Lessons Learned on Planning and Scoping for Environmental Risk Assessments

Prepared by the Planning and Scoping Workgroup of the
Science Policy Council Steering Committee

U.S. Environmental Protection Agency
Washington, DC
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Acknowledgments

This document reflects contributions of many individuals whose talents and toils we gratefully acknowledge.

The case studies mentioned in this document are works in progress, not final resolutions. These individuals deserve special thanks for sharing their work and for responding to comments from their peers at the practica. Nader Elkasabany, Wanda Jacob, and Allen Vaughan (Office of Pesticide Programs) presented and developed the case for Pentachlorophenol. Carole Braverman presented and George Bollweg (both from Region 5) developed the case for the Cumulative Risk Initiative. Gerald Carney (Region 6) presented and developed the case for Concentrated Animal Feeding Operations. We are also indebted to Joseph Swick, a Region 6 risk manager, who defined risk management needs for the CAFO case in our third practicum. David Guinnup and Roy Smith (Office of Air Quality Planning and Standards) provided figures and background for the discussion of the National Air Toxics Assessment. Jan Young and Elizabeth Cuthbertson (Office of Solid Waste) provided figures and detailed information for the discussion on the Surface Impoundment Study and feedback from their Science Advisory Board review.

The work on case studies proceeded through practica (practical applications of the planning and scoping guidance) which were conceived by Dorothy Patton. Drs. Mark Harwell and Jack Gentile, University of Miami, provided instruction based on their experience with the ecological risk assessment process at two practica. Mary McCarthy-OReilly orchestrated the venue and logistics for the practica that stimulated healthy discussions. During the course of three practica, over 100 participants applied the guidance to case studies. Their thoughtful inquiry, patience, and perseverance has improved the planning and scoping methods and added details, beyond the initial guidance, which we present here.

The document was also improved by thoughtful suggestions on stakeholder involvement, terminology, and presentation from many individuals including: Donald Barnes, David Bennett, Patricia Bonner, Michael Callahan, Kerry Dearfield, Deirdre Murphy, Jeff Morris, and Anne Sergeant.

Our sincere thanks,

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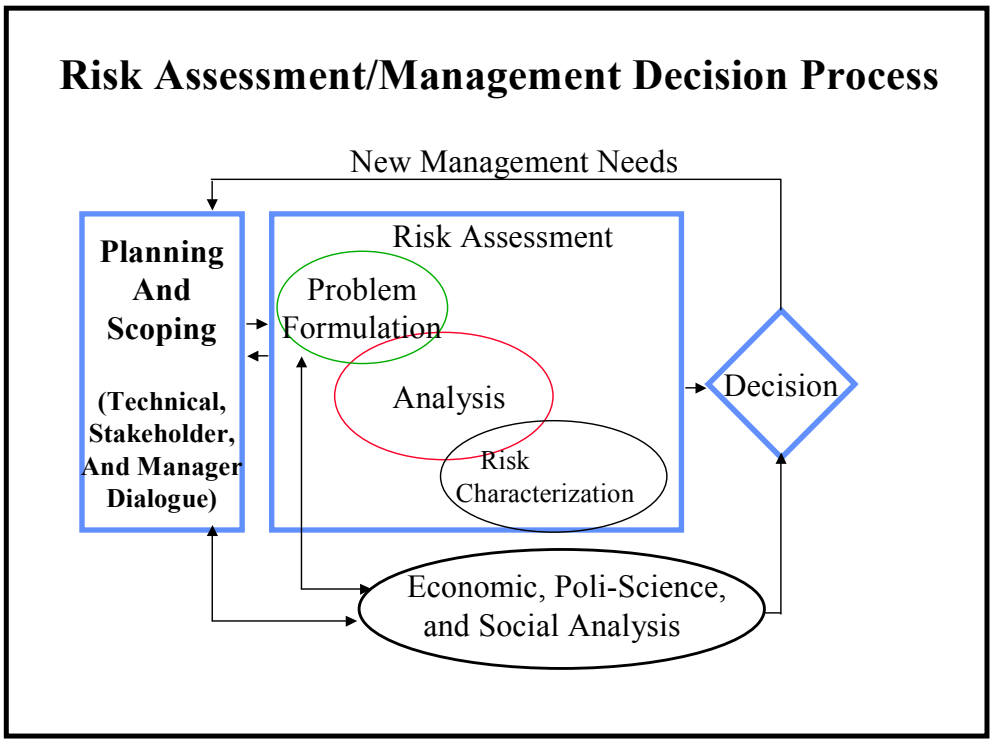
Executive Summary

The purpose of this handbook is to provide early feedback to agency scientists and managers regarding our experiences with planning and scoping as the first step in conducting environmental assessments since the 1997 "Guidance on Cumulative Risk Assessment - Part 1. Planning and Scoping was released (http://www.epa.gov/ordntrnt/ORD/spc/cumrisk2.htm). This handbook is meant to reinforce the concept that formal planning and dialogue prior to the conduct of an environmental assessment can improve the final assessment product in terms of relevancy to an environmental decision and addressing the concerns of decision makers, scientists, economists and stakeholders (where applicable). This handbook is also meant to be a catalyst to encourage agency managers to adopt formal planning and scoping as part of EPA's culture, especially when conducting significant and/or unique environmental assessments. While this handbook is primarily intended to assist agency managers and scientists, it is hoped that its "lessons learned" can also be informative for anyone involved directly or indirectly in the process of developing environmental assessments. It is important to recognize that this handbook does not represent rigid rules which must always be followed, but rather helpful ideas for improving our efforts toward assessing environmental problems.

The figure below depicts how planning and scoping fits into the iterative process to assess and manage environmental risks.



This handbook provides lessons learned from case studies evaluated during a series of practica following release of the 1997 guidance cited above. It is organized around the following key steps:

- risk expert - decision-maker dialogue (management objectives)
- stakeholder involvement
- planning and resource considerations
- defining the scope of an environmental assessment
- development of a conceptual model
- production of an analysis plan

The order in which these steps are taken during any specific assessment may be influenced by the "driver" - for a national assessment, the driver may be a new law which requires up-front agency planning, while a local place-based problem may very well be driven by local stakeholder concerns and involvement. General characteristics for these steps are summarized in the table below for place-based and national assessments:

Steps	Place-based Characteristics	National Characteristics
Stakeholder Involvement	Focuses on diverse groups: a) the affected/interested public and b) regulated parties	Tends to be dominated by expert and advocacy opinions through formal processes.
Defining the Scope and Problem Formulation	Broad discussion, amenable to public concerns and issues.	Legal basis must be satisfied. Additional issues based on technical concerns.
Resources and Planning	Provide public education on problem and process. Accommodate and support public participation.	Provide technical forum, add legal and facilitation support if needed.
Development of a Conceptual Model	Extensive community input helps refine exposure scenarios and health concerns.	Technical and legal input tends to follow the regulatory framework for managing risks.
Risk Management Objectives	Externally driven, multi-agency responsibilities.	EPA proposals, modified based on comments.
Analysis Plans	EPA sets ground rules and definitions, public expands content	EPA, regulated and affected parties negotiate.

The case studies evaluated in this handbook include:

- Registration of Pentachlorophenol under FIFRA (PCP)
- General water permit conditions for a Concentrated Animal Feeding Operations (CAFO)
- Cumulative Risk Initiative for citizen petitions under TSCA (CRI)
- National Air Toxics Assessment of hazardous air toxics (NATA)
- RCRA Surface Impoundment Study to screen for hazardous wastes (SIS)

Key lessons gleaned from the subject case studies include:

1. Early and extensive involvement of the risk manager (decision maker) helped focus the process toward a tangible product.

2. 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 helping to organize everyone's thinking and should result in a better quality assessment.

3. Stakeholder engagement is essential at the beginning, because their patience is directly proportional to their sense of influence in the process. They have been helpful in identifying important public health endpoints that were not initially considered by EPA in the process of developing a conceptual model.

4. Conceptual models are helpful in demonstrating how one program relates to other regulatory activities as well as the relationships between stressors and effects beyond traditional regulatory paradigms.

5. Debate over terminology and brainstorming sessions was necessary to reach a consensus in the practica. A clear set of definitions would aid this process.

6. The planning and scoping process cannot be prescriptive, because the context of each situation is different. Planning and scoping is particularly valuable when the assessment will be complex, controversial, or precedential. At this time, planning and scoping should precede cumulative risk assessments.

7. Clear objectives, resource commitments, and estimated schedules from management will drive the approach and level of detail that can be considered.

8. Explaining uncertainty to stakeholders is critical despite a hesitancy to reveal all that is known and not known about chemicals risks. While revealing these uncertainties may lead to criticism and political ramifications, it can also develop a sense of trust, credibility, and support for the decision making process.

Chapter 1 Purpose, Overview and Organizational Focus

1.1 Background and Purpose

This document supplements the "Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping," July 1997 (hereafter referred to as the 1997 Guidance), and is intended for use by EPA/non-EPA individuals who are interested in the application of planning and scoping to environmental risk assessment and risk management decision making.

Following release of the 1997 Guidance, EPA held a series of practica utilizing several case studies to illustrate the planning and scoping process. The cases considered during the series were: Big Darby Creek (first practicum only); Pentachlorophenol; Cumulative Risk Index Analysis of a Concentrated Animal Feeding Operation; and the Cumulative Cumulative Risk Initiative. The attached case studies illustrate applications of the 1997 Guidance and lessons from that experience. As the 1997 guidance has received wider circulation, additional questions have arisen about its implementation, applications to other assessments and risk management decisions, documentation of the results, and approaches to dealing with stakeholders. The practica and various case studies have increased our experience and understanding of the techniques so that lessons have been learned that will guide future applications of the planning and scoping process. This document is NOT intended to provide guidance for analyses of cumulative or other risks; guidelines and specific program guidance serve that function.

1.2 Overview of the SPC's '97 CR Planning and Scoping Guidance

The 1997 Guidance was developed as much to raise awareness of the need to consider the cumulative risks of exposure to multiple stressors as it was to highlight the importance of a Planning and Scoping dialogue with the assessment and management of risk. Risk assessments use scientific analyses to inform risk management decisions. The analysis may be used to screen candidate stressors or sources for possible adverse health or environmental effects, evaluate planned actions or existing activities and stressors, or support licensing or permits for product development and treatment of the waste streams. Planning and scoping occurs before the risk assessment begins. During planning and scoping, risk experts (including those involved in assessing risk such as ecologists, toxicologists, chemists, along with other technical experts such as economists and engineers) and decision makers work together as a team, informed by stakeholder input, to develop the rationale and scope for the risk assessment and characterization. Listed below are the key steps identified in the 1997 guidance. Although these steps are shown as a sequence, each step may go through several iterations as additional information is gathered.

1.2.1 Determine the overall purpose and risk management objectives for the risk assessment.

The dialogue between the decision maker and risk experts begins with a discussion on risk management objectives and information needed to manage risks for a particular case. The

risk experts and decision maker work as a team to determine how to obtain technical input, whether and how to involve stakeholders, and develop a conceptual model and an analysis plan for the risk assessment. The purpose and risk management objective guide the risk assessment and data collection and establish some guidelines for estimating resources.

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

The boundaries of the problem help define the scope. For example, does the risk occur in a local community or nationally? Problem statements describe the problem or risk situation to be investigated in the risk assessment. Participants should include those with appropriate technical expertise (e.g., scientists, economists, and engineers) and stakeholders (i.e., interested and affected parties) as part of a risk assessment team. Available resources and the schedule for a decision define the resources and time that can be expended to obtain data and analyze the information.

1.2.3 Determine the risk dimensions and technical elements that may be evaluated in the assessment.

The 1997 guidance describes a cumulative risk outline covering the stressors, sources of stressors, environmental pathways, routes of exposure, time frames for exposures, populations exposed, and effects and specific elements to consider for each dimension. This outline is a list of possibilities for what elements will and will not be addressed in the risk assessment. Gaps in knowledge may be filled with assumptions, estimates, or default values. Feasability of obtaining data, its relevance to the problem or risk management objectives, stakeholder concerns about risks, cost, and timing may all affect what elements are included. The rationale for inclusion and exclusion of specific elements should be documented.

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

The conceptual model is both a diagram and narrative description of the theoretical linkages between stressors and adverse effects. It helps demonstrate the plausible cause and effect relationships and the endpoints of concern for the risk assessment. The model (either data driven or hypothetical) can show how multiple stressors might be accumulated or how one stressor may lead to multiple effects. The analysis plan discusses critical data gaps, potential data sources and their value to the risk assessment and deliberations on how the analysis is expected to proceed. 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. The analysis plan also represents an agreement between the assessor and decision maker about the initial scope and level of effort that will be applied to the assessment.

1.3 History and Related Current Agency Activities

Since the 1997 Guidance was released, the Agency has engaged in several planning and scoping activities. In 1998 and continuing forward, the Office of Pesticide Programs began developing guidance to implement requirements for aggregate exposure and cumulative risk assessment of pesticides with common mechanisms of toxicity under the Food Quality Protection Act. The Office of Air and Radiation developed a planning and scoping document and conceptual models as part of its National Air Toxics Assessment (http://www.epa.gov/ttn/atw/sab/ natareport.pdf). The concepts of planning and scoping were derived from concepts that were detailed for Ecological Risk Assessment Guidelines and illustrated in five watershed case studies developed by the Office of Research and Development and the Office of Water. In 2000, a draft Framework for Cumulative Risk Assessment was developed, that described planning and scoping and problem formulation (http://epa.gov/ncea/raf/frmwrkcra.htm). The Agency's current thoughts on stakeholder participation were presented in 2000 as an Interim Policy on Public Involvement. The EPA Risk Characterization Handbook (2000), describes the steps in planning and scoping and the benefits that may accrue by focusing the assessment, addressing appropriate questions for the risk management decision, and examining underlying assumptions and alternate hypotheses about the risks involved (http://epa.gov/ord/spc/rchandbk.pdf).

1.4 Key organizing issues

The key issues associated with planning and scoping are listed as a general sequence of steps; however, planning and resource considerations pervade each of the issues discussed in this section. The steps are iterative and interrelated. For example, questions that may arise with the analysis plan can lead to refinements of the scope or expansion of the participants (see figure).

1.4.1 Risk Expert - Decision Maker Dialogue

Traditionally decision makers and risk experts at EPA (or a state) initiate the process of planning for a risk assessment. They develop the list of participants based on the issues, risk management concerns, affected parties, and technical experience. However, in some instances, the stakeholders request that the agency conduct a risk assessment. Through discussions at the practica and other shared experiences, it has become clear that when the issues relate to communities or specific locations, local representatives should be included in the dialogue. The National Research Council (1996) and the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) described a similar kind of dialogue with stakeholders where values and opinions were discussed in a deliberative phase and data and technical conditions were debated and evaluated by scientific and technical experts in an analytic phase of the dialogue. The case studies that follow illustrate several different approaches for conduicting this dialogue in planning and scoping.

Decision makers help define objectives, schedules, available resources, and approve the analysis plan for the risk assessment. They must decide whether stakeholder input is needed and

if so, what roles stakeholders might have (e.g., information exchange, develop recommendations, or develop agreements). Risk experts may facilitate the discussion of the scope and lead development of the conceptual model and analysis plan. Usually they collect stakeholder data, identify data requirements, select models and default conditions, and explain the rationale for these choices.

1.4.2 Stakeholder Involvement

The extent of stakeholder involvement and commitment to process outcome will depend in part upon their level of interest and their confidence in that process (Glicken, 1999). Stakeholders can help provide information on their concerns, values, and in the case of communities and workers, personal data on exposures and life style. Stakeholders also provide feedback on the relevance and clarity of the risk management objective, scope for the assessment, timing, conceptual model, and analysis plan. Stakeholders may also provide details about releases of stressors from sources, their activity and exposure patterns, and concerns of the community (Folk and Finney, 1992).

Stakeholders may provide technical expertise in hazard and exposure assessment and technology, as well as, 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, health and/or ecological endpoints, and highly exposed/highly susceptible subpopulations and/or lifestages that should be considered in the risk assessment. They may also provide invaluable insights into public values and perceptions on the risk of concern, the preliminary remedial actions being considered and public acceptance of those remedies.

1.4.3 Planning and Resources

It is important that the planning exercise be a transparent effort so that the basis for the final environmental decision (and the alternative options, limitations, and approaches considered but not selected) is 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.

Place-based (e.g., the CRI case study) versus national scale (e.g., the PCP re-registration case study) planning and scoping exercises will necessarily involve different orientations and resource requirements (including those for possible stakeholder involvement) in constructing the conceptual model and analysis plan.

Local versus National Scale Problems

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
- define specifc lifestages of possible concern for health assessments
- identify and inform relevant local/regional stakeholder groups, citizens

If national scale:
- 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 indicators of human health, ecological effects (e.g., epidemiology data, USGS trend data)
- identify and inform the relevant national stakeholder groups

1.4.4 Defining the Scope

Defining the scope - what's in and what's not - is based on the six dimensions of Cumulative Risk (Population at Risk; Stressors; Sources; Routes and Pathways of Exposure; Endpoints; and Time Frame. In the cases studies, potential elements for each dimension were developed by brainstorming and discussions with technical individuals (scientists, economists, engineers, and planners) and stakeholders. Specific elements were selected on specific bases, such as resources; available data; ability to measure, regulate, or control. The scope describes the currently identifiable context of the environmental risk that will (or can) be included in the assessment (see text box for examples).

1.4.5 Conceptual Models

To develop an accurate picture of the risks and risk management options, the conceptual model must explain the elements for each risk dimension; i.e., populations at risk (human, ecological entities, landscape or geographic concerns), sources of stressors, stressors, pathways and routes of exposure, assessment endpoints, and time frames of exposure. Stakeholders and outside expert participants are helpful in exploring 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 stressors, potential loadings, and pathways 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.

The conceptual model should be accompanied by a detailed narrative explaining the rationale for the elements and their linkage in the conceptual model. 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 (figure 1-1) adds confounding factors that contribute to how the effect is expressed. In the figure, adverse ecological effects lead to adverse "quality of life" effects. Quality of life issues are often concerns for siting or expanding existing facilities or projects. Although they are beyond the traditional considerations of risk assessment guidelines, quality of life issues were of great concern to people in the case studies.

Six Questions that define a Risk with examples of Cumulative Risk

1. **Population**: Who/What/ is at risk?
   -Example-Hispanic toddlers or the process of nitrogen fixation
2. **Sources**: What are the relevant sources of stressors?
   -Example-Auto exhaust or exotic species
3. **Stressors**: What are the stressors of concern?
   -Example-Lead or overfishing
4. **Pathways/Routes of Exposure**: What are the relevant environmental pathways/routes of exposure?
   -Example- Surface water/Drinking water ingestion or skin contact
5. **Endpoints**: What are the effects due to exposure? (Assessment/measurement endpoints)
   -Example-cancer/estimated number of cases
6. **Time Frames**: What are the relevant time frames of exposure to a stressor or mixtures of stressors?
   -Example-one generation or 40 hours/week

1.4.6 Analysis Plans

The analysis plan is the final stage of planning and scoping before the risk assessment. The analysis plan identifies data needs, information sources and technical approaches for evaluating risk hypotheses presented in conceptual models and other important issues identified during planning and scoping that may be pursued during the risk analysis phase. Those hypotheses considered more likely to contribute to risk can also be 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 and cost of obtaining them can be taken into account. The analysis 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.

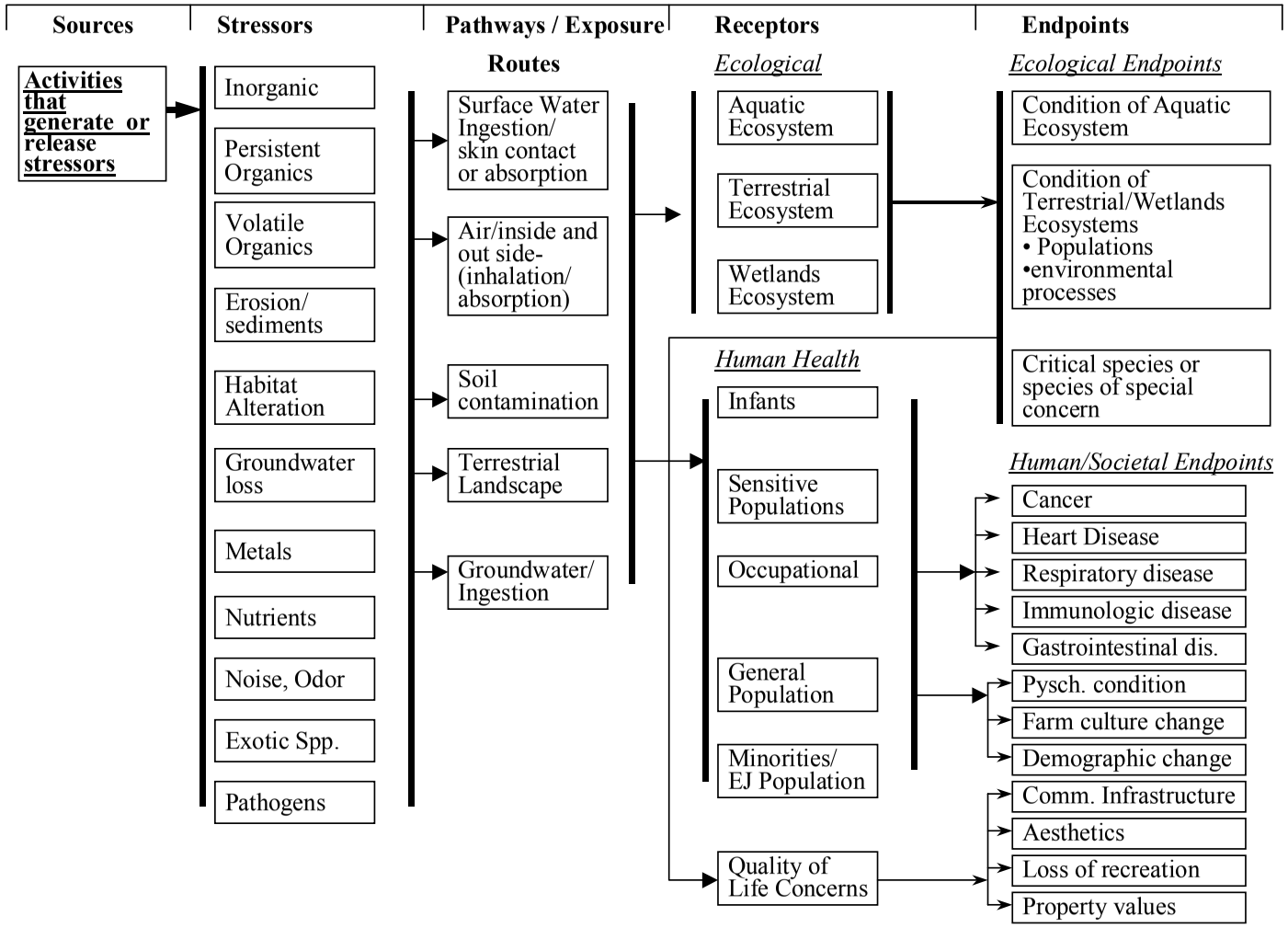
1.5 Case Studies in this Handbook

The cases considered during the 1998-9 practicum series were: General water permit conditions for a Concentrated Animal Feeding Operations (CAFO); Registration of Pentachlorophenol under FIFRA (PCP); and Cumulative Risk Initiative for citizen petitions under TSCA (CRI). Planning for an ecological risk assessment of Big Darby Creek was discussed at the first workshop, but that watershed case study is not included in this document.

In addition, other cases are included to show additional aspects of planning and scoping: a) the National Air Toxics Assessment (NATA) which is a national screening activity for risks from urban air toxic organic chemicals and b) the Resources Conservation and Recovery Act Surface Impoundment Study(SIS) to screen for cumulative risk from hazardous constituents in wastewater treatment ponds. The results of the practica case studies are summarized in Appendices B-D and lessons learned from the other cases are summarized in Appendix E.

The material in the appendices describe how each of the cases addressed the planning and scoping process. The CAFO case, was developed from an approach that Region 6 developed for watershed protection. The conceptual model considers cumulative effects from permitting CAFOs on human health, ecological resources, and quality of life. The PCP case involved detailed technical and risk management discussions which lead to detailed models and analytical plans for the risk assessment. Stakeholders were involved from the beginning in the CRI. They found that planning and scoping helped develop trust between citizen groups and EPA and commitment to a long term study of community hazards. The additional two national studies, NATA and SIS, illustrate how analytical plans and detailed models can help analysts, decision makers and customers focus on the most pressing problems. All of these cases are, in a sense, works in progress. More lessons will be learned in the future.

Figure 1-1. Conceptual Model
with Examples of Possible Elements and Linkages



Chapter 2 Highlights from Case Studies

The primary goal of planning and scoping is to identify scientific and technical information and stakeholder concerns about potential environmental risks that is relevant to inform decisions on risk reduction and management. This is essential in the planning phase to produce a more focused, cost-efficient risk assessment which is defensible (provides a record of initial decisions made, approaches taken and parties involved), allows future accountability and

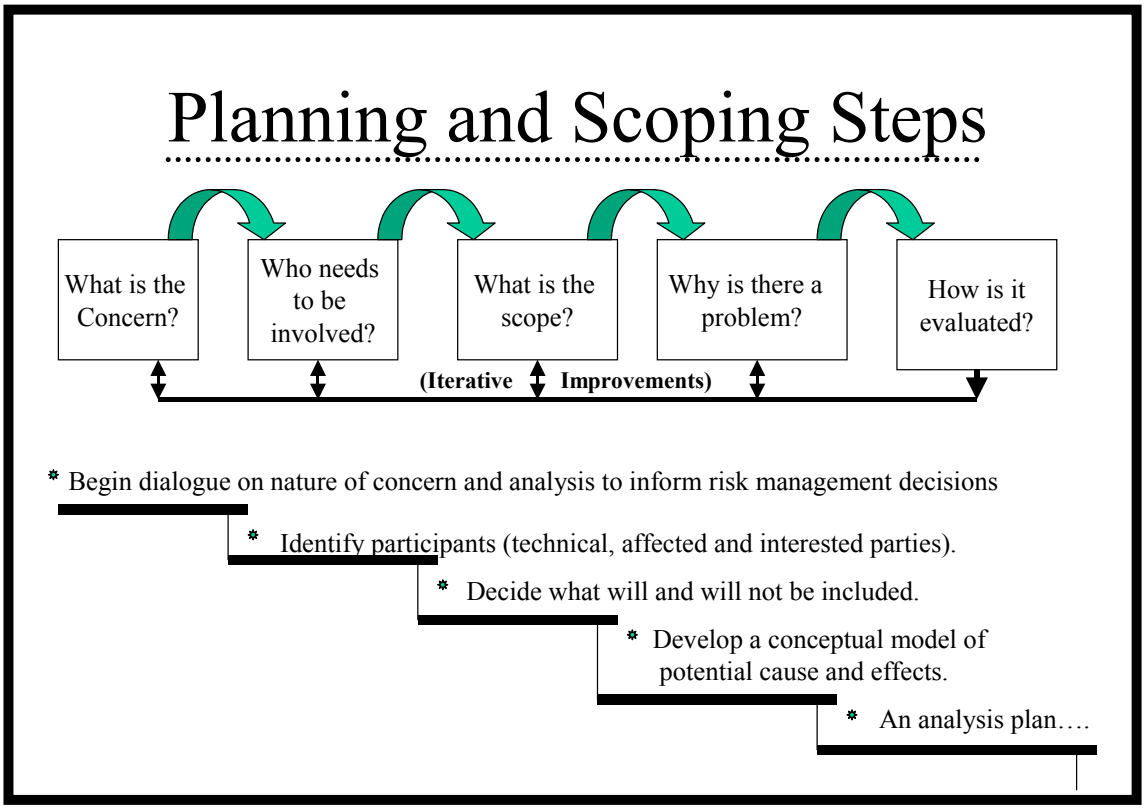


Figure 2.1 Key Steps and Questions for Planning and Scoping

provides a more rational framework for appropriate revisions as needed. Figure 2.1 above shows key questions and activities to accomplish the general steps in planning and scoping. The discussion in this chapter is organized along each of these steps, even though several cases did not follow all of the steps. The process is iterative and involves feedback and adjustment as new information is gathered from participants and as decisions are made to refine the scope of the assessment. It allows for consideration of economic and other data beyond the traditional risk assessment process.

2.1 Risk Assessment and Risk Management Dialogue

Traditionally, EPA risk assessors have been asked to estimate the risks of one or more chemicals, risk assessments were performed, and risk managers would then discuss the assumptions and basis for the assessment, and in many cases, the assessment would be revised to reflect changes in the scope, assumptions, or problem from the risk manager or from public comments.

The 1997 Guidance on planning and scoping recommends that the purpose for the risk assessment be discussed at the outset between the risk assessor and risk manager. From case studies with communities, we have learned that the risk assessor may actually be a team of scientists, economists, and engineers from EPA and from stakeholders. Risk managers, in some cases may be stakeholders and local public officials. This team should plan the process for defining the problem, conducting the assessment or technical activities, inviting/involving stakeholder participation, risk management, and evaluation. All projects are more effective if this team develops a proposal, including tentative schedules that reflect available resources and time. The team could also delegate or suggest leads for discussions.

Agency guidance, glossaries of technical, regulatory and other terms needing definition, and public information packages should be developed to guide the participants in the dialogue. The legal basis for the decision and pertinent policy requirements should also be described.

Planning and scoping is used to frame the activity and the documentation that will be developed. The scope and level of effort that goes into the document is often bounded by the purpose or application that is intended by the manager and the legal requirements or authority of the sponsoring organization. For example, screening assessments require less detail and input from outside parties and the output is usually needed quickly. For cumulative risk assessments, problem formulation will set those boundaries. It is important not to initially narrow the focus based on methods, data, and information that is available at this time, but to allow the scope to reflect concerns from stakeholders. The problem statement can be revised as the analysis plan is developed.

2.2 Planning and Resources

The dialogue discussed earlier should define the process and schedule for planning and scoping. For example, in the RCRA Surface Impoundment Study, the assessment deadline was established by a consent decree and the planning and peer review steps were established to assure the regulatory deadline was achieved. During planning and scoping, many choices are made about the quality of data required for a risk management decision and the scope of the assessment which may affect the time and resources required for conducting the assessment. In the CRI case study, the lack of data on human exposure, dwindling resources, and lack of stakeholder confidence about the assessment of indoor air quality lead to a change in the approach from a cumulative risk assessment to a cumulative hazard assessment.

2.3 Stakeholder Involvement

Depending on the nature and complexity of the issue, planning and scoping may bring stakeholders into the process during the early deliberations about the problem and on what can and cannot be included in the risk assessment. If EPA is convening the process for a community, such as the CAFO case study, stakeholders need some background about the process and how they may participate. To receive effective stakeholder contributions, we need to get some kind of commitment from them, if possible, to accept the validity of the results of the assessment, regardless of what it shows. In some cases, particularly for national rules, individual stakeholders may not be willing or able to participate in the full process and so it may be necessary to provide them with technical support, suggest the appointment of a representative or spokesperson to represent an adversely affected group, and/or provide special access, summaries or data systems they can consult at their convenience. Websites worked well in the CRI, providing access to monitoring data. Other regions have used special information and tutorial sessions preceding public meetings. Professional organizations and members of the regulated community routinely respond to public notices in newspapers, websites, or the Federal Register. Stakeholders may also require technical assistance to comprehend agency technical reports or other data. Agency policy requires that EPA accommodate requests from public citizen groups wherever possible, e.g., technical assistance grants in the Superfund Program. One lesson from the CRI is that citizen stakeholders' patience in that case was high because they had a sense that their comments were being considered in the process.

Stakeholders in community risk assessments can provide invaluable insights about background and baseline conditions which contribute to risks. They can also provide details about personal habits and activity patterns which should be considered particularly for patterns of exposure and mitigation strategies. Stakeholders frequently view the federal government as one huge entity that has common access to all information and broad authority to control any activity or facility that is contributing to their potential exposure and adverse health conditions. Some stakeholders also assume that personal lifestyles (e.g., smoking, health care, exercise, and diet) have little to do with environmental risks. The challenge to the Agency is to get the public to realize the importance of those personal lifestyle choices and that an even-handed assessment must consider all significant sources of risk which have a significant impact on the ultimate environmental decision.

Public participation [in planning and scoping] leads to the incorporation of new kinds of information in environmental decision-making and it has shifted the model from one where the government defines the process and

EPA's Public Involvement Functions

1. Identify the interested and affected public
2. Provide information and outreach to them
3. Establish public consultation activities
4. Assimilate information and provide feedback
5. Plan and budget for public feedback
6. Consider technical or financial assistance as needed

(EPA, 2001. Interim Policy on Public Involvement in Regulatory Decisions)

invites stakeholders to participate toward one in which "every affected group participates" (Bear, 1994). EPA should plan activities to support public involvement, provide background on the problem and EPA perspectives for risk, discuss expectations and needs with stakeholders, and keep stakeholders informed and involved on the key decisions. These principles have been formalized in recent Agency policy. Agency staff need advice and training on how to obtain useful information on risk perceptions, stakeholder concerns and values from stakeholders.

2.4 Defining the scope

It is very helpful to review the definitions of the risk dimensions before brainstorming begins (i.e., develop as many relevant ideas and approaches as feasible). The group should include stakeholders or their spokespersons as well as the traditional assessors and other expertise. In our workshops, exhaustive lists were developed initially, and then criteria were applied to narrow the list. In more than one instance, we made the mistake of narrowing the list based on data availability; however, input from actual stakeholders often led to expanded lists of stressors, sources, or exposure scenarios. Time frames (length of exposure, frequency, etc.) are part of the working definition of cumulative risk, but they may not apply or be needed for some assessments.

2.5 Development of a Conceptual Model

Steps for Developing Conceptual Models

1. Brainstorm what could be included.
2. Prioritize the elements for each dimension.
3. Document reasons for any deletions.
4. Develop linkages among the elements.

Each conceptual model was case specific. The conceptual model may be a simple diagram (as for screening) or a complex, multi-level graphic representation of the sources, stressors, environmental pathways, routes of exposure, and receptors. In several cases, conceptual models were developed in a hierarchical fashion, with hyperlinks to show details for technical discussions of the data requirements and hypothetical cause and effect relationships between stressors and receptor effects.

In practice, the conceptual model is a valuable tool for communication with stakeholders and as a flowchart for planning the analysis. For some audiences, the broad overview was sufficient. In the CAFO case, the model included background conditions, showed feedback from stress on the aquatic ecosystem to secondary impacts on recreation and property values. We also found that training in special software is needed so models can represent both broad and specific relationships.

2.6 Analysis Plan

The analysis plan is the final stage of planning and scoping and has been adapted from the Ecological Risk Assessment Guidelines, section 3.5. The plan describes data needs (qualitative and quantitative), data quality objectives, sampling approaches, and analysis steps for the risk assessment. The Surface Impoundment Study Technical Plan and the National Air Toxics Assessment planning and scoping document provide extensive details about how data are collected, combined, and analyzed for screening risk assessments.

2.7 Planning and Scoping of National versus Place-based Assessments

There are some significant differences in the process for planning and scoping of community or place-based assessments and national assessments which focus on a sector or category of sources across the entire country. These differences are important from a number of standpoints. For example, the general public is usually less interested in the national assessments, so stakeholders tend to reflect technical concerns and economic interests of national organizations from the regulated community and environmental interests. Some general observations gleaned from these case studies and others about the components of planning and scoping for these broad categories of assessment appear in Table 2.1.

Table 2.1. General Characteristics of the Steps in Planning and Scoping for National and Place-Based Risk Assessments.

Steps	Place-based Characteristics	National Characteristics
Stakeholder Involvement	Focuses on diverse groups: a) the affected/interested public and b) regulated parties	Tends to be dominated by expert and advocacy opinions through formal processes.
Defining the Scope and Problem Formulation	Broad discussion, amenable to public concerns and issues.	Legal basis must be satisfied. Additional issues based on technical concerns.
Resources and Planning	Provide public education on problem and process. Accommodate and support public participation.	Provide technical forum, add legal and facilitation support if needed.
Development of a Conceptual Model	Extensive community input helps refine exposure scenarios and health concerns.	Technical and legal input tends to follow the regulatory framework for managing risks.
Risk Management Objectives	Externally driven, multi-agency responsibilities.	EPA proposals, modified based on comments.
Analysis Plans	EPA sets ground rules and definitions, public expands content	EPA, regulated and affected parties negotiate.

2.8 Basic Lessons

1. **Early input from decision makers and stakeholders is essential.** Risk assessments need to identify and evaluate the problems that these groups want to solve. The nature of the decision, the degree of public concern, the level of scientific understanding, and the complexity of the issue will profoundly affect the input that is needed and how it can be obtained. Public involvement policies and procedures should be consulted to assure requirements are met.

2. **Stakeholder participation is most beneficial when the participation process, expectations, and responsibilities for all parties are discussed and accommodated up-front**. EPA should develop background materials and plan for stakeholder support if public involvement is desired. For example, there could be discussion with stakeholders on their roles (e.g., as advisors or decision makers), possible outcomes from the assessment, and what EPA plans to provide.

3. **When the risks are complex, the context for exposure and risk management must be considered in planning and scoping steps**. The approach will likely be tailored by an iterative process. Sometimes screening or range finding analyses precede formal risk assessments. Stakeholder input on their potential exposure, diet, and lifestyle can be considered in exposure scenarios and risk communication.

4. **Conceptual models can help reveal assumptions, provide common background and definitions for participants, and explain choices for the assessment**. They can be developed at different levels of detail to explain technical issues and management options and to focus input and data collection. Conceptual modeling provides opportunities for integrating the analysis across sources, receptors, and endpoints.

5. **Risk managers are critical players in the planning and scoping process**. In some cases, the public is the principal risk manager and a key decision maker. Risk managers should clarify risk management objectives to help formulate the problem for the risk assessment.

6. **Planning and scoping has improved individual assessments of risk even though the analysis may be qualitative, focus on hazard, or be limited to a single stressor**. The process is especially useful for complex, controversial, or precedential assessments. Stakeholder input and discussion helps validate the process for selecting risk management options.

7. **Analysis plans that provide roadmaps and data inventories for the risk assessment inform participants and decision makers as well as risk assessors**. Planning and scoping is especially desirable to use for situations which involve cumulative risk assessments, multiple stakeholder groups, multiple stressors, a high degree of uncertainty, input and data from multiple groups, and high costs for analysis.

8. **All of the case studies described are works in progress**. For some cases, initial stages of analysis have begun; for other cases, the approach is being refined and applied to new problems. As risk management decisions are made and implemented, we can use this experience to reflect further on the role of planning and scoping.

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Appendix A. Risk Assessment Terminology

This is a partial list of risk assessment terms that are 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 dietary and residential 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 is calculated based on the hazard identification, dose-response assessment, and the exposure assessment.

Assessment endpoint- an explicit expression of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes.

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.

Dimensions of risk- these are components of risk from the 1997 guidance (see USEPA, 1997), including sources of stress, stressors, pathways and routes of exposure, receptors, and effects.

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

environment.

Elements of Risk- these are specific aspects of each dimension that may be included in an assessment. Elements comprise the scope of the risk that will be described in the conceptual model and analysis plan (USEPA, 1997).

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.

Risk Assessment- a process that evaluates the likelihood that adverse effects such as disease or injury) may occur as a result of exposure to a chemical, physical, or biological agent.

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.

Appendix B. Case Study on Concentrated Animal Feeding Operations

B.1 Background History

Concentrated Animal Feeding Operations (CAFOs) are a common and significant concern throughout EPA Region 6. CAFOs are large farms (often occupying a quarter square mile—significant in terms of watershed areas) and they produce enormous quantities of waste that is discharged 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). 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 which cover many CAFOs expired in 1998, and Region 6 wanted to consider if cumulative impacts from CAFOs and other existing regional sources (agriculture, oil and gas exploration, roads and transportation infrastructures, and domestic waste) may exceed applicable water quality standards, pose threats to groundwater supplies, or degrade air quality. 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 was public concern over the rapid expansion of CAFOs and their impact on surrounding communities.

There was no method or approach to determine when a watershed reaches a significantly polluted state. Region 6 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.

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

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).

B.2 Highlights and Key Findings

B.2.1 Risk Assessor - Risk Manager Dialogue

During the third workshop, a Region 6 risk manager assisted the case presenter. He said that the risk management objectives for Region 6 were two-fold:

1) develop new general permits for CAFOs in the state of Oklahoma
2) identify the point where cumulative impacts may exceed the current permit requirements.

B.2.2 Defining the Scope

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.

Participants in the third practicum 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. 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.

B.2.3 Planning and Resources

In the practica, the participants brought different levels of knowledge to each session. Most were unfamiliar with CAFOs and few had experience with water quality issues. For region 6, planning and scoping has been used to expand this project to a national strategy on permitting for CAFOs. They have pooled resources with state and county agricultural officials, regional land-use planners, natural resource agencies, and universities and colleges to strengthen the data base and analytical capability.

B.2.4 Stakeholder Involvement

Region 6 program managers and staff involved with NEPA enforcement, NPDES permits, watershed quality, groundwater, surface water, risk assessors, RCRA, Superfund, and GIS comprised the in-house experts. Stakeholders for this case include 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.* 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 the 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

Region 6 has developed background materials based on the planning and scoping process for public involvement. They routinely brainstorm with community groups to develop ideas for conceptual models on the key human health and environmental concerns.

B.2.5 Development of a Conceptual Model

The Concentrated Animal Feeding Operations (CAFO) model includes input and deliberation from three practica, regional meetings, and stakeholder comments. The model includes the major elements of each planning and scoping dimension. The relationships flow from the sources that produce categories of stressors through environmental pathways and routes of exposure to affect receptors. The endpoints were for ecological, health or economic system (quality of life) effects. The setting 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. In the figure, solid vertical lines are used to show common linkages between elements within a dimension.

Stressors

Stressors were aggregated with consideration to their pathways and routes of exposure to particular receptors, and common endpoints of concern. Nutrients includes phosphate, ammonia, and water soluble nitrogen compounds that may be released from the land application or discharge. 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 physical particles from land application, infrastructure construction, and transportation of supplies, animals, and wastes at the CAFO. Habitat alteration includes soil compaction, construction of the facility, fragmentation of habitat, and changes in vegetation. Groundwater loss reflects the net consumption of water by the facility. Odor is an obvious public concern along with noise from the facility and traffic to and from the site. The Nitrate stressor includes nitrite that are special concerns for groundwater. Methane and greenhouse gases are stressors associated with the odor that are known to have health consequences as well. 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/Routes of Exposure

The environmental pathways are represented by four elements shown to aggregate the processes of transport, transformation, decomposition, accumulation, and transfer. The route(s) of exposure for the receptors are associated with each medium and represent best judgment of the group about those that are most likely significant. Surface water flow in Oklahoma is intermittent and generally does not serve as a drinking water supply. The strongest linkages are between nutrient stressors and ecological receptors, especially aquatic and wetland ecosystems. Stressors in air or aerosols are most strongly linked to human health receptors. The hypothesized linkage between the stressor nutrients and air 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, the land is already used for grazing or row crops and human health is not significantly affected by this stressor. There is also an important link between the terrestrial and habitat alteration stressors and socioeconomic receptors.

Receptors

As discussed during the workshops, receptors are the entities that are exposed to the stressors. These entities exhibit 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 stressor-effects linkages apply to all three. For human health, infants are shown as a special group because of concern about nitrite in private drinking water wells and the possibility of methemoglobinemia. The other elements (sensitive populations, CAFO workers, other off-site residents and minorities) are likely to have the same stressor-effects linkages.

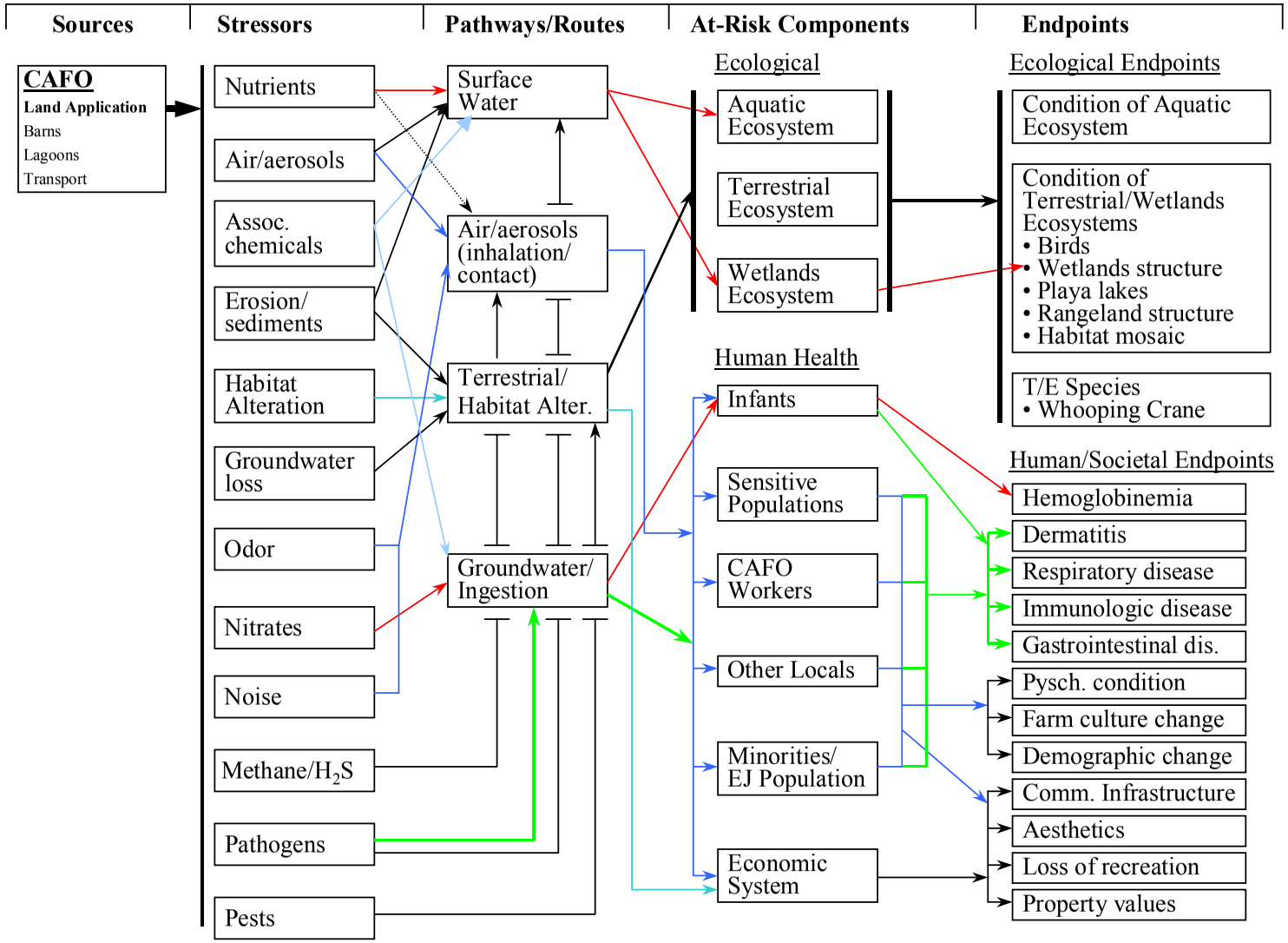
Assessment Endpoints

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 methemoglobinemia. This cluster also includes asthma. It is linked to four receptors. Note that cancer is not among the principal effects. 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 analysis and risk management of the CAFO in a watershed.

The CAFO discussion lead to a very detailed conceptual model, with a very high degree of aggregation. In some cases, such as nutrients, the level of aggregation in the model was too great to fit the control technologies (i.e., nitrogen and phosphate removal require different technologies in waste water systems). Expert judgement was used to select which linkages were highlighted. While it was easier to communicate the broad set of potential concerns to the public, the development of the analysis plan was difficult to extract from the broad aggregation. Therefore, a more detailed version of the model was retained for technical use.

Since the practica, Region 6 has used written materials and detailed sub-models to show how stressors like nitrogen and phosphate affect human health and ecological receptors. The additional details (e.g., for individual stressors such as nitrogen and phosphorus, or pathways of exposure) allow analysts to separate potential risks so their significance and susceptibility to management options can be evaluated. Aggregation in the model does not necessarily mean that the risks are combined.

CAFO Conceptual Model



B.2.6 Analysis Plan

The practica participants did not develop an analysis plan for the CAFO, but they did discuss how it might be done. They said that the analysis plan should provide the rationale for limiting the scope of the risk assessment, because it is not possible to address everything in the conceptual model. The criteria for analyzing a stressor-effect linkage should include feasibility, likely significance (contribution to the overall risk), and data availability or likelihood of obtaining it. The analysis plan should describe the tools to be used and explain the procedures and rationale for the analysis. It should discuss data limitations, assumptions, and uncertainties.

Under NEPA, permit applicants usually prepare and submit their own Environmental Impact Analysis (EIA), which requires them to do their own planning and scoping. Since national program offices and regions generally do not require EIA/EISs for permits, EPA may want to add EIA-relevant questions to its permit application. Region 6 is working to: identify data requirements and sources in collaboration with other agencies, set priorities for missing pieces, formulate hypotheses for the linkages within the model, develop a crosswalk with the CRIA and general permit process, and establish a generic schedule.

B.3 Lessons Learned

1. Early involvement of the risk manager (decision maker) helped focus the process toward a tangible product. Once the discussion focused on establishing the terms and conditions of a general NPDES permit for the facility, the data requirements, a general approach, and processes for involving the public emerged quickly.

2. Participants developed a conceptual model which identified specific public health endpoints that were not covered in the Region 6 CRIA. Region 6's case presenter indicated that the Region probably will go back and add them. EPA staff who were not familiar with the NPDES program or CAFOs assumed the roles of community stakeholders. The workshops helped the region to practice communication techniques with stakeholders for other problems.

3. Initially, the key public concern with CAFOs was for odor. Although this was not related to known health risks, it could still be included in this discussion and management options will be included in the general permit. After the workshops, further literature reviews uncovered research on health effects of some odors, particularly from ammonia compounds.

> Region 6 used the planning and scoping process to create a strategy for dealing with CAFOs and has also applied it to other community based issues, even where a risk assessment may not be developed.

4. Debate over terminology and brainstorming sessions were necessary to reach a consensus. A clear set of definitions would aid this process.

5. The planning and scoping process cannot be prescriptive, because the context of each situation is different. Clear objectives, resource commitments, and estimated schedules from management will drive the approach and level of detail that can be considered.

6. Consideration of "measurement endpoints" during formulation of the conceptual model may unduly restrict the model because of concerns over data availability.

7. The workshop participants observed that EPA needs to overcome a cultural bias within the agency that risk assessment is an internal function. Stakeholder engagement is essential at the beginning.

8. The intent of NEPA is to include all stakeholders in the scoping process. Experience with NEPA improved how ideas, recommendations, and agreements were solicited from stakeholders.

Region 6 used planning and scoping to create a strategy for dealing with CAFOs, which they discussed with regional and program managers, other federal agencies, and stakeholders. The planning and scoping process has also been applied to other community based issues, even where a risk assessment may not be developed.

Appendix C. The Reregistration of Pentachlorophenol: Case Study

C.1. Background/history

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 (now called "Special Review") 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 commercial/residential structures, such as decks, fences, and walkways.

C.2 Purpose

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.

C.3. Highlights and Key Findings

C.3.1 Risk Assessor-Risk Manager Dialogue

The purpose of planning and scoping in this case was to develop a risk assessment to inform a pesticide use Reregistration Eligibility Decision (RED) document for heavy duty wood preservatives. Participants of all three workshops accepted this regulatory purpose without debate.

C.3.2 Defining the scope

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 be performed separately and later integrate the results with the PCP component.

C.3.3 Planning and Development of a conceptual model

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.
The participants considered the use of treated wood for utility poles and their disposal after use 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, OPP/AD had prepared a tentative PCP conceptual model for ecological effects (Figure 1). The third workshop reviewed that model and recommended several changes:

- Create one inclusive ("generic") conceptual model and sub-models as appropriate to expand 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 and highlight the critical pathways from the top of the model to the bottom.
- Add ingestion or food chain as a pathway.
- 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 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 other sources of stressors, 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 imposed by the workshop, and complete a draft submodel for clean PCP (Figure 2). 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.

Most participants 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 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 duration and frequency of exposure are important variables that influence endpoints and they 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 micro-contaminant submodel for PCP, again using the wood treatment plant as the source (Figure 3).

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 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 yet been completed, but is under study.

C.3.4 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:

1. 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).

2. 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 th National Coalition Against the Misuse of Pesticides. 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.

3. 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.

4. 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.

5. 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.

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

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

C.3.5 Lessons Learned

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

A. Ecological and human health assessment planning can be harmonized conceptually, but a common vocabulary will be needed.

B. Both top-down and bottom-up approaches to developing conceptual models are useful—there is no wrong method.

> Risk assessors and risk managers already perform some aspects of planning and scoping but the planning and scoping process helped organize thinking, develop trust among participants, and should produce a quality assessment.

C. 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.

D. The interplay between risk assessors and risk managers was valuable. For instance, it provided insight into the potential PCP risks to workers versus neighbors.

E. 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 helps organize everyone's thinking and should result in a smoother and better quality assessment than is possible without it.

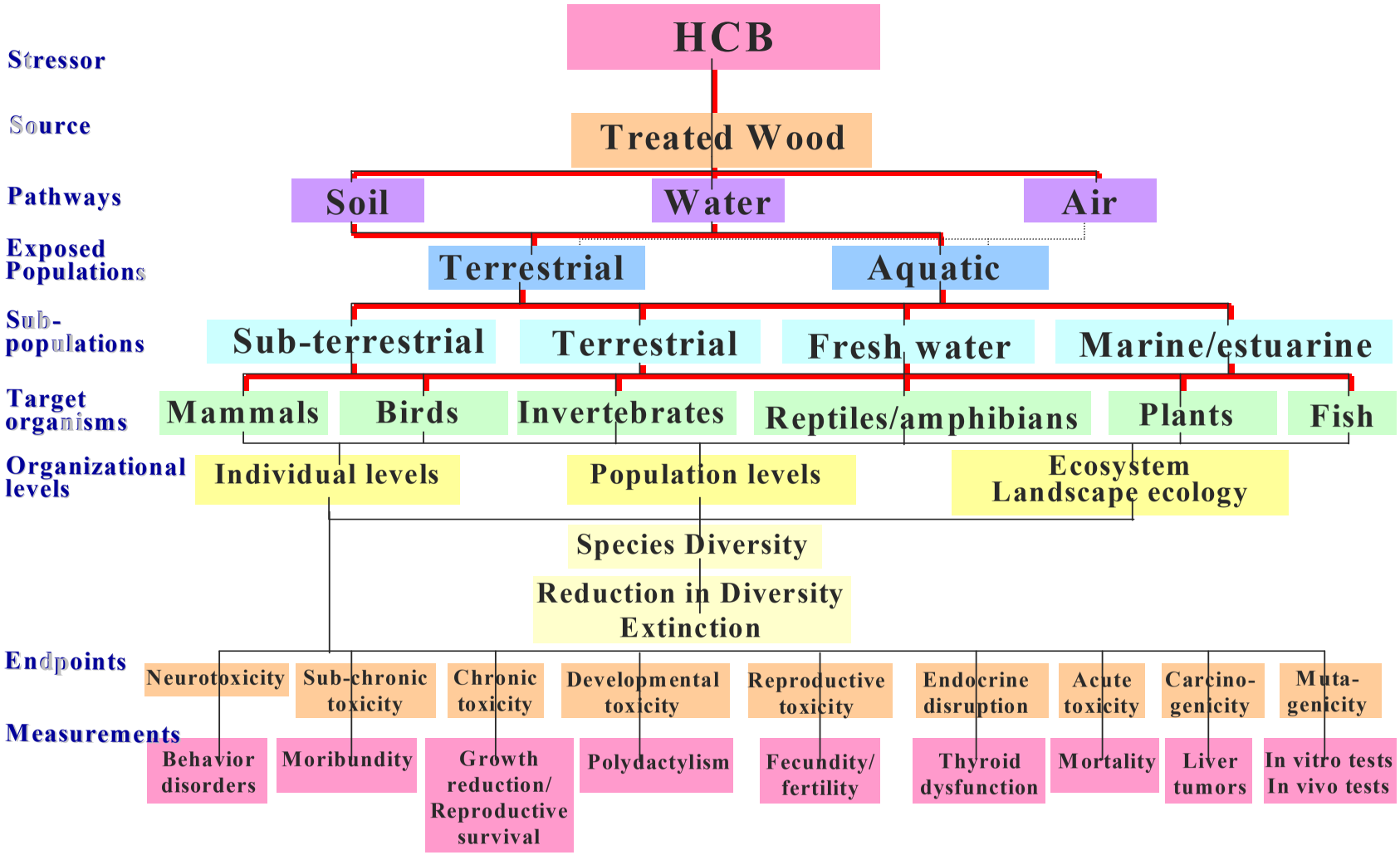
F. Planning and scoping offers a good opportunity to identify problem scenarios early and the potential risk management options to address them. It also offers an opportunity to determine if data exist to compare management options and to develop contingency plans for potential risks.

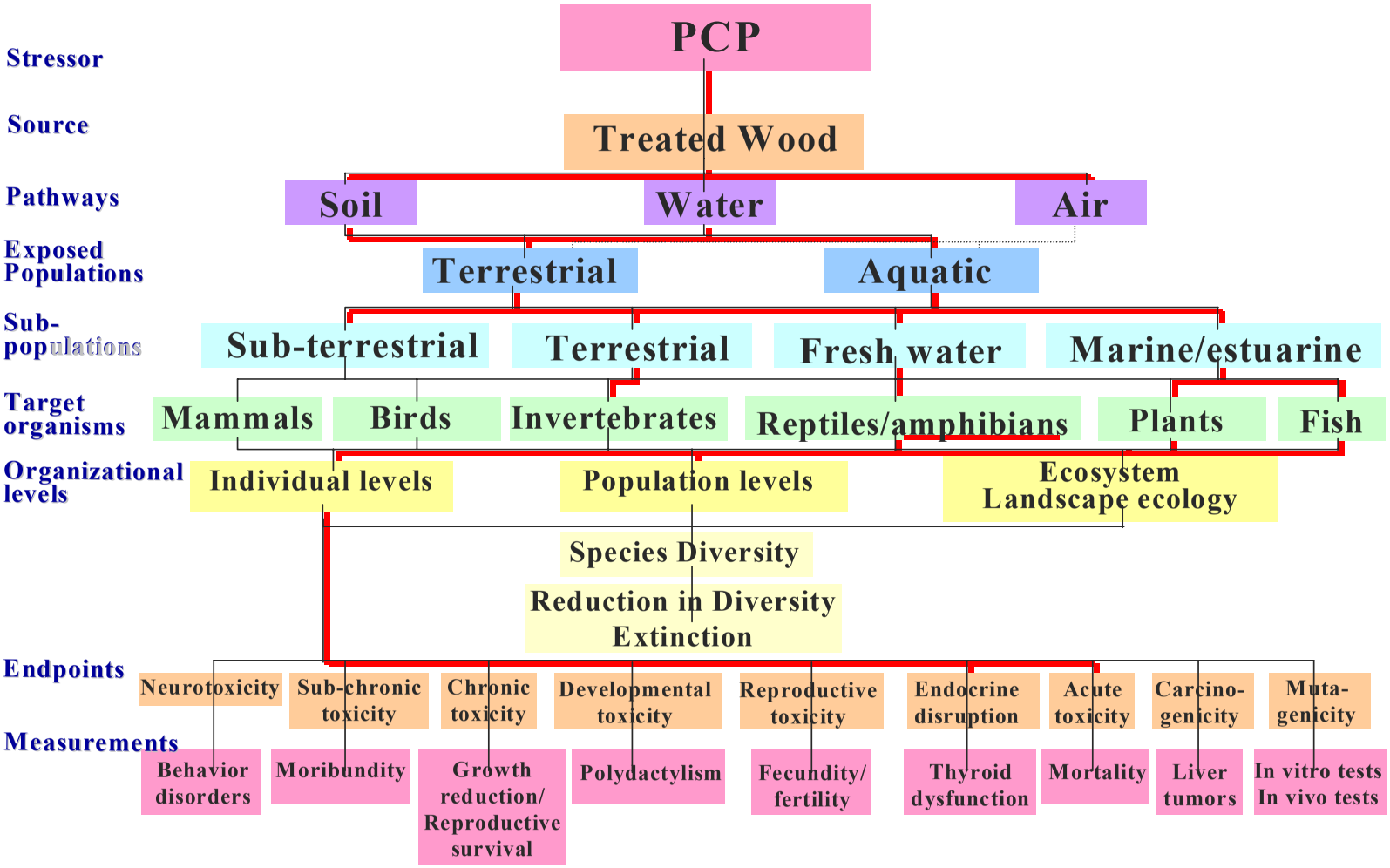
G. There are a lot more questions than answers, which is why an iterative planning and scoping approach involving many different but knowledgeable people is valuable for developing a good conceptual model.

H. Planning and scoping is not risk assessment, the deliberation involves a broader set of participants in a dialogue.

I. 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).

C.4 Details on Conceptual Models for PCP




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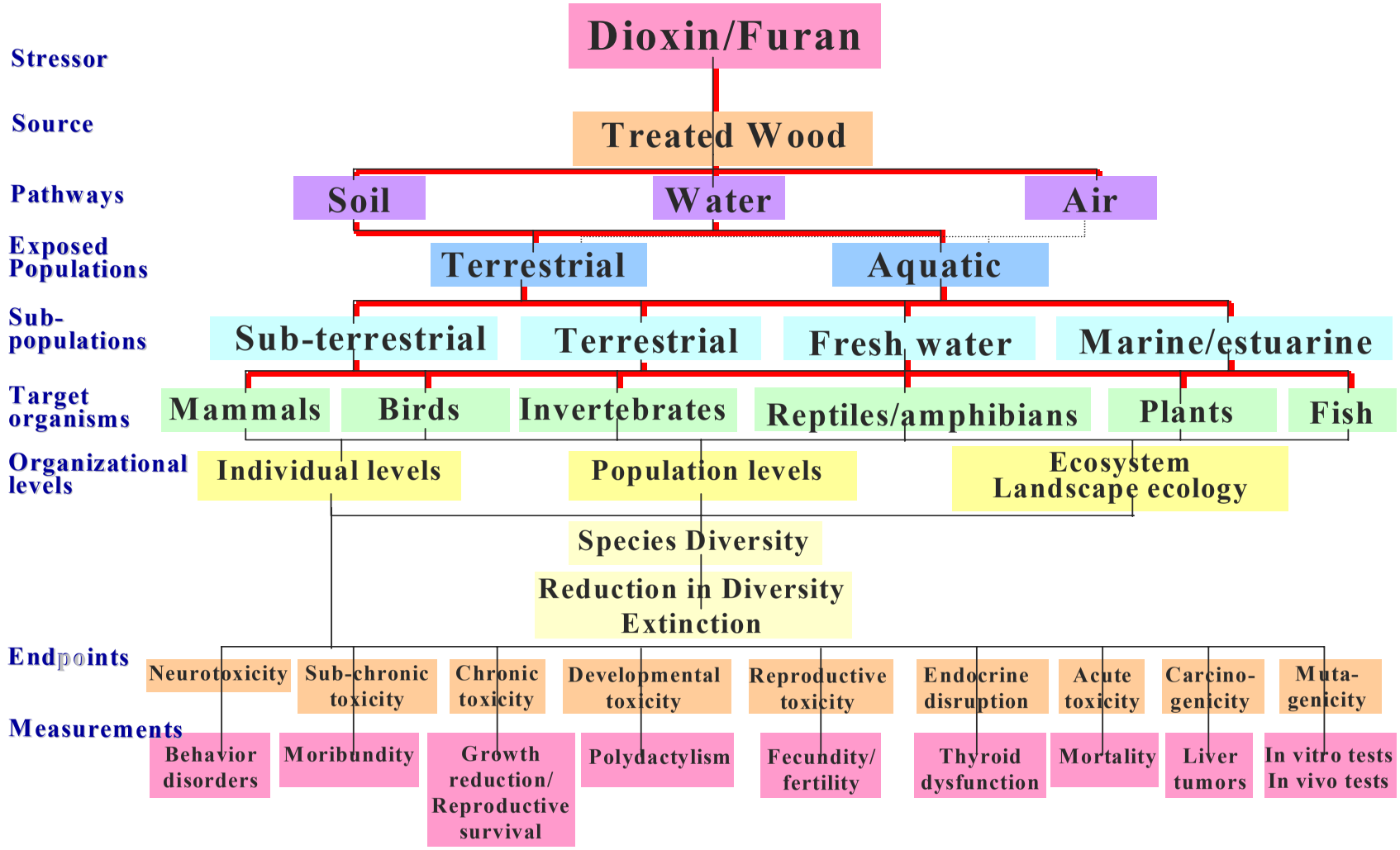
Fresh water
Marine/estuarine
Target organisms
Mammals
Birds
Invertebrates
Reptiles/amphibians
Plants
Fish
Organizational levels
Individual levels
Population levels
Ecosystem
Landscape ecology
Species Diversity
Reduction in Diversity
Extinction
Endpoints
Neurotoxicity
Sub-chronic toxicity
Chronic toxicity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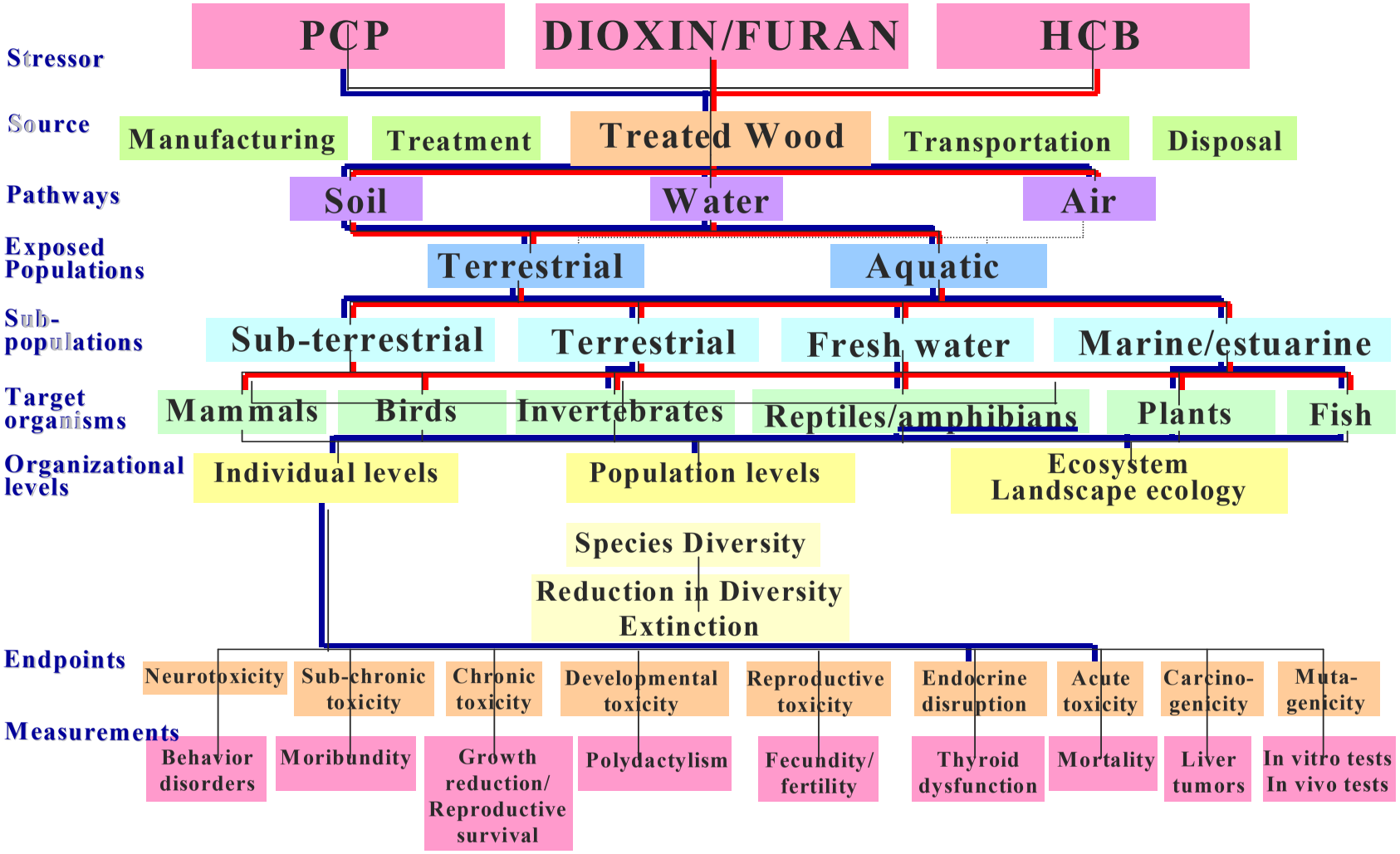
Polydactylism
Fecundity/ fertility
Thyroid dysfunction
Mortality
Liver tumors
In vitro tests
In vivo tests


Stressor
PCP
DIOXIN/FURAN
HCB
Source
Manufacturing
Treatment
Treated Wood
Transportation
Disposal
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Soil
Water
Air
Exposed Populations
Terrestrial
Aquatic
Sub-populations
Sub-terrestrial
Terrestrial
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Extinction
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Polydactylism
Fecundity/ fertility
Thyroid dysfunction
Mortality
Liver tumors
In vitro tests
In vivo tests

C.5 Narrative for the Human Health Conceptual Models for Pentachlorophenol (PCP) and Its Contaminants

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.

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 placed on a concrete drying pad to collect any residual chemical that may leak from the treated wood. Non-pressure treated wood is preserved by dipping or extended soaking 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, 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.

Appendix D. Cumulative Risk Initiative (CRI) for Cook County IL and Lake County IN (*formerly Chicago Cumulative Risk Initiative, CCRI*)

The planning and scoping focus in the present summary relates primarily to the second and third phases of CRI, a four phase project: (1) Environmental Loading Profile; (2) Petitioner Risk Workshop; (3) Hazard Screening Assessment; and (4) Risk Management Response. The Environmental Loading Profile is not discussed here, and outcomes from the fourth phase (risk management) have not yet been implemented. "Lessons learned" are thus tentative at this writing.

D.1. Background and History

In 1995 the Chicago Legal Clinic and 11 Chicago-area community advocacy groups filed a petition under the Toxic Substances Control Act (TSCA) requesting that the USEPA Administrator prohibit or further regulate the emissions from eight proposed or constructed incinerators in the Chicago metropolitan area, including one proposed in Northwest Indiana. The petitioners believed that neither current statutes nor local siting laws adequately address the cumulative impacts of multiple sources of toxic pollutants in a geographic area, and requested that the Administrator prohibit or further regulate the emissions of dioxins, furans, mercury, lead and cadmium from these sources. In May 1996 the petition was withdrawn in response to a USEPA offer to participate in an investigation of the multimedia impacts of pollutants in Cook County, Illinois and Lake County, Indiana. This effort was named the Chicago Cumulative Risk Initiative (CCRI) and later renamed Cumulative Risk Initiative (CRI) for Cook County IL and Lake County IN. CRI is an attempt to investigate the issue of cumulative loadings and hazards from pollutant sources, develop community-based activities to help address these concerns, and use the results of the analyses to assist in prioritizing the use of regulatory agency resources. The Agency and petitioners agreed to a four-phase project: (1) Environmental Loading Profile; (2) Petitioner Risk Workshop; (3) Hazard Screening Assessment; and (4) Risk Management Response.

As of this writing phases 1 and 2 are complete, and the third (Hazard Screening Assessment) is near completion. The scope of that assessment reflects stakeholder deliberations, focuses on cumulative hazard (not "risk" as typically defined by USEPA) associated with non-criteria air pollutants ("air toxics") in the two county study area, and relies on "off-the-shelf" air pollutant information sources, including USEPA's Toxics Release Inventory and Cumulative Exposure Project, the Regional Air Pollutant Inventory Development System (RAPIDS), and outdoor air monitoring data. Emission estimates are "toxicity weighted", while modeled/monitored outdoor air pollutant concentrations are compared with reference values to develop "hazard index"-like ratios. The ratios or toxicity weighted emission estimates are used to derive indicators of cumulative hazard, and then mapped over study area locations. Another part of the study assembles pollutant hazard information and data on existing human disease rates and blood lead concentrations to identify geographic areas where potentially elevated hazards and individuals with potentially elevated susceptibilities are collocated.

D.2. Highlights and key findings

D.2.1 Stakeholder involvement

CRI emerged as a regulatory agency response to a citizen petition. Stakeholders were therefore defined by the circumstances of this petition and the response it generated, although other potential stakeholders were considered during the scoping process (e.g. industry; residents not represented by the community advocacy groups). Stakeholders included:

- 11 advocacy groups represented by the Chicago Legal Clinic
- Indiana and Illinois state government representatives
- Chicago Department of Health
- Chicago Department of the Environment
- USEPA (Region 5, OPPT, OAQPS, OAR)

D.2.2 Planning and scoping, conceptual model, analysis plan, resource considerations

Participants in the three CRI case study workshops defined the problem, goals, stakeholders, stressors, sources and endpoints, sketched out a conceptual model of the planned assessment, and developed a preliminary analytical plan. Discussion included a broad list of stressors, sources, and endpoints, including some elements that were likely to be outside the project's scope (e.g. assay for DNA adducts as biomarkers of pollutant exposure). The process was an iterative one: while participants in each subsequent workshop considered, revised, and expanded upon the work completed by previous groups, they did not consider themselves bound to prior decisions.

The first workshop 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 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:

(1) Define the purpose of the assessment. Goals and objectives were developed [NOTE: these pertain to all four CRI phases, not just the Hazard Screening Assessment (third phase)]:

Goals:

- 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.
- to develop the data upon which to develop a strategic plan to improve public health by effectively targeting intervention activities.

Objectives:

- 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.

(2) Define the scope of the assessment. The following decisions were made:

1. Conduct a cumulative rather than comparative analysis
2. Focus specifically on children
3. Focus on sources rather than receptors
4. Concentrate on USEPA-regulated sources
5. Use only existing data
6. Cover a broad two-county geographic area rather than smaller geographic subareas
7. Limit study to air pathway/medium
8. Do not associate health outcomes with causes
9. Consider hazard rather than risk (i.e. no explicit exposure assessment).

(3) Develop a cumulative risk (hazard) outline. A conceptual model with eight elements in the following hierarchy was generated:

Activity→Sources→Stressors→Pathways→Media→Route→Population←Health Effects Measures/Biomarkers

(4) Formulate the technical approach to the assessment

Discussion focused on the conceptual model, analytical plan, and data (availability, limitations, sources and outputs). The conceptual model and the analytical plan resulted from the planning and scoping process. After drafting a broad and inclusive CRI 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 (hazards) "in context" to interested and affected parties and to the public at-large. Each functional submodel is a subset of the broad-based, inclusive CRI 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 CRI 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 CRI 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 USEPA 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 USEPA to focus on children.

D.3 Risk Assessor - Risk Manager Dialogue

The terms "risk assessor" and "risk manager" are difficult to separate and may not be particularly useful for purposes of the CRI Hazard Screening Assessment. This is due in part to the Report's objective (i.e., a hazard, rather than risk assessment) and in part to the circumstances in which the effort occurred. Argonne National Laboratory and USEPA developed an interagency agreement in which Argonne was to conduct technical analysis involved in a hazard assessment, the scope of which was defined by petitioner and governmental stakeholders. In addition, all stakeholders had representatives reviewing and commenting on Argonne drafts of the Report's chapters. In many cases this review led to substantial revisions or novel analyses. Thus, one could argue that stakeholders had both "assessor" and "manager" roles as those terms are typically used in the context of designing and conducting a risk (hazard) assessment.

The term "risk manager" is also used in describing the use of risk assessment results for some decision or action. Because it's likely that both governmental and petitioner stakeholders will use CRI results in their own way, both are also likely to play this "risk manager" role. It's anticipated that governmental stakeholders will use the results to assist in prioritizing program activities and directing resources. Petitioner stakeholders could use the results for similar purposes, e.g. to argue that elevated hazard estimates in particular geographic areas support the need for additional air monitoring in those areas.

D.4. Lessons Learned

"Interim Lessons" related to stakeholder involvement:

1. Despite understandable frustration with the slow progression of CRI, relations between petitioner representatives and the current coordinating government agency (USEPA Region 5) appear to be generally good, even after a multiple-year process. This may be due to the "self-selection" of the stakeholders and the apparent patience of some in waiting for a project designed largely as a result of their input. One potential lesson is that citizen stakeholders' patience is directly proportional to their sense of influence in the process.

The duration of the planning and scoping process can expand or (in the present case) narrow the resulting scope. In hindsight, this reduced scope probably helped to maintain citizen and management support so that the report can be completed.

2. Whether other stakeholders (e.g. industry, residents not represented by Petitioners) should have been involved earlier in the CRI process is likely to remain unknown until "risk management actions" based on CRI results have been taken. Also unknown is whether or how including such stakeholders against the wishes of Petitioners might have changed the project for better or worse.

3. The extended deliberations involved in planning, scoping, writing, reviewing, revising and completing the CRI Hazard Screening Assessment appear to have both strengths and weaknesses. On the one hand, the extensive review that occurred in preparing the Report makes more likely that it addresses the objectives of its designers. The Report also seems to incorporate recent expert advice on stakeholder inclusiveness in issues relating to environmental and human health risk assessment (e.g. NRC 1996; Presidential Commission, 1997). On the other hand, conducting and completing such a process is labor and time intensive/extensive, costly, associated with substantial management needs (e.g. coordination), frequent delays, mistakes, misunderstandings and miscommunication ("too many cooks in the kitchen"). Those initiating complex projects with many participants and multiple-year time lines, in some cases extending beyond some participants' employment tenure, should carefully consider these costs (including opportunity costs) during planning and scoping. Whether such costs are merited is likely to be a difficult and subjective evaluation.

"Interim lessons" related to the planning/scoping process:

1. The duration of the planning and scoping process can expand or (in the present case) narrow the resulting scope. For example, noise, odors and indoor air quality were discussed by planning and scoping participants and considered relevant to cumulative hazard assessment. However, these topics were eventually excluded from the Hazard Screening Assessment as the scope was narrowed to focus on hazards of outdoor "air toxics". In hindsight, this scope attenuation was probably a good thing, given the difficulties and expense of completing the Report even without these topics.

2. "Focus specifically on children": the Hazard Screening Assessment's children's focus is mostly limited to the perspective that information on the co-location of potentially elevated pollutant hazards and more susceptible children (those with asthma, elevated blood lead, leukemia, upper respiratory tract infections) is valuable. The extent to which environmental pollutant exposure is related to these diseases was not assessed, nor was pollutant exposure in the study area explicitly assessed. With regard to the developmental toxicity of the ~250 pollutants included in the Hazard Screening Assessment, the available toxicology literature is rife with data gaps for individual pollutants, to say nothing of mixtures. Only a few of these pollutants or classes (e.g., lead, mercury, and PCBs) are relatively well characterized for effects in developing organisms such as children. The effects of exposure to changing-component pollutant mixtures at varying environmental concentrations over the early lifespan (e.g. preconception, in utero, infancy, childhood, adolescence) are mostly unknown.

Thus, while addressing the agreed-upon scope, the Report also reinforces the notion of large data gaps and enormous uncertainty associated with a "focus on children".

3. "Use only existing data" and "off-the-shelf tools"; this decision led to unanticipated problems that are briefly described:

(a) One problem not addressed until late in the analytic process was verification of the census tract(s) within which air emission facilities named in the Report were located. This verification procedure supported the notion that both of the emissions databases utilized (e.g. TRI, RAPIDS) are likely to contain a fairly high rate (~20%) of inaccurate geographic location information.

(b) uncertain data and estimates: constant change in scientific knowledge and the long duration of CRI led to difficulties, compromise, and expense. For example, the USEPA inhalation unit risk (cancer potency) factor for 1,3-butadiene was under review starting early in the CRI process. Because the revised value and the date of its "finalization" were unknown, outputs based on this factor were frequently done twice (using both the current and expected value), generating two versions of many analyses. Although still unknown at this writing, it now appears that a value between that of the current and expected factor will actually be finalized.

4. Surprises: even something as apparently fixed as initial written objectives became the subject of debate and modification during review of the CRI Hazard Screening Assessment. One CRI objective developed during planning and scoping was "develop a transferable methodology that can be used in other urban areas". During the several year duration of CRI, the separate effort of the National Air Toxics Assessment (NATA) led by another USEPA office (Office of Air Quality Planning and Standards, OAQPS) was initiated, with objectives intersecting those of CRI. NATA activities include a national scale assessment, as well as development of local scale hazardous air pollutant (HAP) evaluations. These local scale evaluations are likely to comprise specific local information (e.g. terrain, weather patterns) and refined air modeling protocols, and could provide a basis for national guidance on local scale HAP evaluations. The potential conflict between CRI's "transferable methodology" objective and that of the NATA local scale HAP evaluation element was identified by OAQPS reviewers. To avoid this potential conflict

and the idea that the CRI Hazard Screening Assessment is intended to provide general USEPA guidance on local scale HAP evaluations, it was necessary to modify the objective in the Hazard Screening Assessment to "develop methods that can be adapted for use in other urban areas".

5. Despite the name "Cumulative Risk Initiative", the CRI Hazard Screening Assessment is quite limited in its "cumulative-ness" (e.g. it excluded water and dietary pollutants), it did not address risk in that exposure assessment was excluded, and it may be as much a response as an initiative. Some may be disappointed by these limitations.

6. For community-based assessments, Region 5 personnel have found that planning and scoping can be aided by addressing the following questions:

1. Who are the parties proposing the assessment?
2. Are there other interested or affected parties?
3. What questions do the parties want the assessment to answer?
4. What analysis will be done to answer these questions?
5. Who will conduct the analysis?
6. When are the assessment results needed?
7. Who will pay for the assessment?
8. How will the assessment results be used?

Appendix E. Planning and Scoping for the National-Scale Assessments

Two other cases involving national assessments are discussed below. The nature of the stakeholders and their discussions are very different from our experience with place-based assessments.

E.1 The National Air Toxics Program Assessment

The Office of Air Quality Planning and Standards (OAQPS) described their approach to planning and scoping for the 1996 national-scale assessment of air toxics performed as part of its National Air Toxics Assessment (NATA) activities. The NATA national-scale assessment is a geographically broad study of potential inhalation exposures and health risks associated with 33 hazardous air pollutants of concern in urban air. It includes cumulative exposure and risk assessments. This summary highlights the technical products from planning and scoping and shows the link to the risk analysis.

E.1.1 Purpose for this assessment

The information from public comments, monitoring, and assessments developed by NATA activities will help:

1. Determine priorities for regulatory programs as well as for national, regional, and community-based initiatives;

2. Assess progress toward statutory and future risk-based GPRA goals;

3. Inform state, local, and tribal programs; support public right-to-know initiatives with regard to the risks associated with exposure to HAPs; and

4. Support prospective assessments of the benefits attributable to implementation of statutory air toxics mandates (as required by section 812 of the CAA).

E.1.2 Stakeholder Involvement

The Office of Air Quality Planning and Standards (OAQPS) solicited the perspectives of key stakeholders as they developed and implemented the air toxics program and integrated urban strategy. Key stakeholders include regulatory partners (including State, local, and tribal governments), environmental justice communities, public health and environmental groups, small business, industry, and urban developers.

EPA initially received hundreds of stakeholder public comments on the draft integrated urban strategy notice published in the Federal Register on September 14, 1998, and at several stakeholder meetings across the country. EPA also held informal discussions with several stakeholder groups, including representatives from the State and Territorial Air Pollution

Program Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPO), the National Environmental Justice Advisory Council (NEJAC), the Clean Air Act Advisory Committee (CAAAC), and the Conference of Mayors. Additional meetings will be held to discuss implementation of the integrated urban strategy after the assessment is completed.

E.1.3 Details of the Conceptual Model

The following subsections include summary descriptions of the risk dimensions and elements of the national scale assessment for NATA, as recommended by EPA's Cumulative Risk Assessment Guidance [1]. The conceptual model for the NATA appears in Figure 3. The discussion below covers the rationale for what is included and excluded in the assessment and assumptions for the analysis plan of this project.

A. Sources

The dispersion modeling (from which the exposure assessment and risk characterization will arise) will include all major, area, and mobile sources that have been entered in EPA's 1996 National Toxics Inventory (NTI) for the contiguous US, Puerto Rico, and the Virgin Islands. The 1996 NTI, which has been assembled from information on individual sources submitted by state and local authorities, is the most recent and best available emissions database for the United States.

By limiting the initial NATA to inventoried sources, EPA is thereby excluding releases from sources that are not included in the NTI. This limitation will effectively exclude releases (1) from natural processes, (2) to indoor air (e.g., from paints, carpets, etc.), and (3) to surface water, groundwater, or soil. While EPA takes these releases and their potential to cause adverse health effects seriously, adequate model inputs (i.e., data on substance identities and release rates) are still needed to include them in the assessment. Furthermore, because most of these releases fall outside EPA's mandate to control emissions of HAPs under the CAA, it is uncertain that the information would be useful to the development of air toxics control strategies.

B. Stressors

The initial NATA will encompass the 33 substances that EPA has identified as urban air toxics under the Urban Air Toxics Strategy. Later NATA assessments will expand to cover as many of the 188 Clean Air Act HAPs as available emission and toxicity data will support. EPA has chosen to limit the initial assessment to the 33 urban HAPs for two reasons. First, these HAPs, in aggregate, are highly likely to encompass most of the total HAP-related inhalation risk to human populations. Second, EPA intends to use the initial assessment for NATA as a principal vehicle to fulfill assessment commitments under the UATS, which is focused specifically on these HAPs.

C. Pathways/ Media

The dispersion modeling and exposure assessment will include transport of particles and gases through air to receptors within 50 km of sources. Atmospheric transformation and losses from the air by deposition will be included in the modeling, as data permit. The initial assessment will exclude accretion in water, soil, or food associated with deposition from air, or bioaccumulation of airborne HAPs in tissues. Although EPA takes potential transport of HAPs into other media very seriously, tools to model multi pathway concentrations on the national scale do not yet exist. Future local- or urban-scale assessments will include multi-pathway calculations, and they will be added to national assessments when adequate models become available.

D. Routes

The NATA will focus on exposures due to inhalation of ambient air. Human receptors will be modeled for separate micro environments, including residences, offices, schools, outdoor work sites, automobiles, etc. The exposure assessment will estimate air concentrations of each substance within each micro environment, using the outdoor concentration, time of day, air exchange rate, and other factors. Human behaviors and physiology will be reflected in the assessment by the amount of time individuals spend in each micro environment, and by the inhalation rate during their time there.

The NATA will exclude human exposures via ingestion or dermal contact. This is a consequence of the lack of multi pathway models suitable for calculations at the national scale. As modeling tools become available to estimate transfers of substances from air to other media, future national assessments may include dermal and ingestion exposures.

E. Subpopulations

The NATA will characterize risks to 12 distinct human subpopulations, divided into four age cohorts and three socio-economic cohorts. Subpopulations planned for separate assessment include (cohorts are inclusive): (1) young children aged 7 or less, (2) older children and adolescents aged 8-17, (3) adults aged 18-64, and (4) people aged 65 or greater. Each of these age groups will be divided by income level, at the 0-25, 25-75, and 75-100th percentile income levels. Risks will be estimated separately for each group. The median and 95th percentile individuals within each census tract will represent multiple descriptors of risk for all groups combined.

The initial assessment will exclude non-human receptors. This limitation results from the extreme complexity of considering potential adverse ecological impacts to the multiplicity of different ecosystems that exist within such a large area. Future local- and urban-scale assessments may be expanded to include non-human receptors, contingent on the availability of necessary resources, data, and methodologies. However, non-human receptors will not be included in future national-level assessments unless radical new models and tools become available.

F. Endpoints and Measures

1. Cancer

"Cancer" describes a group of related diseases that affect a variety of organs and tissues. Cancer results from a combination of genetic damage and non-genetic factors that favor the growth of damaged cells. At current cancer incidence rates, approximately one third of U.S. residents may be expected eventually to contract some form of cancer. Cancer is associated with a wide range of factors, of which exposure to HAPs is only one. Other causes of cancer, including genetic susceptibility, background radiation, diet, smoking, and other lifestyle factors, are thought to be the dominant factors determining total cancer incidence. Against the very high total cancer rate of about one in three from all risk factors, the rate of cancer incidence associated with HAPs alone cannot be observed directly. Attributing cancer to specific HAPs is also complicated by the fact that many cancers do not appear for years or decades after exposure and, therefore, may have been caused by past exposures in different locations. As a result, the National Site Assessment will rely on modeled estimates of cancer risk rather than on direct measurements for assessing risks.

The NATA will incorporate predictions of lifetime cancer risk to exposed populations. Predictions will consider both EPA's 1986 cancer guidelines and the most recent draft version of EPA's guidelines for cancer risk assessment, currently undergoing Agency science policy review. For most carcinogenic HAPs, unit risk estimates developed by linear extrapolation from high to low doses will not be used to estimate the upper bound of lifetime probability of contracting cancer from inhalation. Available peer-reviewed dose-response assessments developed from evidence of a threshold for carcinogenicity, or on sublinear low-dose extrapolations, will be used as appropriate for specific HAPs.

The upper-bound lifetime cancer risk will be estimated for each HAP that has been assessed as a known, probable, or possible human carcinogen, and for which a unit risk estimate is available from a peer-reviewed source. Individual-HAP risk estimates will be calculated for receptor populations within each census tract. Risks will then be aggregated across carcinogenic HAPs.

Cancer risks will not be aggregated across weight-of-evidence categories (i.e., combining known, probable, and possible human carcinogens), to avoid inappropriate mixing of assessments having widely varying levels of uncertainty.

2. Effects Other Than Cancer

Adverse health effects other than cancer ("noncancer risks") include a wide range of health endpoints in all organ systems (e.g., cardiovascular, immune, liver, or kidney). As with cancer, other factors such as genetics, diet, lifestyle, and other exposures (e.g., smoking) may exert a dominant influence over incidence of adverse noncancer health effects. Therefore, as with carcinogens, the NATA will rely primarily on risk estimates rather than on direct measurements of changes in the incidence of adverse noncancer health impacts due to reductions in emissions. These estimates will in most cases be expressed in terms of the hazard quotient, or HQ (defined as the ratio of the inhaled exposure concentration to the reference concentration, or RfC).

The HQ for effects other than cancer will be calculated for each urban HAP that has a peer-reviewed RfC or equivalent value. HQs for individual HAPs will be estimated for receptor populations within each census tract. HQs will then be aggregated across HAPs. Where evidence exists for non-additive interactions among HAPs (e.g., synergism, antagonism, potentiation, etc.), these will be considered as appropriate.

Probabilities of adverse non-cancer effects may not be possible to estimate. The approach will generally aggregate HQ across HAPs on the basis of target organ and by toxic mechanism if data permit. HQs will be separated according to total uncertainty in the RfC, to avoid inappropriate mixing of assessments having widely varying levels of uncertainty.

E.1.5 Analysis Plan for Cumulative Risk Assessment and Characterization

The document also provides a detailed analysis plan, including references to Agency guidelines and program procedures. The plan describes the data, models, and key assumptions that will be used in each phase (exposure assessment, dose-response assessment, and risk characterization) of the risk assessment. Uncertainties associated with each and the use of models are described, as well as the approach that will be followed.

The initial assessment will include four major steps: (1) compiling a 1996 national emissions inventory of HAP emissions from outdoor sources; (2) estimating 1996 HAP ambient air concentrations for the 33 urban HAPs nationwide; (3) estimating 1996 population exposures to these HAPs; and (4) characterizing potential public health risks due to inhalation of HAPs, including both cancer and noncancer effects. The document also includes additional information from the risk assessment process, including a preliminary risk characterization and a detailed discussion on their plan for aggregating the data.

E.1.6 Lessons Learned

1. Planning and scoping required extensive involvement of the risk manager and technical staff to develop a rationale for what would be included and excluded from the NATA. It would not have been a problem if it was recognized and planned, but some of the time was consumed by

learning what needed to be done and interpreting the 1997 guidance.

2. Because this was a national assessment for screening, stakeholders had technical and regulatory expertise, so there was little background or discussion of non-technical issues. Planning and scoping dealt with details of defining the dimensions of the risk assessment and the methods for combining effects.

The review of the conceptual model led to significant savings in the application of the model for calculating air dispersion, exposure, and risk estimation. More than a third of the possible analyses were shown to be unnecessary to address the problem formulated in the planning and scoping discussion.

3. The conceptual model showed how the program related to other regulatory activities as well as the relationships between stressors and effects. This context helped clarify how the results would be explained and presented. Boxes using hyperlinks were very effective ways to present both an overview and examine the technical details where specific questions occurred.

4. The review of the conceptual model lead to significant savings in the application of the model for calculating air dispersion, exposure, and risk estimation. More than a third of the possible analyses were shown to be unnecessary to address the problem formulated in the planning and scoping discussion.

E.2 RCRA Surface Impoundment Study-Technical Plan for Human Health and Ecological Risk Assessment [1]

The Office of Solid Waste developed a technical plan for complex and cumulative risk assessments of surface impoundments. The objective of the study was to conduct risk assessments to determine, within an acceptable degree of certainty, what risks to human health and the environment are posed by industrial wastewaters managed in surface impoundments. This technical plan covers several steps which are described in the planning and scoping guidance. This brief summary of the background and technical plan highlights some of the techniques this exercise used that show how to implement the planning and scoping process.

E.2.1 Background

In 1996 the Resource Conservation Recovery Act (RCRA) was amended to exempt decharacterized nonhazardous wastes from land disposal restrictions. Such wastes it was assumed, have lost their hazardous waste characteristics (i.e., ignitability, corrosivity, reactivity, and toxicity) through dilution or other treatment. Congress required that the Agency study the health and environmental risks of exempted wastes managed in surface impoundments or wastewater treatment systems and evaluate the extent to which existing regulations address any

[1] Surface Impoundment Study-Technical Plan for Human Health and Ecological Risk Assessment, U.S. Environmental Protection Agency, Office of Solid Waste, Washington, D.C., February, 2000

such risks (1996 Land Disposal Program Flexibility Act). The scope of the study was expanded to cover all nonhazardous industrial wastewaters in surface impoundments through consent decree (Civ. No. 89-0598, *EDF vs Browner*). Based on statistical surveys, the Agency estimates that there are 19,000 impoundments at 8,500 facilities within the study's scope. The technical plan describes a screening process to select facilities, impoundments and constituents for further assessment.

E.2.2 Purpose and objectives for the study

The study began with a subsample of impoundments to clarify the industries involved, size range of facilities, constituents (stressors) present, and other key factors that might be described for planning a risk assessment. After the survey, the Agency developed a technical plan, then obtained peer review and public comment on the approach. The approach comprised two phases: Phase I, a screening and prioritization process and Phase II the detailed plan for analysis. The purpose of Phase I is to eliminate constituents (stressors) and impoundments (sources) from further analysis which posed negligible risks and prioritize the remaining units and constituents for further analysis. Phase II is a plan for detailed multimedia modeling which is continuing. Phase I leads to a decision on whether a risk assessment is necessary and if so, what will be included. Phase II develops theoretical relationships between constituents and effects (a conceptual model) including fate and transport of the constituents.

E.2.3 Phase I (Conceptual Models and Analysis Plan)

Health and ecological risks are screened separately in each phase. A simple conceptual model is presented in Phase I for sources through potential receptors (figure 2-2). The model also serves as a checklist for screening each unit and constituent. Equations and data sources are also provided for developing screening factors and each screening factor is presented in the context of a flow diagram for the overall analysis and in a decision tree for evaluating the significance of various pathways of exposure for each facility.

The analytical plan specifies that calculated screening risks (Phase I) for each constituent in a specific impoundment and facility will be combined to generate three cumulative risk estimates: an impoundment risk, constituent risk, and facility risk. The cumulative risks will be used in the risk screening and risk distributions as follows. The *hazard quotient* (HQ) is the ratio of estimated exposure (dose or concentration) and the appropriate toxicity value (reference dose of reference concentration) for a single exposure pathway and chemical. The *hazard index* (HI) is the summation of HQs across pathways and across chemicals affecting the same target organ.

Following screening and prioritization (based on scores from cumulative risk screening and cumulative risk distributions), further data collection, model simulation, and refinement of the risk assessment occurs under Phase II.

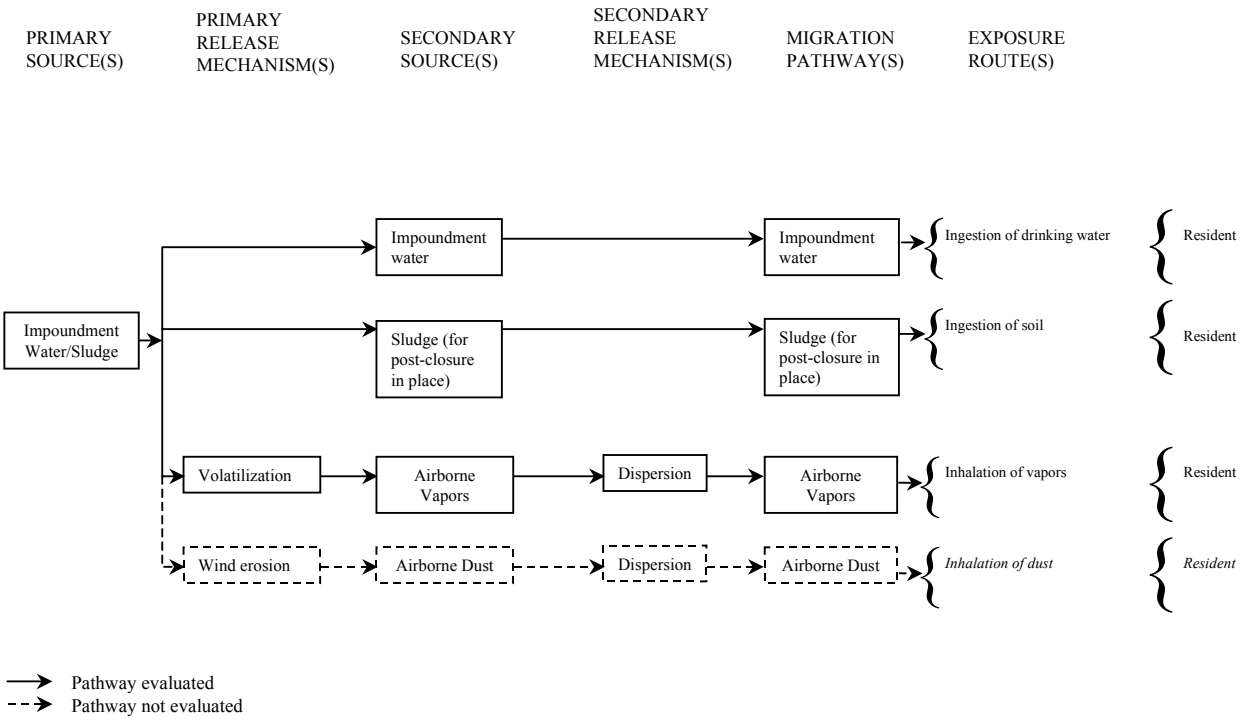

Figure E-1. Human health risk conceptual site model and potential exposure pathways.

E.2.4 Phase II (Assessment Plan)

Impoundment units and constituents identified for the Phase II analysis will be further characterized with greater precision for potential human health and environmental risks.

As in Phase I, health and ecological risks are screened separately (see human health and ecological conceptual models, figures E-2 and E-3) using the 3MRA[2] conceptual model (HWIR) for surface impoundments (see figure E-4, dimensions). One of two approaches will be taken. If, as anticipated, a fairly limited number of units and constituents proceed to Phase II, EPA will conduct multimedia fate and transport modeling of potential human and ecological risks using the HWIR multimedia model and using, to the extent possible, the site-specific hydrogeologic data, watershed parameters, and receptor data provided in the surveys and available through other data sources such as GIS files. Due to its intensive modeling requirements, only a relatively limited number of cases will be completed.

Alternatively, if a large number of sites meet the criteria for proceeding to Phase II, EPA will develop a range of appropriate hydrogeologic an watershed "scenarios" (~20 to 30 representative scenarios) to simplify the process of data file development and modeling. This will greatly streamline the use of the HWIR model while maintaining the advantages of this powerful tool to describe multimedia fate and transport. The Agency is also considering extending the "representative scenario" approach to include representative ranges of population exposures. Phase II results will be used to revise the risk profile for the surface impoundment universe based on more realistic exposure assumptions and multimedia fate and transport modeling.

[2] 3MRA is a multimedia, multipathway, multireceptor risk analysis model. See Appendix D of Surface Impoundment Study Technical Plan for assumptions, limitations, inputs and outputs. Use of this model includes the ability to use many of the same data files for default parameters that had been developed to support the HWIR effort; the automatic integration of the various modules for different media thereby minimizing the quality assurance/quality control (QA/QC) necessary for manual integration of modules; and the feasibility of using the system in screening-level multimedia analyses and comprehensive multimedia analyses.

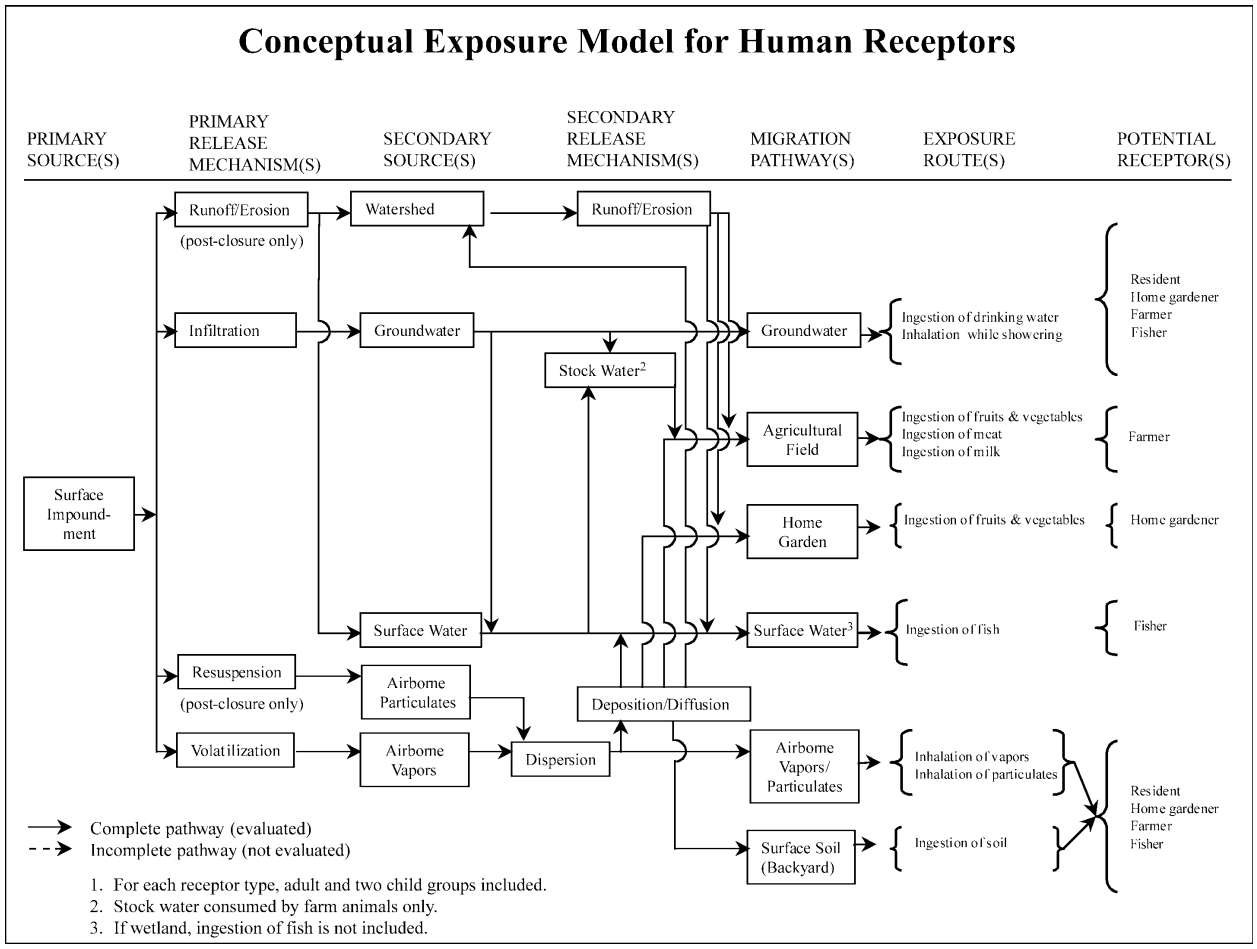

Figure E-2. Conceptual exposure model for human receptors.

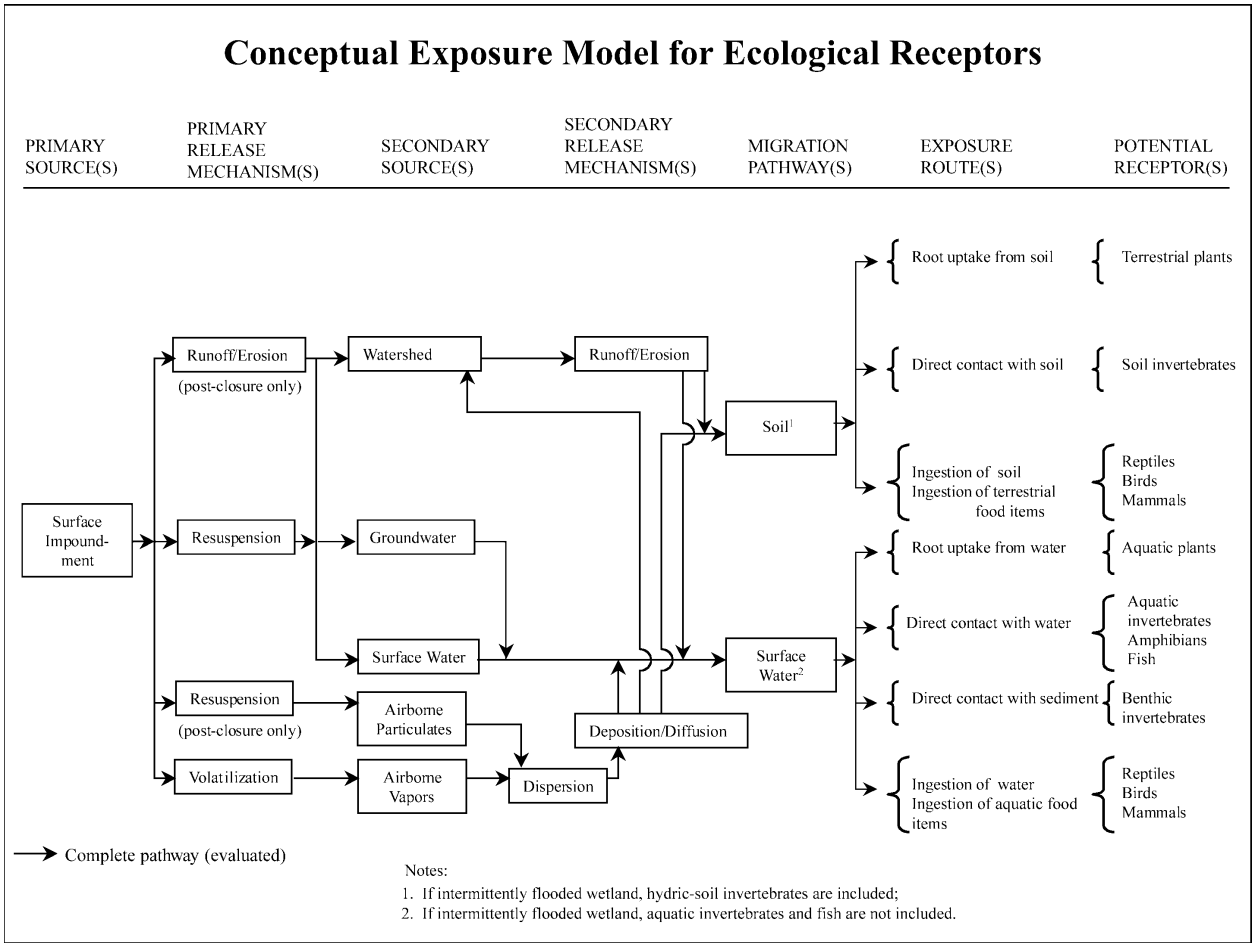

Figure E-3. Conceptual exposure model for ecological receptors.

CHEMICALS
- Organic chemicals (227)
- Metals (17)
- Nonmetallic inorganic chemicals (8)

SOURCE TYPE
- Surface impoundment

SOURCE TERM CHARACTERISTICS
- Mass balance
- Multiphase partitioning
- Source degradation

SOURCE RELEASE MECHANISMS
- Volatilization
- Leaching
- Runoff (post-closure, surface failure)
- Erosion (post-closure, surface failure)
- Particle resuspension (post-closure)

TRANSPORT MEDIA
- Atmosphere
- Watershed
- Vadose zone
- Groundwater
- Surface water

FATE PROCESSES
- Chemical/biological transformation (and associated products of transformation)
- Linear partitioning (water/air, water/soil, air/plant, water/biota)
- Nonlinear partitioning (metals in vadose zone)
- Chemical reactions/speciation (mercury in surface waters)

INTERMEDIA CONTAMINANT FLUXES
- Source → Air (volatilization, resuspension)
- Source → Vadose zone (leaching)
- Source surface soil → Local watershed soil (erosion, runoff)
- Air → Watershed/farm habitat soil (wet/dry deposition, vapor diffusion)
- Air → Surface water (wet/dry deposition, vapor diffusion)
- Watershed soil → Surface water (erosion, runoff)
- Surface water → Sediment (sedimentation)
- Vadose zone → Groundwater (infiltration)
- Watershed soil → Air (volatilization)
- Groundwater → Surface water

FOOD CHAIN/FOOD WEB
- Air → Vegetation (particulate deposition; vapor diffusion)
- Farm/habitat soil → Vegetation (root uptake, translocation)
- Vegetation, soil, water → Animals (uptake)
- Surface water → Aquatic organisms (uptake)

RECEPTORS AND HABITATS

Ecological Habitats:
- Terrestrial
- Freshwater aquatic
- Wetland

Human Receptors*:
- Resident
- Home gardener
- Dairy farmer
- Beef farmer
- Fisher

Ecological Receptors:
- Plants
- Invertebrates
- Amphibians
- Reptiles
- Birds
- Mammals

*For each human receptor type, consider 5 age cohorts

EXPOSURE PATHWAYS

Human
- Ingestion (plant, meat, milk, fish, water, soil, breast milk)
- Inhalation (gases, particulates)

Ecological
- Ingestion (plant, animal, water, soil)
- Direct contact (surface water, sediment, soil)

HUMAN AND ECOLOGICAL RISK MEASURES
- Cancer (risk probability)
- Noncancer (hazard quotient)
- Human: population
- Ecological: population

Figure E-4. Dimensions of the 3MRA conceptual model for surface impoundments.

E.2.5 Internal and External Stakeholder Process

The following details the stakeholder process utilized to try to achieve stakeholder acceptance of the study methodology and thus, the results:

1) At the beginning of the study, EPA staff tasked with performing the work met with stakeholders, prepared a Federal Register notice requesting comment on the proposed study methodologies, and consulted with the Science Advisory Board.

2) Using the SAB consultation notes, EPA staff researched relevant background topics and convened a group of technical experts (under a contract mechanism) to assist in study design, which was then peer reviewed. Due to time limitations, a detailed written methodology was not possible, so the study design concepts were conveyed to the peer reviewers using a briefing format.

3) During the same time period as #2, stakeholders[3] (all of whom had provided written comments in response to the Federal Register notice) requested a face to face meeting to learn the direction, and what scope of the project OSW envisioned. Since the study was not part of a regulatory development process, per se, OSW was not constrained by the Administrative Procedures Act, and was able to meet and talk freely with the stakeholders.

4) Once the proposed study design methodology was presented to the SAB peer review subcommittee, the initial planning and scoping process stopped, and OSW proceeded with study implementation - about 20% of the way through the time budget allowed by the statute.

5) Concurrent with #2 and #3 OSW ensured that Office-director level management concurred with the proposed study objectives, and on scope issues (temporal scope, geographic scope, industries to include vs. exclude).

6) Throughout the initial implementation, stakeholders (both affected industry representatives and environmental groups) requested several face to face meetings and had two more opportunities to provide public comment. OGC said the Federal Advisory Committee Act was not a concern, since the stakeholders were the ones requesting the meetings and OSW was not looking for consensus from them. OSW shared copies of contractors' deliverables and this openness may have helped win stakeholder acceptance of the study methodology. The stakeholders supported the survey instruments, which may have helped in the OMB clearance process. OSW also informed state environmental

[3] During the comment period, EPA received eight comments: three from trade associations (the Utilities Solid Waste Activities Group, the Chemical Manufacturer's Association, the American Petroleum Institute), an industry representative (the General Motors Corporation), two from electric utilities (Virginia Power and Central and South West Services), a combined comment from a group of environmental organizations (the Environmental Defense Fund, the Green Environmental Coalition, and the Montana Coalition for Health, Environment and Economic Rights), and a comment from the National Council of the Paper Industry for Air and Stream Improvement, Inc. which did not directly address the questions in the Federal Register notice.

agency managers about the study early in its design stage, and communicated directly with states in the early implementation stage.

7) During the data collection, which was a critical study element, several of the data-providing stakeholder groups organized workshops to encourage survey recipients (their members) to provide data for the study. OSW also encouraged the survey recipients by offering toll-free telephone assistance and putting answers to frequently asked questions on EPA's internet site.

In conclusion, the Surface Impoundment Technical Plan provides excellent references and examples of planning techniques for screening and analysis of risks based on conceptual models and successful stakeholder interactions. It also provides a detailed rationale for aggregating risks from industrial wastewater facilities.

E.2.6 Lessons Learned

1. The RCRA Study did not rely on the guidance for planning and scoping, however, the project did rely on a detailed plan which included clear objectives, a conceptual model, and analytical plan. The analytical plan had a strong statistical basis for its sampling and interpretation approach. The statistical basis added quantification and specificity to the plan.

The conceptual model showed how stressors, pathways, and effects (both health and ecological) would be combined and presented. This presentation helped inform reviewers of what was planned and enabled EPA to learn from comments how the scheme could be modified.

2. The project established and maintained a schedule for developing the analytical approach, peer review, and analysis that was driven by court deadlines. While the initial schedule appeared to be generous, ultimately, it helped define how long stakeholder deliberation would last.

3. The conceptual model showed how stressors, pathways, and effects (both health and ecological) would be combined and presented. This presentation helped inform reviewers of what was planned and enabled EPA to learn from comments how the scheme could be modified.