk

assessors must consider. The risk management options are the means to achieve the goals and objectives. The objectives are considered by risk assessors in the problem formulation and the development of the risk assessment. The risk assessment is used by risk managers to evaluate risk management options. In some cases, managers may want to clarify or modify the options based upon further data analyses and they may wish to determine how to achieve the risk management goal(s). For example, risk management options for the CAFO case study (see Appendix B) include general permit conditions that limit contaminant releases or specify control technologies. The risk management objectives for that case are to protect existing water quality, groundwater purity, and public health and welfare. The objectives consider legal requirements and authorities of the Agency as well as conditions which stakeholders value and want to preserve. The risk management options also consider legal authorities, jurisdiction of the Agency and control mechanisms that are available. In the CAFO case, the objectives were developed by the risk assessor and risk manager with input from the farmer and affected parties in the community.

4. ROLES OF PARTICIPANTS IN THE PROCESS

4.1 Overview Statement

The planning and scoping process involves risk managers, risk assessors and other technical participants. It also involves stakeholders (parties who are involved or affected by environmental risks). Public participation in the planning stage helps ensure that the risk assessment targets aspects of the environment impacted by relevant human activities. Public participation leads to the incorporation of new kinds of information in environmental decision-making and has shifted the model for public participation from a paternalistic one where the government defines the process and invites stakeholders to participate toward the consensual type in which "every affected group participates" (Bear 1994).

Most of the discussion in this section focuses on stakeholders participation in the planning and scoping process It requires communication throughout the process (Glicken, 1999). The nature and degree of stakeholder involvement varies among different risk management decisions. The venue for participation is defined by the risk manager. Early in the planning and scoping of the risk assessment, decisions must be made about the participants such as: Who should participate? What could they contribute? How can they be involved? Affected parties can share their points of view about the risk and how it should be managed. Their input is particularly helpful in determining what should be included in the assessment, how they might be affected or exposed to the risk, and what additional data or exposure scenarios should be developed. Interested parties often bring special expertise to planning and scoping, including technical knowledge of monitoring data or models of effects or exposure or practical knowledge on their lifestyles, potential routes of exposure, or habits.

4.2 Who does planning and scoping?

The risk manager, risk assessor and technical staff of EPA (or a state) initiate the process. They develop the list of participants based on the issues, affected parties, and technical experience. Stakeholders (interested and affected parties) may participate during any steps of planning and scoping depending upon the nature of the problem, their interest, and ability to contribute. The risk assessor and risk manager should establish some ground rules for participants and describe the process that will be used to gather information.

4.2.1 What are the roles of the risk manager and the assessor in planning

and scoping?

Risk managers define objectives, schedules, available resources, and approve the analysis plan for the risk assessment. They must plan how they will solicit public input, analyze it, and communicate with the stakeholders. Risk assessors may facilitate the discussion of the scope and lead development of the conceptual model and analysis plan. The assessor must include and evaluate stakeholder data, identify data requirements, select models and default conditions, and explain the rationale for these choices in comparison with other alternatives.

Members of the regulated community are relatively easy to engage; however, public citizens may have difficulty participating in highly technical discussions or in attending multiple meetings during the course of the planning and assessment process (e.g. the PCP case study). In the CCRI case study, many stakeholders were represented by one or more spokespersons and detailed information was posted on a website by EPA that provided them with analytical tools to prepare maps of sources and stressor concentrations monitored in their communities.

4.2.2 What is the role of economists, engineers and the stakeholder community in the risk assessment?

Economists evaluate costs and benefits, equities for stakeholders, and the efficiency of risk management options. Engineers develop alternative approaches to control, avoid, or mitigate sources of risk or protect against the effects of risks. Stakeholders provide information on their concerns, values, and personal data on risks. Stakeholders provide feedback on the relevance and clarity of the risk management objective, scope for the assessment, conceptual model, and analysis plan. Stakeholders may also provide details on the release of stressors from sources, behavior and exposure patterns, and concerns of the community.

In public meetings over concentrated animal feeding operations (CAFOs), citizens expressed concerns about health effects from odors and decreases in property values. Regional risk assessors were able to find some data on adverse health effects from chronic odors and local zoning officials were included to begin an analysis of the economic impact of CAFO sitings on property assessments and tax revenues. The conceptual model also includes effects on quality of life which may be considered in future assessments.

In CCRI, citizens participated in development of a cumulative risk outline and recommended which stressors, sources, and human health effects should be

given priority. Their concerns are reflected in the conceptual model.

For PCP, both health and ecological effects were developed in great detail. OPP is considering ways to engage multiple stakeholders in planning and scoping.

For the National Air Toxics Assessment (Appendix D), other regulatory agencies were consulted to plan the assessment and the analysis. Other stakeholders were also invited to comment on the proposed urban air toxics strategy (Appendix E).

4.3 Who Are Stakeholders?

Identified CAFO Stakeholders

- Residents
- CAFO Workers
- Other Farmers (small farmers)
- Owners and shareholders (corporate farmers)
- State/federal regulators
- Environmental groups (local and national)
- Trade associations
- Academic/university/Ag cooperative researchers
- Elected officials
- Non-Governmental Organizations
- Regionally compiled list of interested parties from previous interactions

Participants informing the environmental decision-making process include regulators, the regulated community and the affected and interested public (see examples from the CCRI and CAFO case study). Stakeholders may consist of 1) parties and individuals who are affected by a risk management decision, 2) parties or individuals who are interested in the management of a particular risk, 3) members of the community who may be affected financially, 4) stakeholders who health may be at risk, and 5) elected representatives of interested or affected parties. Common approaches to involving stakeholders may include public hearings, citizen advisory committees and task forces, alternative dispute resolution including mediation, policy dialogues or negotiated settlements (e.g., regulatory negotiations), citizen juries and panels, surveys, focused group discussions, interactive technology-based approaches or combinations of deliberative methods (Appendix B, NRC, 1996).

4.3.1 What Is the Purpose of Stakeholder Involvement in Planning and Scoping?

Stakeholders add both credibility and valuable information to environmental decisions. Just as the scientific peer review is designed to assess the quality and relevance of technical information so, in a parallel fashion, stakeholder involvement provides a form of social peer review which enables interested parties to contribute

information and review options in the conceptual model under development to address an environmental concern (Yosie and Herbst, 1998). By involving stakeholders in the planning and scoping process they can add knowledge and gain understanding about the rationale and plans for the risk analysis. Public participation in planning and scoping allows the risk assessors and risk managers to understand how the interested and affected parties perceive the risk, and incorporate their perspectives and specialized knowledge into the process (NRC, 1996). Without this input, the conceptual model may overlook potential risks that concern stakeholders.

4.3.2 What Do Stakeholders Provide?

Stakeholder input can focus the risk management goals, as in the case of the Chicago Cumulative Risk Initiative (CCRI) where the risk assessment was initiated at the behest of concerned citizens.

Stakeholders may provide technical expertise in hazard and exposure assessment, technology, economic, social, political and legal areas. For example, affected parties may help identify concerns and costs so they can be considered in the problem assessment and the general deliberation process. With a clearer statement of costs, benefits, uncertainties, and other implications available to the assessor, experts, and stakeholders, a wider range of risk assessment options may be characterized or developed, including some that may be more innovative, more protective, voluntary, and more economical. In addition, exposed communities or groups can often provide critical information on potential or actual exposure scenarios, endpoints, or subpopulations that should be considered in the risk assessment. They also provide invaluable insights into public values and perceptions on the risk of concern, the preliminary remedial actions being considered ,and public reception of those remedies.

To develop an accurate depiction of the risks and risk management options, the conceptual model must reflect the risks dimensions; i.e., populations at risk (human, ecological entities, landscape or geographic concerns), sources of stressors, stressors, pathways of exposure, assessment endpoints, and time frames of exposure. Stakeholders are needed along with all other participants to explore the elements in the conceptual model. For a regulated chemical, for example, the industry representative will usually have the most definitive information on its chemical synthesis, production and use, which can more completely define the sources of exposure. Exposed groups or individuals can confirm or more accurately reflect the qualitative or quantitative aspects of the exposure pathways, including

routes of exposure and the relevant time frames involved in the proposed model. Stakeholders may suggest alternative methods of looking at the problem that may allow more flexible approaches to remediation of the risks, the development of additional conceptual models not originally considered, or novel, non-regulatory solutions to a problem..

4.3.3 What Is the Process for Selecting Stakeholders?

Identification of need: We recommend an initial brainstorming effort, using a set of diagnostic questions, such as those provided here from the third Planning and Scoping workshop (see textbox) the answers to these questions should allow identification of the most relevant, affected and interested parties. While determining the right mix of stakeholders to involve in a specific problem can be challenging, the Agency has taken steps to increase the opportunities and quality of stakeholder participation through its Stakeholder Involvement Action Plan (EPA, 1999).

Diagnostic Questions for Stakeholders
Who are the "interested and affected parties"?
What approaches should be considered (focus groups, etc)
What should be deliberated?
When?
How should participants be selected?
Should the program enlist outside help in establishing the deliberative process?
What are the external constraints for deliberation? (Budget, time, legal)
(Planning and Scoping Summary Report, 1999)

Value added: Due to the limitations of time, resources, and regulatory or legal requirements, stakeholder input must be evaluated in the context of value added. When the manager and assessor determine that stakeholder input is critical, there should be an opportunity for involvement by the appropriate stakeholders based upon the potential impact on their affected group(s), their experiences, and/or expertise. It is important to advise the stakeholders when their input will be most valuable, since there will be situations in which specific regulatory remedies are required by law and stakeholder involvement would not affect the choice of remedy but may affect the implementation schedule. The nature and number of participants within each step in the decision making process, including planning and scoping, should be clearly defined by the manager or assessor as well as the methods for identifying and notifying the stakeholder representatives.

Each stakeholder contributing to the planning and scoping process should come to the table with a willingness to define objectives and inform the process with data, surveys, experiences or other information that might support their concerns about the risk(s), mitigating circumstances, or impacts of various risk assessment

approaches. While all parties should work to achieve consensus wherever possible, it may not be possible in some instances. See a caution regarding consensus in section 4.4.

Assurance of fairness: Stakeholders involved during the process should be assured by the regulatory Agency(ies) that their input will be used in a fair and open manner. The degree of input will differ from assessment to assessment for various reasons including: differing complexities of each analysis, the resources available for interaction, the risk mitigation options proposed and time limitations.

4.3.4 When Can Stakeholders Participate in Planning and Scoping?

Stakeholders may participate in the initial planning and scoping exercise, the revision of the conceptual model, or at the peer review stage.

Initial Planning and Scoping: Depending on their expertise, stakeholders may be able to contribute to the development of:

1) the overall purpose and general scope of the risk assessment;
2) the products needed by management for risk decision-making;
3) the approaches, including the risk dimensions and technical elements, that may be evaluated in the assessment;
4) the relationships among potential assessment endpoints and risk management options;
5) an analysis plan and conceptual model;
6) the resources (e.g., data or models) required or available;
7) the identity of other critical participants and their roles; and
8) the schedule to be followed (including provision for timely and adequate internal, and independent, external peer review) (Guidance, 1997).

Revision of the conceptual model: Feedback throughout the planning and scoping process is critical. Therefore, all participants and assessors should remain flexible during any particular phase of risk assessment discussions, and recognize the need to revisit previous assumptions in the conceptual model based on new data or information.

Peer Review: The conceptual model must be peer reviewed before major risk assessments are completed. Qualified and active stakeholders should be expected to be considered in the selection of the peer reviewers where appropriate. Selection of the appropriate representatives should be a flexible process, since it requires a

specific analysis of the needs for each individual risk management case and the constituencies of the affected parties, which may change as the decision making process evolves.

4.3.5 How Does the Spectrum of Stakeholder Issues Affect the Planning and Scoping Exercise?

Discussions among the three case workgroups highlight the case-specific nature of each risk assessment and the need to be sensitive to the perceived or real needs of the stakeholders in addressing the risk issues. The topics discussed and the length of the discussion in each case was influenced by the experience of the participants, the problem they faced, and the dynamics of the group.

In the pentachlorphenol (PCP) case study, originally it was believed that stakeholder groups should be limited to PCP registrants, utility companies and the Agency. However, the facilitated discussion expanded the list of stakeholders to include international parties (Canada, Mexico/NAFTA), other agencies involved in OSHA issues, the general public, Congress and environmental groups. Workers (e.g., linemen, treatment), the public and environmental groups were not involved on the PCP issues (although currently, the Pesticides Program is actively engaged in examining mechanisms (e.g., putting Registration Eligibility Decisions on the internet) to open up the process more fully). The workgroup noted that in developing national criteria for a chemical, it is often difficult to define who the stakeholders are or should be. The workgroup was also concerned that preliminary dissemination of risk information may lead to erroneous conclusions on the part of the public, resulting in adverse economic effects (i.e., raising some health concerns may result in pesticide users prematurely rejecting a product).

The concentrated animal feeding operations (CAFO) case study included a complex risk assessment involving many inputs and considerations. These included CAFOs and their component operations, as well as other regional sources such as agriculture, oil and gas exploration and production, roads and transportation infrastructure, and domestic waste; multi-media (surface- and groundwater and air), multiple pathways and routes of exposure (drinking water and surface-water contamination from microbiological contamination; odors); scientific disciplines (ecological, human health, social sciences/economics); and statutory overlap (CWA, CAA, NEPA, FQPA, RCRA). It illustrates the challenge of involving a wide range of stakeholders in a complex ecological and public welfare issue (see stakeholder list in textbox under Section 4.3) where states are being influenced by local economic considerations and need flexibility to make regulatory or mitigation decisions.

The Chicago Cumulative Risk Initiative (CCRI) case study is an example of a stakeholder-initiated assessment. It illustrates the importance of stakeholder concerns and demonstrates how stakeholder interests may diverge from EPA's standard risk assessment approaches. The stakeholders[2] were involved in deliberations regarding the scope of the assessment, data needs and constraints, "products" to be produced, and the project schedule. Consensus was achieved in Region 5's deliberations with stakeholders on the scope of the assessment to be performed (see textbox). An important breakthrough occurred at the final workshop. The breakout group recognized that the real objective of CCRI was hazard assessment, not cumulative risk assessment. The project does not involve assessment of "cumulative risks" but rather "cumulative hazard". CCRI is not a true risk assessment, but rather a hazard mapping exercise showing the air quality impact of point, area, and mobile sources (environmental loading) within the two-county area. This realization helped them avoid spending unneccessary time and expense on a risk assessment.

The type of information provided by non-scientists is different from that provided by technical experts. This non-technical information enters the decision-making process at a different point from scientific information, and informs the decision in a different manner. It thus should not substitute for science, but supplement or augment it. In an ecological risk assessment process, for example, this non-technical information generally enters in the planning stage where a suite of social values relative to the environmental issues is elicited from stakeholders. These values are then converted to assessment endpoints used by the scientists to structure data collection and analysis. The public thus delineates the universe within which the risk is defined.

EPA/Stakeholder Recommendations on Scope of the Assessment for CCRI

- Conduct a cumulative rather than comparative analysis
- Focus specifically on children
- Focus on sources rather than receptors
- Concentrate on EPA-regulated sources
- Use only existing data
- Cover a broad two-county geographic area
- Limit study to air pathway/medium
- Do not tie health effects to causes

(Planning and Scoping Summary Report, 1999)

[2]Stakeholders include 11 advocacy groups, represented by the Chicago Legal Clinic (CLC), state, county and city governments, the Chicago Department of Health, the Chicago Department of the Environment (also representing industry interests related to brownfields), EPA Region 5, Asthma Coalition, University of IL School of Public Health.

4.3.6 What are the lessons learned from the case studies?

Several key points can be extracted from the workshop case studies.
a) It is important to involve stakeholders in the planning and scoping process very early, before a formalized conceptual model is developed.
b) Planning and scoping helps to organize thinking and to document the process.
c) The conceptual model is a useful tool for communicating with interested and affected parties and the general public (e.g., presenting information, explaining analysis, and cause-effect hypothesis) . It allows them to see risks in context. The systematic thoroughness and rigor of model development enables effective risk communication.
d) Explaining uncertainty to stakeholders is a problem that needs up-front planning. There is a hesitancy to reveal all that is known and not known about chemicals and their risks, because it reveals uncertainties that can lead to criticism and political ramifications. Yet, uncertainty is inevitable since there will never be sufficient data to answer all questions.
e) The public should be involved in the cumulative risk assessment as early as possible. They should be involved in helping make decisions necessary for development of the conceptual model, and should be invited to participate and provide feedback for revisions to the conceptual model, and at each step in the deliberative process.
f) Careful analysis of the problem can focus the effort and clarify what type of analysis is needed.
g) National assessment.

4.4 How Does FACA Apply to Planning and Scoping?

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) prescribes steps that federal agencies must take in order to receive consensus advice from two or more individuals that are not employees of the federal government. The steps include establishing a committee charter, maintaining records or minutes of the meetings, public notice of the meetings and meetings must be open to anyone. Planning and scoping sessions are exempt from FACA if they do not require consensus. Further details on planning and scoping exercises involving peer review of consensus products are referred to in Section 2.7.3 of the SPC Peer Review Guide.

4.5 What Are the Best Ways for Communication with Citizens and Other Interested Parties?

Initially, "face-to-face" meetings with the participating stakeholders will be necessary in firming up the problem to be resolved and its scope, and for drafting the conceptual model, narrative and analysis plan. Subsequent consultations or informational briefings may also be necessary, depending on the length or the nature of the problem. If the stakeholders are contributing data, a schedule must be developed with appropriate time for questions and interaction. Additional meetings of contacts may be necessary if there are new data requirements, modifications to the conceptual model and/or analysis plan. The nature of the information that is shared will vary with the expertise and interest of the stakeholder groups. This could be achieved through a workgroup meeting with hardcopy products, or it may be sufficient to share the changes electronically (e.g., via email, webpage, "virtual work environments" or an interactive listserver) with the opportunity for feedback and observation of the interim and final products. A process manager may be needed who should recognize that public participation will always involve problems, and that the problems will be specific to the particular participatory process.

If the risk assessment examines a problem of sufficient economic, human health, or environmental impact, an intranet website (and password) with information on the conceptual model could be established for the specific stakeholder workgroup. A website providing examples of "finished" conceptual model products could be made available on the internet. The users (stakeholders) may wish to compare the planning and scoping documents with the final decision. The Agency must be prepared to reconcile any differences.

It is important to remember that science has a language all its own; non-scientists do not know this language and can feel excluded by its use. However, scientists often feel that the precision of information captured in scientific terminology is lost in its translation to lay terms. Accomplished and trusted translators between scientific and lay communities can help bridge this gap. Communication between the risk manager and all stakeholders must be ongoing throughout the risk assessment process (DeFur in press), and not occur just at the beginning and the end. The nature of the communication will vary throughout the process: some situations require a simple conveyance of information or findings; other situations require a solicitation for input or dialogue surrounding a decision.

5. DEFINING THE SCOPE OF THE ASSESSMENT

5.1 Overview Statement

The *1997 Guidance* states "The scope of Agency risk assessments describes the currently identifiable context of the environmental risk that will (or can) be analyzed. It is defined according to *who* or *what* is at risk of *adverse effects* from identifiable *sources* and *stressors* through several *routes of exposure* over varied *time frames*. . . A review of possible risk dimensions. . . done at the beginning of the assessment can help to define its scope and how the risks will be integrated . . . (T)his guidance is designed to help risk managers and risk assessors plan and document the scope of risk assessments and to consider appropriate participants (that is, technical, advisory or stakeholder) or information to enrich the risk assessment" (EPA, 1997).

The scope of Agency risk assessments describes the currently identifiable context of the environmental risk that will (or can) be analyzed.

5.2 What is a cumulative risk matrix?

The cumulative risk matrix is an outline of risk dimensions and elements that might apply to a complex risk assessment and is intended to help risk managers, risk assessors, economists, engineers, and other experts discuss the assessment's technical dimensions and specific elements. It can be used as both a checklist to note how the risk assessment will be framed, and also for planning the risk assessment with the risk manager and explaining the scope of the risk assessment to the interested and affected parties. The possible dimensions of the risk assessment are presented below. Details of the elements are presented in pages 10-13, Section IV of the EPA guidance (Appendix A).

- Population: Who/What/ is at risk?
  - Example-Hispanic toddlers or the process of nitrogen fixation
- Sources: What are the relevant sources of stressors?
  - Example-Auto exhaust or exotic species
- Stressors: What are the stressors of concern?
  - Example-Lead or overfishing

- Pathways: Environmental Pathways and Routes of Exposure: What are the relevant routes of exposure?
  - Example- Drinking water or ingestion

- Endpoints: What are the assessment endpoints and their measurement metric?
  - Example-biodiversity and number of species

- Time Frames: What are the relevant time frames of exposure, frequency, duration, intensity, and overlap of exposure intervals for a stressor or mixtures of stressors?
  - Example-one generation, chronic

5.3 Why should options, technical or resource limitations, or approaches that will not be included in the risk assessment be presented or discussed?

It is important that the planning exercise be a balanced, transparent effort so that the basis for the final environmental decisions (and the alternative options, limitations, and approaches considered but not selected) are clearly understood early in the process by the public and regulated community. Thus, the reasons to limit the technical scope of the assessment must be stated explicitly and must include details on limitations of resources, data, the impact of risk elements on the risk estimate and methods available. In cases where an element of risk is likely to be important but cannot be quantified due to lack of data, the assessor must highlight this deficiency, using professional judgement or estimates(if possible) to approximate the missing data. Judgements and approximations must be clearly noted and explained to the relevant risk manager and/or relevant stakeholder participants in the final risk characterization.

5.4 Why are health and ecological risks considered in the same matrix?

To achieve the goal of a comprehensive environmental risk assessment, human health and ecological risks must be considered together. In terms of mechanics, this may initially entail separate analyses with a combination of the risks in the final phase of development. EPA has developed the "problem formulation" process for ecological risk assessment, but not for human health risk assessments. In effect, the "planning and scoping" process for developing conceptual models and analysis plans for cumulative risk assessment is much the same as problem formulation for ecological risk assessment. The conceptual models for Pentachlorophenol, Concentrated Animal Feeding Operations, and the Chicago

Cumulative Risk Initiative (Appendix B) illustrate the value in developing aspects of human health effect models along with ecological effect models. However, ultimate integration of the two models into an "environmental effects" conceptual model awaits further work. Agency scientists are considering methods to fully address the integration of human health and ecological risks for environmental assessments.

Additional informaton will be added here referencing NCEA work.

5.5 How do you decide what is in the assessment and what is out?

In the first round, the risk matrix includes all options that were considered for each dimension of the risk assessment (e.g., sources, stressors, effects, pathways, etc). Next, a prioritization process should take place to define the initial scope of the assessment including milestones for revisiting the issues as the assessment proceeds and additional data or advisory input is received. The basis for prioritization will vary among risk assessments but will include scientific, technical or regulatory support for the selection of the sources, stressors, environmental pathways, populations/receptors and endpoints of concern, as well as other consideration such as economic resources, public pressures for action, national and international trade issues, etc. For screening assessments, this may be a relatively simple selection process. Priority should be given to those elements that are supported by data most relevant to the risk management objective and the hypothesized relationship between stressors and assessment endpoints.

5.6 Is it necessary to establish a cause and effect relationship between a stressor(s) and endpoints?

No. Adequate information may not be available to establish a cause and effect relationship between the stressor (s) and endpoints. The purpose of the conceptual model is to provide a template for generating risk hypotheses while providing explicit expressions of the basic assumptions and understanding of the risk problem. Hopefully, by the time that the environmental risk assessment is complete, the cause-effect relationship will be strengthened, confirmed, or in some cases modified based on additional data or analyses.

5.7 What is the difference between assessment endpoints and measurement endpoints?

Assessment endpoints are functions or characteristics of a group or population of people or organisms (such as reproduction, growth, and lack of disease) that can be measured in relation to the intensity or concentration of a stressor. For example, measurement endpoints are the specific indices to help quantify and predict potential or real changes in the assessment endpoint. Examples include measurements of chlorophyll used to estimate the photosynthetic function of algae in a water body or acetylcholinesterase inhibition as an indicator of certain types of neurotoxicity. See Section 6.2, 6.3 for additional details and examples.

5.8 Does the risk problem represent a place-based or national risk?

Place-based (e.g. CCRI case study) versus national-based (e.g. PCP reregistration case study) planning and scoping exercises will necessarily involve different orientations and sets of requirements (including those for stakeholder involvement) in constructing the conceptual model and analysis plan.

- If place-based:
  - define the boundary of the problem area
  - determine the relevant pollution sources
  - identify the stressors of possible concern
  - scope out the location of targets
  - identify and inform relevant local/regional stakeholder groups, citizens

- If national-based:
  - define general and specific subpopulations of concern within the national boundaries; establish a clear rationale for their inclusion
  - define the stressors and their sources
  - identify sources or indicators of human health, ecological effects (e.g., epidemiology data, USGS trend data)
  - identify and inform the relevant national stakeholder groups

6. THE PRODUCTS: CONCEPTUAL MODEL WITH NARRATIVE, ANALYSIS PLAN

6.1 Overview Statement

Central to the *1997 Guidance* is the conceptual model with its risk hypothesis (es) and narrative and an analysis plan. The analysis plan is the implementation strategy for performing the cumulative risk assessment. Consistent use of the conceptual model approach should result in a consistent, transparent process for planning assessments, communicating risks of concern, and explaining risk management decisions.

6.2 What is a conceptual model and what is its utility?

The conceptual model is a visual representation relating:

1) *sources* of contaminants, physical, chemical, radiological, psychological *stressors,* etc.;
2) to their potential or actual release;
3) through environmental media;
4) resulting in exposure via single or multiple *routes*;
5) to *populations*, subpopulations or groups of individuals (human health), communities, and ecosystems;
6) resulting in adverse (or potential adverse) *effects* to human health or the ecology as
7) measured by *assessment endpoints* (see textbox) such as carcinogenicity, reproductive toxicity, population or species effect, alteration in species diversity, keystone species or loss of habitat structure, etc.

The conceptual model should always be accompanied by a detailed narrative explaining the rationale for the nature of the conceptual model developed.

The simple diagram of a generic conceptual model given below illustrates the application of the terms in the *1997 Guidance* document. Sources are activities that generate or release stressors. These may include industry, municipal waste and wastewater treatment, solid waste disposal, transportation, agriculture, and natural resource management. Stressors are chemical, physical, or biological agents that cause an adverse effect. The stressors move from the source to the receptors through pathways (e.g., air or surface water), where they may be converted or metabolized in some way. Exposure occurs in similar ways for plants and animals, although ecological entities, like communities and ecosystems, are exposed in more complex ways. Receptors express the effects of the stressors, usually in response to the dose or quantity of stressor they experience. Under health endpoints, the generic model adds confounding factors that contribute to how the effect is expressed. Quality of life issues are often concerns for siting or expanding existing facilities or projects. Although they are beyond the normal considerations of risk assessment guidelines, quality of life issues are of great concern to people.

The narrative shows the basic rationale for pursuing particular courses of action in a cumulative risk assessment. It provides a record of decisions for future reference during risk analysis, characterization, and communication of the risk management decision. It is also valuable as a risk communication tool both internally within the Agency and externally in interactions with the public. For peer review, the conceptual model provides a scientific or technical work product that includes:

Selected Measures of Ecological Assessment Endpoints (Ecological Risk Assessment Guidelines, 1995)

Assessment endpoints and conceptual models help risk assessors identify measurable attributes to quantify and predict change. However, determining what measures to use to evaluate risk hypotheses is . . . critical to the success of a risk assessment. There are three categories of measures :

o Measures of effect are measurable changes in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed .

o Measures of exposure(s) are measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint.

o Measures of ecosystem and receptor characteristics are measures of ecosystem characteristics that influence the behavior and location of entities selected as the assessment endpoint, the distribution of a stressor, and life-history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor." A table of measures for ecological and human health assessment endpoints is presented below (excerpted in part from text box 3-16, Eco-Risk Guidelines).

Measures of human health assessment endpoints include:

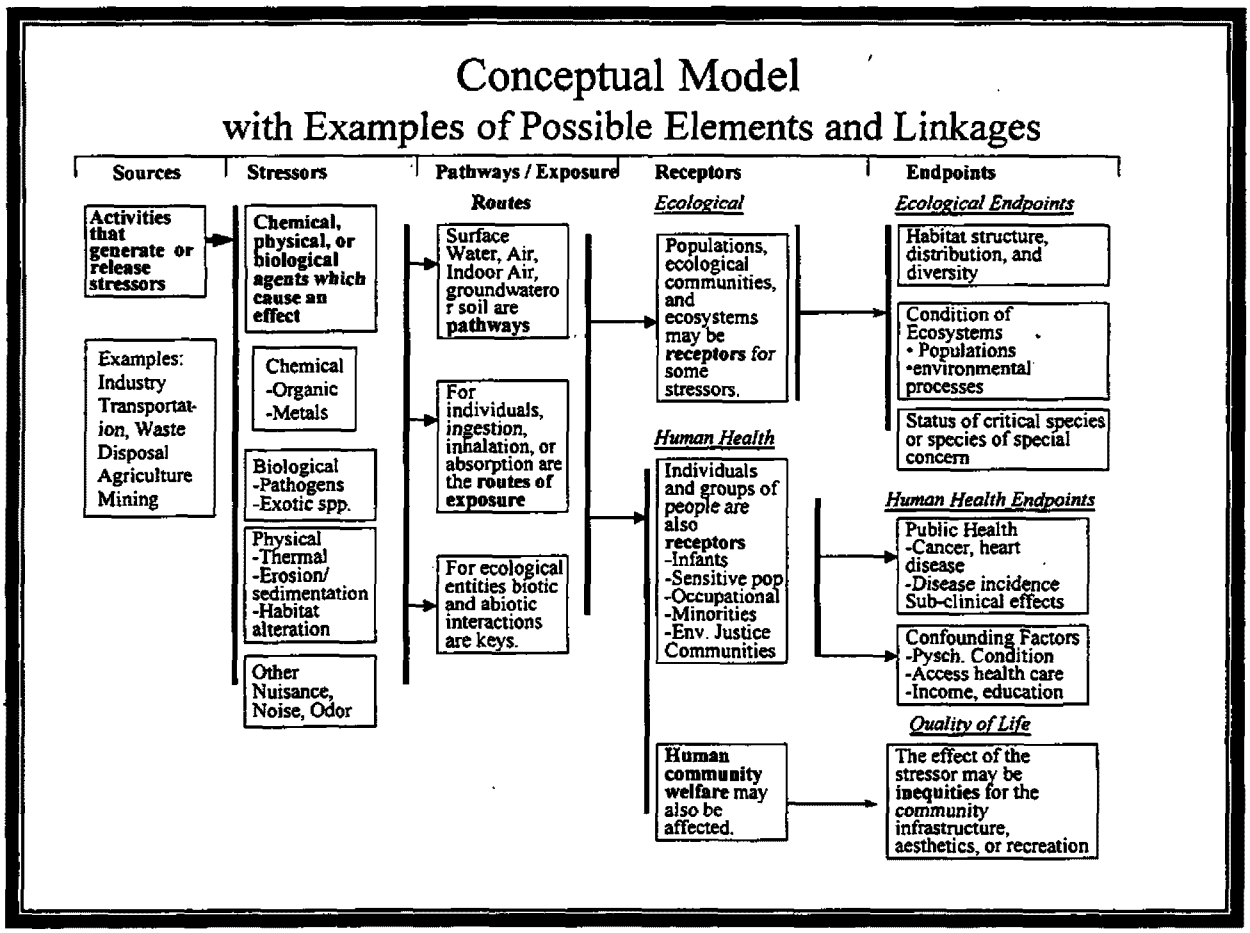
o Toxicological responses (human and/or experimental animal) including cancer rates or unique cancer types, neurotoxicological changes including pathology and neurofunction, reproductive dysfunction, developmental toxicity, cardio-vascular insult, immunotoxicity, renal effects, hepatotoxicity, others, etc.

1) the scientific rationale for the selection of the stressor (s), source(s), receptor(s) (exposed populations), exposure or environmental pathways, assessment endpoints, and measurement endpoints;

2) the scientific, technical, economic, or sociologic basis for the construction of the conceptual model; and,

3) the scientific implications of additional data gathering.

Figure . Generic Conceptual Model



6.2.1 Who develops and supports the conceptual model?

The conceptual model is developed by risk assessors and other technical experts such as ecologists, toxicologists, economists and engineers, working together with risk managers as a team. Depending upon the nature and complexity of the risk assessment, stakeholders will inform the development of the model to various degrees, and may continue to play a part in the selection of elements and linkages from the model which are included in the analysis (see Sections 4.3.2 and 4.3.4). Ultimate responsibility for its development and support lies with senior management in the Program Offices or Regions.

6.2.2 What are the rules for developing conceptual models?

The conceptual model must be developed within the context of the overall purpose and general scope of the risk assessment (see Tasks 1, 2 , Section III of guidance). Once that context is established, we recommend using an iterative process to achieve the final structure of the conceptual model.

Developing a conceptual model is a four-step process.

1. Bring together appropriate technical, managerial and stakeholder expertise and brain-storm the risk dimensions and technical elements of the assessment (see Section IV of the *1997 Guidance*). At this initial stage, it is important not to exclude any options (see 5.3).

2. Develop a cumulative risk outline of the elements for each dimensions: sources; stressors; affected groups; entities, or populations; environmental pathways and routes of exposure; relevant time frames, and assessment endpoints (ecological, human health). Reflect in this outline the resources (e.g., data or models) required or available.

3. Prioritize the dimensions and elements within this outline and include the rationale (see Section 6.2.5 below on narrative) for excluding any elements.

4. Develop the linkages between all the dimensions of the outline and construct a visual model[3] to represent these relationships (graphic illustration).

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[3]This step is the technical approach (also called Problem Formulation in the Agency's Ecological Risk Assessment Guidelines), a process in which the analysis plan and preliminary hypotheses about the relationship between stressors and effects on receptors are developed in a conceptual model.

The strength of these linkages should be clearly defined (e.g., thin versus thick lines, etc) (see Section 6.2.4 for tools for constructing the models). The linkages should represent hypotheses about the relationship between the stressors and the assessment endpoints. If needed, hypertext links may be employed where additional detailed modeling is required to fully describe the risk dimensions/elements relationships to the endpoints.

6.2.3 How much detail is required for the conceptual model?

The conceptual model may be a simple diagram (e.g., for a screening level risk assessment) or a complex, multi-level graphic representation of the sources, stressors, exposed populations, or ecosystem elements of concern. The economic or societal importance, complexity, and novelty of the risk, and the data and resources available for the risk assessment will determine the degree of sophistication and detail needed. Sufficient detail is required to clearly articulate the rationale for the inclusion of major dimensions/elements of the conceptual model and to support the peer review of the scientific and technical bases for the model (see Section 6.2). Depending on the case, and the area of interest of the risk assessor, risk manager, and/or any stakeholder, a part of the conceptual model could be isolated and its details further examined (see 6.2.6).

6.2.4 What tools are available for constructing the model?

- For the brainstorming phase of the conceptual model, poster paper, Post-It© notes, whiteboards, and writing implements (magic markers, pens) are used to write down needed information, options, data available, data needs, resource constraints, etc. No limit should be set on the ideas or information until the group feels that all bases have been sufficiently covered. Then, criteria may be developed to focus ideas and to sort and prioritize the different bits of information in preparation for developing a cumulative risk outline. In some cases, facilitation may be necessary.

The outline (EPA 1997) can be used as a checklist to frame the dimensions of the risk assessment, to plan the risk assessment with the risk manager and to explain its scope to the stakeholders.

- For constructing the conceptual model, graphics capability is available in Corel WordPerfect© (limited capability), Microsoft PowerPoint© or Lotus Notes Freelance© . Other, more advanced graphics systems (e.g., Visio©) may

be available from your information technology support personnel. The USDA offers training in these graphics systems. Hypertext links to expand a particular aspect of the conceptual model may be created using WordPerfect© [4]. Figures in this report (Appendix NATA) were developed in Microsoft PowerPoint© and imported to WordPerfect© as windows metafiles.

6.2.5 What are the components of the narrative?

The narrative is a written description of the conceptual model; i.e, 1) what are the dimensions of the model [stressor (s), sources, receptors (exposed populations), exposure or environmental pathways, assessment endpoints and measurements of endpoints], and 2) what is the scientific, technical, economic, or sociologic basis for the construction of the conceptual model. Examples of ecological and human health narratives for pentachlorophenol (PCP) are presented in Appendix B. The rationale for selecting assessment endpoints and where possible, supporting data or information should be described.

6.2.6 When do you know that you have achieved an acceptable level of refinement of the conceptual model?

The level of refinement for the conceptual model must be determined by the group constructing it and involves a flexible, iterative process. When the risk assessors, risk managers and stakeholders determine that the model includes the risk factors of concern, the data and resources available to address the risk assessment are described along with their limitations, and transparent, clear hypotheses for determining the potential risks are acceptable to the participants, the conceptual model should be considered "complete". Subsequent information affecting the structure and assumptions of the conceptual model (feedback loop) or peer review comments may require additional adjustments to the model. Thus, while a model may be developed that is acceptable to the workgroup it should always be viewed as a "work in progress".

6.2.7 Are conceptual models and their narratives subject to peer review?

In general, conceptual models are subject to peer review. The Peer Review Guide (EPA, 1998) states "...that all major scientific and technical work products

[4]Go to the help function, select Create Reference, Create Online Jump, Create Hypertext Link.

used in decision making..." are subject to peer review. Major scientific or technical work products:

1) establish a significant precedent or application for a model or methodology,

2) address significant controversial issues,

3) focus on significant emerging issues,

4) have significant cross-Agency/inter-agency implications,

5) involve a significant investment of Agency resources,

6) consider an innovative approach for a previously defined problem/process/methodology, or,

7) satisfy a statutory or other legal mandate.

When the risk manager determines that a model does not meet the criteria for a major product, a rationale for its exclusion from peer review should be developed. For example, one rationale might be that the conceptual model is for a routine, narrow-impact environmental decision such as a screening-level site-specific risk characterization or a screening-level chemical use-specific characterization in the premanufacturing notice program for new chemicals under the Toxic Substance Control Act (TSCA).

6.3. How do you develop an analysis plan?

The analysis plan is the final stage of planning and scoping before the risk assessment. The analysis plan is based upon the analytical plan discussed in the Ecological Risk Assessment Guidelines, Section 3.5. The analysis plan includes pathways and relationships identified during planning and scoping that will be pursued during the risk analysis phase. " . . . Those hypotheses considered more likely to contribute to risk are targeted. The rationale for selecting and omitting risk hypotheses is incorporated into the plan and includes discussion of data gaps and uncertainties. It also may include a comparison between the level of confidence needed for the management decision with that expected from alternative analyses in order to determine data needs and evaluate which analytical approach is best.

When new data are needed, the feasibility of obtaining them can be taken into account . . . ".

> In situations where data are few and new data cannot be collected, it may be possible to extrapolate from existing data. Extrapolation allows the use of data collected from other locations or organisms where similar problems exist . . . When extrapolating from data, it is important to identify the source of the data, justify the extrapolation method, and discuss recognized uncertainties.

> A phased, or tiered, risk assessment approach . . . can facilitate management decisions in cases involving minimal data sets. However, where few data are available, recommendations for new data collection should be part of the analysis plan. When new data are needed and cannot be obtained, relationships that cannot be assessed are a source of uncertainty and should be described in the analysis plan and later discussed in risk characterization.

> When determining what data to analyze and how to analyze them, consider how these analyses may increase understanding and confidence in the conclusions of the risk assessment and address risk management questions. During selection, risk assessors may ask questions such as:
> o How relevant will the results be to the assessment endpoint(s) and conceptual model(s)?
> o Are there sufficient data of high quality to conduct the analyses with confidence?
> o How will the analyses help establish cause-and-effect relationships?
> o How will results be presented to address manager's questions?
> o Where are uncertainties likely to become a problem?

> When direct measurement of assessment endpoint responses is not possible, the selection of surrogates measures is necessary . . . The analysis plan provides a synopsis of measures that will be used to evaluate risk hypotheses. The plan is strongest when it contains explicit statements for how measures were selected, what they are intended to evaluate, and which analyses they support. Uncertainties associated with selected measures and analyses and plans for addressing them should be included in the plan when possible.

6.3.1 What does the analysis plan look like?

The analysis plan can be a brief summary of what the key components of the risk assessment are and how each component will be measured or calculated. Examples of ecological and human health risk analysis plans that might be developed are presented below.

A. Ecological Risk Analysis Plan

Risk management/regulatory goal: Viable, self-sustaining coho salmon population that supports a subsistence and sport fishery.
Assessment endpoints: Coho salmon breeding success, fry survival, and adult return rates.
Measures of Effects:
- egg and fry response to low dissolved oxygen
- adult behavior in response to obstacles
- spawning behavior and egg survival with changes in sedimentation
- population data over time in relation to fish passage

Measures of Ecosystem and Receptor Characteristics:
- water temperature, water velocity, and physical obstructions
- abundance and distributions of suitable breeding substrate
- abundance and distribution of suitable food sources for fry
- feeding, resting, and breeding behavior
- natural reproduction, growth, and mortality rates

Measures of Exposure:
- number of hydroelectric dams and associated ease of fish passage
- toxic chemical concentrations in water, sediment, and fish tissue
- nutrient and dissolved oxygen levels in ambient waters
- riparian cover, sediment loading, and water temperature

What Can and Cannot be Done Based on Planning and Scoping
- pathways and relationships to be evaluated
- resource restraints
- milestones for completion of risk assessment

Methods for Conducting Risk Analysis
- quotients
- narrative discussions
- stressor-response curves with probabilities

Data Needs and Uncertainties

B. Human Health Risk Analysis Plan

Risk management /regulatory goal: Protection of the general human population and susceptible subpopulations to adverse effects from exposure to pesticide X under the 1996 Food Quality Protection Act (FQPA)

Assessment endpoints:

- human or animal health status of exposed versus unexposed populations/cohorts/dose groups

Measures of Effects:

- general toxicological effects including subchronic, chronic, reproductive, developmental, neurotoxicity, developmental neurotoxicity, immunotoxicity, hepatotoxicity, pulmonary, cardio-vascular, etc.
- carcinogenicity
- mutagenicity

Measures of Exposure:

- monitoring of food, water, residential, occupational exposures, etc. (direct or surrogate)
- monitoring of biological fluids or biomarkers (blood, urine, DNA or other macromolecules)

What Can and Cannot be Done Based on Planning and Scoping

- pathways and relationships to be evaluated
- resource restraints
- milestones for completion of risk assessment

Methods for Conducting Risk Analysis

- RfD
- Margin of Exposures (MOEs)
- quantitative risk assessment with probabilities on dose-response or exposure parameters
- quotients
- narrative discussions

Data Needs and Uncertainties

6.3.2 How much detail is required in the plan?

As in the conceptual model, the economic or societal importance, complexity, data and resources available will determine the degree of sophistication and detail

needed in the analysis plan. Key data gaps should be identified. It should also include thoughts about how to fill the information needs in the near-term using existing information, in the mid-term by conducting tests with currently available test methods to provide data on the agent(s) of interest, and over the long-term to develop better, more realistic understandings of exposure and effects and more realistic test methods to evaluate agents of concern. The plan should explain how measures were selected, what they are intended to evaluate, and which analyses they support. Uncertainties associated with selected measures and analyses, and plans for addressing them, should also be explicitly stated.

6.3.3 When should the plan be revisited?

The analysis plan should include (where feasible) milestones for completion of the risk assessment. These milestones offer an opportunity to revisit the analysis; to plan and modify it based upon new information (data generation); to refine analyses of exposure and toxicity; to modify the conceptual model risk hypothesis; or to compare public concerns with the projected risk management options.

7. CONCLUSION

The Planning and Scoping process is a vital step to coordinating the assessment of risks for complex problems. The concept has been applied to ecological risk assessments, cumulative risk assessments, community based risk assessments, and to the development of national standards for pesticides and the manufacture of toxic chemicals. The process relies heavily on the dialogue between the risk manager and the risk assessor and their experience and judgement about the potential scope and stakeholders for the problem. The level of effort and the effectiveness of the process and the risk management decision can be significantly improved by their hard work in this first phase of the risk management decision process. Risk assessments of this type are too complex and costly to be conducted without a clear understanding of the risk management objectives, stakeholder concerns and values, and consideration of the full range of stressors and effects. This planning and scoping guide is intended to help organize that approach.

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APPENDICES

A-F

APPENDIX A
CUMULATIVE RISK ASSESSMENT GUIDANCE
PLANNING AND SCOPING

MEMORANDUM Dated July 3, 1997

SUBJECT: Moving Toward More Comprehensive, Integrated, And Cumulative Risk Assessments at EPA

TO: Assistant Administrators
Regional Administrators
General Counsel
Associate Administrators
Inspector General

A major advance of the last few years has been steadily increasing attention on how to assess environmental problems in all of their currently identifiable dimensions. To explain what this means for the U.S. Environmental Protection Agency's (EPA) evolving risk assessment and decision-making activities, we are providing guidance on Integrating Environmental Risks in order to move us toward more comprehensive and integrated risk assessments (that is, cumulative risk assessments). This guidance provides principles that EPA Programs and Regions can follow in the planning, scoping and problem formulation stages of their future risk assessments. This guidance will be updated as our understanding and experience develops. The goal is a clear explanation of which aspects of total environmental risk (for both human health and ecology) will and will not—and in some cases due to gaps in our current knowledge cannot—be included in an Agency risk assessment.

For most of its history, EPA risk assessment and decision-making have focused on individual environmental contaminants. One by one, EPA has regulated and reduced pollution from such agents as ozone, lead, particulate matter, chlordane, kepone, and DDT, with risk assessments for these chemicals often focused on single endpoints, pathways, or sources. By contrast, new risk emphases and methods allow EPA to move toward cumulative risk by evaluating multiple stressors, endpoints, sources, pathways and other factors. As a result, EPA assessments now often describe and, where possible, quantify the risks of adverse health and ecological effects from multiple stressors. In analyzing risks, EPA looks at sensitive subpopulations (1992 Exposure Assessment Guidelines), including those characterized by age (such as the priorities established by our October 1995 Policy on Evaluating Health Risks to Children) and by differences in susceptibility which may relate to gender, ethnicity, or geographic origin.

There are integrated and cumulative risk issues, dimensions and concerns, however, that this guidance cannot address, at this time. This broader set of concerns, recognized as potentially important by many participants in the risk assessment process, relate to social, economic, behavioral or psychological stressors that may also contribute to adverse

health effects. These stressors may include—among other factors—existing health condition, anxiety, nutritional status, crime, and congestion. Currently, assessment of this broader perspective of risk is very difficult due to major deficiencies in: the data establishing plausible cause and effect relationships; capability to measure exposure to such risks, and to understand their incidence and individual susceptibilities; availability of methods for assessing such risks; and techniques or approaches for their management. In this guidance, therefore, EPA will focus initially on risk assessments that integrate risks of adverse health and ecological effects from the narrower set of environmental stressors noted above. For the longer term, the Agency is focusing research to improve integrated risk assessments as well as stakeholder and scientific community outreach efforts on the broader set of concerns.

In recent years, EPA's risk assessment emphasis has shifted increasingly to a more broadly based approach characterized by greater consideration of multiple endpoints, sources, pathways and routes of exposure; community-based decisionmaking; flexibility in achieving goals; case-specific responses; a focus on all of the environmental media; and significantly, holistic reduction of risk.. This more complex assessment involves cumulative risk assessment. It is defined in each case according to who or what is at risk of adverse effects—from identifiable sources and stressors—through several routes of exposure over varied time frames.

Key features of the guidance include a dialogue among the risk assessor and risk manager, and economists, engineers, and other technical experts in planning and formulating the problem for the risk assessment. It provides details on the nature of the risk assessment planning dialogue and activities that, in the immediate future, should lead to the next generation of integrated risk assessments from the Programs and Regions.

Deliberative planning discussions involving risk assessors, economists, managers, and other technical advisors, with early and continued input from the public and other stakeholders, are important components of this guidance. It is important that each member of the team (that is, a risk assessor, economist, or risk manager), the public and other stakeholders understands the nature of the problem and how the data would be used in the risk assessment and in risk decision-making before the assessment is completed.

These discussions will ensure that the Risk Characterization principles of clarity, transparency, reasonableness and consistency in our decision making are embraced in the planning and scoping stages of the risk assessment. Activities that consider the broad dimensions and cumulative aspects of risk will be required for all major risk assessments; and, such integration should be considered for routine applications where appropriate. The scope of these integrated assessments often will extend beyond the boundaries of individual program offices—and even beyond the traditional statutory mandates for the analysis of major environmental risks. Indeed, recent legislation on drinking water and

pesticide food safety requires more comprehensive and integrated approaches to the assessment and management of risk.

Already, integrated or cumulative risk approaches are being used in some cases by Regions and Program Offices within the Agency. They range from assessments addressing multiple pathways and multiple endpoints to place-based assessments covering a wide range of stressors and endpoints. Several cumulative risk assessments and problem formulation cases, discussed during the Agency's recent Colloquia on Risk Characterization, illustrate the approach described in the attached guidance document. This guidance will evolve as it augments the Agency's next generation of Risk Characterization.

This approach needs to be used for all major risk assessments undertaken by Program Offices and Regions. We challenge Agency risk assessors and managers to expand the traditional scope of their assessments to help us better advise concerned and affected citizens and stakeholders about the environmental risks they face and how these risks can be addressed and managed.

Carol M. Browner
Administrator

Fred Hansen
Deputy Administrator

Attachments

Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping

Science Policy Council
U.S. Environmental Protection Agency
Washington, DC 20460
June, 1997

Cumulative Risk Assessment-Planning and Scoping

Section I. Introduction

The practice of risk assessment within the Environmental Protection Agency (EPA) is evolving away from a focus on the potential of a single pollutant in one environmental medium for causing cancer toward integrated assessments involving suites of pollutants in several media that may cause a variety of adverse effects on humans, plants, animals, or even effects on ecological systems and their processes and functions.

In recent years, EPA's risk assessment emphasis has shifted increasingly to a more broadly based approach characterized by greater consideration of multiple endpoints, sources, pathways and routes of exposure; community-based decisionmaking; flexibility in achieving goals; case-specific responses; a focus on all of the environmental media; and significantly, holistic reduction of risk (Table 1). This more complex assessment involves cumulative risk assessment. It is defined in each case according to who or what is at risk of adverse effects—from identifiable sources and stressors—through several routes of exposure over varied time frames.

Table 1. Transition in EPA Risk Assessment Characteristics

Old	New
Single Endpoint	Multiple Endpoints
Single Source	Multiple Sources
Single Pathway	Multiple Pathways
Single Route of Exposure	Multiple Routes of Exposure
Central Decision-making	Community-based Decision-making
Command and Control	Flexibility in Achieving Goals
One-Size-Fits-All Response	Case-Specific Responses
Single Media-focused	Multi-media Focused
Single Stressor Risk Reduction	Holistic Reduction of Risk

This evolution has occurred at an uneven pace, propelled at times by the public and by Congressional concern about environmental risks and their cumulative effects; and, it has been restrained in some cases by statutory authority or limitations of technical knowledge, data and resources.

The scope of Agency risk assessments describes the currently identifiable context of the environmental risk that will (or can) be analyzed. It is defined according to *who* or *what* is at risk of *adverse effects* from identifiable *sources* and *stressors* through several *routes of exposure* over varied *time frames* (see Section V, Risk Assessment Terminology). A review of possible risk dimensions (shown in italics in the previous sentence) done at the beginning of the assessment can help to define its scope and how the risks will be integrated.

The term "cumulative risk assessment" covers a wide variety of risks. Currently, EPA assessments describe and where possible quantify the risks of adverse health and ecological effects from synthetic chemicals, radiation, and biological stressors. As part of planning an integrated risk assessment, risk assessors must define dimensions of the assessment, including the characteristics of the population at risk. These include individuals or sensitive subgroups which may be highly susceptible to risks from stressors or groups of stressors due to their age (for example, risks to infants and children), gender, disease history, size, or developmental stage. There are other risk issues, dimensions and concerns, however, that this guidance cannot address, at this time. This broader set of concerns, recognized as potentially important by many participants in the risk assessment process, relate to social, economic, behavioral or psychologi-cal stressors that may contribute to adverse health effects. These stressors may include—among other factors—existing health condition, anxiety, nutritional status, crime, and congestion. Currently, assessment of this broader perspective of risk is very difficult due to major deficiencies in: the data establishing plausible cause and effect relationships; capability to measure exposure to such risks, and understand their incidence and individual susceptibilities; availability of methods for assessing such risks; and techniques or approaches to manage them.

On the important topic of special subpopulations, EPA and others are giving more emphasis to the sensitivities of children and to gender-related differences in susceptibility and exposure to environmental stressors. New legislation requires that the Agency expand its historical approaches to determining human exposures and health impacts to improve our understanding of gender-related differences. It is the goal of the Agency to address gender-specific issues and use gender- and age-differentiated data, whenever it is appropriate and available, in Agency risk assessments and risk management decisions. Likewise, the Agency will pursue further research to provide this kind of information and address relevant data gaps once they are identified.

In this guidance, therefore, EPA will focus initially on risk assessments that integrate risks of adverse health and ecological effects from the narrower set of environmental stressors noted above. For the longer term, the Agency is focusing on research to improve integrated risk assessments as well as stakeholder and scientific community outreach

efforts on the broader set of concerns. For example, pilot projects such as the Office of Prevention, Pesticides and Toxic Substances Baltimore Project and the Office of Policy Planning and Evaluation's Cumulative Exposure Project will likely lead to new ways to incorporate qualitative factors, also mentioned above, into our integrated risk assessment process.

Recommendations from the National Research Council's (NRC) "Understanding Risk: Informing Decisions in a Democratic Society" and a report from the Commission on Risk Assessment and Risk Management suggest that a variety of experts, including economists and social scientists, and stakeholders must be involved throughout the environmental risk assessment and risk management process. This guidance also recommends involving experts and stakeholders in the planning and scoping of risk assessments. The Agency is engaged in several activities that involve working with stakeholders. Experience from these activities will provide the solid basis for engaging interested and affected parties in risk assessment and risk management issues.

As it evolves, this guidance is designed to help risk managers and risk assessors plan and document the scope of risk assessments and to consider appropriate participants (that is, technical, advisory, or stakeholder) or information sources to enrich the risk assessment. Additionally, it augments the Agency's March 1995 Policy for Risk Characterization by providing a clear, transparent, reasonable, and consistent basis for any assessment. Regions and Program offices are strongly encouraged to undertake a formal problem formulation exercise for all risk assessments.

Section II. Key Characteristics of a Process for Integrating Environmental Risks

Agency risk assessors and risk managers need to make judgments early in planning major risk assessments regarding the purpose, scope, and technical approach (that is, the conceptual model) by evaluating the full range of discernible human health and ecological dimensions of risk (that is, stressors, sources, effects, exposed populations, pathways of exposure, and time frames of risks). Agency managers need to place special emphasis on *cumulative risk* (that is, the potential risks presented by multiple stressors in aggregate). The specific elements of risk evaluated need to be determined as an explicit part of the Planning and Scoping (PS) stage of each risk assessment. During PS, risk assessors, such other technical experts as ecologists, toxicologists, economists and engineers, and risk managers work together as a team, inform by stakeholder input, to determine:

1. the overall purpose and general scope of the risk assessment;

2. the products needed by management for risk decision-making;

3. the approaches, including a review of the risk dimensions and technical elements that may be evaluated in the assessment (see sections III and IV);

4. the relationships among potential assessment end points and risk management options and;

5. an analysis plan and a conceptual model;

6. the resources (for example, data or models) required or available;

7. the identity of those involved and their roles (for example, technical, legal, or stakeholder advisors); and

8. the schedule to be followed (including provision for timely and adequate internal, and independent, external peer review).

Due to the current state of the practice and limited data, the aggregation of risks may often be based on a default assumption of additivity. The Agency will support research to improve our understanding of cumulative risks and to develop methods to account for the multiple elements of risks that affect humans, animals, plants and their environment. In addition, the Science Policy Council will support workshops for risk assessors and managers to discuss implementation opportunities and problems, and solutions.

To aid those involved in developing this planning and scoping process (including risk assessors, risk managers, ecologists, toxicologists, economists and other social scientists) an outline has been developed (see Section IV of this guidance) listing six dimensions of risk (that is, sources, stressors, pathways or routes, populations, endpoints and time frames) and specific elements that will be considered for evaluation in major risk assessments[5]. This outline of risk dimensions and elements is part of a systematic approach in which risk managers and technical experts develop a specific, yet broadly-based, conceptual plan for major risk assessments.

The conceptual model (mentioned above) is a description or diagram, of the relationship between the predicted responses of a population (or entity of concern) and its stressors laying out the environmental pathways and routes of exposure in the context of the assessment. The analytical plan needs to show how data sources and information will be used and integrated in the assessment and how measurement endpoints and uncertainties are related to the assessment endpoints. Decisions on the purpose, scope and conceptual plan must be summarized and attached to the final risk assessment. The conceptual plan must be available for peer review before major risk assessments are completed.

[5] Major assessments are defined here as those that require a Regulatory Impact Analysis or external peer review.

Section III. Implementation Tasks

Planning and scoping involves several steps that are described in this paper (see EPA (1996) for a more complete discussion of the steps). The planning and scoping process involves specific participants and processes. In the first step, a risk assessment dialogue among the risk manager, risk assessors, economists, and other technical experts should develop the broad dimensions and elements of the risk assessment, the management goals for the assessment, a tentative budget and schedule, and an approach for conducting the risk assessment. The overall approach for integrated risk assessment and management is shown in Figure 1. This figure shows that stakeholders (interested or affected parties) need to be involved in the process. The NRC in "Understanding Risk: Informing Decisions in a Democratic Society" and a draft report from the Commission on Risk

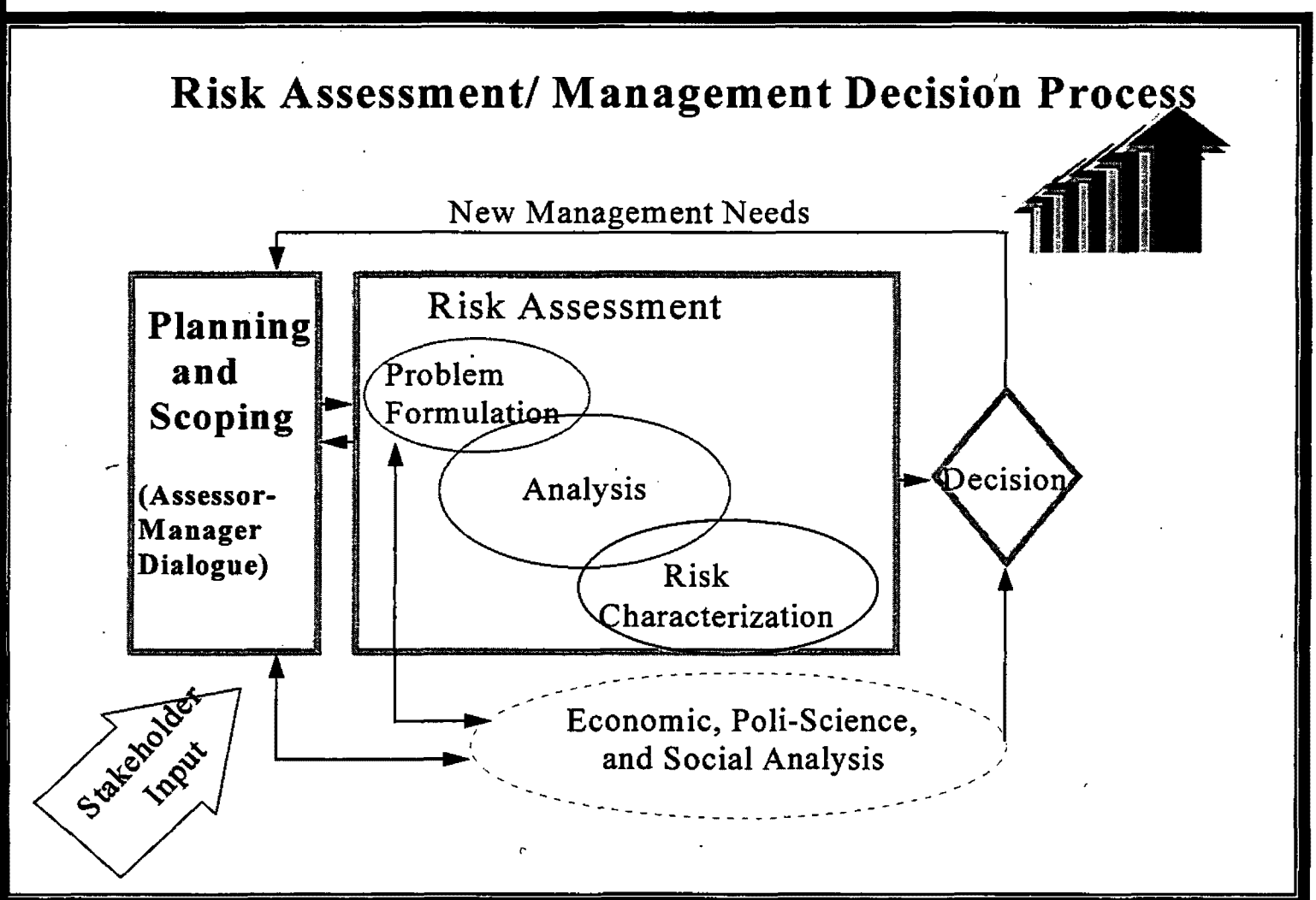

Figure 5 Stages in the integrated Risk Assessment Process

Assessment and Risk Management recommend that stakeholders be involved throughout the process. The Agency is engaged in several activities that involve stakeholders in risk assessment and in the risk management decision process. Risk managers must decide on a case by case basis when and how stakeholders can be involved.

Risk Assessment Planning Dialogue

Task 1. Define the purpose for performing the risk assessment.

The risk manager must explain clearly why the assessment is being performed and what questions need to be addressed. The manager must also advise the assessors, economists, engineers, and other contributing experts on the planning team of any interested party, affected party, or policy interests to be considered in the context of the risk issue. These factors may influence the risk management options, management goals, key participants, data sources, selection of assessment endpoints, or the schedule for the developing the assessment. The manager and assessment planning team must discuss any regulatory basis for the risk assessment and what kind of information is required to satisfy such requirements.

Task 2. Define the scope of the risk assessment.

Initially, the risk assessor and manager (and the planning team) need to evaluate and select the kind of risk information, exposure scenarios and assessment issues that need to be covered. At this point, most EPA assessments focus on technical information related to the sources, effects, populations and the routes of exposure. Reasons to limit the technical scope of the assessment must be stated explicitly and must include details on limitations on resources, data, the impact of risk elements on the risk estimate, and methods available. In cases where an element of risk is likely to be important, but no valid data are available, the assessor must highlight this deficiency or use judgement or assumed values to approximate the missing data. Such judgements and approximations must be noted clearly and explained to the manager in the risk characterization.

Task 3. Develop a Cumulative Risk Outline

Use the example outline (section IV, or other appropriate and documented outline of risk dimensions and elements) to develop through brainstorming the specific elements that may be relevant to each dimension of the risk . In practice, *cumulative risk* as a term must be defined in each particular case in the context of the elements that will or will not (as well as can or cannot) be included in the risk assessment. This is done through a planning and scoping process that considers the following dimensions:

A. Who, what or where is being affected or stressed?

B. What are the stressors?

C. What are the sources?

D. What are the environmental pathways and routes of exposure?

E. What are the relevant time frames?

F. What are the assessment endpoints?

For example, one could attempt to assess:

* cumulative acute and subchronic health risk to field workers' infants and toddlers in farm communities to organophosphate pesticide exposure (that is, through respiratory dermal, dietary and non-dietary ingestion) resulting from agricultural and residential uses in light of the nutritional status of field worker families; or

* cumulative ecological risk to the survival and reproduction of populations of blue crabs or striped bass in the Chesapeake Bay resulting from water and air emissions from both urban and agricultural sources.

* cumulative risk under the Food Quality Protection Act may be defined using terms such as aggregate exposure (that is, the exposure of consumers, manufacturers, applicators, and other workers to pesticide chemical residues with common mechanisms of toxicity through ingestion, skin or inhalation from occupational, dietary, and non-occupational sources)[6] or cumulative effects (that is, the sum of all effects from pesticide chemical residues with the same mechanism of toxicity).

Participants and Process. The risk assessor and the risk manager need to review the outline initially to identify elements that may be included. Once the possibilities (that is, the elements of each dimension of the outline) have been identified through initial brainstorming, the risk assessor should indicate who could assist with technical information and how such information may affect the overall uncertainty of the assessment. The risk manager and assessor must determine what elements will and will not (or, can and cannot) be included in the risk assessment. Information gathered at this stage is preliminary and may be modified during the analysis phase.

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[6] Actually, the language of FQPA excludes occupational exposure and pesticide workers.

Product. Ultimately, after iteration, this stage likely will produce a well-developed outline of cumulative risk possibilities (that is, a combining of the elements under each dimension) and document what is included and what is left out of the risk assessment, with an explanation of the reasons for the latter. The outline and rationale need to be available for risk characterization.

Task 4. Problem Formulation (the Technical Approach)

Problem formulation is an iterative process within which the risk assessor develops preliminary hypotheses about why adverse effects might occur or have occurred. It provides the foundation for the assessment. The *analytical plan* is used in defining the work required in the risk assessment and how the risks will be integrated.

Conceptual models are used to represent the predicted responses of populations to stressors to which they are exposed. The model is developed by the risk assessor and may include input from other experts (including stakeholders). The model needs to distinguish between what is known or determined and what is assumed or based on default values. Also, it needs to include a discussion of uncertainties in the formulation of the assessment. In some cases, conceptual models will be submitted for peer review.

Players and Process. Although the development of a conceptual model is inherently a technical process, the selection of assessment endpoints should use input from the interested and affected parties either directly or by a summary of their opinions and concerns. Assessment endpoints should also be discussed with economists.

Product. The principle outputs from this stage are assessment endpoints that are related to the management objectives, the plan for analysis of the risk, and the conceptual model. These final products are summarized in the description of the risk assessment dialogue outcomes (the planning, scoping, and problem formulation tasks) required by this guidance. The conceptual model has features of both a scientific hypothesis and of a work plan. For a major assessment—for example, on dioxin, mercury, or pollutants with controversial methodological or scoping issues—this model needs to be peer reviewed.

Section IV. An Outline of Risk Dimensions and Elements

This outline is intended to help risk managers, risk assessors, economists, engineers and other experts discuss the technical dimensions and specific elements that might apply to a particular risk assessment. This outline can be used as a checklist to note how the risk assessment will be framed in terms of the sources, stressors, pathways, population, endpoints, and time frames. It can also be used to plan the risk assessment with the risk manager and explain the scope of the risk assessment to the interested and affected parties. The next step is the technical approach (also called Problem Formulation in the Agency's draft Ecological Risk Assessment Guidelines), a process in which the analysis plan and preliminary hypotheses about the relationship between stressors and effects on populations are developed in a conceptual model. This model needs to be peer reviewed.

For the purposes of this outline, six dimensions are used: sources, stressors, pathways, population, endpoints, and time frames. Each dimension is defined below by a question; and, some of the most likely answers are listed as elements for the risk assessment.

Dimension A. Population
("Who /What/Where is at Risk?")

1. Humans
   a. Individual
   b. General population distribution or estimation of central tendency and high end exposure
   c. Population subgroups
      (1) Highly exposed subgroup (for example, due to geographic area, age group, gender, racial or ethnic group, or economic status)
      (2) Highly sensitive subgroups (for example, asthmatics or other pre-existing conditions, age, gender)

2. Ecological Entities
   a. Groups of individuals
   b. Populations
   c. Multiple species
   d. Habitats or ecosystems

3. Landscape or Geographic Concerns
   a. Groundwater aquifers
   b. Watersheds (that is, surface water bodies and their associated terrestrial ecosystems)
   c. Airsheds
   d. Regional ecosystems

e. Recreational lands

Dimension B. Sources
(What are the Relevant Sources of Stressors?)

1. Single source
   a. point sources (for example, industrial or commercial discharge, superfund sites)
   b. non-point sources (for example, automobiles, agriculture, consumer use releases)
   c. natural sources (for example, flooding, hurricanes, earthquakes, forest fires)

2. Multi-sources (Combinations of those above)

Dimension C. Stressors
(What are the Stressors of Concern?)

1. Chemicals
   a. Single chemical
   b. Structurally related class of substances
      (1) Individual substances (that is, only one is present at a time)
      (2) Existing in a mixture
   c. Structurally unrelated substances with similar mechanism of impact and/or same target organ
      (1) Individual substances
      (2) Existing in a mixture
   d. Mixtures (that is, dissimilar structures or dissimilar mechanisms)
2. Radiation
3. Microbiological or biological (these range from morbidity to ecosystem disruption)
4. Nutritional (for example, diet, fitness, or metabolic state)
5. Economic (for example, access to health care)
6. Psychological (for example, knowledge of living near uncertain risks)
7. Habitat Alteration (for example, urbanization, hydrologic modification, timber harvest)
8. Land-use changes (for example, agriculture to residential, public to private recreational uses)
9. Global climate change
10. Natural Disasters (for example, floods, hurricanes, earthquakes, disease, pest invasions)

Dimension D. Pathways
(Environmental Pathways and Routes of Exposure. "What are the Relevant Exposures?")

1. Pathways (recognizing that one or more may be involved)
   a. Air
   b. Surface Water
   c. Groundwater

d. Soil

e. Solid Waste
f. Food
g. Non-food consumer products, pharmaceuticals

2. Routes of Human and single species exposures
   a. Ingestion (both food and water)
   b. Dermal (includes absorption and uptake by plants)
   c. Inhalation (includes gaseous exchange)
   d. Non-dietary ingestion (for example, "hand-to-mouth" behavior)

3. Routes of Exposure within communities and ecosystems
   a. Direct Contact or ingestion (without accumulation)
   b. Bioaccumulation
   c. Biomagnification
   d. Vector transfers (for example, parasites, mosquitoes)

Dimension E. Endpoints
(What are the assessment endpoints?)

1. Human Health Effects (for example as based on animal studies, morbidity and disease registries, laboratory and clinical studies, or epidemiological studies or data)
   a. Carcinogenic
   b. Neurotoxicologic
   c. Reproductive dysfunction
   d. Developmental
   e. Cardio-vascular
   f. Immunologic
   g. Renal
   h. Hepatic
   I. Others

2. Ecological Effects
   a. Population or Species
      (1) Loss of fecundity
      (2) Reduced rate of growth
      (3) Acute or Chronic toxicity
      (4) Change in biomass

   b. Community
      (1) Loss of species diversity
      (2) Introduction of an exotic species

(3) Loss of keystone species

c. Ecosystem
   (1) Loss of a function (for example, photosynthesis, mineral metabolism)
   (2) Loss of habitat structure
   (3) Loss of a functional group of organisms (for example, grazers, detritivores)
   (4) Climate change (for example, sunlight, temperature change)
   (5) Loss of landscape features (for example, migration corridors, home ranges)

Dimension F. Time frames
(What are the Relevant Time Frames: Frequency, Duration, Intensity and Overlap of Exposure Intervals for a Stressor or Mixtures of Stressors)?

1. Acute
2. Subchronic
3. Chronic or effects with a long latency period
4. Intermittent

Section V. Risk Assessment Terminology

This is a partial list of risk assessment terms that often associated with risk assessment practice. The list is not exhaustive, but it does include terminology used in this guidance and other terms that are closely related to the planning and scoping of risk assessments.

Agent-Suter et al. (1994) suggested it as an alternative for the term stressor. It is considered to be more neutral than stressor, and is used in EPA's Guidelines for Exposure Assessment.

Aggregate exposure - the sum of exposures to pesticide chemical residues with a common mechanism of toxicity from multiple sources and multiple routes of exposure (Food Quality Protection Act, 1996).

Analysis- The analytical phase of the risk assessment in which the potential for adverse effects are calculated based on the hazard identification, dose-response assessment, and the exposure assessment.

Assessment endpoint- functions or characteristics of a group or population of people or organisms (such as reproduction, growth, and lack of disease) that can be measured in relation to the intensity or concentration of a stressor.

Comparative Risk Assessment- A process that generally uses an expert judgement approach to evaluate the relative magnitude of effects (relative risk) and set priorities among a wide range of environmental problems (US EPA, 1993b). In some cases this may be done as a preliminary risk assessment.

Cumulative Risk Assessment- involves the consideration of the aggregate ecologic or human health risk to the target entity caused by the accumulation of risk from multiple stressors, [multiple pathways, sources] (US EPA, 1995).

Cumulative effects- 1) the sum of all environmental effects resulting from cumulative impacts (Liebowitz et al., 1992), and 2) the combination of effects from all pesticide chemical residues which have a common mechanism of toxicity (Food Quality Protection Act, 1996).

Cumulative impacts--the sum of all individual impacts occurring over time and space, including those of the foreseeable future (CEQ, 40 CFR Sect. 1508.7)

Conceptual model- a diagram or written description of the predicted key relationships between the stressor(s) and the assessment endpoint(s) for a risk assessment.

Disturbance-(See physical stressor) any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment.

Environmental Impact Assessment- an assessment required by the National Environmental Policy Act to evaluate fully potential environmental effects associated with proposed federal actions.

Exposure-the contact or co-occurrence of a stressor with a receptor.

Integrated Risk Assessment- a process that combines risks from multiple sources, stressors, and routes of exposure for humans, biota and ecological resources in one assessment with a defined point of focus (See also cumulative risk assessment).

Receptor-the entity which is exposed to the stressor.

Relative Risk Assessment- a process that involves estimating the risks associated with stressors or management actions that often uses qualitative risk techniques.

Source- an entity or action that releases to the environment or imposes on the environment chemical, biological, or physical stressor or stressors.

Stakeholder - a person, group of people, an organization (public or private), a business, or other party that has an interest in terms of knowledge or jurisdiction or is affected in terms of their health, property rights, or economy by an environmental risk (s).

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

Stress Regime- (1) a characterization of multiple exposures to stressors, (2) a synonym for exposure, or (3) a series of interactions of exposures and effects resulting in secondary effects. Because of its potential for confusion, the term is not used in guideline documents.

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APPENDIX B
WORKSHOP CASE STUDIES:

1. The Reregistration of Pentachlorophenol
2. Chicago Cumulative Risk Initiative–Region V
3. Cumulative Risk Index Analysis (CRIA) Method in Concentrated Animal Feeding Operations (CAFO) In Region VI

B-1. The Reregistration of Pentachlorophenol: Case Study

The Situation

Pentachlorophenol (PCP), a heavy duty wood preservative, is an organic oil-borne pesticide first registered in the United States in 1948 to prevent wood decay from fungal and insect damage. PCP is formed by the high temperature chlorination of phenol, which results in the formation of microcontaminants (dioxins, furans, and hexachlorobenzene) in PCP.

In 1978, USEPA issued a Federal Register Notice initiating an administrative process to consider whether pesticide registrations for wood preservative chemicals should be cancelled or modified due to adverse toxicological effects noted in animal toxicity studies. The Agency issued notices of "Rebuttable Presumption Against Registration" (RPAR) for PCP based on teratogenicity and fetotoxicity findings. In addition, the Agency determined that PCP use posed the risk of oncogenicity due to the presence of microcontaminants (dioxins/furans/HCB). The Agency subsequently published Position Documents to address comments made by stakeholders on the Federal Register Notice. The conclusion of the RPAR process in 1984 and final settlement agreements with registrants in 1986 restricted PCP uses and modified its terms and conditions of registration. The RPAR process also resulted in cancellation in 1987 of certain non-wood preservative uses of PCP as a herbicide, defoliant, mossicide, and mushroom house biocide. In 1993 uses of PCP were terminated as a biocide in pulp and paper mills, oil wells, and cooling towers.

Currently, two U.S. manufacturers produce PCP, and approximately 100 wood treatment plants apply the pesticide to wood. Treatment plants vary considerably in age and design. Utility companies nationwide use 92.5% of all PCP-treated lumber for utility poles and cross arms. Secondary uses include railroad crossties, wood pilings, fenceposts, and 6868commercial/residential structures, such as decks, fences, and walkways.

The Office of Pesticide Programs/ Antimicrobial Division (OPP/AD) is reassessing the potential risks of PCP on human health and the environment. The reassessment is driven by a FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) requirement for a Reregistration Eligibility Decision (RED) on heavy duty wood preservatives, due in 2001, and will conform with the Food Quality Protection Act (FQPA). Although the reregistration of PCP is regulated under FIFRA, PCP also is regulated under the Clean Water Act, Clean Air Act, and Resource Conservation and Recovery Act.

Reregistration of PCP is unusual in that it requires risk assessment harmonization with Canada under the North American Free Trade Agreement (NAFTA). Mexico is not an active participant in this process, but EPA and Canada keep Mexico informed.

Risk Assessment Planning and Scoping Dialogue:

Task one: Define the purpose for performing the risk assessment

The purpose of the risk assessment was already determined by the regulatory requirement to produce a Reregistration Eligibility Decision (RED) document for heavy duty wood preservatives. Participants of all three workshops accepted this regulatory purpose without debate.

Task two: Define the scope of the risk assessment

Workshop participants accepted the decision to limit the reassessment process to PCP and address the other two wood preservatives (CCA and creosote) separately. Due to the time limit, participants of the third workshop decided to focus mainly on PCP and dioxins/furans, but not to address hexachlorobenzene. The participants recommended that the risk assessment for HCB separately and later synthesize the results with the PCP component.

Task three: Develop a cumulative risk outline

Ecological

The participants of the first two workshops identified the components of six dimensions of ecological risk that form the elements of a conceptual model for ecological effects (see the sidebar).

The participants considered treated wood and disposal as the most important sources of PCP release into the environment. Utility poles are widely distributed even in residential neighborhoods, and while a lot of used wood is incinerated, some is sold and even acquired by unsuspecting homeowners. Facilities that treat wood were not considered a major source because drip pads and recapture technologies are supposed to prevent release to the environment. However, participants in the third workshop suspected that treatment plants may be an important source of PCP to the environment during the drying process at the plant and possibly due to runoff. OPP/AD does not account for misuse in risk assessment, but participants generally agreed that the conceptual model could encompass it.

Using the dimensions of ecological risk developed during the first two workshops (see the sidebar), OPP/AD had prepared a tentative PCP conceptual model for ecological effects [Figure 1 of Summary Report, EPA (1998)]. The third workshop reviewed that model and each component of the six dimensions and recommended several changes:

- Create one inclusive ("generic") conceptual model and create others as appropriate to expand on and highlight specific areas of focus.
- Consider changing the emphasis for PCP (but not necessarily PCP's microcontaminants) from the treated wood and disposal sources to wood treatment at the plant and disposal. Participants suggested that treated wood in use as utility poles may not be a major concern because PCP metabolizes rapidly under aerobic conditions and has a short half-life and thus may not migrate far from the pole.
- Describe miscellaneous sources (does it mean decks, retaining walls, garden borders?) and whether they are important to the ecology or human health.
- Add furans to the dioxin stressor (i.e., dioxins/furans).
- Reexamine the pathways and highlight the critical pathways from the top of the model to the bottom.
- Add ingestion or food chain as a pathway.

Ecological Conceptual Model Components

- **Sources**
  The six primary sources that may release PCP into the environment are facilities where PCP is manufactured, facilities where PCP is used to treat wood, transportation of treated wood, disposal of treated wood, treated wood that is in use, and miscellaneous uses
- **Stressors**
  The stressors are PCP and its contaminants, dioxin and hexachlorobenzene
- **Pathways**
  The air, soil, and water carry PCP from a source to the environment
- **Exposed Populations**
  Two major categories of exposed populations are terrestrial and aquatic. Examples of terrestrial organisms that may be subject to potential impacts from PCP might include invertebrates in and on the soil, birds, small mammals, and plants. Aquatic populations may be subdivided into freshwater and marine/estuarine organisms. Representative aquatic organisms might include invertebrates, fish, and plants. Fish-eating birds also might be affected indirectly
- **Endpoints and Time Frames**
  The potential impacts may exist for individual organisms, populations, and entire ecosystems. Effects on individual organisms (flora and fauna) may include direct toxicity of varying time periods (acute, subacute, and chronic), teratogenic effects, and effects on reproduction and behavior. Population effects may occur from lowered survival and reduced reproduction. Ecosystem effects may occur due to a decline in species diversity

- Add assessment endpoints and measures so the model can be used to develop practical management goals.

OPP/AD agreed to revise their conceptual model for ecological effects based on the group's recommendations and distribute it to workshop participants for comment after the third workshop. The revised conceptual models are presented below along with a narrative description.

Human Health

The third workshop began developing a conceptual model for human health. Participants concurred that while one generic human health model is needed, it may be easier to construct separate submodels for each stressor or source and then combine them to create one comprehensive model. The participants also recognized that the generic conceptual models for ecological and human health should be comparable at some levels, such as sources and stressors. When aggregating submodels to create a complete picture, it should be possible to determine which components go together and which can be de-emphasized or eliminated from the assessment.

The group agreed with a suggestion to use a materials-flow approach to try to identify potential human exposures to a stressor from a source. The half-life in the environment and potential of the chemical to bioaccumulate were also considered useful in identifying relevant pathways of exposure.

The group briefly discussed several sources, such as PCP manufacturing, PCP transportation, treatment of wood at the plant, transportation and handling of treated wood, wood in use, remedial treatment (usually ground-line treatment of utility poles), and transportation and disposal. The group decided to concentrate on one source only—wood treatment—and one stressor—"clean" PCP (i.e., without microcontaminants)—due to the time limitation, and complete a draft submodel for clean PCP (Figure 2 of Summary Report). They then began a conceptual submodel for the dioxins and furans and acknowledged that the Agency's reassessment of dioxins and furans will affect OPP/AD's assessment.

The participants generally agreed that the sources should be the same for PCP, dioxins/furans, and hexachlorobenzene submodels. They also indicated that the sources for human health should be similar, if not the same, as those identified for the ecological conceptual model.

Participants concurred on several components for the clean PCP conceptual submodel using wood treatment at the plant as the primary source of PCP exposure to humans (see the sidebar).

While developing the PCP submodel, several participants acknowledged the importance of defining the terms used in the models. For instance, participants had to try to clarify definitions for pathway and route and found that ecological and human health risk assessment guidelines use some terms differently. They also acknowledged that in their conceptual models for human health they reversed the order of the dimensions listed in the guidance, putting the stressor before the source.

Participants agreed that a clear rationale is needed to explain why a component may be eliminated from a model. For instance, the indirect occupational pathway and non-occupational visitors to the treatment plant probably could be eliminated from the clean PCP submodel because their risks are so minimal. Using professional judgment, they expected that the oral route for the direct occupational

Human Health Conceptual SubModel (PCP)

- **Stressor**
  Clean PCP
- **Source**
  Wood treatment at plant
- **Pathways**
  Occupational, categorized as direct occupational (mixers, loaders, etc) and indirect occupational (office workers) pathways; and non-occupational (e.g., neighbors and visitors) pathways
- **Exposure Routes**
  Oral (hand to mouth), dermal, and inhalation. Dermal and inhalation are the main routes for the direct occupational pathway while oral exposure through contamination on the hands is a minor route. Oral, dermal, and inhalation are relatively minor for the indirect occupational pathway. For the non-occupational pathway, inhalation is probably more important than oral or dermal routes
- **Potential Subpopulations** (receptors)
  Due to time limitations, participants chose to focus only on the direct occupational pathway and selected adults as the most important subpopulation for this pathway. They further subdivided adults into males over age 16, females over age 16, and pregnant females with fetus. They eventually eliminated pregnant females because they are not allowed to work directly with PCP, and there are no known health endpoints directly related to pregnant women. Thus, the most important pathway flowed from direct occupational exposure through mainly dermal and inhalation exposure routes to working-age adult males and females (over 16 years of age)
- **Endpoints**
  Endocrine disruption, neurotoxicity, skin irritation, cancer, chronic toxicity, and mutagenicity
- **Measures**
  Thyroid dysfunction as a measure of endocrine disruption; nerve conduction, sleep disorders, etc as measures of neurotoxicity; liver tumors as a measure of cancer; and liver

pathway probably represents a minor risk compared to dermal and inhalation, especially since oral exposure (hand to mouth) is preceded by dermal exposure. Also, workers may wear gloves and wash their hands before eating. Adults were selected because younger people would not be allowed to work at the plant. Since data indicate that clean PCP does not have reproductive, developmental, or immunological effects, these endpoints probably could be eliminated from the clean PCP submodel. However, they may be relevant to PCP's microcontaminants.

Participants discussed eliminating non-occupational pathways (neighbors as well as visitors) from the submodel on the basis that if workers are protected then little or no risk can be expected to reach people in the neighborhoods. However, risk managers pointed out that actually the neighborhoods might be at greater risk because controls, such as protective clothing, available for workers are not generally used by residents in the neighborhoods. Also, OSHA typically allows less stringent risk standards for workers than EPA allows for residents.

Several participants recognized that while duration and frequency of exposure are important variables that influence endpoints are relevant for ecology and human health. They are best captured in the text supporting the models rather than in the models themselves. Most participants preferred the terms short-term and long-term rather than acute and chronic.

Participants then attempted to identify the major components of a dioxin/furan microcontaminant submodel for PCP, again using the wood treatment plant as the source (see sidebar and Figure 3, Summary Report).

Note that the lines drawn on the conceptual model and the submodels represent only selected linkages for illustrative purposes. A complete conceptual model would require filling in all appropriate linkages, and the arrows on the conceptual model ideally would be drawn in various widths to

Human Health Conceptual Submodel (Dioxins/Furans)

- **Stressor**
  Dioxins/furans
- **Source**
  Wood treatment plant
- Pathways
  Same as clean PCP submodel above
- **Exposure Routes**
  Oral, dermal, and inhalation. Participants chose to follow the direct occupational pathway and identified dermal as the principal exposure route
- **Potential Subpopulations**
  Adults including males over age 16, females over age 16, and pregnant females with fetus
- **Endpoints**
  Same as clean PCP submodel above but with the addition of immunological endpoints, and for pregnant females with fetuses, reproductive and developmental endpoints. Dioxins and furans are considered non-mutagenic
- **Measures**
  Not addressed due to time limitations

indicate the strength or importance of each linkage.

A complete conceptual model and submodels for PCP would show differing levels of depth and detail that the reader could view as desired. At the most aggregated level, the conceptual model would show only the most important items and linkages. The level of detail would increase with subsequent diagrams. That way, a nonscientific audience could visualize the essence of the problem without getting lost in a highly detailed diagram, and a technical audience could view the more detailed diagrams and locate all plausible linkages and feedback loops.

A revised conceptual model for PCP and the contaminants is presented below along with a narrative description. A combined eco/human health conceptual model has not been completed at this time but is under study.

Task 4: Formulate the technical approach of the risk assessment

Participants in the third workshop outlined a human health risk analysis plan for PCP using instructions provided for the workshop.

Risk Management/Regulatory Goals

- Protect general and susceptible subpopulations
- Distinguish between occupational and non-occupational exposure pathways in the context of reassessment for reregistration
- Determine who the stakeholders are and when to involve them
- Evaluate resource needs
- Compile available data
- Identify key uncertainties that require the use of default assumptions
- Identify possible regulatory and remedial options for mitigating exposure

Assessment Endpoints (exposed populations)

Who is at risk—occupational and non-occupational populations and subpopulations based on age, gender, and reproductive status (dioxins/furans)

Measures of Effect (examples)

- Cancer—liver tumor indicators
- Liver toxicity—incidence data
- Neurotoxicity—nerve conduction/sleep disorders

Measures of Exposure (examples)

- Pest Handlers Exposure Database (PHED) and chemical-specific data for occupational exposures
- No ambient data are available for air and water

- Biomonitoring

What Can and Cannot be Done Based on Planning and Scoping

Need more analysis (e.g., completed conceptual models and data analysis) before can identify management options

Methods for Conducting Risk Analysis

- RfD
- Margin of exposure
- Quantitative risk assessment with probabilities on dose response and exposure parameters
- Narrative discussions

Data Needs and Uncertainties

- Exposure data
- Toxicity data

Stakeholder Involvement

Dr. Lauren Zeise of the California Environmental Protection Agency led participants of the PCP group in the third workshop in applying the lessons from the National Research Council's *Understanding Risk: Informing Decisions in a Democratic Society*. She posed six questions that risk assessment planners should consider during planning and scoping:

- Who are the interested and affected parties (stakeholders)?

Participants identified a wide variety of stakeholders: trade associations for manufacturers and users (e.g., American Wood Preservatives Institute AWPI, American Wood Preservatives Association AWPA, Chemical Manufacturer Association CMA); PCP manufacturers, utility companies and others, such as workers (linemen, treatment), Penta Task Force (registrants), NAFTA (Canada as co-regulator, Mexico as affected party), other EPA offices (e.g., ORD, OAR, OW, OSW, OPPT), EPA regional offices, other agencies regarding OSHA issues, public, Congress, and environmental groups such as National Coalition Against Misuse of Pesticides (NCAMP).

- What should be deliberated? When?

The group indicated that what is deliberated should depend on the stakeholder group. OPP/AD has established regulatory negotiation procedures for deliberating with industry and is considering broadening stakeholder involvement in this process.

Several participants suggested meeting early with stakeholders to scope the risk assessment and to decide what should and should not be in the assessment. Secondary and tertiary exposures of concern, impact on resources, and data needs to address management options also may be discussed at this time. Intra-Agency deliberations may be required on disposal issues and on contaminant issues, such as dioxin, which EPA's Office of Research and Development is currently assessing. Most participants agreed that public involvement should be limited to appropriate assessment endpoints and that regulatory negotiations should not be conducted in public forums. However, one person suggested that OPP/AD discuss the entire conceptual model, not just the endpoints with the public.

During the intermediate stages of the reassessment process, OPP/AD could distribute a draft of the science chapter of the RED and meet with all stakeholders to make mid-course corrections. OPP/AD usually hold meetings with industry to describe data gaps, the approach to the risk assessment, and assessment endpoints before the draft RED is completed. OPP/AD also hold meetings on the draft RED with NCAMP. A final meeting with various stakeholder groups may be helpful to discuss the findings and avoid surprising anyone.

OPP/AD cautioned that when preliminary findings are widely distributed before the risk assessment is complete, people may misinterpret EPA's intentions. This occurred when OPP/AD put the preliminary risk assessment for organophosphate (OP) pesticides on the Internet in a pilot program requested by the registrant. On the basis of this preliminary assessment, which raised some health concerns, several OP users stopped buying OP products for fear EPA would soon ban their use.

- What approaches might be taken in interacting with stakeholders during deliberation? (Focus groups, etc.)

Participants suggested that meetings would fulfill most needs. However, the Internet could also be used to distribute information to the general public if costs allow. The current practice of involving the public is through EPA's Science Advisory Board and Scientific Advisory Panels. Dozens of meetings generally occur during the long pesticide registration process. Most of them occur only with the registrants, but a few involve the public (e.g., NCAMP). Although OPP/AD has not decided when and how to share information with the public, OPP/AD has no plans to open the reregistration meetings with registrants to the public, mainly due to insufficient resources.

- How should participants be selected?

Participants acknowledged that some stakeholders, such as workers, environmental groups, and the public, have not been directly involved in the regulatory process for PCP. Participants

recognized that public stakeholders for the PCP risk assessment are difficult to define because there is no specific site to point to.

- Should the program enlist outside help in establishing the deliberative process?

Since a formal regulatory process is already established, participants questioned the value of outside facilitation and saw no need for it in the development of the RED.

- What is the external constraints for deliberation (budget, time, legal)?

Participants acknowledged budget, time, and legal constraints as applicable to the pesticide reregistration process.

Lessons Learned

Participants discussed briefly what they had learned from this case study. Their remarks are summarized below:

- Ecological and human health assessment planning can be harmonized conceptually, but a common vocabulary will be needed.
- Both top-down and bottom-up approaches to developing conceptual models are useful—there is no wrong method.
- Explaining uncertainty to stakeholders is a problem that needs up-front planning. There is a hesitancy to reveal all that is known and not known about chemicals and their risks because it reveals uncertainties that can lead to criticism and political ramifications. Yet, uncertainty is inevitable since some questions will have no answers.
- The interplay between risk assessors and risk managers was valuable. For instance, it provided insight into the potential PCP risks to workers versus neighbors.
- Planning and scoping for cumulative risk has proven to be very valuable. Risk assessors and risk managers already perform the components of planning and scoping but generally in an unorganized protracted way. Early planning and scoping help organize everyone's thinking and results in a smoother and better quality assessment than is possible without it.
- Planning and scoping offers a good opportunity to identify problem scenarios early and the potential risk management options to address them. It also offers an opportunity to determine if data exist to compare management options and to develop contingency plans for potential risks.
- There are a lot more questions than answers, which is why an iterative planning and scoping approach involving many different but knowledgeable people are valuable for developing a good conceptual model.
- Planning and scoping is not risk assessment.

- The utility and the time involved in planning and scoping need to be presented honestly to risk managers. Purporting that planning and scoping will be quick and easy is likely to be counterproductive; it is a lot more work than people assume. However, it ultimately saves time by explicitly organizing an assessment that would have to be done at least implicitly anyway. Also, documenting the planning and scoping leads to clearer thinking and greater credibility, and it captures the thinking for others (stakeholders, risk managers, and next generation risk assessors).

DRAFT NARRATIVE FOR THE ECOLOGICAL CONCEPTUAL MODELS FOR PENTACHLOROPHENOL (PCP) AND ITS CONTAMINANTS

Context of Conceptual Model Development

The Antimicrobials Division (AD), Office of Pesticide Programs (OPP), U.S. Environmental Protection Agency (USEPA) is in the process of developing the Reregistration Eligibility Decision (RED) documents for the Heavy Duty Wood Preservatives, (HDWP) including Pentachlorophenol (PCP)[7]. In conjunction with the Science Policy Council's Cumulative Risk Working Group, AD scientists have undertaken the development of conceptual models for PCP. The purpose of conceptual model development is to describe the relationships among predicted responses of a population of concern and its stressors, including the environmental routes of exposure. The conceptual model also describes endpoints of concern and how they will be measured. This approach (of developing conceptual models) is intended to assist in the process of cumulative risk assessment, cumulative risk being defined as "the potential risks presented by multiple stressors in the aggregate." During model development, key questions are addressed: who is affected or stressed? ; what are the stressors? ; what are the sources? ; what is the time frames for the

[7]All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards. When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document.

risks? ; what are the assessment endpoints? For now, the Agency intends to focus on assessments that integrate risks of adverse human health and ecological effects where possible. A separate conceptual model and narrative for the human health effects of PCP are included and may be integrated in the future with the ecological effects model.

Stressors

Pentachlorophenol is an organic pesticide which was used in the past for a number of applications. Its use today is limited to the preservation of wood, but it is widely used in the treatment of utility poles and pilings in the United States. During the manufacture of PCP several types of contaminants are formed, specifically dioxins, furans, and hexachlorobenzene. Considerable progress has been made toward the production of "pure" PCP; however, complete removal of contaminants is not economically feasible at this time. Therefore, for the purposes of assessing cumulative risks associated with PCP, and based on data showing that PCP and its contaminants have different inherent toxicities and chemical characteristics, separate submodels for the dioxin/furan and hexachlorobenzene contaminants were constructed.

Although some data are available on these chemicals, we do not have sufficient information to estimate levels of environmental contamination via the leaching of these microcontaminants from treated wood.

Sources

The group identified five primary sources, related to wood preservation, from which PCP may be released into the environment. These included: facilities where PCP is manufactured; facilities where PCP is used to treat wood, and; the actual treated wood (during transportation, during the in-use period, and after the in-use period [disposal]). They agreed that the actual treated wood (during the in-use period) is the most significant source for environmental exposure. While the other sources were considered valid, there were reasons for not considering them as the focus of the model[8]. It was felt that a description

[8]Manufacture of PCP, use of PCP in wood treatment, disposal of treated wood and transport all represent potential sources of environmental exposure. However, treated wood (in-use) was chosen as the focus of these models, for the following reasons:

- The first three sources (manufacture, treatment, and disposal) fall outside the scope of the Agency's regulatory authority;
- The last source (transport of treated wood), while considered a source for potential exposure, is insignificant when compared with actual in-use treated wood.

of a conceptual model using treated wood (in-use) would be representative of a worst-case scenario for environmental exposure to PCP and its contaminants. Treated utility poles and pilings represent the most significant reservoir of treated wood in the United States.

Media/Pathways

There are three potential environmental pathways by which PCP and its contaminants may travel from the sources to the environment: air, soil, and water. The most important pathways for PCP transport, in regard to potential exposure of terrestrial and aquatic ecosystems, are through soil and water. This is because significant exposure of fish and wildlife populations is most likely to occur via ingestion or direct contact with soil and water, as opposed to inhalation.

Volatilization and deposition were not considered as significant environmental pathways. There are little or no data to account for the amount or levels of volatilized PCP nor the potential adverse impact it may have on the surrounding environment. Without sufficient data, it is difficult to justify the importance of volatilized PCP.

Exposed Populations

The model breaks out exposed populations into two major categories, terrestrial and aquatic. As indicated, aquatic populations may also be subdivided into freshwater vs. marine/estuarine, and terrestrial populations into subterrestrial (below ground) vs. terrestrial (above ground). Terrestrial organisms subject to potential impact from PCP exposure might include soil and ground-dwelling invertebrates, birds, reptiles, small mammals, and plants. Representative aquatic organisms could include aquatic invertebrates (such as shellfish and shrimp), fish, amphibians, and aquatic plants. In addition to the organisms subject to direct exposure, other organisms (e.g., fish-eating birds) may be exposed to PCP indirectly (secondary effects).

In addition to breaking out the potentially exposed populations, subpopulations, and target organisms, the ecological effects conceptual model illustrates that effects may occur at different levels of organization. That is, exposure to PCP or its contaminants may cause effects at the individual level, the population level, or the ecosystem level.

Assessment Endpoints

The next area of the ecological effects conceptual model relates to potential impacts or changes in the ecosystem. These assessment endpoints are ecological system attributes that, if changed, would indicate a change in the health of the system. The universe of potential endpoints is large. However, all of them fit under one of the three "levels of organization"

categories: effects on individual organisms, effects on populations, or effects on ecosystems

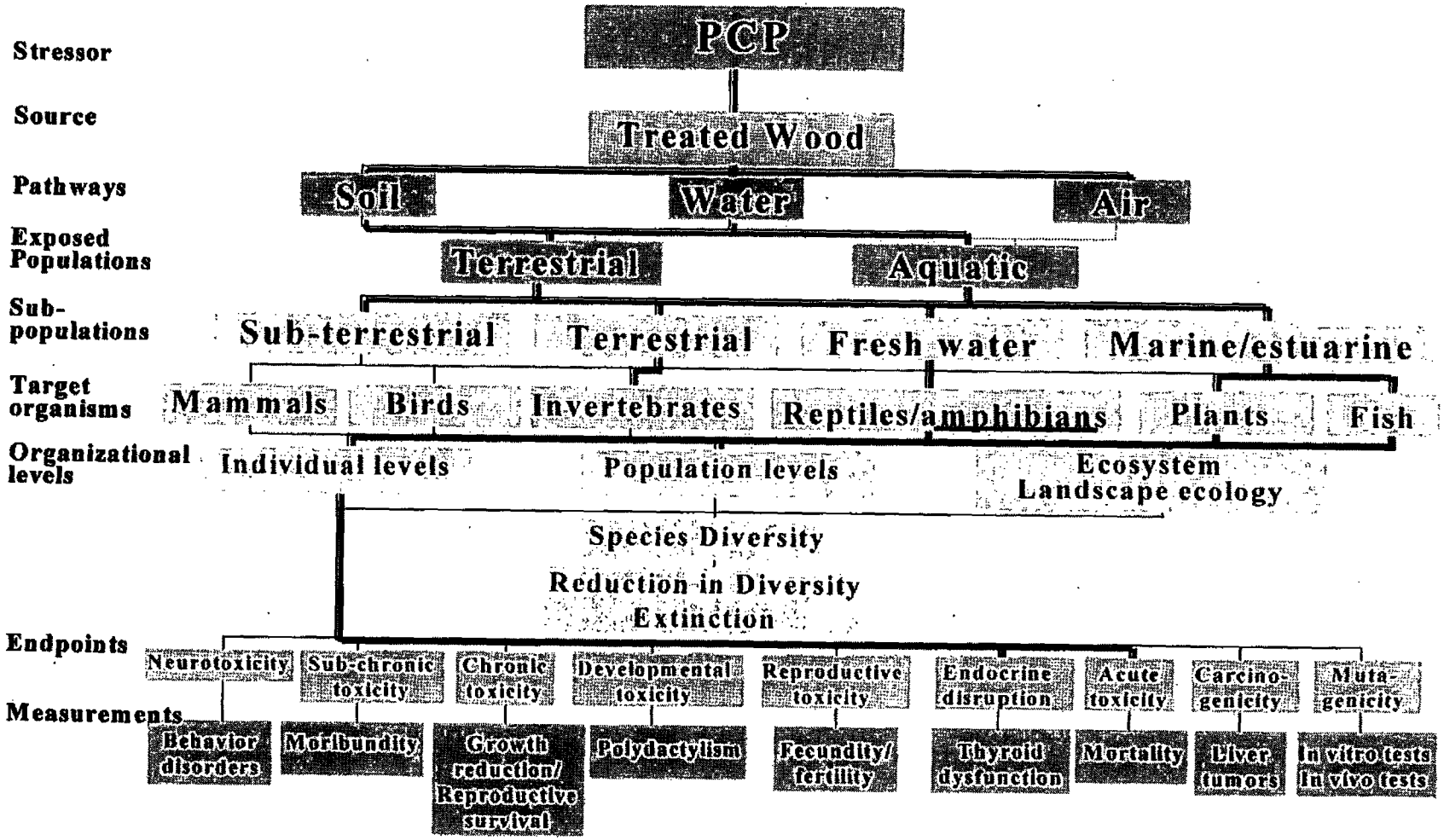
Endpoints identified with the two latter categories are very limited, and include species diversity (at the population level) and effects on the landscape ecology (at the ecosystem level). Endpoints identified on individual organisms are numerous, and include direct toxicity (acute, subacute, and chronic), teratogenic effects, and effects on reproduction, development, and behavior, among others.

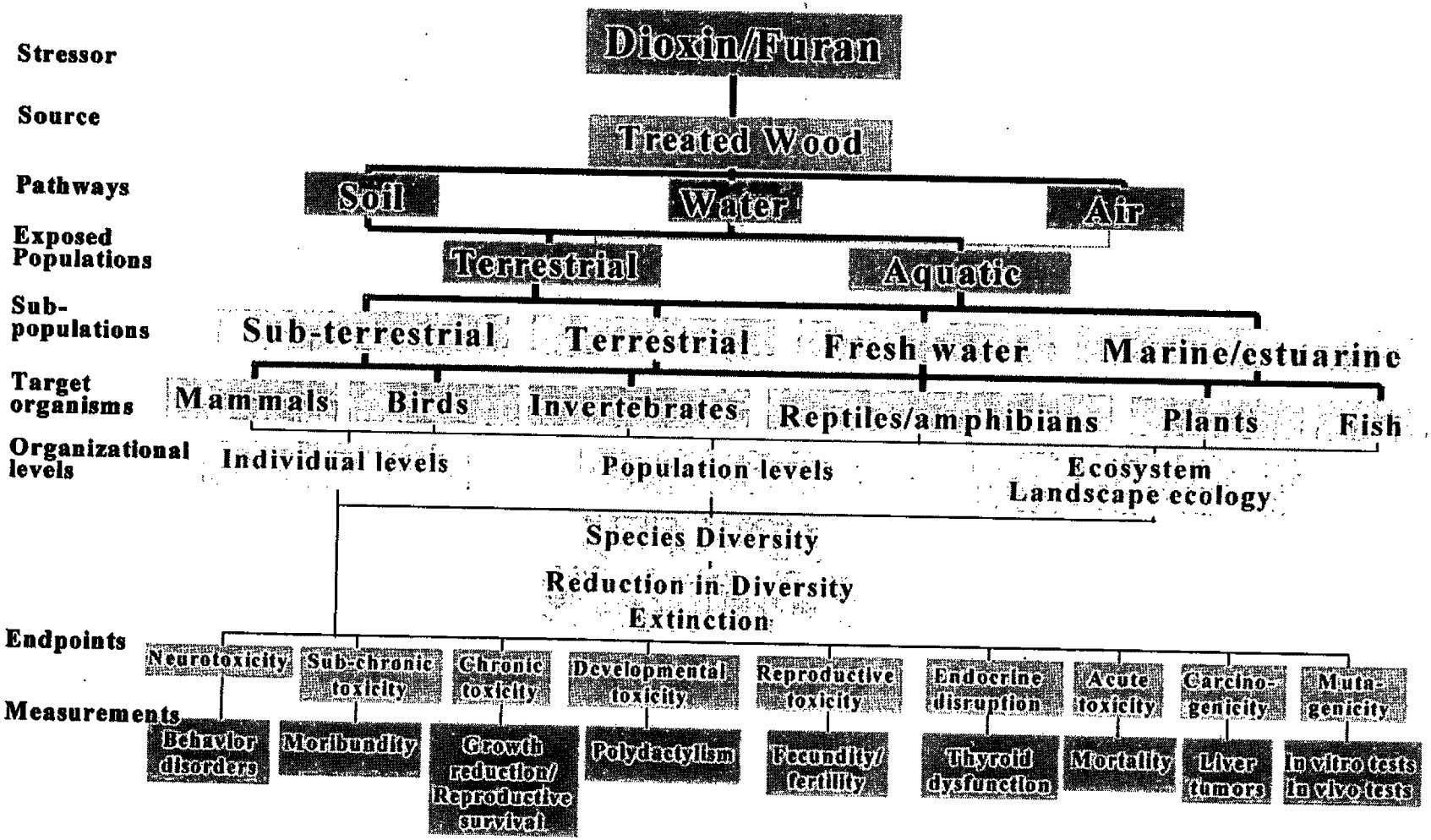
We have listed all the potential endpoints and measurements that could be explored, however, it should not be implied that as an Agency we test and measure for these effective endpoints. The Agency's current focus is to concentrate on acute and chronic impacts of pesticides on the environment. This exercise provides what the "universe" has to offer and to make one aware of potential areas of concern.

Measurement Endpoints

There are one or more measures corresponding to each of the endpoints presented in the conceptual models. These measures represent indicators for the endpoints identified above. For example, evidence of behavioral disorders (measure) may indicate adverse impact in the area of neurotoxicity (endpoint). Other measures and their corresponding endpoints include: mortality (for acute toxicity); growth reduction (for chronic toxicity); reduced fecundity or fertility (for reproductive toxicity); and thyroid dysfunctions (for endocrine disruption). These measures were selected because they are relatively reliable indicators of the affected endpoints, and because methods have been developed to assess endpoint impacts using these measures.

As discussed above, considerable progress has been made toward the production of "pure" PCP; however, complete removal of contaminants is not economically feasible at this time. Therefore, for the purposes of assessing cumulative risks associated with PCP, and based on data showing that PCP and its contaminants have different inherent toxicities and chemical characteristics, separate submodels for the dioxin/furan and hexachlorobenzene contaminants were constructed. An integrated model with PCP and its contaminants was also developed. These models are presented below.


Stressor
PCP
Source
Treated Wood
Pathways
Soil
Water
Air
Exposed Populations
Terrestrial
Aquatic
Sub-populations
Sub-terrestrial
Terrestrial
Fresh water
Marine/estuarine
Target organisms
Mammals
Birds
Invertebrates
Reptiles/amphibians
Plants
Fish
Organizational levels
Individual levels
Population levels
Ecosystem
Landscape ecology
Species Diversity
Reduction in Diversity
Extinction
Endpoints
Neurotoxicity
Sub-chronic toxicity
Chronic toxicity
Developmental toxicity
Reproductive toxicity
Endocrine disruption
Acute toxicity
Carcino-genicity
Muta-genicity
Measurements
Behavior disorders
Moribundity
Growth reduction/ Reproductive survival
Polydactylism
Fecundity/ fertility
Thyroid dysfunction
Mortality
Liver tumors
In vitro tests
In vivo tests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Dioxin/Furan
Source
Treated Wood
Pathways
Soil
Water
Air
Exposed Populations
Terrestrial
Aquatic
Sub-populations
Sub-terrestrial
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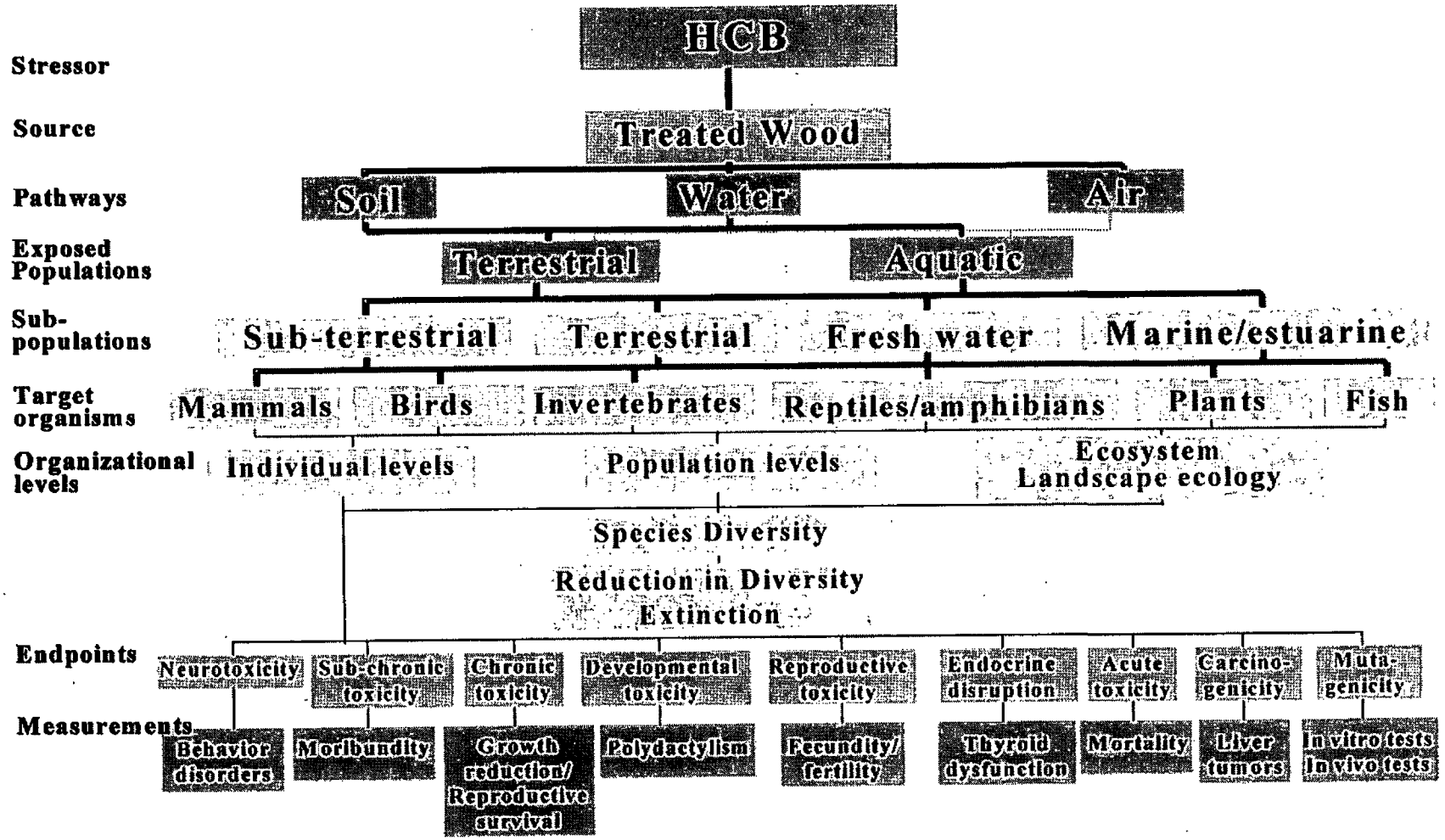
Fresh water
Marine/estuarine
Target organisms
Mammals
Birds
Invertebrates
Reptiles/amphibians
Plants
Fish
Organizational levels
Individual levels
Population levels
Ecosystem
Landscape ecology
Species Diversity
Reduction in Diversity
Extinction
Endpoints
Neurotoxicity
Sub-chronic toxicity
Chronic toxicity
Developmental toxicity
Reproductive toxicity
Endocrine disruption
Acute toxicity
Carcino-genicity
Muta-genicity
Measurements
Behavior disorders
Moribundity
Growth reduction/ Reproductive survival
Polydactylism
Fecundity/ fertility
Thyroid dysfunction
Mortality
Liver tumors
In vitro tests
In vivo tests


Stressor
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Fresh water
Marine/estuarine
Target organisms
Mammals
Birds
Invertebrates
Reptiles/amphibians
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Organizational levels
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Polydactylism
Fecundity/ fertility
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Liver tumors
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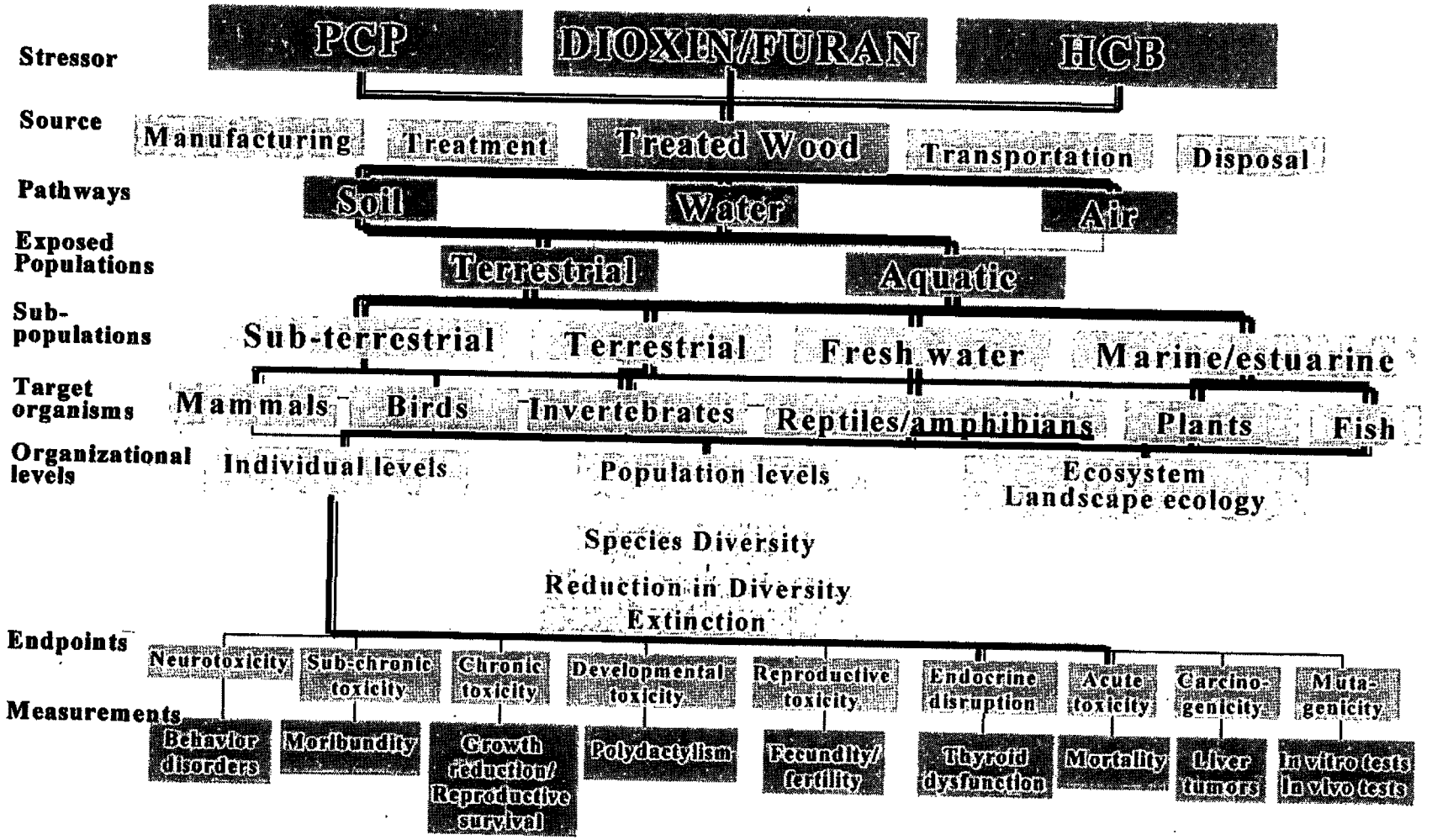
In vivo tests


Stressor
PCP
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Source
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Disposal
Pathways
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Sub-populations
Sub-terrestrial
Terrestrial
Fresh water
Marine/estuarine
Target organisms
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Birds
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Behavior disorders
Moribundity
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In vivo tests

DRAFT NARRATIVE FOR THE HUMAN HEALTH CONCEPTUAL MODELS FOR PENTACHLOROPHENOL (PCP) AND ITS CONTAMINANTS

Context of Pentachlorophenol (PCP) Human Health Conceptual Model Development

The Antimicrobials Division (AD), Office of Pesticide Programs (OPP), U.S. Environmental Protection Agency (USEPA), is currently developing the Reregistration Eligibility Decision for pentachlorophenol, a heavy-duty wood preservative (HDWP). The purpose of the RED document is to ensure that currently registered uses of pentachlorophenol are supported by adequate science data and risk assessments that reflect current USEPA policy for regulation of pesticide chemicals. In conjunction with the Science Policy Council's Cumulative Risk Working Group, AD scientists have undertaken development of conceptual models for pentachlorophenol. The purpose of conceptual model development is to describe the relationships among predicted responses of a population of concern and its stressors, including the environmental routes of exposure. The conceptual model also describes endpoints of concern and how they will be measured. This approach (of developing conceptual models) is intended to assist in the process of cumulative risk assessment, defined as "the potential risks presented by multiple stressors in aggregate." During model development, key questions are addressed, such as who is affected or stressed (receptors), what are the stressors (physical, chemical, biological or psychological agents), what are the sources, the time frame of the risks, and the assessment endpoints. For now, the Agency intends to focus on separate assessments of adverse human health and ecological effects. A separate conceptual model and narrative for the ecological effects of pentachlorophenol have also been developed by AD. This model may, in the future, be integrated with the ecological conceptual models.

Stressors

Pentachlorophenol is an organic oil-borne pesticide used in the past for a wide variety of applications (including herbicidal), but which is currently under restricted use status for preservation of wood only. During manufacture of pentachlorophenol, dioxin and furan contaminants as well as hexachlorobenzene are formed as the result of the high temperature chlorination of phenol. Although considerable progress has been made towards reduction of these contaminants within manufactured pentachlorophenol, they cannot be completely eliminated. The wood preservation industry has argued that complete elimination of PCP contaminants would represent a costly option and may present an undue economic burden. However, there are efforts being undertaken to determine if the contaminants can be eliminated completely from manufacture of PCP. At present, because this goal has not been achieved, separate sub-models for the dioxin/furan and hexachlorobenzene contaminants were constructed for purposes of assessing cumulative risk from exposure to pentachlorophenol. A further reason for

developing sub-models for the contaminants of pentachlorophenol was based on the distinct toxicities resulting from exposure to the contaminants as opposed to pentachlorophenol alone. A human health model which integrates the contaminants with pentachlorophenol is anticipated at some point in the future.

In order to construct the conceptual model for pentachlorophenol and the contaminants, sources of pentachlorophenol had to be identified. In conjunction with the EPA's Planning and Scoping Working Group, workshops were held to aid in development of these models.

Perhaps this could be stated initially for both ecological and health models? Five sources of pentachlorophenol which could result in environmental exposure as related to wood preservation were identified. These sources included manufacture of pentachlorophenol itself; transport of pentachlorophenol to the wood treatment plant; treatment of wood with pentachlorophenol; use of the treated wood; and eventual disposal of the treated wood once its useful life has expired. Manufacture of pentachlorophenol and disposal of pentachlorophenol treated wood were identified as outside the scope of regulation for the Office of Pesticide Programs. These aspects of pentachlorophenol regulation, while recognized as relevant to the cumulative risks from pentachlorophenol exposure, are under the regulatory authority of other offices within EPA. The use of wood treated with pentachlorophenol does not present a significant source of exposure as most of the pentachlorophenol remains within the treated wood. Further, use sites for treated wood are restricted mainly to utility poles, further lowering the potential for exposure. Thus, the treatment of wood with pentachlorophenol was felt to offer the greatest potential for exposure to this chemical out of all of the identified sources. In the treatment of wood, there are several opportunities for exposure to pentachlorophenol that do not occur from the other sources that are within EPA's regulatory authority. Personnel treating wood with pentachlorophenol will come into contact with the technical material when preparing wood for pressure treatment, and may also contact the chemical when cleaning equipment used for pressure treatment, or when handling freshly treated wood. Persons living within the vicinity of the wood treatment facility or those visiting the facility may also come into contact with pentachlorophenol through dermal or inhalation contact. These types of scenarios do not exist for the other sources of exposure to pentachlorophenol; therefore, in relation to the other sources of exposure, treatment of wood with pentachlorophenol was felt to be one of te most significant sources for exposure. Thus, it was felt that description of a conceptual model using wood treatment (in a plant and which represents a key exposure pathway) would be representative of the other potential sources of exposure to both pentachlorophenol and the contaminants.

The conceptual model for "clean" pentachlorophenol focuses upon the use of pentachlorophenol in the wood preservation process. Within the realm of wood preservation, there are various

types of treatments that can be performed with PCP. Commercial treatment of lumber, such as utility poles, usually involves a pressure treatment process in which a quantity of wood is subjected to treatment with PCP within a long metal cylinder (or retort). Treatment times can vary based upon the type of wood being treated, but the process is an enclosed one. After treatment, the treated wood is withdrawn from the retort and then mechanically placed on a drying pad made of concrete to collect any residual chemical that may leak from the freshly treated wood. Non-pressure treatment of wood also exists, such as dipping or extended soaking of wood in open vats. For remedial ground line treatment of existing utility poles, brushing, swabbing, spraying, bandage wrap, or low pressure injection techniques are employed. In each case of treatment, appropriate precautions are specified with regard to the required protective equipment and clothing. However, as can be seen, the types of treatments just described can result in or provide opportunities for significant exposure to both PCP and the contaminants.

Pathways

Pathways for exposure to PCP during treatment of wood can be either occupational (workers within the treatment plant who actually handle treated wood and/or PCP) or non - occupational (visitors to the plant as well as persons living in proximity to the plant). Within the occupational pathway, direct exposure can occur (such as to workers handling treated wood) as well as indirect exposure (workers not handling treated wood but who may be exposed to PCP by virtue of their job being located within the treatment plant, i.e., administrative workers). Persons living within proximity to the plant as well as visitors to the plant are considered to have an indirect, but not necessarily lower, exposure to PCP, through volatilization of PCP or contamination of soil and water surrounding the treatment plant.

Routes of Exposure

Dermal and inhalation routes of exposure are considered significant routes for human exposure to PCP in the wood treatment plant setting. Oral exposure through hand-to-mouth transfer can also occur but is not considered as significant in the wood treatment setting. Oral exposure may become more significant for other sources of PCP, such as use of treated lumber in residential settings, especially for infants and children who accidentally ingest soil surrounding treated wood.

For occupational pathways, both the dermal and inhalation routes are considered significant, while for non-occupational pathways (visitors and those living in proximity to wood treatment plants), the inhalation route would be most significant as a route of exposure. Within the occupational setting, adults are the only subpopulation of concern, as children under 16 are not expected to be employed in the wood treatment industry. The adult subpopulation

includes both males over 16 years of age as well as females (pregnant and non -pregnant). For the non -occupational pathway, both adults and children have the potential for exposure.

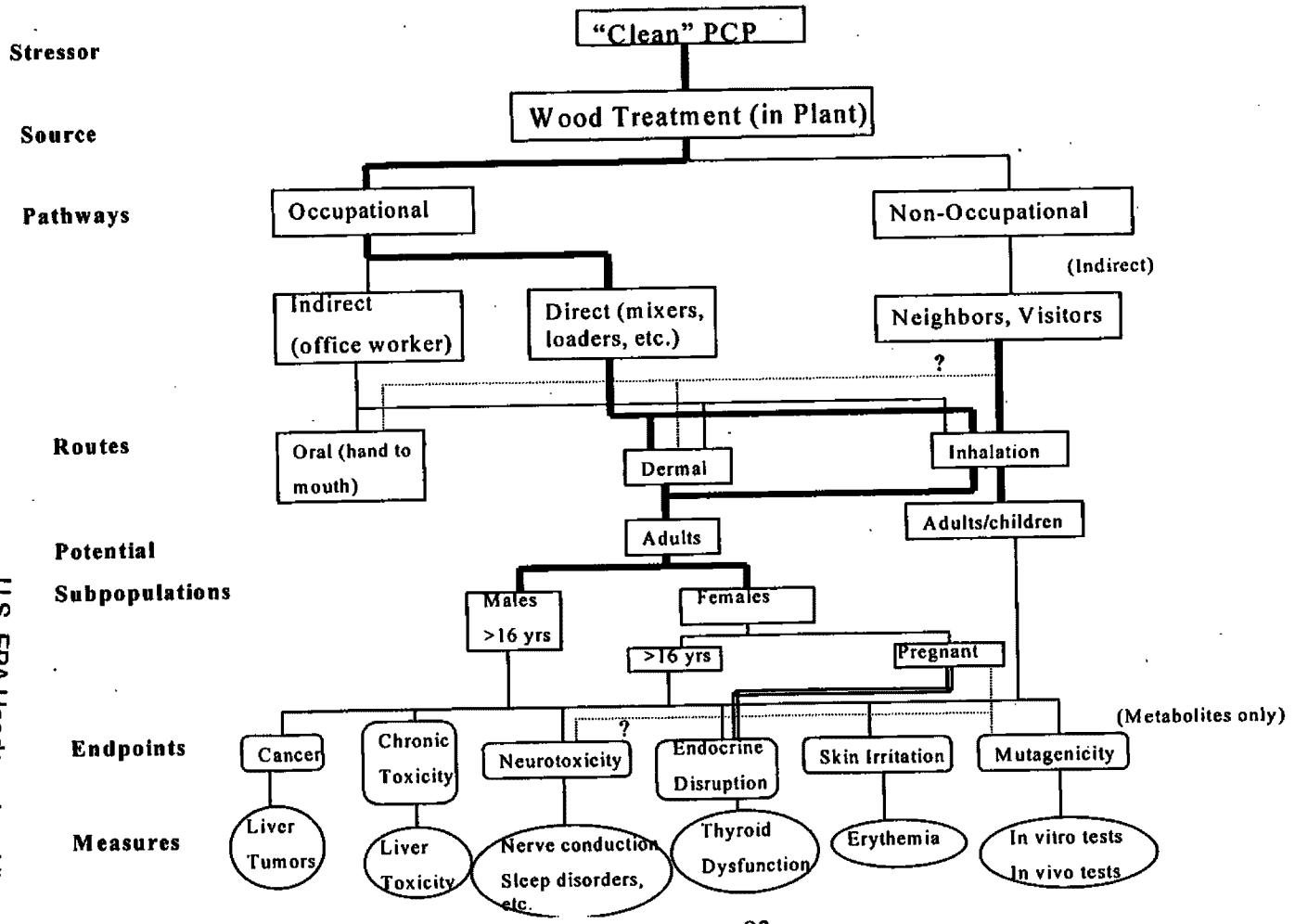
Assessment Endpoints

Human health "effects" are equivalent to ecological endpoints. There are several endpoints of concern resulting from exposure to PCP. The conceptual model identified several endpoints of concern, including cancer (represented by liver tumors which have been observed from animal studies of "clean" PCP), chronic toxicity (liver effects), neurotoxcity, endocrine disruption (specifically, disruption of thyroid function), skin irritation, and mutagenicity. For both occupational and non -occupational pathways, all of these endpoints were felt to apply, with emphasis on the endocrine disruption endpoint as applied to pregnant females in both the occupational and non -occupational setting. The developmental and reproductive toxicity of PCP was not listed as an endpoint, as studies have shown that "clean" PCP is not selectively toxic to the developing organism. In contrast, the dioxin/furan contaminants have been shown to have selective toxicity for the developing organism.

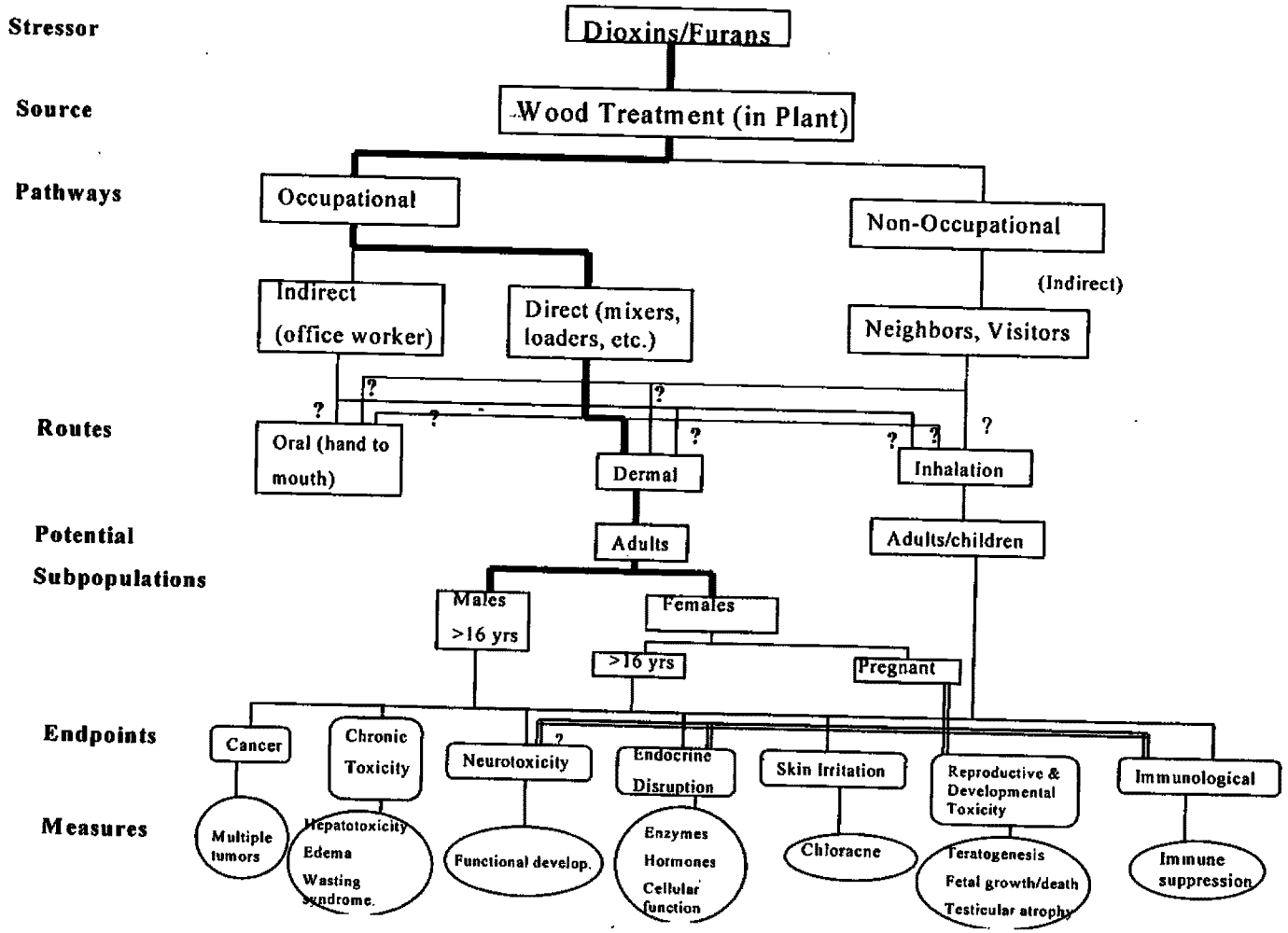
Measurements of Endpoints

For the endpoints of concern, specific measures are used to characterize the relative significance of each endpoint. In contrast to other conceptual models, data for pentachlorophenol was available to define the effect(s) associated with each endpoint of concern. Liver tumors were selected for the endpoint of cancer as it is known that the liver is a target organ of pentachloro-phenol toxicity, and chronic studies have demonstrated the occurrence of liver tumors after administration of pentachlorophenol. Other types of tumorigenic responses are not observed to any significant degree after chronic exposure to pentachlorophenol Liver tumors would also be expected to a part of the sub-model for the contaminants of pentachlorophenol as data for the dioxins/furans and hexachlorobenzene also demonstrate liver carcinogenicity. Several reports from the scientific literature also suggest effects such as nerve conduction abnormalities as well as sleep disorders from exposure to pentachlorophenol either occupationally or experimentally; definitive studies are still necessary in order to better characterize the endpoint of neurotoxicity. Pentachlorophenol is a known disruptor of endocrine function, specifically thyroid homeostasis. Studies have demonstrated a potent effect of pentachlorophenol on decreasing the levels of thyroxine and triiodothyronine. Pentachlorophenol is also a known irritant, and from dermal exposure this measure would be expected to adequately characterize the endpoint of skin irritation. Metabolites of pentachlorophenol, particularly the tetrahydroquinone metabolites have been shown to be potent mutagens, which may also contribute to the carcinogenic response.

PCP Human Health Conceptual Submodel



Dioxins/Furans Human Health Conceptual Submodel: Microcontaminants in PCP



Possible next steps:

1. A composite human health affects model illustrating all the stressors, is anticipated at some point.

2. A composite ecological-human health effects model is a long-term goal but requires bridging efforts between the two disciplines prior to its development.

3. A more complete analysis plan is appropriate.

4. Study of the potential for PCP/contaminants volatilization.

5. Application of the planning and scoping paradigm to additional REDs on a wider basis is under study.

B-2 Chicago Cumulative Risk Initiative–Region V: Case Study

The Situation

The Chicago Cumulative Risk Initiative (CCRI) is a multi-office effort to measure and reduce the risks posed by cumulative exposure and hazard to residents of the Chicago metropolitan and northwestern Indiana areas. CCRI was initiated in response to a Toxic Substances Control Act §21 Citizen's Petition from 11 Chicago-area community advocacy groups. The petition focused upon the regulatory gap in the Clean Air Act that allowed industrial air permits to be approved on a site by site (rather than cumulative) basis. The advocacy groups' purpose in submitting the petition was to convince the Agency to implement activities that would measure and mitigate the cumulative risks faced by area residents. CCRI's focus has expanded beyond the limited, sector- and media-specific concerns (*e.g.*, incinerator siting) originally expressed in the petition to include information and planned action on multimedia sources of pollution. CCRI is a multi-phased process. This case study focuses on the cumulative assessment phase. Implementation of pollution prevention or other hazard reduction activities is planned as the ultimate outcome.

CCRI is being conducted outside the scope of a traditional regulatory construct and the assessment phase is both a hazard assessment and mapping exercise designed to provide information for problem prioritization and better decision-making. Objectives of the two-county screening study are to: (1) better understand environmental conditions in Cook and Lake counties by examining the air quality impact of point, area and mobile sources; (2) foster dialogue with stakeholders; (3) develop a transferable methodology that can be used in other urban areas; and (4) inform enforcement targeting and pollution prevention strategies. At the request of the citizens' groups, the project includes a special focus on children. The project also is a pilot for the Region in the collection and use of a limited number of environmental health susceptibility indicators (e.g., blood lead, asthma, etc.). Improved access to and understanding of health data is a regional management objective.

Stakeholder Involvement

At the third workshop, Dr. Lauren Zeise of the California Environmental Protection Agency was invited to lead a discussion on applying the lessons from the National Research Council's 1996 report, *Understanding Risk: Informing Decisions in a Democratic Society.* In her remarks, she posed six questions that risk assessment planners should consider during planning and scoping:

• Who are the "interested and affected parties (stakeholders)?

CCRI was initiated in response to a TSCA §21 Citizen's Petition from 11 Chicago-area community advocacy groups, represented by the Chicago Legal Clinic(CLC). To date, stakeholder involvement in the process has been limited to the parties involved in the

petition process. In addition to these groups, workshop participants noted that other stakeholders should be involved in the process. (See sidebar). The most conspicuous omission is representation from permitted facilities and industries. However, case presenter Carole Braverman, Region 5, noted that industry interests were represented by the City of Chicago's Department of the Environment, which is very interested in promoting industrial development as part of its overall brownfields strategy.

Stakeholder Considerations

Interested and Affected Parties Currently Involved

- 11 advocacy groups, represented by Chicago Legal Clinic (CLC)
- State, County and City governments
- Chicago Department of Health
- Chicago Department of the Environment (also represents industry interests)
- EPA Region 5 (Chicago and Indiana teams, OPPT, OAQPS, OAR, etc.)
- Asthma Coalition
- University of IL School of Public Health

Other Interested and Affected Parties that Should be Involved

- Permitted facilities and Industries
- Workers and Unions
- Chambers of Commerce
- Residents not represented by 11 advocacy groups
- Groups representing schools/children
- Commuters and tourists

- What should be deliberated? When?

Because the CCRI case was initiated in response to a petition filed by stakeholders, their involvement in the process has been a central focus throughout the process, and workshop participants agreed that stakeholders should continue to be involved in deliberations on an ongoing basis, as the process unfolds. Braverman explained that the stakeholder groups have been involved in deliberations regarding the scope of the assessment, data needs and constraints, "products" to be produced, and project schedule and timing issues.

Deliberations with stakeholders allowed EPA and the interested and affected parties to make a number of key decisions defining the scope of the proposed assessment:

- Conduct a cumulative rather than comparative analysis
- Focus specifically on children
- Focus on sources rather than receptors
- Concentrate on EPA-regulated sources
- Cover a broad two-county geographic area rather than smaller geographic subareas
- Limit study to air pathway/medium
- Do not link health effects to causes.

Workshop participants agreed that stakeholders also should be involved in future discussions relating to development of a strategy and action plan based on data findings, peer review, and future involvement of additional stakeholder groups. They also suggested that EPA present to the stakeholder groups the two assessment goals articulated by the workshop group. (See discussion of "Defining the Risk Assessment Purpose" below).

• What approaches should be considered (focus groups, etc.)?

Region five currently works closely with the Chicago Legal Clinic, as representative of the 11 citizens' advocacy groups. The group listed the communications approaches currently used to promote stakeholder involvement and suggested additional approaches, as follows:

- Periodic meetings with CLC
- Meetings with all 11 individual groups when there is something major to discuss.
- CLC Newsletter
- Future Web site
- Technical training of citizens (through EPA contractor, Argonne National Laboratory)

• How should participants be selected?

Participants are the TSCA §21 petitioners. EPA solicited involvement by state, county, and local governments. Bring in representation of appropriate permitted facilities and industries, once data are analyzed and affected parties can be identified.

• Should the program enlist outside help in establishing the deliberative process?

Braverman said Region 5 briefly engaged the services of an outside party to facilitate the deliberative process, but found this did not work well. She pointed out the importance of understanding the difference between a mediator and a facilitator, as the two roles are very different. However, outside help will be enlisted for the external peer review process.

• What are the external constraints for deliberation? (Budget, time, legal)

Braverman stated that all parties are interested in getting something done in a reasonable amount of time. The deliberative process also is subject to legal and ethical constraints (regarding data sharing). Participants noted that budgetary limitations sometimes can help focus efforts.

CCRI was initiated in response to stakeholder concerns, and their involvement has been an integral part of the project from the beginning. Participants in the third workshop acknowledged the importance of stakeholder input and often sought information from the case presenter on stakeholder interests and positions, which they carefully considered and factored into their discussions at numerous points in the planning and scoping dialogue process.

Risk Assessment Planning and Scoping Dialogue:

Participants in the three CCRI case study workshops defined the problem, goals, stakeholders, stressors, sources and endpoints, sketched out a conceptual model of the risk assessment, and developed a preliminary analytical plan. The discussion during the three sessions ranged over a broad list of stressors, sources, and endpoints that are beyond the scope of the actual project. The process was an iterative one: While participants in each subsequent workshop considered, revised and refined, and expanded upon the work completed by previous groups, they did not consider themselves bound to prior decisions.

The first workshop group concentrated on identifying the elements of a conceptual model and developed tools to measure effect level and monitor trends over time. The second workshop developed a list of sources, stressors, and endpoints and drafted first-order draft models of human health and ecological risk. By the third workshop, the idea of preparing a conceptual model for ecological risk was discarded because ecological concerns were not raised by petitioners. Participants in the third workshop refined the human health conceptual model and concentrated on the four tasks associated with the planning and scoping dialogue.

Task one: Define the purpose for performing the risk assessment

Goals of the CCRI Assessment

Goal 1: To develop the data upon which to base a strategic plan to improve air quality in the two-county area by effectively targeting emission reduction activities.

Goal 2: To develop the data upon which to develop a strategic plan to improve public health by effectively targeting intervention activities.

While the focus of discussion during the first workshop was on developing the elements of a conceptual model for CCRI, participants in the second and third workshops spent considerable time defining the objectives of the study, in addition to revising and expanding upon the conceptual model. They clarified stakeholder and EPA objectives of the two-county screening study, as follows:

- Better understand environmental conditions in Cook and Lake counties by examining the air quality impact of point, area, and mobile sources;
- Foster dialogue with stakeholders;
- Develop a transferable methodology that can be used in other urban areas; and
- Inform enforcement targeting and pollution prevention strategies.

The third workshop accepted the stakeholder and EPA objectives articulated by the previous group, although these did not provide clearly defined risk assessment purposes. After drafting a conceptual model, the group revisited this issue as a necessary prelude to

development of a risk assessment technical approach. Participants observed that stakeholder groups and EPA each had their own set of objectives—some of which seemed to overlap and others that appeared to conflict—but they had not articulated distinct common goals upon which to base the analysis.

EPA/Stakeholder Decisions Regarding Scope of the Assessment

- Conduct a cumulative rather than comparative analysis
- Focus specifically on children
- Focus on sources rather than receptors
- Concentrate on EPA-regulated sources
- Use only existing data
- Cover a broad two-county geographic area rather than smaller geographic subareas.
- Limit study to air pathway/medium.
- Do not tie health effects to causes.

After considerable discussion of EPA and stakeholder interests and concerns, the workshop group was able to define two distinct common goals for the project, as shown above. The "breakthrough" occurred when the group recognized that the real objective of CCRI is hazard assessment, not cumulative risk assessment. The project does not involve assessment of "cumulative risks," but rather "cumulative hazard." CCRI is not a true risk assessment, but rather a hazard mapping exercise showing the air quality impact of point, area, and mobile sources (environmental loading) within the two-county area.

Task two: Define the scope of the risk assessment

Participants at all three workshops discussed some of the six dimensions of the planning and scoping process:

- Who, what, or where is being affected or stressed?
- What are the stressors?
- What are the sources?
- What are the environmental pathways and routes of exposure?
- What are the relevant time frames?
- What are the assessment endpoints?

The first workshop started with sources and identified stressors (ozone, particulates, lead), defined the media (air, soil, water) and pathways (inhalation, dermal contact, and ingestion), and identified potential diseases and health impacts (such as eye irritation, asthma, neurological effects). The second workshop group revised and expanded the list of sources, stressors, and endpoints drafted by the previous group and drafted first order models of human health and ecological risk.

The third workshop group used the work of previous groups as a starting point to outline the elements of a human health conceptual model. At the suggestion of facilitator Don Barnes, the group decided to develop a broad conceptual model showing multimedia sources of

pollution that goes well beyond the limited, sector- and media-specific concerns (*e.g.*, incinerator siting) addressed in the §21 petition and beyond the specific goals of the assessment. The inclusive model provides a broad framework that can be used to make judgements about "what's in and what's out" of the risk assessment based on specific goals and to illustrate the rationales for these decisions.

Task three: Develop a cumulative risk outline

The group slightly revised and expanded upon the dimensions of risk specified in the *Guidance* to design a conceptual model with eight elements in the following hierarchy: Activity→Sources→Stressors→Pathways→Media→Route→Population←Health Effects Measures/ Biomarkers (See conceptual model).

Activities

The group identified several "activity" categories, and then identified related sources of pollution. Activities included: industrial, residential, transportation, commercial, and agricultural. They noted that agriculture was a minor activity in this two-county urban area.

Sources

Sources included in the conceptual model are incinerators (a focus of the original §21 petition), industries, mobile sources, indoor air, and "background/other," a category that participants defined as inclusive of all other sources of environmental pollution.

Stressors

Stressors include particulate matter (PM); dioxin; heavy metals; VOCs and benzene; O_3, No_x and So_x; noise; and odor.

Pathways

Participants had difficulty agreeing on the definitions for "pathways" and "routes of exposure." They decided to add another dimension, "media," to provide a bridge between the two. Pathways included in the conceptual model are outdoor air, indoor air, water, and soil.

Media

In the CCRI conceptual model, stressors travel through pathways to various media, which participants identified as soil, outdoor air, indoor air, water, and fish.

Route

Routes of exposure from these media to receptors include inhalation (from indoor air, outdoor air, and soil), dermal contact (from water and soil), and ingestion (from soil, water, and fish).

Populations

Potentially affected populations were identified as: children, infants, adolescents, adults, pregnant women, elderly, and immuno-compromised populations. At the request of petitioners, the project will focus on children.

Health Effects Measures/Biomarkers

Petitioners expressed an interest in looking at blood lead levels, asthma, and childhood leukemia as measures of health effects. Participants also identified several other potential measures/biomarkers, including DNA adducts, chronic obstructive pulmonary disease (COPD), and endocrine disruptors residing in adipose tissues. In the conceptual model, these measures are tied to specific populations, but the model does not attempt to address causality, nor are observed effects/biomarkers tied to specific sources or exposures.

The group noted that the model cannot connect emissions to effects because exposure is not addressed. This is not problematic because the objective is to enable GIS mapping of emissions.

Due to the press of time, workshop participants did not fill in every detail showing linkages between the various levels of the model. They acknowledged the need to show these linkages, but moved on to discuss the risk assessment scope and development of an analytical plan. A complete conceptual model would require filling in all the appropriate linkages, and the arrows on the conceptual model ideally would be drawn in various widths to indicate the strength or importance of each linkage.

A complete conceptual model for CCRI would show differing levels of depth and detail that the reader could view as desired, so that at the most aggregated level, the conceptual model would show only the most important items and linkages, and the level of detail would increase with subsequent diagrams. That way, a non-scientist audience could visualize the essence of the problem without getting lost in a highly detailed diagram, and a technical audience would be able to local all the plausible linkages and feedbacks.

Case presenter Carole Braverman reviewed a number of decisions outlining the scope of the proposed assessment that were made by consensus in Region 5's deliberations with stakeholders. She noted that Region 5 decided to include information on indoor air as well as outdoor air pathways/media in order to provide risk information "in context." The decision to include indoor air in the analysis is a source of disagreement and concern among stakeholders.

Task 4: Formulate the technical approach of the risk assessment

In addition to development of a conceptual model, participants in the third workshop were tasked with preparing an analytical plan that flows from the conceptual model.

Conceptual Model

Most of the time the third group devoted to this task was spent on developing the conceptual model (see Figure 1). Once the cumulative risk outline was completed (see Task 2) building the conceptual model proceeded quickly through iterative and free-flowing discussion among the group. Participants agreed that the conceptual model, once developed, is extremely valuable—not only for formulating the approach for the assessment, but as a communications tool to ensure that all participants (within EPA as well as outside stakeholders) understand the scope of the issues.

Analytical Plan

The conceptual model and the analytical plan are the two products from planning and scoping process. Together, they provide the basis for risk assessment. The analytical plan provides the rationale for limiting the scope of the risk assessment, since it is not possible to address everything in the conceptual model. It is the next level of "filter"—transparent rationale. This is the place where feasibility and data availability are considered and factored in. The analytical plan describes the tools to be used, and explains how, and why the analysis will be conducted in a certain way. It discusses measures, surrogates, and rationale. It should discuss data limitations and uncertainties.

After drafting a broad and inclusive CCRI conceptual model, workshop participants developed "functional" conceptual submodels to address each of the overall assessment goals, given data availability and limitations. They noted that developing a broad-based inclusive model from which to draw submodels provided a "tool" that Region 5 could use to communicate risks "in context" to interested and affected parties and to the public at-large. Each functional submodel is a subset of the broad-based, inclusive CCRI model modified to fit the scope of the proposed assessment, and each addresses one of the two overall assessment goals.

Goal 1: *To develop the data upon which to base a strategic plan to improve air quality in the two-county area by effectively targeting emission reduction activities.*	"Functional"Conceptual Submodel: Uses CCRI Conceptual model from"top/down" to focus on source emissions and to map distribution of pollution in subareas. Elements: Activity→Sources→Stressors→Pathways (Outdoor and Indoor Air only) →Media (Outdoor and Indoor Air only)→Route (Inhalation only).

Goal 2: *To develop the data upon which to develop a strategic plan to improve public health by effectively targeting intervention activities.*	"Functional"Conceptual Submodel: Uses CCRI conceptual model from "bottom/up" to look at public health issues, i.e., health effects on various sub-populations, without tying effects to causes or to specific sources. Elements: Populations (Children)←Health Effects Measures/ Biomarkers.

Participants emphasized that the conceptual submodel for Goal 1 focuses on outdoor and indoor air pathways and the inhalation route—not because other pathways are not important, but because of the objectives agreed upon by EPA and the stakeholder groups. Similarly, the conceptual submodel developed to address the public health objective in Goal 2 is limited to addressing effects on children and infants because stakeholder petitioners asked EPA to focus on children.

Data Availability and Limitations

Case Presenter Carole Braverman discussed the elements of a Region 5 matrix providing an overview of existing databases, showing data type, year, sectors covered, sources and areas covered, chemicals covered for the two counties, and comments on each database. The group used this information to define data sources and outputs and determine the products that will be produced under the project (See sidebar below).

Data Sources and Outputs

The basic output for the project are GIS maps by neighborhood. Maps will show ambient concentrations based on monitoring data for Ozone, HAPs, and Criteria Pollutants; and modeled from EPA's Cumulative Expose Project (CEP). They will show Toxicity Weighted Emissions, calculated using OPPT toxicity weighting from the Environmental Indicators Model, as follows:

For Cancer Endpoints

$$\sum \left(\text{Amount}_{i,j} \times \text{IUR}_i\right)$$

where:

i = chemical i

j = facility j

$\text{Amount}_{i,j}$ = total emissions of chemical i from facility j

IUR_i = inhalation unit risk for chemical i

Data Sources for Emissions

- TRI (Toxic Release Inventory)
  - -includes 121 air toxics
  - -self-reported and generally estimates
- RAPIDS (Regional Air Pollutant Inventory Development System)
  - - includes HAPS, PBTs, and Criteria Pollutants
  - - county level estimates allocated to census tracts based on population.

Planned CCRI Project Products

Baseline measures for different geographical areas.

For Goal 1 (Emissions)

- Ambient Concentrations (monitoring and modeling
- Toxicity Weighted Emissions
- Emissions of Respiratory Concern and Lead
- Facility Density

For Goal 2 (Public Health)

- Biomarkers (Blood lead)
- Disease (asthma, COPD, childhood leukemia)

Data Sources for Toxicity Weights

- OPPT
  - -toxicity weights
- CEP Benchmarks
  - - modeled for 111 air toxics

Data sources and outputs for Goal 2 (Public Health) include:

Health Indicators

- - Blood lead
- - Hospital admissions
- - Asthma
- - Chronic obstructive pulmonary disease (COPD)
- - Childhood leukemia

Exposure/Susceptibility Indicators

- - Age of Housing
- - Household Income
- - Proportion of children, elderly residents
- - Ethnic distributions
- - Population changes since 1990 Census

Lessons Learned

- Developing a broad-based inclusive model from which to draw functional submodels provided a "tool" that Region 5 could use to communicate risks "in context" to interested and affected parties and to the public at-large.
- The major hurdle in defining the purposes of the assessment was in acknowledging that risk assessment was not the objective. Once they did so, they were able to define distinct common goals for the assessment.
- Chicago "Cumulative Risk" Initiative may be a misnomer. The project addresses cumulative hazard rather than cumulative risk. It does not address risk or exposure to specific groups

nor tie causes to effects. CCRI will not involve a true risk assessment; but rather a hazard assessment mapping exercise.

- The four tasks in the planning and scoping dialogue may not always be accomplished in the order specified in the *Guidance*. The process is an iterative one. In this case, participants completed the cumulative risk outline and drafted a conceptual model before determining assessment goals. They then developed working models—subsets of the broad and inclusive CCRI conceptual model—to address each of the assessment goals.

B-3. Cumulative Risk Index Analysis (CRIA) Method in Concentrated Animal Feeding Operations (CAFO) In Region VI: Case Study

The Situation

Concentrated Animal Feeding Operations (CAFOs) are a common and significant concern throughout Region 6. CAFOs are large (often occupying a quarter square mile—significant in terms of watershed areas) and produce enormous quantities of waste discharge into on-site lagoons. These lagoons and associated operations are permitted under the Clean Water Act's National Pollutant Discharge Elimination System (NPDES) and require environmental impact reviews under the National Environmental Policy Act (NEPA). NEPA requires "cumulative" evaluations of the proposed threat. For some watersheds that are not meeting state-prescribed standards, there may be Total Maximum Daily Load analyses and additional restrictions or penalties imposed. General statewide permits under which many CAFOs operate expired in 1998, and Region 6 needs to consider if there is a threshold above which cumulative impacts from CAFOs and other regional sources (agriculture, oil and gas exploration, roads and transportation infrastructures, and domestic waste) may cumulatively exceed the permitted pollution levels. The risk evaluation was requested by Region 6's Compliance Office to meet the NEPA requirement to review waste lagoons for NPDES permits. In addition, there is public concern over the rapid expansion of CAFOs.

The cumulative-risk considerations include multi sources (CAFOs and their component operations as well as other regional sources such as agriculture, oil and gas exploration, roads and transportation infrastructures, and domestic waste), multimedia (surface water, ground water, and air), multiple pathways and routes of exposure (drinking water and surface water contamination from microbiological contamination, and odors), scientific disciplines (ecological, human health, social sciences/economics), and statutory overlap (CWA, CAA, NEPA, FQPA, RCRA).

There was no method or approach to determine when a watershed reaches a significantly polluted state. Region six developed Cumulative Risk Index Analysis (CRIA), a novel approach

based upon a mathematical algorithm that established the potential for significant environmental risk for each CAFO. Cumulative risks are identified through evaluation of: 1) Areas of regulated and unregulated CAFOs; 2) environmental vulnerabilities (e.g., ground water depth or soil permeability); and 3) impacts from known CAFO projects (water quality, vector/odor, wildlife habitats) specific to each water shed subunit.

$$\text{CRIA} = \frac{\text{Watershed Unit Subarea}}{\text{(Total Affected Area} \div \text{Watershed area)}} \times \underset{\text{(scale of 1-4)}}{\text{Degree of Vulnerability}} \times \underset{\text{(scale of 1-5)}}{\text{Degree of Impact}}$$

CRIA facilitates communication of technical and regulatory data upon which better agency decisions can be made. The CRIA is designed to better understand the effectiveness and results of CAFO controls. The tool is not intended to be used alone but in concert with other environmental program perspectives and data (i.e., endangered species and fish and wildlife service, state environmental agencies with cultural resources' concerns)

Risk Assessment Planning and Scoping Dialogue:

Task one: Define the purpose for performing the risk assessment

It is important to recognize the difference between state and federal goals and objectives. States may be more influenced by local economic considerations. However, recent administrations are providing more flexibility to states in deciding regulatory or mitigatory decisions, which adds a new dimension to decision making and cumulative risk considerations.

After considerable discussion, the participants in the third workshop stated their risk management objectives for region VI as:

1) develop new general permits for CAFOs in the state of Oklahoma

2) identify the point where cumulative impacts go beyond the level of the current permit

Task two: Define the scope of the risk assessment

The participants succeeded in defining management objectives with a geographic dimension and rationale after spending considerable time debating the merits of adopting a broad or narrow geographic scope (the temporal dimension did not arise). Region 6's Case Presenter explained that waste lagoons are generally regulated on the basis of nitrogen/ nitrate concentrations, while ignoring phosphate. However, Region 6 (at least) may be leaning toward regulating phosphate instead. There is a tradeoff between avoiding a discharge to the atmosphere (the basis of limiting nitrogen) and avoiding a phosphorous buildup in the soil. There is also a water quality dimension: phosphate runoff to streams and lakes or percolation of nitrogen to groundwater. How much excess phosphate or

nitrogen might result in human health consequences is not yet known. Also, the total amount of nitrogen being released from all sources (not just CAFOs) is unknown.

The Oklahoma panhandle alone may process 4.5 million hogs per year, in addition to ongoing beef ranching, dairy production, and crop production. Virtually all the water comes from the groundwater, and most is used for agriculture (cattle and crops; now hog production). CAFOs use groundwater for irrigation and to dilute hog manure for fertilizing grasslands and rangelands for grazing cattle. The area's natural system was probably a grassland prairie with some riparian vegetation. It is on a major flyway for migratory birds. The natural ecology depends on playa lakes. Concern has been raised that CAFO waste lagoons will send greenhouse gases to the atmosphere, perhaps with far-reaching consequences. These waste lagoons are constructed to be extremely large, so as to avoid the need to plan for future sludge disposal (capacity is judged to be 10-15 years).

General NPDES discharge permits are issued statewide. Participants in the third group considered several alternatives to define the geographic scope of the assessment: One was to look at only two counties in the Oklahoma panhandle for permit renewals; another was to consider the nationwide perspective of risks anywhere in the country; a third was to focus locally but identify considerations (almost as "asides") that would apply in other areas. The narrowest perspective would focus on a single CAFO. Region six preferred an assessment to address all five states. The group initially preferred an assessment that would address nationwide perspective, but recognized that the decision maker may not want to consider issues unrelated to his or her own risk management goal or to expend resources without direct benefit. Ultimately, the group decided to focus the risk assessment on the watersheds affected by CAFOs in a single county in the Oklahoma panhandle as the basis to develop a risk assessment for all CAFOs in Oklahoma.

Task three: Develop a cumulative risk outline

Participants in the CAFO breakout groups at three workshops spent considerable time discussing the six dimensions of the planning and scoping process.

The focus of the workgroup was on:

- Who, what, or where is being affected or stressed?
- What are the stressors?
- What are the sources?
- What are the environmental pathways and routes of exposure?
- What are the relevant time frames?
- What are the assessment endpoints?

Region 6's CRIA materials used the term "criteria" within its algorithm to identify components (see sidebar and Attachment 1). While these criteria were defined for and relevant for the CRIA model, they are not structured according to the hierarchy of sources→ stressors→pathways→assessment endpoints→ measurement endpoints recommended in the *Guidance*.

CRIA Model "Criteria"

Groundwater probability
Rainfall
Surface water use
Distance to surface water
Population around facility
Other industries/sources [existence]
Wildlife habitat [proximity]
Soil permeability
Groundwater quality [nitrate/ nitrite]
Economics [Environmental Justice]
Minorities [Existence and proximity]
Surface water quantity
Surface water quality
Other CAFOs
Livestock population density
Lagoon loading rate
Treatment system liner
Land application technology
Nitrogen budget
Storage capacity [lagoon]
Wellhead protection [existence]
Employment
Odor
Transportation
Habitat area affected
Density of CAFOs
Proximity of CAFOs
Phosphorous budget
Endangered and threatened species
Cultural resources

Participants in the third workshop addressed all six dimensions of the planning and scoping process. The third group's lists of stressors, pathways, at-risk components, and endpoints built upon the progress made by the first two groups, but went beyond both to a considerable degree. However, the third group was advised by the facilitator to ignore "measurement endpoints" (which require data) and instead consider "at risk components" to assist in conceptualizing the linkages between stressors and endpoints so that they would not be distracted by issues related to data availability.

Stressors

A "stressor" is "any physical, chemical, or biological change that is affecting a system." The group recognized that a complete list of stressors must include those associated with non-CAFO sources as well as second-order stressors, but due to the time constraints limited themselves to CAFO-related stressors.

All three workshop sessions addressed human health and ecological stressors. Throughout the workshops, there was considerable discussion on what constitutes a "stressor," and whether stressors should be aggregated or disaggregated. By the third session, the facilitator advised the participants that it depends on the stressor's relationship to regulatory or pathway considerations. For example, if hog-nursery barns have the same permit conditions as

finishing barns, is it necessary to distinguish the two? Ultimately, participants concluded that they should have the greatest degree of disaggregation that can be handled, and information can be re-aggregated later. "Associated chemical substances" became the aggregated stressor for several specific stressors treated individually by the first two workshops.

Sources

Region 6's Case Presenter discussed the various operations going on within a CAFO, each contributing its own source of pollution (land application of diluted hog manure over very large areas as fertilizer; hog barns; waste lagoons; truck washing and local transportation). However, the Region considers land application as the primary concern and in the interests of time, the participants discussed the other sources only in passing. Similarly, non-CAFO sources (agriculture, oil and gas exploration, roads and transportation, and domestic waste) were recognized by the Region and workshop participants as contributing to the regional cumulative risk, but time did not permit their consideration.

Pathways

All three workshops had difficulty with defining "pathways" and "routes of exposure." Some of the confusion stemmed from the different way these terms are used by ecological and human health specialists and some arose from consideration of non-traditional sources ("odor") and endpoints ("property value"). Traditionally, human-health specialists define "inhalation," "ingestion," and "dermal absorption" as the pathways, but these do not apply as well to ecological endpoints. In some cases, sources, pathways, and endpoints became confused ("sediment" can be a source and an endpoint, and "sedimentation" is a stressor). In the end, participants constructively redefined pathways to include concepts of importance.

Receptors

Participants in the third workshop session opted not to consider "measurement endpoints" because they could not adequately address data availability. As an alternative, the facilitator in the third workshop session suggested that the group consider "at-risk components" to assist in conceptualizing the linkages between stressors and endpoints without being distracted by data availability. Here we will use the term receptors, which is already in wide use for health risk assessments. Receptors are the entities (individuals, populations, species, communities, and ecosystems) exposed to stressors. The participants defined three categories of receptors—human health, ecological, and economic system—for the CAFO risk assessment

Endpoints

An "assessment endpoint" is a human health or ecological system attribute that, if changed, would indicate a change in the health of that system. Endpoints depend on scale of system as well as societal values. Endpoints should be measurable, but not necessarily directly (they may have surrogate measures). The purpose of endpoints is to focus attention on the effects of stressors on attributes of societal importance (such as an endangered species) or system significance (a keystone species) in the ecological system. Human health "effects" are equivalent to ecological endpoints; ecological "effects" are changes in endpoint conditions. These effects are expressions of risks that need to be managed.

Ecological Endpoints

Participants considered the ecological systems at risk from the stressors already identified. Participants defined three ecological systems, with specific endpoints for each:

(a) Condition of aquatic ecosystem — a generic endpoint because there are no specific components of concern either to stakeholders or to environment.

(b) Condition of terrestrial/wetlands ecosystems
- Population of migratory birds (area is on the Central Flyway)
- Wetland community structure
- Rangeland community structure
- Habitat mosaic (including fragmentation)

(c) Condition of threatened/endangered species: Whooping crane (the only listed species)

The group recognized that planners normally would get experts to define system components and functions, but the size and makeup of the groups usually did not permit this in the workshops. Also, groundwater and atmospheric communities are not normally considered "ecosystems" — they are more pathways or avenues of exposure.

Human Health and Other Societal Endpoints Related to the receptors

The second workshop identified infants, minorities, farm workers, and other residents as human health endpoints. The third workshop's participants listed specific diseases or health affects as "endpoints," but added "societal" endpoints as well. There was some discussion of how some of these endpoints could be measured, but the discussions generally concluded by assuming that some quantification would be possible, without going into details.

Task 4:Formulate the technical approach of the risk assessment

Participants succeeded in formulating the problem and developing a conceptual model. During the introduction to the third workshop (and in the pre-registration materials), participants were instructed that, in addition to development of a conceptual model, one major product of

their sessions should be the "analytical plan" that flows from the conceptual model. Together, they provide the basis for risk assessment.

Conceptual Model

Most of the time the third group devoted to this task was spent on developing the conceptual model with linkages among the stressors, pathways, at-risk components, and endpoints (see Figure 1). Note that the lines drawn on the conceptual model shown in Figure 1 represent only selected linkages that the workshop groups worked on for illustrative purposes. While the overall conceptual model elements are shown, a complete conceptual model would require filling in all the appropriate linkages, and the model would also be expanded to include other drivers beyond CAFOs. The arrows on the conceptual model ideally would be drawn in various widths to indicate the strength or importance of each linkage. The rationale for the model is described below.

A complete conceptual model for CAFOs would show differing levels of depth and detail that the reader could view as desired, so that at the most aggregated level, the conceptual model would show only the most important items and linkages, and the level of detail would increase with subsequent diagrams. That way, a non scientist audience could visualize the essence of the problem without getting lost in a highly detailed diagram, and a technical audience would be able to locate all the plausible linkages and feedbacks.

Analysis Plan

The analysis plan provides the rationale for limiting the scope of the risk assessment, since it is not possible to address everything in the conceptual model. It is the next level of "filter"—transparent rationale. This is the place where feasibility and data availability are considered and factored in. The analysis plan describes the tools to be used, and explains how, and why the analysis will be conducted in a certain way. It discusses measures, surrogates, and rationale. It should discuss data limitations in data and uncertainties.

Under NEPA, permit applicants should be required to prepare and submit their own Environmental Impact Analysis (EIA), which requires them to do their own planning and scoping. This may be a significant departure from the way EPA does business, since programs and regions generally do not do EIA/EIS for permits.

Stakeholder Involvement

Stakeholders include Region 6 program managers and staff (involved with NEPA enforcement, NPDES permits, watershed quality, groundwater, surface water, risk assessors, RCRA, Superfund, and GIS experts), academics, industry (primarily swine production but also beef producers who may have a future stake), state and county regulators, EPA

headquarters (NEPA, agriculture sector), Department of Agriculture's Natural Resource Conservation Service, national and local environmental groups, and community residents.

At the third workshop, Dr. Lauren Zeise of the California Environmental Protection Agency was invited to lead a discussion on applying the lessons from the National Research Council's *Understanding Risk: Informing Decisions in a Democratic Society.* In her remarks, she posed seven questions that risk assessment planners should consider during planning and scoping. Due to limited time, participants concentrated on two of Dr. Zeise's questions, 1) who the stakeholders were and 2) how to engage them. The group recognized the value of stakeholder involvement in the preparation of the conceptual model, and identified several ideas for expanding stakeholder involvement in process:

- Sharing the conceptual model with local residents and stakeholders (may need to engage disadvantaged groups)
- Holding scoping meetings with plans and then follow up to the public comments
- Providing training opportunities for citizens to follow the project over the long-term
- Developing interactive communications tools based on the conceptual model

Lessons Learned

- The workshops permitted participants to identify the structure and linkages of all the components in the systems. Participants realized that doing the Conceptual Model was the key to the Guidance.
- Participants succeeded in developing a conceptual model which identified specific public health endpoints that are ignored in the Region 6 CRIA. Region 6's case presenter indicated that the Region probably will go back and add them.
- Initial public concern with CAFOs was over odor. Ironically, an odor is not considered to be a health risk.
- Originally, the workshops focused on ecological risk and new terminology. Debate over terminology and brainstorming sessions were necessary to reach a consensus.
- The Cumulative Risk Assessment planning process cannot be prescriptive.
- Consideration of "measurement endpoints" during formulation of the conceptual model (before the Analysis Plan) may unduly restrict the model because of concerns over data availability.
- EPA needs to overcome a cultural bias within the agency that risk assessment is an internal function. Stakeholder engagement is essential at the beginning.
- The intent of NEPA is to include all stakeholders in the scoping process.

Conceptual Model Development

The Concentrated Animal Feeding Operations (CAFO) Model represents input and deliberation of three sessions of EPA assessors and analysts. The model was developed to include the major elements of each dimension. The relationships flow from the sources that produce categories of stressors through a set of pathways to affect receptors. The effects are expressed as a series of endpoints for ecological, health or economic system (quality of life) effects. The frame of reference for this model is a watershed in the panhandle of Oklahoma.

Sources

The CAFO is the primary source of stressors that are considered in this model. Also within the watershed some of the same stressors may be contributed by existing sources which may include: Agriculture (primarily livestock and row crops); oil and gas exploration; roads and vehicular traffic; and domestic waste treatment facilities (both private and public). Existing sources form a background for the type of stressors that the CAFO may add to the watershed. The solid vertical line has been used to show common linkages between elements within a dimension.

Stressors

The list of stressors represents some aggregation. Stressors were aggregated with consideration to their pathways and routes of exposure to particular receptors, and common endpoints of concern. The element for nutrients includes phosphate, ammonia, and water soluble nitrogen compounds that may be released from the land application or discharge. Note that the linkage to the air/aerosol pathway is represented by a dotted line to indicate the group considered it to be insignificant. Air/aerosols are primarily volatile organic compounds released from lagoons or the barns directly to the air. Associated chemicals include antibiotics, pesticides, and nutritional supplements released from land application or surface water discharge. Erosion and sediments include stressors which are physical particles from land application, infrastructure, and transportation of supplies, animals, and wastes at the CAFO. Habitat alteration includes stressors such as soil compaction, construction of the facility, fragmentation of habitat, and changes in vegetation. Groundwater loss reflects the net consumption of water by the facility. The odor is an obvious public concern along with noise from the facility and traffic to and from the site. Nitrate distinguishes stressors such as nitrite that are special concerns for groundwater. Methane and GHG are stressors associated with the odor that are known to have health consequences as well. They are separated to tract the health endpoint. Pathogens are shown as stressors for surface and ground water pathways. CAFO workers are most likely to be exposed by inhalation and direct contact, but that is not shown in the conceptual model. Pests, including mosquitoes, rats, and

flies, may carry disease beyond the facility by a terrestrial route. They also contribute to the nuisance factor of the facility.

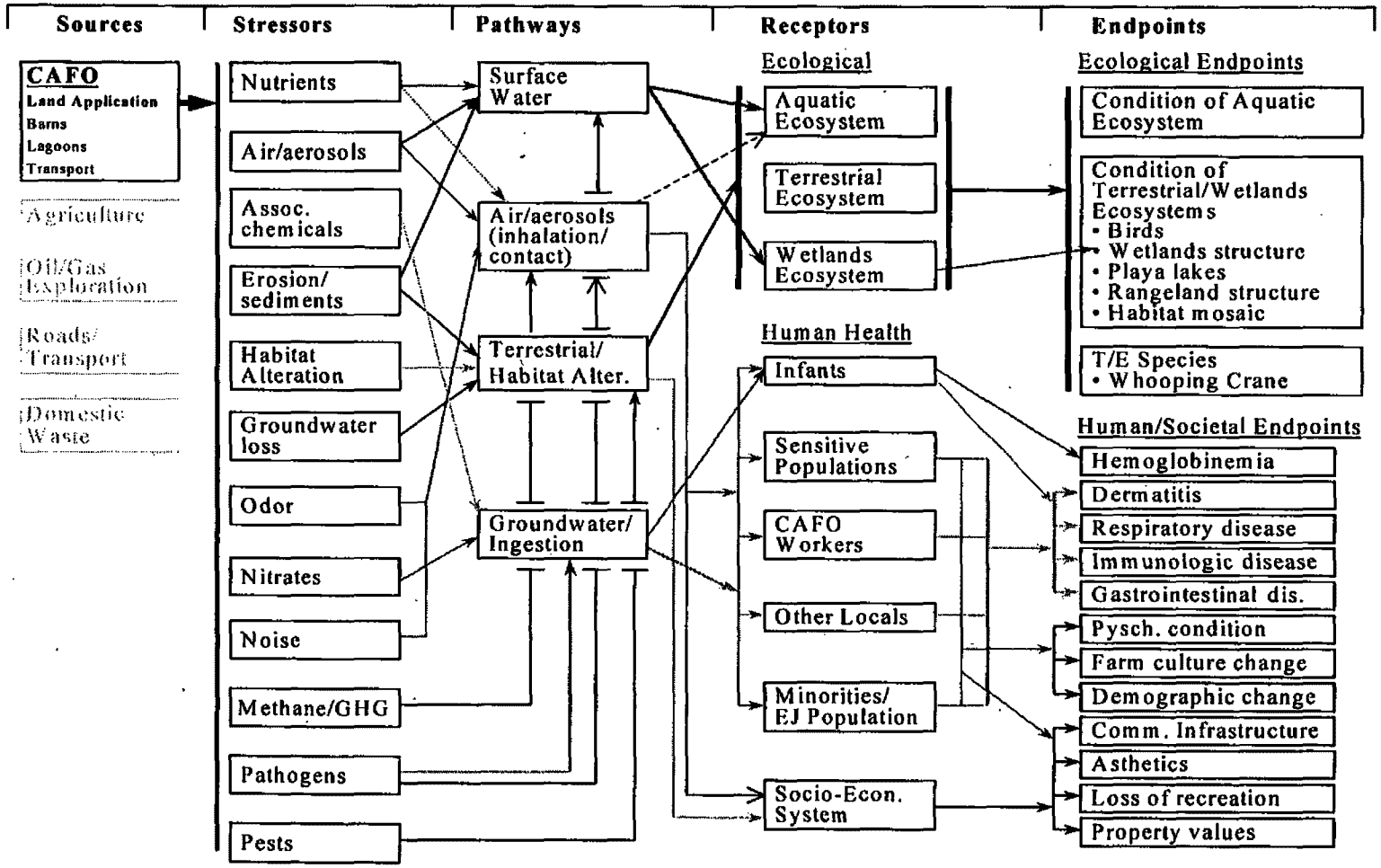
Environmental Pathways: The pathways are key elements of the routes of exposure to the receptors. The four elements shown aggregate the processes of transport, transformation, decomposition, accumulation, and transfer which may occur. The linkages to receptors represent best judgement of the group about those that most likely significant. Surface water in Oklahoma is intermittent and generally does not serve as a drinking water supply. The strongest linkages are to ecological receptors, especially aquatic and wetland ecosystems. Air/aerosols are linked to human health receptors. The hypothesized linkage between the stressor nutrients and this pathway would be linked to all ecological receptors. It is not shown, because it was considered to be insignificant. Terrestrial/habitat alteration integrates the principal changes to the structure of the watershed and the habitats it provides. Presumably, this area is already used for grazing or row crops and human health is not significantly by this stressor. There is an important link between the terrestrial and habitat alteration stressors and socioeconomic receptors.

Receptors As discussed with the workshops, receptors are the entities that are exposed to the stressors. These entities express the effects (endpoints). There are three groups of elements: ecological; human health and socioeconomic. The aquatic, terrestrial, and wetland's ecosystems are considered interrelated and most of the linkages apply to all three. For human health, infants are a special group because of concern about nitrite in private drinking water wells and the possibility of methemiglobanemia . The other elements (sensitive populations, CAFO workers, other off-site residents and minorities) are likely to have the same linkages.

Assessment Endpoints The elements under this dimension of the model are highly aggregated. They relate directly to concerns and values that the stakeholders and risk manager may hold. They may also relate directly to risk management objectives. In most cases, these are not directly measurable endpoints (also called measurement endpoints). Again, there are three groups: ecological, human health, and societal. The ecological endpoints highlight significant aspects of each ecosystem and the whooping crane as a possible threatened and endangered species which may occur in these watersheds. Health endpoints are clustered as three diseases and dermatitis and the special

concern for methemiglobanemia. This cluster also includes asthma. It is linked to four receptors. Note that cancer is not among the elements. The last two clusters are societal endpoints which transcend traditional human health. In the diagram, three receptors (sensitive populations, other residents, and minorities) are linked to these clusters. CAFO workers are excluded because they have an economic interest in the CAFO. Psychological condition of the surrounding community is an endpoint which interacts with elements in both clusters. Odor, noise, pathogens, pests and habitat change are of particular interest for analyzing and ameliorating this endpoint for a CAFO watershed.

CAFO Conceptual Model



Next Steps:These are activities that Region 6 may consider pursuing in the future in order to apply planning and scoping to their CAFO general permitting program. This framework should complement their own CRIA analysis.

The conceptual model:

1. Refine the details of the linkages for key stressors (nutrients, air/aerosols, habitat alteration, odor and methane).

2. Clarify the problem of habitat fragmentation/alteration for ecological effects.

3. Add details for the ecological receptors below the ecosystem level.

4. Discuss the interaction and overlap between the human health receptors, add nursing and pregnant women. Reexamine methiglobanemia.

5. Look for typical data and measurements to address each endpoint.

6. Share and discuss the model with stakeholders.

The analysis plan:

1. Identify data requirements and sources.

2. Set priorities for missing pieces.

3. Formulate hypotheses for the linkages within the model.

4. Develop a crosswalk with the CRIA and general permit process.

5. Establish a generic schedule.

Implementation:

1. Incorporate planning and scoping into a strategy for dealing with CAFOs.

2. Discuss with regional and program managers.

3. Share the revised program with other federal agencies and stakeholders.

4. Test on specific sites.

1 5. Evaluate and improve.

APPENDIX C
CUMULATIVE RISK GUIDANCE PLANNING AND SCOPING WORKGROUP AND OTHER KEY PARTICIPANTS

1997 Guidance Workgroup

Donald Barnes (OA/SAB)
Ed Bender (ORD)
Carole Braverman (Region 5)
Pat Cirone (Region 10)
Penny Fenner-Crisp (OPP)
Michael Firestone (OPPTS)
Edward Ohanian (OW)
Mary McCarthy-O'Reilly (ORD)
Larry Reed (OERR)
Joe Reinert (OP)
James Rowe (ORD)
Bill Wood (ORD)

Practicum Organizers and Case Presenters

Donald Barnes (OA/SAB)
Ed Bender (ORD)
Carole Braverman (Region 5)
Penny Fenner-Crisp (OPP)
Michael Firestone (OPPTS)
Mary McCarthy-O'Reilly (ORD)
Larry Reed (OERR)
Joe Reinert (OP)
James Rowe (ORD)
Bill Wood (ORD)
Vic Serveiss (ORD)- Big Darby
Nader Elkassabany, Wanda Jakob, Al Vaughn (OPP)- Pentachlorophenol
Carole Braverman, George Bollweg (Reg 5)- Chicago Cumulative Risk Initiative
Gerald Carney, Joseph Swick (Region 6) - CRIA for Concentrated Animal Feeding Operations

Council Cumulative Risk Subcommittee
Michael Shapiro (OSWER) Co-Chair
Penelope Fenner-Crisp (OPP) Co-Chair
Steven Galson (OPPTS)
Donald Barnes (OA)
Sally Shaver, Deirdre Murphy (OAR)
Michael Callahan (ORD)
William Muszynski, Roland Hemmett (Reg 2)
Michael Firestone (OCHP)
Peter Grevatt (OSWER)
Tudor Davies (OW)
Joe Reinert (OP)

Appendix D. Planning and Scoping for the National Air Toxics Assessment

Paper under preparation

Appendix E. Surface Impoundment Study - Technical Plan for Human Health and Ecological Risk Assessment

Under preparation and Review by OSWER..

Appendix F. Considerations for Integrating Health and Ecological Risk Assessments-References and Status Report

Under preparation....