Summary Report on
Cumulative Risk Assessment Practicum No. 2
(Phase I: Planning and Conceptual Model Development)

Prepared by:

Office of Science Policy
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

June 8, 1999
Draft

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Preface

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

In July 1997, Administrator Carol Browner issued the *Cumulative Risk Assessment Guidance—Phase I Planning and Scoping*, which set forth certain fundamental values to guide the U.S. Environmental Protection Agency's (EPA's) risk assessment and communication efforts. The *Guidance* directed all EPA offices to take into account the combined effects of multiple environmental stressors in planning and scoping major risk assessments, and to integrate multiple sources, effects, pathways, stressors, and populations where data are available. The *Guidance* placed particular importance on the right-to-know opportunities for citizens and on enabling all stakeholders to understand EPA's ongoing risk assessments and become involved in the decision-making process.

The Guidance defines "cumulative risk" as the aggregate ecologic or human health risk caused by the accumulation of risk from multiple stressors and pathways. The importance of planning and scoping for cumulative risk assessments cannot be over-emphasized. As part of this planning, risk assessors and risk managers are encouraged to define the dimensions of the assessment, including the characterization of the populations (human and ecological) at risk. These include individuals, sensitive subgroups (such as children, the elderly, or critical plant or animal species). The *Guidance* also acknowledges that a broader set of important issues relating to societal, economic, behavioral, and psychological stresses may contribute to adverse health effects. The present state of data and science do not permit a quantitative assessment of risk that encompasses these broader concerns, important though they are.

The *Guidance* identifies a set of eight key aspects of the risk assessment that risk assessors, risk managers, technical experts, and stakeholders must determine during the planning and scoping phase of risk assessment. They are:

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

2. Products needed by management for risk decisions;

3. Approaches and consideration of the dimensions and technical elements that need to be evaluated;

4. Relationships among potential assessment endpoints and risk management options;

5. Analysis plan and conceptual model;

6. Resources (data, models, or other technical tools) required and available;

7. Identity of those involved and their roles; and

8. Schedule to be followed (including timely and adequate internal and external peer reviews).

The "conceptual model" that emerges from the planning and scoping phase of the process is a description or diagram of the relationships among predicted responses of a population of concern and its stressors, including the environmental routes of exposure. The conceptual model also contains an analytical plan that documents how data will be used, how endpoints will be measured (directly or in surrogate), and what uncertainties exist.

The Science Policy Council's (SPC's) Cumulative Risk Working Group[1], in order to implement the *Guidance*, was directed to conduct a series of workshops intended to introduce the concepts of cumulative risk planning and scoping throughout the Agency. The workshops, or practica, are designed to offer guidance and training to EPA risk assessors on cumulative risk and to bring EPA risk assessors and managers together to exchange information and experience in implementing the *Guidance*. The first workshop was held in Washington, D.C. in July 1998.

The second practicum was held in Chicago, IL, on November 12-13, 1998, and attracted more than 40 EPA, state, and Canadian scientists and risk managers. This practicum featured a mix of presentations and facilitated discussions in both large and small group settings. Drs. Mark Harwell and Jack Gentile, both of the University of Miami's Rosentiel School of Marine and Atmospheric Science, lectured and facilitated the development of the cumulative risk conceptual models through case studies of actual risk assessments going on in the Agency.

This report summarizes the highlights of this second practicum, including the information that was presented and exchanged and key themes that emerged from the discussions, which are highlighted throughout the report. The report is organized following the Practicum agenda. Copies of the agenda, the case materials distributed to participants, a roster of attendees and conceptual models drafted as a result of the second practicum are included in appendices.

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[1]Donald Barnes (OA/SAB)
Ed Bender (ORD)
Carole Braverman (Region 5)
Pat Cirone (Region 10)
Penny Fenner-Crisp (ORD)
Michael Firestone (OPPTS)
Edward Ohanian (OW)
Larry Reed (OERR)
Joe Reinert (OPPT)
James Rowe (ORD)
Jeanette Wilste (ORD)
Bill Wood (ORD)

1. Introduction

"Planning and Scoping for Cumulative Risk Assessments" occurs before the assessment begins. It sets the stage for the questions that will be addressed through the analysis.

When asked about their thoughts upon hearing the term "Cumulative Risk Assessment," participants expressed the following ideas:

-resources
-integrated risk
-total environment
-relationship between risk assessors and risk managers
-single vs multiple chemicals
-multiple compounds, multiple pathways
-difficulties in obtaining good data
-skepticism as to how to get good answers
-whole ecological system
-everything but incremental risk
-spectrum of kinds of assessments needed
-overall risk
-multiple risks
-potential exposure
-traditional and nontraditional, sources of risk
-inclusive assessment
-complexity, challenges to decision making
-useful to public, how to integrate with site specific risks
-complex interactions and relationships
-what people want
-uncertainty, unknowns-how to deal with them
-total exposure-sources; similar mechanism/mode of action of chemicals
-complex considerations, less than complete data base but requiring decision; cradle to grave; expanding scope to include stakeholders--broad and complex in nature
-developing systemic approach
-need framework for scoping and strategies to address

2. Overview of the Planning and Scoping Process

EPA's *Guidance on Cumulative Risk Assessment: Phase I-Planning and Scoping* draws on the process and procedures described in the ecological risk assessment guidelines. Planning and scoping begins with a dialogue between the risk manager and risk assessor to help define the risk management needs for the assessment. For the long term, EPA's Risk Assessment Forum (RAF) is developing a framework for cumulative risk assessment guidelines which will discuss traditional approaches for performing risk assessments.

This workshop addresses the preparations for the risk assessment, which involves discussing what to include or exclude from the risk assessment through brainstorming, identifying participants and contributors, and formulating stressor-response hypotheses. These principles are applied to both hypothetical and real case studies. Definitions of cumulative risk are developed in context on a case by case basis.

The planning and scoping guidance includes these basic steps: 1) problem formulation dialogue (risk assessors, risk managers, stakeholders, economists, etc); 2) defining the purpose of the risk assessment; and 3) developing a conceptual model. The conceptual model is a hypothesis about the relationship between stressors (biological, chemical or physical promoters of some effect) and endpoints (receptors). Human health assessors are still trying to determine if this is a useful process.

<u>Definition of Cumulative Risk</u>

1. Who is affected or stressed?
2. What are the stressors?
3. What are the sources?
4. What is the time frame for the risk(s)?
5. What are the assessment endpoints?

Questions and Discussion:

Integrated vs Cumulative Risk? In this case, these terms are almost equivalent. The use of the term "dimension" in the *Guidance* may be confusing. (Some think it refers to spatial aspect like landscapes).

Should stakeholders be in dialogue with risk assessors and risk managers? In the model derived from ecological guidelines, problem formulation occurs within EPA as a scientific task. There are internal discussions within EPA on this point. Some interpret the ecological guidelines to say this is a scientific endeavor. We are trying to find that boundary between the risk assessment and this broader discussion.

Cumulative risk assessment is neither generic nor consistent across the Agency. On the one hand are site-specific Superfund and RCRA assessments, while, on the other hand, there are air and water rules which set national standards. We cannot resolve differences across programs here. Those issues will be addressed in cumulative risk guidelines and other projects.

In the SPC guidance, we are trying to capture needs across the Agency while deferring to offices for specifics. The guidance encourages using other sources of help and input. At this time, cumulative risk planning and scoping is a qualitative process, but it could become quantitative if we choose to bring data to the discussion. Planning and scoping provides a broad foundation for cumulative risk assessment and allows users to develop a reasonable subset of decisions upon which to move forward. This process provides benefits in many situations. The RAF will address this issue in the future. It is necessary to break down the problem of cumulative risk into bite-sized pieces. This process can be exceedingly difficult, but we need to listen to the questions asked by risk managers and stakeholders and to frame our approach to address those questions.

3. Conceptual Model Development

Dr. Mark Harwell explained that the risk assessment process has evolved over the past twenty years. The basic structure of a risk assessment includes: hazard assessment, exposure assessment, and risk characterization as described by the National Research Council (NRC) in 1983. Ruckelshaus incorporated this paradigm into Agency policy. The Agency also distinguished between risk assessment and risk management. Due to concern about risk managers "having a on thumb on scale" (Gorsuch era); the Agency kept a "bright line" that separated risk assessment from risk management so that risk assessments would not be biased by non-scientific factors. This separation between risk assessment and risk management still is maintained in parts of the Agency.

Since the 1980's, there has been more consideration to entwining risk assessment and risk management in documents, including the ecological risk guidelines, cumulative risk guidance, and recent National Academy of Science (NAS) recommendations on "Understanding Risk". The Agency also has attempted to rank risks in its 1985 "unfinished business" project, and in the Science Advisory Board's (SAB) 1988 "reducing risk" project. This project recommended that EPA elevate ecological risk in addition to human health. The process used by the Risk Assessment Forum to develop an ecological risk framework (1992, 1997) put together a structure to tackle more difficult problems while understanding many uncertainties still exist.

The "Framework for Eco Risk Assessment" found that the Agency had concerns about multiple chemicals. They said that the "Red Book" paradigm was insufficient to deal with ecosystems and the multiplicity of risks, and that EPA needed a more broadly defined paradigm. The framework also expanded from a focus on chemicals to stressors (agents of change). Stressors are any change leading to ecological effect (physical, chemical, biological stresses). Stressors also may include psychological and economic factors.

3.1 Problem formulation

The first stage in the process is *problem formulation,* in which the scope, spatial extent, goals, initial ideas on stressors, human activity, and other issues are discussed. At present, the problem formulation phase is more developed for ecological risk assessment, but it has parallels in human health risk assessment. In fact, the terms "planning and scoping" and "problem formulation" mean much the same thing. A major output of the planning and scoping phase is a conceptual model leading to the analysis phase (qualitative or quantitative in nature), which leads to development of an analysis plan. The analysis plan is a scientific planning activity which includes sensitivity and uncertainty analyses and conclusions about endpoints for the assessment. This type of preliminary thinking and dialogue is essential to promote adaptive management–a flexible way of making decisions that also deals with uncertainties, which we have found valuable in dealing with stakeholders.

Human Health Risk Assessment	Ecological Risk Assessment
Hazard Identification	Selection of end points
Exposure Assessment	Characterization of ecosystems, communities, and populations potentially at risk

In ecological risk, any human action can affect an ecosystem. In problem formulation (planning and scoping) for ecological risk assessment, we distinguish significant from trivial actions (based both on societal concerns and ecological impacts). We define a parsimonious set or suite of health changes and identify those that really matter (in terms of economic or societal consequences). For the risk assessment, we measure endpoints and surrogate measures. The conceptual model is a graphical representation of these societal drivers, environmental stressors, and ecological effects. In planning and scoping for cumulative risks in the human health context, we follow the same problem formulation approach for systems at risk from similar stressors.

3.2 Societal goals and scientific endpoints

Goals for society are set by society and constrained by science. The goal must be established first (*e.g.*, restore everglades). Science translates what that means (*i.e*, ecosystem attributes of importance). Endpoints are the bridge between society and science. Measures are chosen as a scientific function to address a technical question. There needs to be a feedback loop to ensure that the technical question supports measuring attainment of the goal. The NRC (1996) discussed the feedback loop as an analytic deliberation that is an iterative process. The basic concept of this iterative process is what the Agency is struggling to adopt through the cumulative risk guidance. The current EPA Science Advisory Board (SAB) project on integrated risk also is working on this problem.

Dr. Harwell described categories of ecological endpoints, noting that they were different for different ecosystems. These ecological endpoints increase in complexity from endangered species and population survival to landscape-level endpoints. A comparable set of endpoints for human health should be developed. There also is an interesting set of interactions between ecological and human health concerns (*e.g.*, vectors may have direct relevance to human disease; plants producing cancer drugs). Some of these could be added to the cumulative risk guidance.

Dr. Harwell presented a comparative ecological risk assessment from Tampa Bay, where the Port Authority compared the potential impacts of a spill of two chemical mixtures (oils). He explained the endpoints of concern, critical habitats (including sea grass beds, mud flats, and marshes), and systems at risk, to be assessed. The physical processes in fate and transport models for fuel oils were key elements in the study. Toxicity tests were conducted on principal biota. Risks were evaluated under scenarios for shipping the oil with selected sets of conditions for comparing stressors. The audience found that the conceptual model was very helpful for defining the scenarios and interpreting the data.

3.3 Conceptual Model Development

Dr. Jack Gentile discussed principles and examples for developing conceptual models. A conceptual model is a spatially explicit graphical or text description of the candidate causal linkages among sources, stressors, receptors and endpoints describing the spectrum of potential risks. He recommended the following steps for developing conceptual models:

1. Define the goals and assessment context.
2. Delineate scales and boundaries.
3. Inventory land uses/activities.
4. Describe potential stresses and sources.
5. Identify contaminant release mechanisms.
6. Describe exposure pathways.
7. Identify health/ecological endpoints.
8. Determine specific health/ecological endpoints..
9. Determine specific health/ecological measures.
10. Develop a suite of risk hypotheses.
11. Rank relative importance of potential risks.

Dr. Gentile also presented a General Conceptual Model Sequence, as follows:

Societal Drivers⇒System stress⇒Stress regime/Exposure Pathways⇒Disturbance/Stressor Co-occurrences with Receptors⇒Primary/Secondary Effects⇒Health/Ecological Endpoints⇒Measurements

He described several examples to demonstrate some of the principles and methods listed above. Highlights are summarized here. (See the appendix for additional information). The first example is the Waquoit Bay Conceptual model. Dr. Gentile showed how the sources (drawn from human activities) might contribute to exposure. He also discussed how to aggregate kinds of stressors (toxics, nutrients, etc.), system stressors toward ecologic effects, and measurement assessment endpoints. He noted that it helps to identify how various stressors affect the ecosystem and to prioritize stressors. One must choose how to partition out major stressors and determine whether and how are they acting independently or synergistically. For example, are major stressors acting cumulatively on an endpoint or across endpoints in interrelationships? He also recommended that each pathway be developed independently and then put back together in the context of the complete model. Dr. Gentile showed another example that used an Impact Matrix for Green Bay, which involves looking at nutrient loading (stressors) vs impact criteria (human health, aesthetics). In this example, major gaps were determined with BPJ.

Drs. Gentile and Harwell applied these processes to a set of water resource management problems for South Florida which involved extensive interaction among governments and other stakeholders. Initially, societal goals were developed in order to get stakeholders and scientists to discuss both the science of the problem and restoration options. Here, societal goals guided science efforts. A Governor's Commission was created, and the commission was effective in promoting cooperation between the groups. He described spatial boundaries of the risk assessment using ecological criteria, hydrological criteria, and physiological transcripts/designations (sawgrass, mangrove estuary, etc). (The conceptual model Dr. Gentile described is included in Appendix D).

For the analysis phase for the Biscayne Bay model, hydrology was the major factor. In fact, hydrology was found to have impacted all 13 different models used in the study. To confirm this, the best relationship was selected, and a holistic model incorporating the concerns for each endpoint was used.

A member of the audience asked how to establish performance criteria for each stressor. Criteria for impact will be different across stressors. He was told that you can rank major stressors and dominant effects to be sure they are represented in the conceptual model.

The discussion also highlighted an example of the development of RI/FS conceptual site models being developed for a Superfund site in a western state. The problem in the example was mining waste that was distributed over many miles of a watershed and reservoir system. Mining waste was represented by a chemical-physical stressor model. Effects were both ecological and human health. The basin was subdivided using geology, hydrology, and ecology into five sub-basins, a series of potential watershed segments. For each sub-basin the habitat and contaminant levels were graded. Inputs, release mechanisms, affected media, exposure routes, receptors and systems, effects, endpoints, and measures were estimated for each sub-basin. Geography, topography and sediment movement were also evaluated for remediation options. Based on contaminant levels, two segments were termed heavily polluted. Biota were characterized according to class 1 streams through generalized models.

The conceptual model was constructed from the preliminary process models and the biological models. Most important pathways were determined from the most likely exposures and endpoints of greatest concern. For humans, ingestion of fish and inhalation of contaminants in domestic water supplies are being scrutinized as major routes. The chemical-physical process model links the stressors to both ecological concerns and human health concerns. The conceptual model also has helped identify key characteristics of remediation approaches.

4. Hypothetical Case Study

Dr. Harwell described a hypothetical case involving an industrialized and agricultural watershed. The scenario (See Appendix E) involves a new hazardous waste incinerator which has been proposed for this area. The community was concerned about the cumulative risk associated with this additional source of air emissions and solid waste. Dr. Harwell led the group through an exercise using the planning and scoping guidance to define cumulative risk for each of the possible dimensions, narrow the possibilities to a parsimonious set, and develop a conceptual model.

The group brainstormed ideas on risk dimensions. These are summarized below:

o **Sources**: Single sources, point sources, non-point sources; multi-sources: combination of those above

o **Stressors** (by source category):
- Agriculture--stressors-nutrients, pesticides, sedimentation, particulates
- Petrochemicals--stressors--toxic organics, criteria air pollutants, toxic inorganics, hydrocarbons
- Industrial— stressors— ammonia, SO2, particulates, metals, temperature, economic =noise, odors, cultural, aesthetics, property values
- Aquaculture stressors--nutrients, pesticides and drugs, disease/pathogens, exotic species, odors, habitat alteration--wetland conversion, levee, hydrologic effects

Urban Stressors— pesticides, nutrients, toxic organics, toxic inorganics, flooding (physical), mobile air emissions, habitat alteration, turbidity, PAHs, pathogens, exotic species,

Societal: thermal increases, odor, noise, air pollutants, crowding

Receptors: (what's at risk?)
(eco receptors usually talking about populations or higher not single species)

Aquatic Habitat
-fish
-amphibians
-macrophytes
-water fowl
-macro invertebrates
-trophic structure (?)

Human
-women of child-bearing age
-worker populations
-respiratorily sensitive
-subsistence fishers
-swimmers

Endpoints (what should you worry about/minimal set)

Ecological (aquatic)
-biodiversity-community richness, evenness
-habitat quality-eco
-water quality-eco

-economic fish health-pop
-critical species loss-pop
-habitat species/seagrass-pop

-ephemeral wetland loss-landscape

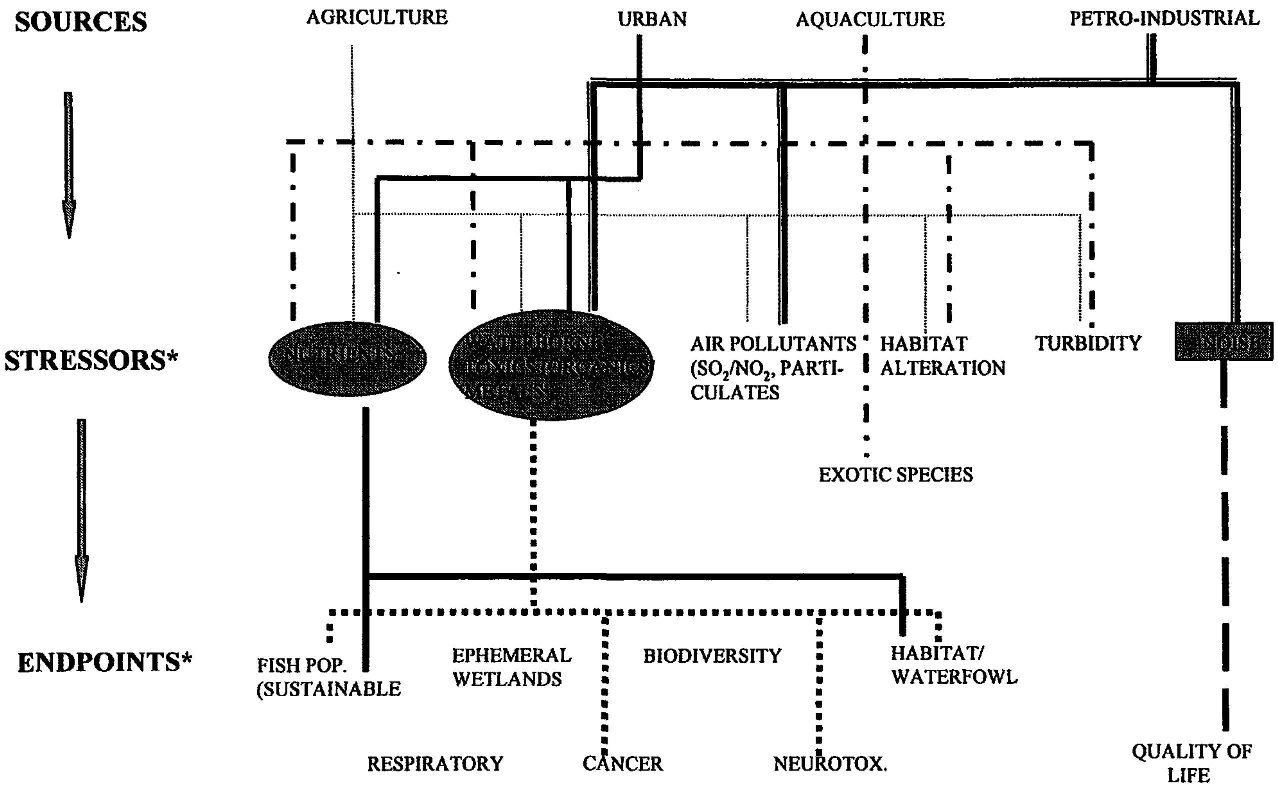
Human Health (go to specific Dose Response level)
-cancer (bladder)
-the array in the guidance
- respiratory
- (may want to go back and do attributable risk exercise; 4x increase in bladder cancer)
- capture endpoints people care about!!!!

It was noted that it is important to look at similarities and dissimilarities of eco and human risk assessment. For example, .causation is always a problem in human health risk assessment and this is a factor that differentiates human health from eco risk assessment.

Dr. Gentile presented a hypothetical case example for cumulative risk which incorporated both ecological and human risk concerns. (See Appendix E). After discussing the case example, Dr. Gentile reviewed the six basic cumulative risk questions used to flesh out details on sources, stressors, exposure pathways, single species routes, community/ecosystem routes, receptor categories at risk, and human health and ecological endpoints that are incorporated into the conceptual model. Based on the hypothetical case example, a preliminary conceptual model was sketched out to illustrate the approach that could be taken.

Observations of the group

1. Include quality of life as an endpoint.
2. It is not a good idea to present complex models to uneducated stakeholders, but if you get them to help you build the model, you can get buy-in. You must get stakeholders involved.
3. Important to work with stakeholders on endpoints of significance.
4. Different parts of country will accept different levels of risk.



* It is critical to identify what are the mechanisms/causal relationships between stressors and endpoints.

Conceptual Model developed at the Practicum for the Hypothetical case.

5. Case Studies

On the second day of the workshop, Mark Harwell introduced the EPA case studies. They are: 1) the Chicago Cumulative Risk Initiative(CCRI), presented by Carole Braverman (Region V); 2) Wood Preservative (PCP/HDWP) , presented by Nader Elkassabany and Wanda Jakob (Office of Pesticide Programs): and 3) the Cumulative Risk Index Analysis for Concentrated Animal Feeding Operations (CAFO), presented by Gerald Carney (Region VI). The three cases represent a spectrum of cumulative risk problems in the broadest sense. They concern human health and ecological impacts, and involve place-based and national assessments. All are multimedia and all are presently underway. Also, each has significant stakeholder involvement outside the Agency. The case materials for each study are provided in the Appendix.

Practicum participants were divided into three break out groups to focus on the application of planning and scoping guidance for each of these cases. Each group worked separately. Case presenters provided an introduction to the problem and facilitators led each group through the guidance.

Each case study summary below is followed by the break out group's report. Comments and suggestions pertaining to each case study are shown in boxes.

5.1 The Chicago Cumulative Risk Initiative

The Scenario

The Chicago Cumulative Risk Initiative (CCRI) is a multi-Office effort to measure and reduce the risks posed to residents of the Chicago metropolitan/Northwest Indiana areas by cumulative exposure and hazard. CCRI was initiated in response to a Toxic Substances Control Act §21 Citizen's Petition from eleven Chicago-area community advocacy groups. The Petition focused upon the regulatory gap in the Clean Air Act that allowed industrial air permits to be approved on a site by site (rather than cumulative) basis. The advocacy groups' purpose in submitting the Petition was to convince the Agency to implement activities that would measure and mitigate the cumulative risks faced by area residents. CCRI's focus has expanded beyond the limited, sector- and media-specific concerns (*e.g.*, incinerator siting) originally expressed in the §21 Petition to include information and planned action on multi-media sources of pollution. CCRI consists of four phases:

Phase I: Generating the environmental loading profile.

- The Agency will establish quantities and destination of toxics released into the Chicago-area environment.
- The Agency will analyze this data to approximate cumulative environmental and human exposure.

Phase II: Convening a facilitated workshop to discuss loading profile data, risk assessment, and pollution prevention/remediation options.

- The Agency will work with State/local regulators and community groups (Stakeholders) to create a consensus on data interpretation, calculation of the toxics hazard, and the general approach for "cumulative"risk analysis.

Phase III: Performing "cumulative" risk assessment.

- The Agency will act to develop the consensus procedure (from Phase II) into a scientifically valid methodology for approximating cumulative risk for residents of the Chicago metro area.

Phase IV: Implementing Pollution Prevention/Remediation activities (e.g., initiating industry negotiations, public education campaigns).

The Results

> **CCRI Evaluation Comments**
>
> - Covered basic elements and the conceptual model very effectively.
> - Take environmental justice into account.
> - Stakeholder involvement discussion was limited.

This break out group defined the problem, goals, stakeholders, stressors, sources, and endpoints, and presented a simplified flow diagram/conceptual model for the risk assessment. Ecological risk was separated from human health risk for later discussion. They concluded that the cumulative risk conceptual model is really a "living document" and should be subject to iterative changes and refinement by the stakeholders as the study progresses. The group started with sources and identified stressors (ozone, particulates, lead), defined the media (air, soil, water) and pathways (inhalation, contact, ingestion), and identified potential diseases and health impacts (such as eye irritation, asthma, neurological effects). They developed similar but separate approaches for ecological risks. They developed measurement tools to recognize effect levels and monitor trends over time.

The group reported that they benefitted from having participants who were very familiar with the case, the available data, and the risk assessment. Many of the group members felt that having a better understanding of environmental conditions in Cook and Lake Counties would help future permit decisions and communication with stakeholders. It also would help in framing societal goals within the region.

5.2 Wood Preservative (PCP/HDWP)

The Scenario

Pentachlorophenol (PCP) is used throughout North America as a wood preservative. PCP is used primarily in the treatment of utility poles, and also is used to treat railroad crossties, wood pilings, fenceposts, and commercial/residential decks. PCP is teratogenic, fetotoxic, and oncogenic, and has been banned from use on all non-wood applications since 1987. It is classified as a "probable human carcinogen." The risk assessment is driven by PCP's Reregistration Eligibility Decision Document, which is due in 1999, and will consider FIFRA, FQPA, Clean Water Act, Clean Air Act, RCRA, and input from the North American Free Trade Agreement (NAFTA). Stakeholders include industry and trade associations, environmental groups, and the public. Unlike the other cases discussed in the workshop, the PCP risk assessment does not address a particular site–it is nationwide in scope.

The hazard identification will examine all available data for acute toxicity, developmental effects, chronic effects, carcinogenicity, and endocrine effects. Epidemiological studies and pesticide incident data will be used as available. PCP is highly toxic to fish (acute and chronic), moderately toxic to birds in acute oral doses, but is virtually nontoxic to birds in dietary doses. Human exposure scenarios include occupational exposure (wood treatment workers; construction workers). Primary pathways are dermal absorption, inhalation of treated dust and aerosol, and ingestion (indirectly, from contaminated hands). Environmental exposure pathways under consideration include emissions from utility poles and other treated lumber via air, soil, and water routes. Uncertainties and remaining issues include the statutory overlaps, disposal of treated/ contaminated wood after service, limited emissions data, and a focus on individual risk.

The Results

The group began with a presentation on highlights of the regulatory history, chemistry, usage, hazard identification and human and environmental exposure concerns, including the issue of microcontaminants.. The group agreed to a process that involved identification of sources, stressors, pathways and endpoints for a conceptual model, primarily focused on PCP and microcontaminants. A previous ranking exercise on human and environmental sources and pathways, which was completed at the last practicum, was the basis for ranking the degree of exposure (low, medium or high). The ranking relied on professional judgement.

HUMAN	ECOLOGICAL	SOURCES
Occupational	Aquatic	Manufacturing
Accidental (L)*	Spill	Transport [of chemicals and logs]
Occupational (H)*	Aquatic (L)	Wood Preservative Facility
Occupational (L)	Soil (L)	Utility Poles [localized]
Occupational (RCRA)	Aquatic (H)	Disposal of Treated Poles [consumer misuse]
Children (L) (?)		Residential Uses (e.g., decks)
(L)	Soil (L)	Fences
(L)	Aquatic	Pilings, Piers, Docks
Residential Occupational	Soil/Water (H)	Remedial Ground line Treatment
(L)	(L)	Farm buildings/Industrial buildings

*L=Low, H=High

Human Pathways/Routes of Exposure

SOURCE	DERMAL	INHALATION	INGESTION
Manufacturing	High	Low	Low
Transportation			
Wood Preservative Facility	High	Medium	Low
Utility Poles	Low	Low	Low
Disposal of Treated Poles	Low (RCRA Issue)	Low	Low
Residential Uses/ subpopulation-children	Medium - children	Low	Medium
Fences	Low	Low	Low
Pilings, Piers, Docks	Low (N/A)	Low	Low
Remedial Ground line treatment			
a. **Occupational**	Low	Low	Low
b. **Residential**	High	Low	High
Farm Buildings/Industrial Buildings	Low	Low	Low

The group used a broad pathway design with major sources at top, followed by stressor sources, pathways and major habitats impacted (a Biscayne Bay model). Major habitats of concern were evaluated and a table of receptor habitats and endpoints affected by PCP and dioxins/furans was developed. For example, for soils: earthworms, microbes and invertebrates were highlighted as potentially affected endpoints. The group also attempted to construct a rough conceptual model. (Detailed notes from the breakout group are included in Appendix F).

As follow-up to its discussion, the group developed an example of a draft human health PCP conceptual model. (See Appendix H). Participants emphasized that the final conceptual model should be accompanied by a detailed narrative that describes the thought process and basis for the conceptual model design.

5.3 Cumulative Risk Index Analysis for Concentrated Animal Feeding Operations

The Scenario

Concentrated Animal Feed Operations (CAFOs) are a common and significant concern throughout Region 6. CAFOs are large (significantly so in terms of watershed areas) and produce enormous quantities of waste discharge into on-site lagoons. These lagoons and associated operations are permitted under the Clean Water Act's National Pollutant Discharge Elimination System (NPDES) and require environmental impact reviews under the National Environmental Policy Act (NEPA). NEPA requires "cumulative" evaluations of the proposed threat. For some watersheds which are not meeting state-prescribed standards, there may be Total Maximum Daily Load analyses and additional restrictions or penalties imposed. There is also public concern over the rapid expansion of CAFOs. EPA needs to determine when a watershed reaches a significantly polluted or impacted state, but there currently is no method or approach for doing so. The risk evaluation was requested by Region 6's Enforcement Office due to the NEPA requirement inherent in the NPDES review for waste lagoons.

Stakeholders include Region 6 program managers and staff (involved with NEPA enforcement, NPDES permits, watershed quality, groundwater, surface water, risk assessors, RCRA, Superfund, and GIS experts), academics, industry (primarily swine production), state regulators, EPA headquarters (NEPA, agriculture center), Department of Agriculture's Natural Resource Conservation Service, environmental groups, and residents.

The cumulative/multimedia aspect to CAFOs include surface water contamination (ecological and human health), drinking water contamination from surface water and groundwater, microbiological/pathogen hazards from wastes, statutory overlap (CWA, CAA, NEPA, FQPA, RCRA), and multiple pathways and routes of exposure. In addition to the concern from waste lagoons, there is a significant public concern with odors.

Region 6 developed a new approach based upon a mathematical algorithm that established the potential for significant environmental risk (CRIA) for each CAFO.

$$\text{CRIA} = \frac{\text{Watershed Unit Subarea}}{\text{(Total Affected Area} \div \text{Watershed area)}} \times \text{Degree of Vulnerability} \times \text{Degree of Impact}$$

Watershed Unit Subarea (scale of 1-4); Degree of Vulnerability (scale of 1-5); Degree of Impact (scale of 1-5)

The Results

The case-study break out group developed lists for each dimension in the Cumulative Risk Guidance. They also developed separate lists for assessment and measurement endpoints. The initial discussions clarified the terms "stressor" and the "sources of stress" from a concentrated animal feeding operation. Several members of the group indicated that, in the states in which they worked, feedlots and suburban development were in direct conflict. One participant noted that feedlots were on the ballot of twenty states in recent elections.

The group identified several issues that were unusual to this case study. For example, the primary human concerns concerned quality of life impacts (in terms of odor and nuisance) from the facilities rather than health effects. They also noted that cumulative effects from multiple facilities within the same watershed also could be examined. The group did not reach agreement on how to develop a preliminary conceptual model. They concluded, however, that Region 6's CCRI tool appeared to be valuable for screening site-specific decisions, such as facility siting.

CRI Evaluation Comments

- CRIA approach to screening was very useful.
- Helpful ideas for risk managers. Needed more time to explore the model and linkages.
- Slow starting, but valuable. Need to clarify dimensions and process for building the models.
- Although skeptical at first about the topic of animal feedlots, it was an interesting and important issue.

6. Discussion and Next Steps

Meeting in plenary session, Practicum participants raised several issues and made several suggestions about how to improve Agency efforts for planning and scoping for cumulative risk assessment, and about future workshops on the subject, including the following:

1. Take things a step further in next practicum; Develop a framework for Cumulative Risk Assessment.
2. Value in taking conceptual model further in development (more detail, reality check in process).
3. Clarify the scope in terms of spatial extent of the problem to be addressed.
4. I am optimistic after working through diagrams, at least possibility for future; need to identify important threats and problems with a transition away from programmatic to multi-media risk assessments.
5. It is normal that we do not have a complete database. We need a method to zero in the most important decisions/risk.

Participants made several comments and raised a series of closing questions, including the following:

- When and how should we engage stakeholders?
- Cumulative risk assessment should be used beforehand to organize thoughts and present to public, get feedback from public and then revising conceptual model
- Endpoints will be highlighted by stakeholders
- Includes exposure, habits, activity patterns
- Stakeholder meetings should be held to introduce them to conceptual model approach; trade-offs will be forced by such meetings; need to involve at some point; prioritize issues.

Appendix A. List of Participants

Cumulative Risk Practicum Participants
Chicago - November 12-13, 1998

Elmer W. Akin
EPA/Region 4 (AFC-EPA/WD)
61 Forsyth Street, SW
Atlanta, GA 30303
(404) 562-8634

Mike Beedle
EPA/Region 5 (DE-9J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-7922

Edward Bender
EPA/ORD (8103R)
401 M Street, SW
Washington, DC 20460
(202) 564-6483

David Belluck
MPCA
520 Lafayette Road
Saint Paul, MN 55906
(612) 296-7874

Carol Braverman
EPA/Region 5
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-2910

Lisa Capron
EPA/Region 5 (DE-9J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-0878

John Connell
EPA/Region 5 (DT-J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-6832

Harriet Croke
EPA/Region 5 (DRP-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-4789

Arunas K. Draugelis
EPA /Region 5 (SR-6J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-1420

William Enriquez
EPA/Region 5 (DW-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-1484

Priscilla Fonseca
EPA/Region 5 (OT-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-1334

Jack Gentile
Center for Marine & Environmental
Analyses Rosenstiel School of Marine
and Atmospheric Science
University of Miami
4600 Rickenbacker Causeway
Miami, FL 33149-1098 USA

Mark Harwell
Center for Marine & Environmental Analyses Rosenstiel School of Marine and Atmospheric Science
University of Miami
4600 Rickenbacker Causeway
Miami, FL 33149-1098 USA

Brenda Jones
EPA/Region 5 (SR-6J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-7188

Margaret L. Jones
EPA/Region 5 (DT-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-5790

Lawrence Lehrman
EPA/Region 5 (MG-9J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-0836

Karen McCullagh
(PMRA)
Room E-735
Sir Charles Tupper Blvd.
2250 Riverside Drive, A.L. 6607E
Ottawa, Ontario, Canada K1AOK9

Caje Rodrigues
(PMRA)
Room E-735
Sir Charles Tupper Blvd.
2250 Riverside Drive, A.L. 6607E
Ottawa, Ontario, Canada K1AOK9

William L. MacDowell
EPA/Region 5 (AE-17J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-6798

Marvin Hora
MPCA
520 Lafayette Road
Saint Paul, MN 55155
(931) 296-7201

Mario Mangino
EPA/Region 5 (DRP-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-2589

Chuck Maurice
EPA/Region 5 (DW-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-6635

Daniel Mazur
EPA/Region 5 (DW-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-7997

Rosita Clarke-Moreno
EPA/Region 5 (SR-6J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-7251

Patricia Morris
EPA/Region 5 (AR-18J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-8656

Amy Mysz
EPA/Region 5 (DRP-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-0224

Colleen Olsberg
EPA/Region 5 (DRP-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-46-86

Michele Palmer
Department HHHS (ORHA)
105 W. Adams, 17th Floor
Chicago, IL 60604
(312) 353-7800

Amy Pelka
EPA/Region 5 (B-19J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-9858

Larry Reed
EPA/OERR (5201G)
401 M Street, SW
Washington, DC 20460
(703) 603-8960

Joseph C. Reinert
EPA/OPP (2129)
401 M Street, SW
Washington, DC 20460
(202) 260-0512

George Bollweg
EPA/Region 5 (DW-8J)
77 West Jackson, Blvd.
Chicago, IL 60604
(312) 353-5598

James Rowe
EPA/ORD (8103R)
401 M Street, SW
Washington, DC 20460
(202) 564-6488

Margaret Sieffert
EPA/Region 5 (AE-17J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-1151

Meagan Smith
EPA/Region 5 (DW-8J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-4446

Mary Beth Smuts
EPA/Region 1 (CPT)
JFK Federal Building
Boston, MA 02203
(617) 565-3232

Maryann Suero
EPA/Region 5 (AR-18J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-9077

Bilue Thomas
EPA/Region 2 (DEPP/MPB)
290 Broadway
New York, NY 10007
(212) 637-3768

Winona Victery
EPA/Region 9 (PMD-1)
75 Hawthorne Street
San Francisco, CA 94105
(415) 744-0121

Alan Walts
EPA/Region 5 (C-14J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-8894

Amary White
EPA/Region 5 (T-13J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-5878

Howard Zar
EPA/Region 5 (B-19)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 886-1491

Lucy Stanfield
EPA/Region V (B-19J)
77 West Jackson Blvd.
Chicago, IL 60604
(312) 353-3440

Appendix B. Practicum Agenda

Cumulative Risk Assessment Workshop
(Phase I: Planning and Conceptual Model Development)
November 12-13, 1998
Chicago, Ill.
Room 328
77 West Jackson Boulevard

Agenda

Purpose: Demonstrate the use of the Cumulative Risk Assessment Guidance (Planning and Scoping) process and the Ecological Risk Assessment Guidelines principles for developing cumulative risks from multiple sources over a range of spatial scales. Illustrate the feasibility of the planning and problem formulation phases for identifying critical issues such as public values and perceptions, defining sources of stress and potential assessment endpoints and indicators and finally demonstrating the utility and value of conceptual models in the assessment and decision making process.

November 12, 1998

8:00 Registration

8:30 Welcome - David Ullrich, Regional Administrator (Acting)

Introduction of the Cumulative Risk Assessment Theme - Ed Bender

- Participant introductions and expectations

- Highlights of the Cumulative Risk Assessment Guidance

9:30 Overview of Scoping/Planning Process - Mark Harwell
Conceptual Model Development - Jack Gentile

Broad overview of the risk planning process and experience of the outside experts. Include each step through the conceptual model. The model presentation will highlight the principles and process for developing conceptual models, employ examples to illustrate the diversity of models, and discuss how conceptual models could be used to engage decision makers and stakeholders. Cumulative Risk Guidance and Ecological Risk Guidelines will also be compared.

12:00-1:15	Lunch
1:15	Introduction of Hypothetical Case Study and Practicum - Mark Harwell A single case study will be used to give participants an opportunity to apply the planning and scoping guidance and actually develop a conceptual model. The hypothetical case study reflects both non-chemical and chemical categories of stressors as well as both ecological and health concerns. Step through each part of the planning and scoping and problem formulation process.
4:15	Recap
4:30	Adjourn

November 13, 1998

8:00-8:30	Introduction to EPA Case Studies and Instructions to Work Groups - Mark Harwell
8:30	Adjourn to work groups Case Study Presentation (Leaders) Work groups will develop planning and scoping and develop conceptual models Case Study 1 Chicago Cumulative Risk Initiative - Carole Braverman Case Study 2 Wood Preservative (Pentachlorophenol) - Nader Elkassabany, Wanda Jakob Case Study 3 Cumulative Risk Index Analysis (CAFOs) - Gerald Carney
12:00-1:15	Lunch
1:15	Continue work in break outs
3:00	Report Out, Discussion and Next Steps - Ed Bender
4:00	Adjourn (Debrief with Case Presenters)

Appendix C. Preliminary Case Study Materials

Cumulative Risk Assessment Practicum
Case Study Draft
Cumulative Risk Index Analysis
(Swine Concentrated Animal Feeding Operations)
Region VI

Prepared for Practicum
November 12-13, 1998

CUMULATIVE RISK INDEX ANALYSIS (CRIA)

(Swine Concentrated Animal Feeding Operations)

Introduction

Regulated concentrated Animal Feeding Operations (CAFOs) are open lots or facilities where animals have been, are, or will be stabled or confined and fed or maintained for a total of at least 45 days in any 12-month period, and the animal confinement areas do not sustain crops, vegetation, forage growth, or post-harvest residues in the normal growing season (U.S. EPA. 1997a, 40 CFR 122.23[b]).

Animal waste from these facilities can potentially contaminate ground water, surface soils and water, and air. Contamination includes nitrogen and phosphorus compounds, organic amines, fats, and sulfides. Environmental concerns include ecological, human health, and socio-economic issues (i.e., eutrophication, biological oxygen demand, E. coli, Pfisteria pisicida, and other microbial contaminants, carbon dioxide, ammonia, and nitrogen oxide releases, toxic and nuisance odors, fish kills, nitrate drinking water contamination, particulate matter from trucking operations, and other impacts). Region 6 has developed a watershed based geographic information system / cumulative risk screening methodology to assist EPA regulators in environmental assessment and permitting of CAFO facilities through the National Environmental Policy Act (NEPA) and the Clean Water Act (CWA). The environmental assessment tool or CRIA (Cumulative Risk Index Analysis) 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 the Fish and Wildlife Service, state environmental agencies with cultural resources concerns). The analysis identifies thirty-four (34) assessment parameters. The CRIA considers environmental vulnerabilities and potential effects of individual CAFO projects by watershed subunits. These subunits are called Hydrologic Unit Codes or HUCs. A watershed subunit is created by merging watershed area data and state stream segment information. The HUC becomes the methodology's base analytical unit.

The scope or base area of analysis could be an entire state a few selected counties, a circle drawn around the project site, or a watershed. The CRIA methodology does not just list various risk concerns for projects but, applies a ranking criterion to each of the 34 environmental and industry operation concerns. This effectively rates the parameters from desirable to less desirable compelling EPA regulators, industry, and others concerned with CAFO siting and operations to communicate regarding the industries potential impact within a given watershed or larger drainage area. The watershed level of analysis is reasonable (ecologically based and not so geographically large that cause and effect relationships among criteria are lost). The level of analysis is also consistent. Watersheds are a common denominator for other programs, agencies, the public. A systematic GIS analysis sums the % areas of projects within 11-digit HUCs and scores the projects on a 1-5 scale based on a number of location specific "vulnerability" criteria and industry imposed "impact" criteria. A list of the 34 criteria is provided in Table 1. Specific 1 - 5 rankings are provided in Appendix A (the CRIA methodology is also found on the web at http//www.epa.gov/xp/earth1r6/enxp4a.htm). Region 6 is currently using the CRIA in NEPA for evaluation of swine CAFOs in western Oklahoma. The CRIA results are documented into a NEPA Statement of Findings for the Pig Improvement Company (U.S.EPA, 1997b) and an Environmental Assessment(EA) for Vall, Inc. (U.S. EPA, 1998). Region 6 have used CRIA results to communicate regulatory concerns, consistently compare CAFO operations, secure remediation agreements, and gain assistance from industry to conduct basic ecological research around CAFOs. The research field tested the accuracy of CRIA evaluations for odor and wildlife ecology (U.S.EPA, 1997), Region 6 has performed CRIA analyses for over fifty swine CAFOs. The Region plans to expand the methodology to cattle, chicken, and other animal agriculture operations throughout Texas, Oklahoma, Louisiana, Arkansas, and New Mexico.

CRIA Methodology

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; and 3) impacts from known CAFO projects (water quality, vector/odor, wildlife habitat) specific to each watershed subunit. Table 1 lists these criteria for cumulative risk consideration.

Cumulative risk criteria are summed using a mathematical algorithm. Key components of the algorithm are Area of known CAFO projects (AI), Area of the Watershed Subunit (AWS), Degree of Vulnerability (DV), and Degree of Impact (DI).

The CRIA algorithm is as follows:

$$CRIA = [\Sigma A / AWS]\ (DV)\ (DI)$$

where:

CRIA = Potential for significant environmental risk

A = Area of known CAFO projects

AWS = Area of watershed subunit

DV = Degree of Vulnerability for subunit (e.g., ground water depth, rainfall, soil permeability, populated areas).

DI = Degree of Impact produced by regulated CAFO projects within the watershed subunit (e.g., animal population density, land application, lagoon systems).

The CRIA for swine CAFOs is calculated for each facility in a watershed subunit area. Total areas (A) of known projects in a watershed subunit are scored from 1 to 4 based on the percentage of the watershed area they represent. Vulnerability and impact factors are identified, and criteria for each were developed. Each DV and DI criterion is scored from 1 to 5.

The calculations involve:

1) summing the areas for known projects (A) and determining what percent of a watershed subunit is affected. ([ΣA / AWS] X 100); these percentages are scored on a 1 to 4 scale [no project(s) = 0 score].

2) summing the vulnerability and impact criteria scores, and calculating the average for DV and DI respectively;

3) multiplying the A score by the average DV score by the average DI score.

The <u>maximum score possible</u> in a watershed subunit (HUC) is 100. The summation factor (ΣA) is cumulative for CAFOs in the watershed subunit. Maximum rank for [ΣAI / AWS] is 4, maximum for DV is 5, maximum score for DI is 5.

$$CRIA = [\Sigma AI / AWS] \quad (DV) \quad (DI)$$

$$= [4] \quad (5) \quad (5) = 100$$

<u>Pig Improvement Company Cumulative Risk Evaluation Results</u>

The Region 6 Cumulative Risk Index Analysis (CRIA) was used to supplement the expanded EA's evaluation of the potential for significant, cumulative, environmental impacts from swine CAFOs. The CRIA considered environmental vulnerabilities and potential effects of individual CAFOs by watershed subunits, called Hydrologic Unit Codes, or HUCs.

Table 1
Cumulative Risk Index Analysis (CRIA) List of Criteria

WATERSHED SUBUNIT AREA (AI / AWS) CRITERION

DEGREE of VULNERABILITY (DV) CRITERIA
- Ground Water Probability
- Rainfall
- Surface Water Use
- Distance to Surface Water
- Population Around Facility
- Other Industries, Pollution Sources, or Protected Lands (Quadmapper Data)
- Wildlife Habitats
- Soil Permeability
- Ground Water Quality (Nitrate-Nitrite)
- Economic (Environmental Justice)
- Minority (Environmental Justice)
- Surface Water Quantity
- Water Quality (STORET Data)
- Other CAFO Facilities

III. DEGREE of IMPACT (DI) CRITERIA
- Livestock Population Density
- Lagoon Loading Rate
- Treatment System Liner
- Land Application Technology
- Nitrogen Budget
- Storage Capacity
- Well Head Protection
- Employment
- Odor
- Transportation
- Habitat Area Effected
- Density of CAFOs
- Proximity of CAFOs
- Phosphorus Budget
- Endangered and Threatened Species
- Cultural Resources

The following is a summary of the major findings and conclusions from the CRIA - version 6.0 dated January 24, 1997 (Data is presented in Appendix A):

1) The CAFOs represent a very small percentage of the total surface area of each HUC (i.e., from 0.17 to 2.95 percent).

2) The lowest individual vulnerability average score was 2.538 and the highest was 3.077.

3) The lowest individual impact average score was 1.75 and the highest was 2.812.

4) The lowest HUC vulnerability score was 2.538 and the highest was 2.885.

5) The lowest HUC impact score was 1.875 and the highest was 2.398.

6) HUC 11050002040, with only the PM1 site, had the lowest area effected (0.17%), as well as the lowest vulnerability (2.538), impact (1.875), and total (4.759) scores.

7) HUC 11050002050, with sites C1, C2, C3, L1, L2, L3, L4 and Choate, had the highest area effected (2.95%), as well as the highest vulnerability (2.885), impact (2.398), and total (6.918) scores.

8) The HUC vulnerabilities for the CAFOs are generally high in the areas of soil permeability, ground water quality, surface water use, and population.

9) The HUC vulnerabilities for the CAFOs are generally moderate to high in the areas of ground water probability, water quality, and wildlife habitats

10) The HUC vulnerabilities for the CAFOs are generally low to moderate in the areas of rainfall, distance to surface water, and economics.

11) The HUC vulnerabilities for the CAFOs are generally very low in the areas of surface water quantity, other industries, and minorities.

12) The adverse impacts of the CAFOs are generally very high in the area of proximity of facilities.

13) The adverse impacts of the CAFOs are generally high in the area of ground water well locations, density, and odor.

14) The adverse impacts of the CAFOs are generally moderate to

high in the areas of habitat area effected, employment, and livestock population density.

15) The adverse impacts of the CAFOs are generally low to moderate in the areas of, transportation, land application technology, and phosphorous budget.

16) The adverse impacts of the CAFOs are generally very low in the areas of lagoon loading rate, treatment system liner, nitrogen budget, storage capacity, endangered and threatened species, and cultural resources.

On the 0 to 100 scale, the total scores are very low for all five HUCs. This result is primarily because the area portion of the equation scored a 1 (representing less than five percent of the total surface acres in the HUC). This score is considered reasonable and representative of the situation, since it is expected that in comparison to other HUCs in the Region, the area component should score higher. For example, in HUCs with large concentrations of CAFOs, the area portion of the equation will score higher since it takes only 15 percent of the HUC to be represented by CAFOs to score a 4.

Even though the total scores for the HUCs are relatively low, the individual scores for a specific criterion provide meaningful insight into potential impacts. This is also true for the variation of scores for all sites in a criterion. Scores of 4 and 5 are important considerations at one site and multiple sites, particularly when they relate to both vulnerability and impact criteria. These scores (i.e., ground water quality, soil permeability, density of CAFOs, proximity of CAFOs, and ground water protection) support the conclusions in the expanded EA that potential ground water impacts warrant monitoring. Also, high scores (e.g., odor and habitat area effected) should be verified through follow-up field work to improve the accuracy of the CRIA for future use.

Discussion

The Cumulative Risk Index Analysis is designed to assess location specific environmental vulnerabilities and CAFO industry imposed impacts to watersheds in Region 6. The CRIA was applied to 18 swine operations owned by the Pig Improvement Company. The facilities are located in a semi-arid, rolling grassland area of western Oklahoma. The CRIA identified vulnerabilities of the landscape to be permeable soils, known nitrate ground water contamination in the watershed, and a relatively high number of farm operations in close proximity to one another. The CRIA also identified the ecological concern of large acres of habitat being effected. The CRIA evaluation resulted in EPA working with the facilities to mitigate specific concerns (i.e., protection of playa lakes, construction of dikes and berns to protect surface water) and to allow EPA to conduct ecological studies on the facility property to evaluate species diversity and number, and presence of odors.

References:

1. U.S. EPA, 1997a. 40 CFR 122.23[b], Concentrated Animal Feeding Operations (applicable to State NPDES programs). revised July 1, 1997. Office of the Federal Register National Archives and Records Administration, Washington, D.C.

2. U.S. EPA, 1997b. Swick, J., G. Carney, S. Osowski. Cumulative Risk Index Analysis (CRIA) (Swine Concentrated Animal Feeding Operations), Version 6.0, January 24. Enforcement Division, Region 6 Environmental Protection Agency, Dallas, TX 75202.

3. U.S.EPA, 1997c. Swick, J. National Pollutant Discharge Elimination System (NPDES) Statement of Findings for a General Permit to the Pig Improvement Company (PIC). February 13, 1997, Region 6 EPA, Dallas, TX 75202.

4. U.S. EPA, 1998. Swick, J. National Pollutant Discharge Elimination System (NPDES) Statement of Findings for a General Permit to the VAL Farms, Inc. February 13, 1997, Region 6 EPA, Dallas, TX 75202.

5. U.S.EPA, 1997d. Osowski, S. Swine confined Animal Feeding Operation Ecological Inventory and Odor Study, Publication No. 906-R-98-001, December 1997, Region 6 Environmental Protection Agency, Dallas, TX 75202.

Appendix A: CRIA Data for Pig Improvement Company (PIC)

Cumulative Risk Index Analysis (CRIA)

Appendix A: CRIA Data for Pig Improvement Company (PIC)

Cumulative Risk Index Analysis (CRIA)

Appendix B: Facility and Area Maps

Cumulative Risk Index Analysis (CRIA) for PIG Improvement Company PIC)

CUMULATIVE RISK INDEX ANALYSIS
DEGREE OF VULNERABILITY SCORES
PIC USA, COCHINO RANCH LLC, AND MAJOR FARMS

Facility	GWP		Rf		SWU		DSW		PAF		OI		WH		SP		GWQ		EEJ		MEJ		SWQ		WQ	DV
Choate	30.2%	5	30.75	3	< 50	5	2683	3	114	5	0	1	32.1%	3	<20%	3	5.4	3	43.0%	3	11.8%	1	0.6	1	4	3.077
C1	0.0%	1	30.75	3	< 50	5	2	5	74	4	0	1	32.1%	3	22.9%	5	5.4	3	43.8%	3	8.0%	1	0.6	1	4	3.000
C2	8.2%	3	30.75	3	< 50	5	7297	2	82	5	0	1	32.1%	3	<20%	4	5.4	3	41.7%	2	9.8%	1	0.6	1	4	2.846
C3	1.7%	1	30.75	3	< 50	5	1261	3	56	3	0	1	32.1%	3	93.4%	5	5.4	3	22.8%	1	3.4%	1	0.6	1	4	2.615
L1	12.2%	4	30.75	3	< 50	5	1552	3	95	5	0	1	32.1%	3	<20%	3	5.4	3	47.2%	3	9.8%	1	0.6	1	4	3.000
L2	34.2%	5	30.75	3	< 50	5	8051	2	94	5	0	1	32.1%	3	<20%	3	5.4	3	44.1%	3	10.8%	1	0.6	1	4	3.000
L3	21.1%	5	30.75	3	< 50	5	5208	2	76	4	0	1	32.1%	3	<20%	4	5.4	3	39.2%	2	9.9%	1	0.6	1	4	2.923
L4	2.8%	2	30.75	3	< 50	5	4762	2	58	3	0	1	32.1%	3	86.3%	5	5.4	3	28.8%	1	8.9%	1	0.6	1	4	2.615
L5	0.0%	1	30.75	3	< 50	5	7206	2	72	4	0	1	26.7%	2	95.7%	5	5.4	3	16.9%	1	2.6%	1	1.1	2	4	2.615
L6	0.0%	1	30.75	3	< 50	5	5991	2	50	3	0	1	26.7%	2	100.0%	5	5.4	3	16.7%	1	1.5%	1	1.1	2	4	2.538
Kranseder b-f	0.8%	1	30.75	3	< 50	5	4093	2	64	4	0	1	31.7%	3	<20%	4	10.9	5	18.8%	1	2.9%	1	0.5	1	4	2.692
Kranseder n-f	0.8%	1	30.75	3	< 50	5	4093	2	64	4	0	1	31.7%	3	<20%	4	10.9	5	18.8%	1	2.9%	1	0.5	1	4	2.692
PM1	3.1%	2	27.46	3	>50 - ≤76	4	11852	1	32	2	0	1	58.1%	5	38.0%	5	6.1	4	15.2%	1	0.0%	1	0.7	1	3	2.538
PM2	0.0%	1	27.46	3	>50 - ≤76	4	8559	1	82	5	0	1	49.7%	4	21.4%	5	7.2	4	31.6%	1	9.3%	1	0.7	1	3	2.615
PM3	0.0%	1	27.46	3	>50 - ≤76	4	12358	1	85	5	0	1	49.7%	4	<20%	4	7.2	4	45.1%	3	1.8%	1	0.7	1	3	2.692
PM4	0.0%	1	27.46	3	>50 - ≤76	4	9665	1	[illegible]	4	0	1	49.7%	4	20.7%	5	7.2	4	36.0%	2	6.1%	1	0.7	1	3	2.615
CM1	9.1%	3	27.46	3	>50 - ≤76	4	11575	1	144	5	0	1	49.7%	4	<20%	4	7.2	4	37.0%	2	0.7%	1	0.7	1	3	2.769
CM2	2.8%	2	27.46	3	>50 - ≤76	4	8934	1	95	5	0	1	49.7%	4	23.6%	5	7.2	4	33.8%	2	7.3%	1	0.7	1	3	2.769
CM3	0.5%	1	27.46	3	>50 - ≤76	4	10444	1	100	5	0	1	49.7%	4	<20%	4	7.2	4	45.3%	3	4.8%	1	0.7	1	3	2.692

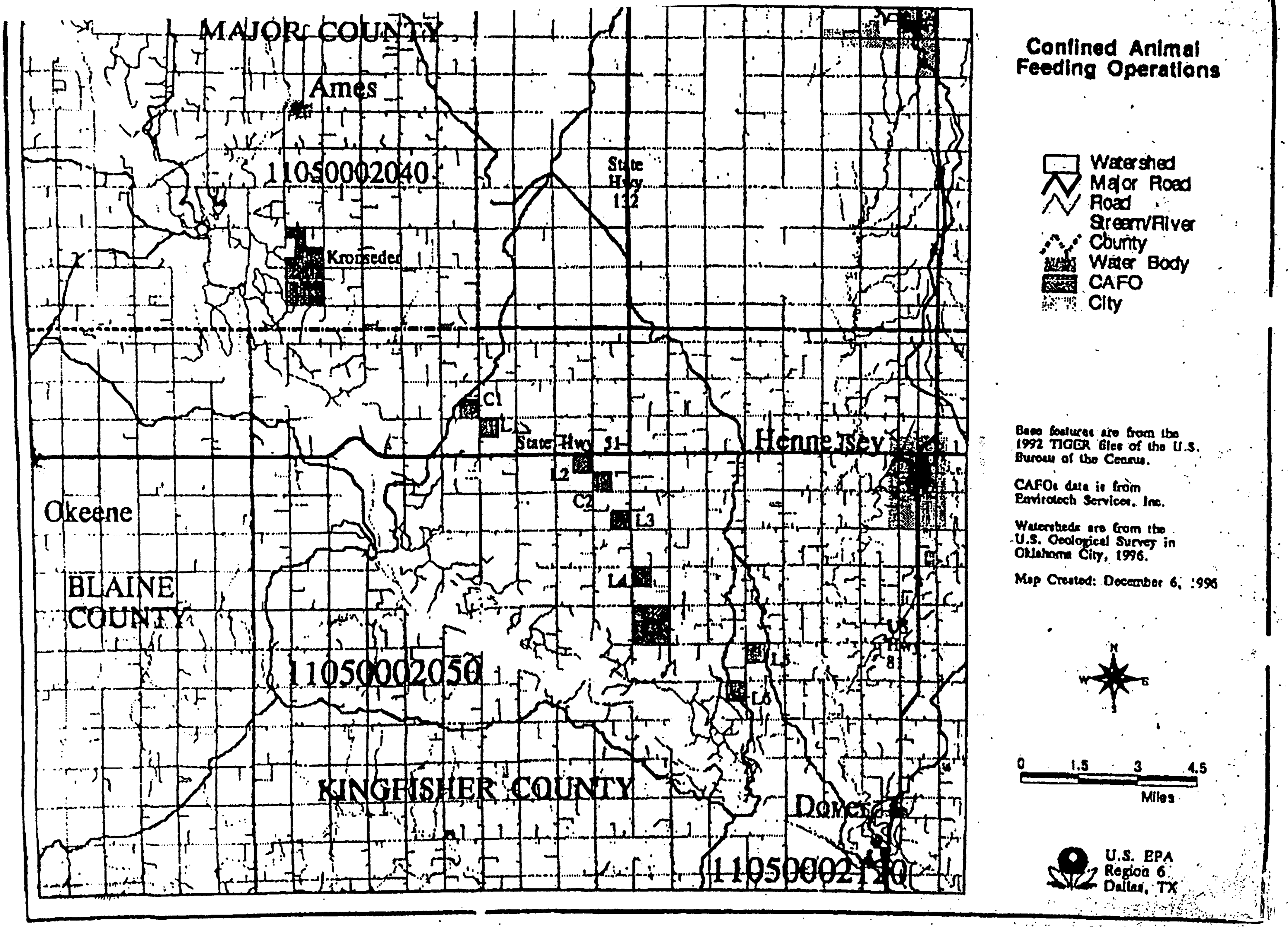
GWP	Criteria 1: Ground Water Probability
Rf	Criteria 2: Rainfall
SWU	Criteria 3: Surface Water Use
DSW	Criteria 4: Distance to Surface Water
PAF	Criteria 5: Population Around Facility
OI	Criteria 6: Other Industries, Pollution Sources, or Portected Lands
WH	Criteria 7: Wildlife Habitats
SP	Criteria 8: Soil Permeability
GWQ	Criteria 9: Ground Water Quality
EEJ	Criteria 10: Economic (Environmental Justice)
MEJ	Criteria 11: Minorty (Environmental Justice)
SWQ	Criteria 12: Surface Water Quantity
WQ	Criteria 13: Water Quality (Storet Data)
DV	Degree of Vulnerability

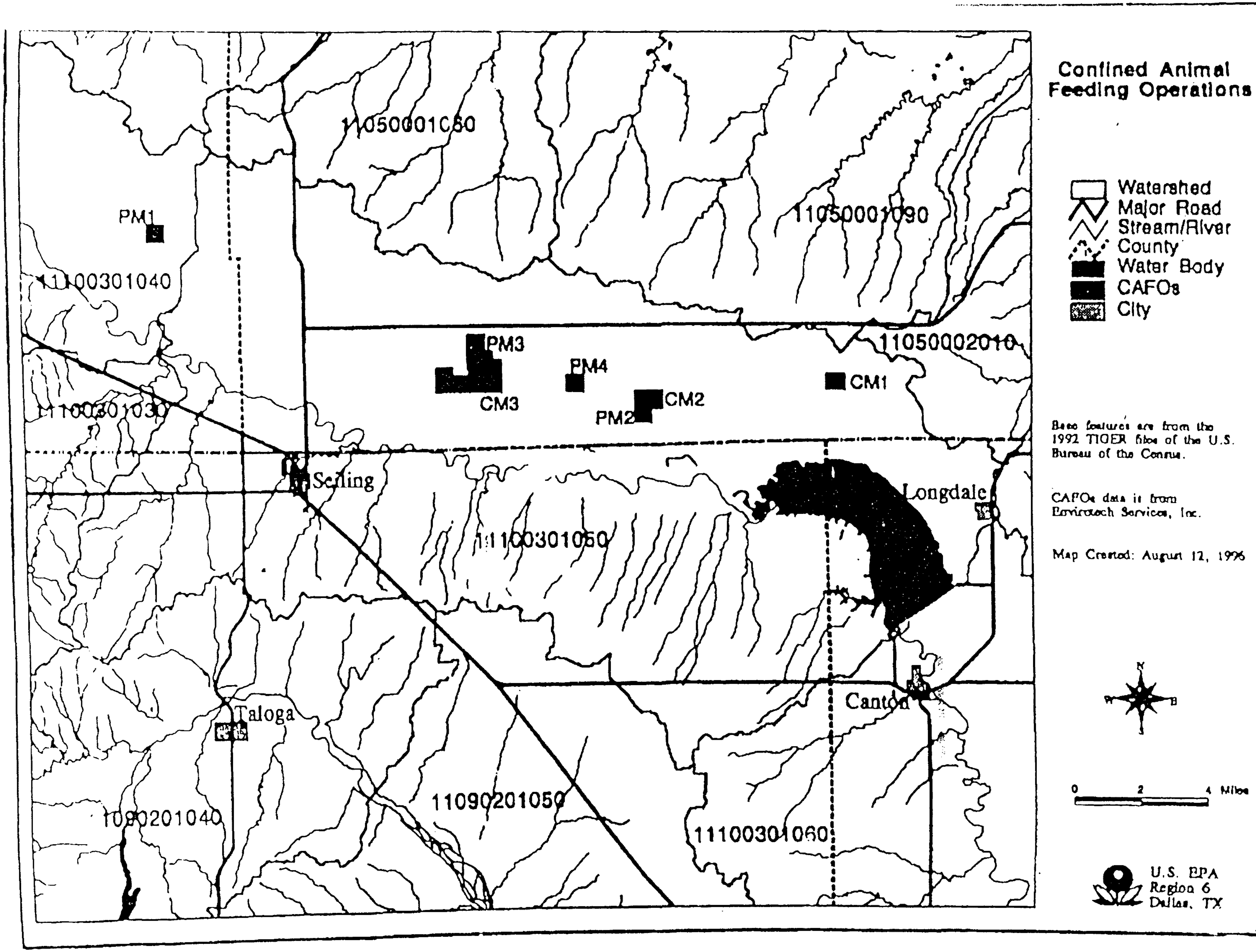
CUMULATIVE RISK INDEX ANALYSIS
DEGREE OF IMPACT SCORES
PIC USA, CO HINO RANCH LLC, AND MAJOR FARMS

Facility	LPD		LLR		TSL		LAT		NB		SC		GWP		E		O		T		HAE		DOC		POC		PB		ET	CR	DI
Chowle	19.6	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	4	1	14510	4	15-21	3	3.4%	1	6	5	2	5	110-120%	3	1	1	2.375
C1	15.3	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	4	1	3590	1	7-14	2	0.4%	1	6	5	1	5	110-120%	3	1	1	2.125
C2	21.0	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	50	5	2	3	10400	3	15-21	3	10.0%	2	7	5	2	5	110-120%	3	1	1	2.562
C3	22.1	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	20800	5	< 7	1	43.0%	5	6	5	3	5	110-120%	3	1	1	2.812
L1	18.9	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	> 90	1	0	5	4	1	3590	1	7-14	2	0.0%	1	6	5	1	5	110-120%	3	1	1	2.125
L2	20.4	3	≤100%	1	≤100%	1	T>3hrs		≤100%	[illegible]	>90	1	0	5	2	3	10400	3	15-21	3	0.0%	1	7	5	2	5	110-120%	3	1	1	2.500
L3	20.2	3	≤100%	1	≤100%	1	T>3hrs	[illegible]	≤100%	1	>90	1	0	5	1	4	5200	2	< 7	1	0.0%	1	9	5	3	5	110-120%	3	1	1	2.375
L4	19.1	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	5200	2	< 7	1	0.0%	1	8	5	2	5	110-120%	3	1	1	2.312
L5	21.7	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	5200	2	< 7	1	0.0%	1	4	1	2	5	110-120%	3	1	1	2.125
L6	20.4	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	5200	2	< 7	1	74.0%	5	4	1	2	5	110-120%	3	1	1	2.375
Kronseder b-f	16.1	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	13232	4	15-21	3	87.0%	5	1	1	0	1	110-120%	3	1	1	2.312
Kronseder n-f	21.1	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	10600	3	15-21	3	87.0%	5	1	1	0	1	110-120%	3	1	1	2.312
PM1	15.3	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	4	1	3590	1	7-14	2	86.0%	5	0	1	0	1	110-120%	3	1	1	1.875
PM2	25.7	4	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	150	5	2	3	10400	3	15-21	3	34.0%	4	4	1	2	5	110-120%	3	1	1	2.500
PM3	20.7	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	15600	5	< 7	1	29.0%	3	4	1	2	5	110-120%	3	1	1	2.438
PM4	21.7	3	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	10	5	1	4	5200	2	< 7	1	22.0%	3	4	1	4	5	110-120%	3	1	1	2.250
CM1	15.1	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	100	5	4	1	3590	1	7-14	2	22.0%	3	2	1	0	1	110-120%	3	1	1	1.750
CM2	25.7	4	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	10	5	2	3	10400	3	15-21	3	15.0%	2	5	5	2	5	110-120%	3	1	1	2.625
CM3	19.9	2	≤100%	1	≤100%	1	T>3hrs	3	≤100%	1	>90	1	0	5	1	4	20800	5	< 7	1	10.0%	5	4	1	2	5	110-120%	3	1	1	2.500

LPD Criteria 1: Livestock Population Density
LLR Criteria 2: Lagoon Loading Rate
TSL Criteria 3: Treatment System Loading
LAT Criteria 4: Land Application Technology
NB Criteria 5: Nitrogen Budget
SC Criteria 6: Storage Capacity
GWP Criteria 7: Ground Water Protection
E Criteria 8: Employment
O Criteria 9: Odor
T Criteria 10: Transportation
HAE Criteria 11: Habitat Area Effected
DOC Criteria 12: Density of CAFOs
POC Criteria 13: Proximity of CAFOs
PB Criteria 14: Phosphorus Budget
ET Criteria 15: Endangered and Threatened Species
CR Criteria 16: Cultural Resources
DI Degree of Impact

Degree of Impact





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Cumulative Risk Assessment Practicum
Case Study Draft
Pentachlorophenol (PCP)
(A Heavy Duty Wood Preservative (HDWP))
OPP

Prepared for Practicum
November 12-13, 1998

July 08, 1998
Cumulative Risk Assessment
Planning and Scoping Document For
Pentachlorophenol (PCP)
A Heavy Duty Wood Preservative (HDWP)

I. Background

U.S. EPA's Office of Pesticide Programs (OPP), as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and amended by the Food Quality Protection Act (FQPA) of 1996, institutes procedures for the registration and reregistration of pesticides. OPP's Antimicrobials Division (AD) has regulatory management over antimicrobial pesticides, including certain wood preservative pesticides such as Pentachlorophenol (PCP). AD is currently responsible for generating Reregistration Eligibility Decision documents (RED's) for three wood preservatives (PCP, Chromated Copper Arsenicals (CCA), and Creosote). These documents will reassess the potential risks these chemicals may have on human health and the environment. All three RED's are slated for release in FY 1999.

Note that as part of the reassessment of the wood preservative chemicals NAFTA harmonization efforts are underway between USEPA and Health Canada's Pest Management Regulatory Agency (PMRA). Since late FY 1997, AD's science and regulatory managers have dedicated staff resources within the division to accomplish the goal of preparing and issuing the PCP RED. AD formed a PCP RED Team charged with generating the draft RED document by the end of FY 1998. Designated staff leads from each science discipline, and regulatory managers prepared a "Workplan" which identified datagaps, created a timeline for completion of the RED, and identified steps to be taken by each discipline in order to expedite the work. Science staff from AD and PMRA are collaborating on data sharing and in conducting joint data reviews in compliance with NAFTA.

Since the PCP RED will be the first RED document to be issued by OPP's newly formed AD, the division welcomes the opportunity to participate in the "Planning and Scoping" exercise for ORD's Cumulative Risk Assessment Workshop. Involvement will foster dialogue with other Agency program offices and enable AD to develop a risk assessment process that is as comprehensive and valid as possible.

II. Regulatory History

A. Regulation Under FIFRA/FQPA

* Pentachlorophenol (PCP) was first registered in the United States in 1948 as an active ingredient.

* In 1978 USEPA issued a Federal Register Notice initiating an administrative process to consider whether pesticide registrations for wood preservative chemicals should be cancelled or modified due to adverse toxicological effects noted in animal toxicity studies. The Agency issued notices of "Rebuttable Presumption Against Registration" (RPAR) for PCP based on teratogenicity and fetotoxicity findings. In addition, the Agency determined that PCP use posed the risk of oncogenicity due to the presence of microcontaminants (dioxins/furans/HCB). The Agency subsequently published Position Documents to address comments made by

stakeholders on the Federal Register Notice. The conclusion of the RPAR process in 1984 and final settlement agreements with stakeholders in 1986 restricted PCP uses and modified its terms and conditions of registration.

* Banned uses of PCP included treatments to wood used for food contact surfaces/containers, log homes, and structures housing livestock which are farrowing, brooding, and/or cribbing.

* 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 papermills, oil wells, and cooling towers.

* In August, 1996, the Food Quality Protection Act (FQPA) was passed. FIFRA, as amended by FQPA, now requires EPA to examine pesticide uses relative to the potential aggregate and cumulative exposures and risks for the general population and for sensitive subpopulations (children and infants). Aggregate exposures/risks represent the multiple exposures/risks from uses of a single chemical (e.g., exposures/risks from the diet, drinking water, or other sources). Cumulative exposures/risks represent the multiple exposures/risks from uses of multiple chemicals sharing a presumed common mechanism of toxicity. For wood preservatives such as PCP, the Agency must now address aggregate and cumulative exposures and risks.

B. <u>Regulation Under Other Acts</u>

PCP is also regulated under other Acts including: Clean Water Act, Safe Drinking Water Act, Clean Air Act, and Resource Conservation and Recovery Act. Attachment B outlines the major points of regulation under these Acts.

III. <u>PCP Use Profile</u>

* PCP is an organic chemical formed by the high temperature chlorination of phenol. These high temperatures result in the formation of microcontaminants (dioxins/furans/HCB).

* PCP is an oil-borne pesticide first registered in the United States in 1948 as a preservative of wood (seasoned/unseasoned) to prevent decay from fungal organisms and insect damage. It is commercially available in various forms, including: as a solid crystalline block, soluble concentrate (solid/liquid), and ready-to-use (grease/liquid).

* Vulcan Chemicals, division of Vulcan Materials Company, and KMG-Bernuth, Inc. are the primary producers of the PCP technical chemical for the Unites States and Canadian markets. These companies are considered the primary stakeholders.

* PCP product labeling and Label Use Information System (LUIS) Reports generated by OPP/BEAD were used as primary sources to confirm PCP use patterns.

* Meetings with stakeholders on The Penta Task Force further clarified banned and current use practices and identified some minor specialty use applications. (See Attachment A for an overview of PCP use patterns.)

* Currently, 25 PCP products remain registered as wood preservatives in above and below ground wood protection treatments and for treating wood for aquatic/marine environments. All 25 products are Restricted Use pesticides: 22 are End-Use Products for commercial use, and 3 are Technical Grade Products for manufacturing use. (Health Canada's PMRA has regulatory purview over three (3) Technical Grade Products. There are no End-Use Products registered in Canada.)

* Utility poles and crossarms represent 92.5% of all uses for PCP-treated lumber. Secondary uses for PCP include the treatment of railroad crossties, wooden pilings, fence posts, and lumber/timber used for the construction of commercial/residential structures (e.g., patios, decks, walkways, and fences).

* There are various types of PCP wood preservation treatments including: pressure/non-pressure treatments to seasoned and unseasoned wood, and remedial treatments to wood previously treated with PCP. Commercial treatment of lumber, such as telephone poles, usually involves a pressure treatment process in which wood is pushed into long cylinders (retorts) that are pressurized in the presence of PCP. Non-pressure treatment processes also exist such as thermal treatment (wood soaked in hot/cold baths), dip treatment, and extended soaking of wood in open vats. Remedial treatments are primarily groundline wood surface treatments (brush-on, sponge-on/swabbing, spraying, low pressure injection, or bandage-wrap) to standing utility poles and other standing timbers to extend their service life.

IV. Hazards, Exposure and Risk Dimensions

A. Hazard Identification

1. Hazards - Human Health

The Agency and PMRA are examining the full range of data, submitted by the registrant(s) or available in the scientific literature, for both the active ingredients and contaminants of concern. Such data include: acute toxicity, developmental/reproductive effects, chronic effects, carcinogenicity, and endocrine effects. Also, if epidemiological studies or pesticide incident data are available for PCP, the Agency will examine these as well.

As a summary, AD presents the following:

* PCP has been associated with both acute and chronic (non cancer) adverse health effects, primarily related to liver toxicity. Also, EPA's weight of evidence carcinogenicity classification for PCP is B2, probable human carcinogen. PCP is known to contain polychlorinated dibenzo(*p*)dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) as contaminants. The toxicity of PCDD/PCDF congeners are typically expressed, based on the comparison of their toxicity to the most toxic congener (2,3,7,8-tetrachlorinated dibenzo(*p*)dioxin; 2,3,7,8-TCDD), using Toxicity Equivalency Factors (TEFs). Toxic Equivalency values (TEQs) are calculated as the sum of the products of individual congener concentrations and their respective TEF. EPA has set regulatory limits on the concentrations of certain PCDD/PCDF congeners in PCP.

* Available scientific literature confirms that PCP targets the liver, kidneys and central nervous system and has been linked to cancers (e.g., acute leukemias, lymphomas, and multiple myelomas). Data suggest PCP damages the nervous, immune, and reproductive systems (including endocrine disruption). PCP is readily absorbed by lungs, skin, and stomach. While much of PCP is excreted in the urine, it does accumulate in tissues, particularly muscle, bone marrow and fat.

2. Hazards - Environmental

The Agency and PMRA are examining the full range of data, submitted by the registrant(s) or available in the scientific literature, for both the active ingredients and contaminants of concern. Such data include: acute toxicity, subacute effects, chronic effects, and endocrine effects. Also, if pesticide incident data are available for PCP, the Agency will examine these as well.

As a summary, AD presents the following:

* Available scientific literature confirms that PCP bioaccumulates in mammalian and fish tissue and laboratory data indicate there is a very high toxicity of PCP to fish on an acute and chronic basis. Data submitted by the registrants to the Agency suggest that PCP is moderately to slightly toxic to avian species (mallards and bobwhite quail) on an acute oral basis. Subacute dietary tests indicate that it is practically nontoxic to avian species.

3. Hazards - Microcontaminants

The hazards of the microcontaminants are an important part of the human and environmental hazards identification process. AD plans to utilize data compiled by the Office of Research and Development (ORD), the lead office for dioxin issues. AD believes that there are likely more data available to identify human health hazards than to identify environmental hazards. Therefore, the environmental hazards identification process may be highly qualitative.

B. Exposure Scenarios

Canada's PMRA will focus on all exposure aspects of PCP: i.e., a "cradle-to-grave" approach which addresses manufacture, wood preservation, utility poles in service, and removal/disposal of utility poles from service to disposal sites (e.g., landfills). However, AD/OPP (because of overlapping Agency statutes) will focus its exposure assessments as follows: (1) human exposure assessments will address occupational, or wood preservation, sites where the greatest human exposures are likely to occur; and (2) environmental exposure assessments will focus on in-service, treated utility poles, since these provide potentially for emissions of PCP and/or microcontaminants into the terrestrial and/or aquatic environments.

1. Exposures - Human Health

AD will examine application and post-application exposures for both occupational and residential settings. AD's focus will be on occupational settings (primarily, wood treatment plants) where the exposures for mixers, loaders, applicators as well as utility pole workers must be evaluated. However, AD plans to address aggregate and cumulative exposures since utility poles are found, and can receive remedial groundline treatments of PCP, in residential settings. Specifically, the following points should be noted:

* Human exposure assessments will focus primarily on workers handling PCP formulations and/or PCP-treated wood. Exposure levels and the dermal/inhalation routes of exposure will be of primary concern. AD will assess exposures to primary handlers who mix/load/apply concentrates to treat wood in treatment facilities. The assessment on secondary handlers will include addressing utility pole installers and repair workers. AD anticipates that the most significant potential exposures will occur at the wood treatment plants during pressure/non-pressure applications and post-application handling; followed by the exposure potential to utility workers engaged in pole installation and remedial groundline treatments to utility poles.

* Human exposure to PCP may occur in occupational settings or among the general population primarily via dermal and inhalation routes. Ingestion of PCP can also occur indirectly through hand-to-mouth transfer after dermal contact. Workers may be exposed through inhalation of PCP-contaminated air in the workplace or by dermal absorption during handling of the PCP formulations or PCP-treated materials. Virtually all workers exposed to airborne concentrations take up PCP through the lungs and skin. Exposure may occur during mixing and loading of PCP into the tanks, loading and unloading the retort, and during maintenance operations. General population exposure may occur through dermal contact with PCP-treated products or contaminated soils, or ingestion of food, soil, or groundwater that has been contaminated from historical uses (i.e., uses now banned under the 1986 RPAR proceedings). General population exposure (i.e., inhalation of contaminated indoor air or dermal contact with treated areas) may also occur among individuals residing in older buildings constructed of PCP-treated wood products (i.e., log homes).

* In 1991, as an outcome of the Agency's RPAR proceedings, USEPA required registrants of PCP-based technical source and end-use products to submit certain applicator exposure monitoring data. These data requirements were designed to estimate the potential dermal and inhalation exposures associated with PCP wood preservative uses (i.e., occupational, at application, exposures). However, the Agency did not require post-application exposure data since the occupational (at application) exposure scenarios are expected to be the scenarios with highest human exposure.

* Following 1991, an industry consortium, headed by Vulcan Chemical, formed the Penta Task Force to address the Agency's reregistration requirements for human exposure data. In 1993 five human exposure studies submitted by the Task Force were deemed unacceptable upon Agency review. These studies had been conducted to evaluate occupational and general population exposures/risks from existing and historical uses of PCP. However, these studies did not provide empirical human exposure data which could be used by the Agency. Thus, limited human exposure monitoring data, which are acceptable for use in the reregistration assessment of all three wood preservative chemicals, are available.

* Present efforts: (1) AD is working with contractor personnel to identify all potential application and post application use scenarios at occupational and residential settings. For

occupational scenarios, a data matrix table has been drafted of the potential levels of exposure associated with certain typical work tasks. However, the residential use scenario component has not yet been drafted for incorporation into this table. Therefore, AD has not finalized how it will approach aggregate and cumulative exposures for residential scenarios; (2) information regarding AD's choice of occupational/residential use scenarios has been shared with PMRA's human exposure assessors. PMRA will conduct a peer review of the completed draft version of the Agency's Human Exposure Science Chapter for the PCP RED in early FY 1999; and (3) recent dialogue with the Penta Task Force has yielded a commitment to conduct an occupational exposure study of treatment plant workers using air sampling pumps to estimate inhalation exposure, and biological monitoring techniques (urine analysis instead of dermal exposure dosimetry testing) to estimate the absorbed dose. This worker exposure study will monitor all application and post-application work tasks associated with PCP wood treatments. However, this study is not likely to be completed until FY 2000, after issuance of the PCP RED.

2. Exposures - Environmental

For PCP, AD believes the primary routes of environmental exposure are water and soil via leaching from utility poles, railway ties, pilings, piers, docks, etc. The most likely environmental compartment to be exposed to PCP is the aquatic. AD will characterize risks using these environmental scenarios. AD will not examine environmental risks from the following scenarios becuase they are regulated under other statutes: manufacture of PCP, use of PCP in wood preservation plants, and disposal of treated lumber in landfills or as hazardous waste.

3. Environmental Fate Chemistry

AD believes that environmental fate chemistry is a key component of both the human and environmental exposure (and risk) assessments for PCP and microcontaminants. For PCP AD has compiled pertinent data from the registrant and literature sources and believes that the fate and degradation of PCP are well understood (see Attachment C). However, for the microcontaminants AD will be working with a contractor and ORD to determine if adequate environmental fate and emissions data can be compiled for dioxins and furans relative to the wood preservation sector. Of particular interest are emissions from in-service utility poles; if inadequate emissions data exist, then AD plans to use modeling (see 4 below).

4. Exposures - Modeling

Because of the apparent lack of monitoring and/or emissions data for PCP (and/or microcontaminants) for various use scenarios, but particularly for in-service utility poles, AD will utilize models, such as the fugacity model, to estimate concentrations of PCP and/or microcontaminants in the environment. Fugacity models identify the percentage distribution of a chemical (e.g., PCP) in various compartments at equilibrium and the proportion of loss through advection and reaction from each compartment. Such models typically utilize three levels of estimates, but AD may also use other models that appear to be appropriate. Also, AD will need to work closely with ORD concerning any emissions estimates the division may develop for the microcontaminants.

C. Risk Characterizations

1. Human Risks

For the Agency to conduct a thorough human risk characterization, data are needed on: (1) the toxicity/effects of the pesticide, (2) the pesticide's use patterns, and (3) human exposure scenarios. To date, AD has compiled extensive information for (1) and (2), but is utilizing surrogate data for (3) as well as requiring an occupational exposure study of treatment plant workers. (However, this study is not likely to be completed until FY 2000.)

As discussed earlier, AD's focus will be on characterizing the occupational risks of PCP: the risks (application) for mixers/loaders/applicators who prepare or apply PCP to wood and the risks (post-application) for workers handling treated wood products (e.g., utility pole installers, repair workers).

However, with passage of FQPA in 1996, AD now must characterize the potential risks associated with non-occupational, or residential, use scenarios. For these AD is planning to assess the aggregate (dietary, drinking water, other) and cumulative risks for PCP that may be associated with any residential use scenarios.[1] Further, we plan to assess the potential risks of PCP to sensitive subpopulations such as children and infants as well as any potential endocrine effects.

For both the occupational and residential risk assessments AD will compare available toxicological hazard data, use pattern information, and exposure data. As an example, Margins of Exposure (MOE's) will be calculated for occupational workers to determine the potential risks of workers exposed to PCP under various occupational use patterns. Also, Because of PCP's carcinogenic potential, the cancer risks will be calculated using the Lifetime Average Daily Dose (LADD) and the Cancer Slope Factor. For residential use patterns similar approaches may be taken also.

2. Environmental Risks

Environmental risk assessments are required under FIFRA to estimate the likelihood or probability that adverse effects (e.g., mortality to single species of organisms, reductions in populations of nontarget organisms due to acute, chronic and reproductive effects, or disruption in community and ecosystem level functions) will occur, are occurring, or have occurred on wildlife and aquatic organisms. Data developed and submitted are used by the Agency for determining potential hazards to nontarget birds, wild mammals, fish, plants, and aquatic invertebrates.

In an environmental risk assessment, toxicological hazard data and exposure data are compared using regulatory risk criteria. Typically the toxicological hazard data may consist of acute LD50 and LC50 values, or chronic no-effect-levels (NOEL's) for the most sensitive indicator species. Exposure data normally consist of model-based Estimated Environmental Concentrations (EEC's) in important media of concern (i.e., water, soil, nontarget organism food items) plus a profile of the nontarget organisms at risk. A Risk Quotient (RQ) is determined by dividing the exposure data (EEC) by the toxicology data (LD50, LC50, etc.). A comparison is then made between the RQ and an Agency Level of Concern

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[1] Aggregate risks: risks associated with multiple pathways of exposure for a single chemical; cumulative risks: risks associated with multiple pathways of exposure for multiple chemicals that share a presumed common mechanism of toxicity.

(LOC) to determine if there is a potential risk to nontarget organisms.

For PCP, the primary routes of exposure are water and soil via leaching from utility poles, railway ties, pilings, piers, docks, etc.. The most likely environmental compartment to be exposed to PCP is the aquatic. Available scientific literature confirms that PCP bioaccumulates in mammalian and fish tissue and laboratory data indicates there is a very high toxicity of PCP to fish on an acute and chronic basis. Data submitted by the registrants to the Agency suggest that PCP is moderately to slightly toxic to avian species (mallards and bobwhite quail) on an acute oral basis. Subacute dietary tests indicate that it is practically nontoxic to avian species.

3. Risks from Microcontaminants

Considering the lack of pertinent emissions data for dioxins/furans for the wood preserving industry sector, AD's human and environmental risk characterizations for PCP microcontaminants is likely to be highly qualitative. However, AD recognizes that the risks of the microcontaminants are an important part of the risk characterization process. AD plans to work closely with a contractor and ORD, the lead office for dioxin issues, in an effort to develop human and environmental risk assessments.

4. Comparative Risk Analysis

Upon completion of the human and environmental risk assessments, AD plans to follow similar steps for evaluating creosote and CCA, two alternative HDWPs. Once all three risk evaluations are finalized then AD will perform a comparative risk analysis of the three compounds (PCP, creosote, and CCA) to determine how the human and environmental risks, associated with similar use patterns, compare.

V. Assumptions, Uncertainties, and Limitations With Risk Characterizations

AD recognizes a variety of assumptions, uncertainties, and limitations exist with the proposed human and environmental risk characterizations. Some of these are:

A. Human Risk Characterization

* It is assumed that the occupational exposure study sponsored by the Penta Task Force will provide risk assessors with valuable data needed for the human exposure risk assessment. Since these data will not be available until FY 2000, the human exposure assessment will need to rely on surrogate data and may fall short of its goal to accurately determine exposure risks to workers.

* The acceptability of biomonitoring data over dermal (passive dosimetry) monitoring data has been questioned. Although the pharmacokinetics of PCP are well known, certain reservations remain regarding test participant compliance in generating urine samples. Dermal monitoring was rejected as an option due to workers overheating while wearing the test garments (whole body dosimeters) in a pilot study.

* The required worker exposure field study will not analyze air and urine samples for the PCP microcontaminants (dioxins/furans/HCB), only for the presence of PCP and its metabolites.

* The default assumptions, based on surrogate data, used by the risk assessors might not reflect real-use conditions, thereby weakening human exposure risk characterizations.

* AD's assessment will not include evaluation of risk concerns for PCP uses "banned" under the RPAR proceedings (e.g., risks to occupants of log homes).

* AD's assessment will not include estimations of potential human exposure risks from contact with PCP-treated wood used for minor specialty applications (e.g., uses in bridges, trusses, architectural restoration), only typical exposure scenarios will be evaluated.

* AD will assume that any existing uses for PCP-treated lumber in groundline contact "interior" building components pose limited human exposure concerns since the 1986 RPAR settlement requires 2 coats of an appropriate sealant be used on all interior wood surfaces.

B. Environmental Risk Characterization

* The Agency does not typically require data on small mammals and does not look at the effects on small mammalian wildlife (voles, mice, bats, etc.). Data is extrapolated from the human toxicology rat studies to be utilized in determining effects on wildlife mammals. This area is of importance because small mammalian wildlife feed on terrestrial invertebrates (insects, earthworms, etc.) and/or plants that may have been exposed to the pesticide. AD is uncertain what effects are occurring in the food chain.

* Canada uses data regarding subchronic exposure of bats to treated timbers used for bridge trusses. Scientific literature documents the lethal effects on bats nesting on bridge trusses newly treated with PCP. The Agency will note this information in their RED, however no further studies will be requested to further investigate the potential hazards to this mammalian population.

* The Agency will not be conducting any field studies on the effects of PCP on terrestrial invertebrates such as earthworms. Canada and Europe do incorporate data collected in this area.

* There is no consensus on reproducible laboratory testing to determine the levels of PCP leached from the wood. To date the levels leached into the environment are unknown. This is true for PCP and its microcontaminants, furans, dioxins, and HCB.

* The environmental risk characterization is focused on the effects on individual organisms as opposed to populations of organisms. AD's environmental risk assessment's weakness is that mesocosms and population effects are not assessed on a routine basis.

* USEPA's ORD will generate a final version of a Dioxin Source Inventory Report for release in late fall of 1998. It is assumed that this report will benefit risk assessors in making quantitative determininations of dioxin releases for use in the environmental exposure assessments.

VI. Stakeholder Input

AD has actively involved stakeholder input in the human and exposure/risk characterization processes. In addition, (1) the review of the HDWPs is a NAFTA project in which Canada and USEPA are working closely together; and (2) AD will need to work closely with other Agency offices such as ORD. Stakeholders who are involved in the review process consist of: industry consortiums (e.g. PCP Task Force), PCP chemical manufacturers, PCP end-use product manufacturers, end-users of PCP products, and end-users of PCP-treated wood.

Attachment A: PCP Use Patterns

Banned Uses:

- * Log Homes
- * Chairs/Outdoor Furniture
  (Bare Treated Wood)
- * Residential/Industrial/Commercial Interiors
  (General Use)
- * Farm Building Interiors (Direct Contact with Domestic/Livestock Animals which Crib(bite) or Lick the Wood.)
- * Farm Building Interiors (Direct Contact with Animal Farrowing or Brooding Facilities.)
- * Farm Structures/Containers for Storing Silage or Food. (Human Food/Animal Feed Contact.)
- * Cutting Boards/Countertops

Allowed Uses:

- * Utility Poles/Crossarms
- * Crossties
- * Single Pole Structures (Radio Towers)
- * Bridges
- * Trusses (Glue Laminates e.g. Swimming Pool Trusses)
- * Timbers
- * Posts
- * Pilings/Piers/Docks
- * Lumber
- * Fencing
- * Porches
- * Shingles
- * Steps
- * Architercural Restoration (Outdoor Tongue & Groove Flooring)
- * Patios/Decks/Walkways
- * Chairs/Outdoor Furniture
  (ONLY if 2 Coats Sealant Applied)
- * Residential/Industrial/Commercial Interiors
  (Laminated Beams or Groundline Contact Building Components.
  Both Uses Allowed if 2 Coats of Sealant Applied.)
- * Farm Building Interiors (Where Domestic/Livestock Animals DO NOT Crib(bite) or Lick the Wood.
  Groundline Contact Building Components Use Allowed if 2 Coats of Sealant Applied.)

Diminished Uses: Joinery/Millworking (No Evidence of Treated Products being Marketed.)

Attachment B: PCP Regulation Under Other Acts

Regulation of PCP under the Clean Water and Safe Drinking Water Acts

* PCP is designated hazardous substance under the CWA (40 C.F.R. pt. 116).

* PCP is a designated toxic pollutant under the CWA and is subject to effluent limitations resulting from application of best available technology (BAT) that is economically achievable. New source emitting PCP also must meet stringent new source performance and pretreatment standards (40 C.F.R. §§ 401.15, 403.55).

* EPA has set a contaminant level of 0.001 mg/L for PCP in drinking water; granular activated carbon is BAT for achieving compliance with this standard (40 C.F.R. §§ 141.32 (3) (46), 141.50 (a) (15)).

* Under federal water quality guidance for the great lakes system, PCP is subject to acute- and chronic-based water quality criteria for the protection of aquatic life in ambient water (40 C.F.R. § 132.6).

Regulation of PCP under the Clean Air Act

* PCP is designated Hazard Air Pollutant (HAP) under section 112 of the CAA. Major sources emitting PCP are subject to stringent Maximum Achievable Control Technology (MACT) emissions standards (42 U.S.C. §§ 7412(b), (d)). PCP wood preserving sites are not a major source for purpose of the MACT standards.

* Units at major sources that manufacture PCP are subject to National Emission Standards for organic HAPs for the Synthetic Organic Chemical Manufacturing Industry (40 C.F.R. pt. 63 subst. F).

* National emission standards apply to off-site Waste and Recovery Operation if, in part, the material being handled contains PCP (40 C.F.R. pt. 63 subst.. DD).

Regulation of PCP under RCRA

* Certain PCP containing waste are listed as acutely hazardous (40 C.F.R. § 261.31).

* PCP wood preserving wastes are identified as toxic (40 C.F.R. pt. 261 subst. D)

* PCP wastes are prohibited from land disposal under EPA's land disposal regulations, unless universal treatment for such wastes are met (40 C.F.R. §§ 268.30, 268.40).

* PCP is subject to groundwater assessment monitoring requirements applicable to municipal solid waste landfills and to owners/ operators of hazardous waste treatment/storage/disposal facilities (40 C.F.R. pts. 258, 264).

Attachment C: Pentachlorophenol (PCP) Environmental Fate Studies and Assessment

Abiotic degradation of PCP

PCP does not hydrolyze in acidic, neutral or basic conditions and can therefore be a persistent molecule in abiotic aqueous conditions. It, however, photodecomposes under uv light in water quickly with a half-life of 3.5 hours at pH 7.3 and 100 hours at pH 3.3. Some of the identifiable degradates are: tetrachlorocathecol, tetrachlororesorcinol, tetrachlorohydroquinone, chloranil, hydroxyquinones, 2,3 dichloromaleic acid which slowly decompose to carbon dioxide, chloride ion and other organic fragments which are hard to identify. In the vapor phase, PCP is moderately stable with a photodegradation half-life of about 37 days under simulated sunlight. 2,3,5,6-tetrachlorphenol was identifed as a major photoproduct. PCP showed no photolytic breakdown tendency on soil surface (sandy loam soil) under dark conditions. However, in the presence of light, it is moderately stable with an estimated half-life of about 38 days.

Biotic degradation of PCP

PCP metabolizes rapidly under aerobic aquatic conditions and has a half-life of less than five days. Under anaerobic conditions, it metabolizes a little more slowly with a half-life of about 34 days. (These results were obtained with blue sandy loam soil.) It is therefore not a persistent substance in natural waters. Under dark but aerobic conditions, soil (sandy loam) metabolizes PCP slowly with a half-life of 63 days. Tri and tetrachlorophenols were identified as degradates. Adsorption/desorption studies on four soils (Georgia sandy loam, Ohio Clay loam, California sandy loam and Nebraska Blue sandy loam) showed that PCP binds moderately to strongly to the soils. K_{OC} values revealed that PCP soil binding is tight with Georgia, Ohio and Nebraska sands and moderately so with the California sand. Thus, PCP has a great tendency to attach to the organic content of sediments (high K_{OC}) and is found to bind more strongly in acidic soils but is mobile in neutral to basic conditions. Based on these data it appears PCP could be transported to surface waters and potentially could be found in drinking water.

Bioaccumulation studies

Bioaccumulation studies with bluegill sunfish revealed that when exposed to 2.5 µg/L PCP for 28 days, the Bioconcentration Factors (BCF) were 190X, 740X and 490X for edible tissue, non-edible tissue and whole body tissue, respectively. Depuration for the whole body was one day, and 98% is depurated within fourteen days. No metabolites were found in these studies.

Leaching Studies

One study on three Southern pine poles soaked with PCP was conducted. Poles were exposed to different solutions: unbuffered water, buffered water at pH 5, 7 and 9, sea water, sea water in 0.10N HCl, and 0.10N HCl. The average leach rate varied between 1.76×10^{-4} to 6.33×10^{-3} mg PCP/kg leachate/in^2 surface area/day. Leaching peaks in one day for most of the solutions except the solution at pH 9 for which leaching peaked in 3 days.

Cumulative Risk Assessment Practicum
Case Study Draft
Chicago Cumulative Risk Initiative
Region V and OPPT

Prepared for Practicum
November 12-13, 1998

DRAFT

Summary of Purpose, Scope, and Technical Approach: Evaluating Cumulative Risks in the Chicago Metropolitan Area

1. INTRODUCTION

The following is a summary of the overall purpose, general scope, and technical approach for the study, "Evaluating Cumulative Risks in the Chicago Metropolitan Area" (the CCRI Phase III risk assessment). The approach is a synthesis of the direction and information that was provided during meetings with stakeholders (petitioners, EPA Region V senior managers, and other state, and local government representatives) in December 1997 and April 1998. As such, this summary does not reflect any one viewpoint, but attempts to balance various needs and concerns with products that are technically feasible. It also attempts to incorporate major concepts suggested by the Petitioners in their strawman proposal and matrix, while following EPA's Cumulative Risk Assessment Guidance on Phase I Planning and Scoping.

The three major study components will be an overview of health indicators, a cumulative risk evaluation for multiple point sources, and a description of other risk pathways. These will be integrated to produce a comprehensive risk assessment that allows comparison of contributions among sources and of risk levels among subareas of the study region. In October 1997, Argonne National Laboratory produced a Concept Paper in which various conceptual approaches for cumulative risk assessment were evaluated. The approach outlined in this summary is essentially the source/receptor hybrid model described in the Concept Paper. Within this approach, the majority of effort will be placed on evaluating the contributions to exposure and risk within study areas from multiple point sources of emissions to ambient air (Section 3.2 below).

Cumulative risk means different things to different people. A general definition is the total health risk associated with multiple stressors from multiple sources. EPA risk assessments have typically addressed the incremental risks (above background) of all chemicals emitted in significant quantities from a single facility. Although a total measure of cumulative carcinogenic or toxic risk for all possible exposures is not currently possible, this study will provide a learning process for evaluating some additional aspects of cumulative risk in the permitting process. This summary presents general direction; the specifics may change to reflect technical feasibility. Where data inadequacies prevent full development of the proposed scope, the scope will be limited.

2. GOALS

The overall purpose of this study is to refine and demonstrate methodologies for assessing children's environmental health risks (both carcinogenic and noncarcinogenic) due to the accumulation of multiple stressors from multiple sources that impact a specific area. A basis will be developed for comparing risks in study areas to reference areas or baseline levels. Specific objectives are to:

a. conduct a cumulative risk analysis that specifically addresses concerns of the Agency and Stakeholders, including identification of health-compromised subpopulations of children and of locales with elevated hazard levels;

b. illustrate implementation of the Administrator's Cumulative Risk Guidance;

c. take the initial steps in developing the basis for transferring a cumulative risk methodology to other units in the Agency.

3. SCOPE

This section describes the general scope of the assessment and provides an overview of the technical approach that will be used. Research on health indicators (Section 3.1) will address the goal of identifying sensitive subpopulations of children. The data produced from the cumulative risk evaluation for multiple air sources (Sections 3.2) will quantify the risks from air contaminants in specific areas, and the description of other risk pathways (Section 3.3) will help to identify other sources of risk. All the above information will be utilized in the risk integration portion of the study (Section 3.4) to gain insight into reducing risks to children. The following list is a summary of elements that apply to the entire cumulative risk study:

- Risk dimensions: Multiple health endpoints (health effects), multiple stressors, and multiple sources will be assessed.
- Stressors: The scope will be restricted to environmental contaminants, with a focus on releases due to human activity. The assessment will include the chemicals that are most important, given the locales and sources selected as the focus of study. The selection of chemicals will be constrained by data availability
- Sources: The emphasis will be on EPA-regulated/permitted sources, with other important source categories added as needed to develop a more complete risk management perspective.
- Geographic Area: The study region will cover Cook and Lake Counties. Within that area, two to four locales will be selected for more detailed study.
- Population: The focus will be on children, from conception through age 17, with assessment of lifetime exposures where appropriate. Particular attention will be given to risk evaluation for health-compromised children (e.g., asthmatic, lead poisoned, etc.) where possible.

The following subsections provide additional information on the technical elements that apply specifically to each task, including assumptions, constraints, implications, and data limitations.

3.1 Health Indicators *(Task 1)*

The availability of data related to children's environmental health status will be investigated for lead poisoning, asthma incidence, and cancer incidence and mortality. If these data permit identification of locales with elevated rates, this information will be one of the factors considered in selecting study areas. Specific health conditions which lead to increased sensitivity (or susceptibility) to environmental pollutants among children may also be included if data are available. For instance, data on prevalence of sickle cell anemia in children within various locales may be of interest. Where data related to a particular issue are absent or lack geographic relevance, further exploration of that issue will be precluded.

3.2 Cumulative Risk Evaluation for Multiple Emission Point Sources *(Task 2)*

This effort will focus on evaluating the contributions to exposure and risk within the study areas from multiple point sources of emissions to ambient air. To provide a basis for comparing the study areas to the rest of the Cook and Lake County area, screening-level estimates of ambient air risks from major source categories and background will be developed for all Census tracts. To develop comprehensive ambient air risk estimates for the study areas, appropriate portions of the detailed modeling and the screening level modeling results will be combined. The task will have three components:

<u>Task 2a</u>: Exposure and risk from multiple EPA-regulated point sources within two or more (up to four) discrete study locales will be evaluated. Possible factors for use in identifying an additional study area or areas include: (a) high levels of toxic emissions, based on information from the Environmental Loadings Profile or emissions databases; (b) high prevalence of one or more health indicators; or (c) Agency/Stakeholder consensus recommendations.

A subset of the most significant point sources affecting the study area will be selected for detailed study. Emissions from these point sources will be modeled to identify locations with maximum risk from multiple contaminants of concern. Cancer risks will be modeled for both child and life-time receptors at these maximum risk locations. (Life-time receptors would be modeled in addition to child receptors because cancer risks are greater when longer-term exposures (i.e., 30 years) are assumed.).

Both direct (inhalation) and significant indirect pathways of exposure will be included in the risk assessment. Examples of indirect pathways which may be evaluated, if data indicate they are significant pathways to children, include contact with soil, water, and sediments to which contaminants have been released through air deposition, and ingestion of contaminated produce or fish which may have accumulated contaminants released from the point sources.

Task 2b: Exposure and risk from area, mobile, and background sources that also affect the study locales will be evaluated, but in less detail. These risks will be combined with the contributions from modeled point-sources impacting locations within the study areas. Similarly, screening-level estimates of both point- and area-source risks will be developed for Census tracts throughout the larger area of concern (i.e., Cook and Lake Counties). These analyses are likely to rely on modeling methods developed for the air toxics portion of the EPA National Cumulative Exposure Project, but to use more recent and more detailed area-specific data.

Task 2c: Estimates produced by the ambient air modeling efforts described above will be validated by comparison to ambient monitoring data and results of detailed studies, where available. An uncertainty analysis will also be conducted to evaluate the robustness of the findings.

3.3 Description of Other Risk Pathways *(Task 3)*

All parties involved in the scoping and planning process have agreed that focusing the cumulative risk assessment on EPA-regulated and EPA-permitted sources is most appropriate. As a result, the most detailed portion of the cumulative risk evaluation will be the community-based assessment of multiple EPA-regulated (and permitted) air sources, plus other outdoor air sources (described in Section 3.2). Since emissions from these sources may contribute only a portion of the potential risks to a community, development of risk estimates for other sources and pathways will be addressed in this task.

This evaluation will include both exposures from sources that are regulated by EPA and some that are outside the direct control of the Agency. Exposure pathways from regulated or permitted sources could include drinking water ingestion and soil ingestion at or near contaminated sites. Examples of exposures that result from lifestyle and behavioral circumstances of children include: ingestion of lead in paint and soil; ingestion of pesticides in the diet; mercury and PCB ingestion from fish consumption (especially subsistence fishing); and inhalation of environmental tobacco smoke, radon, and other indoor air pollutants. Whenever possible, local (community-specific) exposure data will be used in the assessment. In other cases, regional or even national estimates will be used. While a comprehensive, community-based assessment of all exposures is beyond the scope of this study, the attempt will be made to include pathways affecting the particular vulnerabilities of children. Due to data and resource limitations, portions of the assessment of additional sources and personal exposures will be more descriptive than quantitative.

Appendix D. Slides from Presentations

1. Cumulative Risk Assessment Practicum Phase I Planning and Scoping
2. Problem Formulation: Lessons from Ecological Risk Assessments
3. Conceptual Model Development

Cumulative Risk Assessment Practicum

Phase I: Planning and Scoping

November 12-13, 1998

Chicago, Illinois

(Introductory Slides)

Sponsored by the
Science Policy Council

Presenter
Edward S. Bender, Ph.D.
SPC Staff

Cumulative Risk Assessment Practicum

Phase I: Planning an

No 19

Cumulative Risk Work Group

Don Barnes, OA	Larry Reed, OSWER
Ed Bender, ORD	Joe Reinert, OP
Carole Braverman, Reg V	James Rowe, ORD
Pat Cirone, Reg X	Jeanette Wiltse, OW
Penny Fenner-Crisp, OPPTS	Bill Wood, NCEA
Michael Firestone, OPPTS	Ed Ohanian, OW

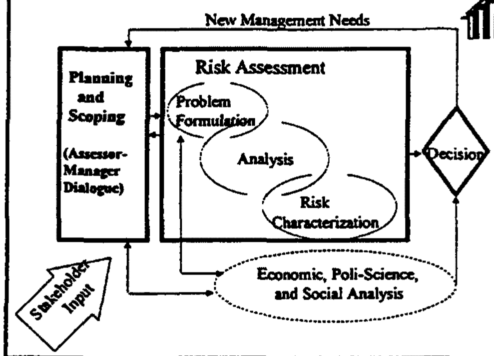
Cumulative Risk Guidance Phase I Planning and Scoping

- *Address aspects of CR within domain of EPA regulations*
- *Establish a framework to plan for integrated risk assessments*
- *Coordinate with Risk Characterization Policy and Guidance*
- *Complement/promote use of guidelines*

Cumulative Risk Objectives & the Practicum

- Learn to apply the guidance on planning and scoping for cumulative risk assessment.
- Develop a Plan and Conceptual models for Case Studies.
- Discuss and practice approaches.
- Identify CR needs and concerns for the assessors and managers.

Risk Assessment/ Management Decision Process



Definition of Cumulative Risk

- *"Risks from one or more stressors considered in aggregate"*
- *Each Assessment is case-specific*
  - *Who is affected or stressed?*
  - *What are the stressors?*
  - *What are the sources?*
  - *What are the pathways?*
  - *What is the time frame for the risk?*
  - *What are the assessment endpoints?*

Planning and Scoping Guida[nce]

- Plan for an Integrated Risk Assessment
- Relies on existing guidance and policy
- Encompass current practice, guidance, and policies.

P&S Guide

Guidelines-Ecorisk, Exposure, Neurotox., Repro., Cancer..
Program Guidance and Policy (RAGS, legislation, training)
Case Studies illustrate application of P&S Guidance
EPA Policy-Risk Characterization
Peer Review, Models, etc.

Planning and Scoping S

1. *Identify the Purpose, Scope, and participants*
2. *Develop a matrix of possibilities*
3. *Define the actual risk matrix*
4. *Determine assessment endpoints*
5. *Conceptual Model*

Problem Formulation ... g

Risk Assessor

1. Background Knowledge
   a. scale of the risk
   b. critical endpoints
2. Available/appropriate data (where?)
3. CR Matrix
4. Gaps
5. Potential RM options

Risk Manager

1. Why is RA needed?
2. Risk Managem't goals
3. Policy concerns
4. Political concerns
5. Timing/Resources
6. Acceptable Levels of uncertainty?
7. Potential RM options

Stakeholders

1. Values
2. Impacts

Economists

1. Benefits
2. Tradeoffs
3. RM option costs

Conceptual Model

Purpose of Dialog

- Risk Manager should explain why a risk assessment is needed and what questions should be answered.
- Surface policy and stakeholder concerns to determine information needs and contributors for planning the assessment.
- Discuss resources and participant roles.

Define the Scope of the risk assessment

- Identify the exposure scenarios, information needs, and assessment issues to be evaluated.
- Set criteria for defining the technical scope.
- Note judgements for risk characterization.

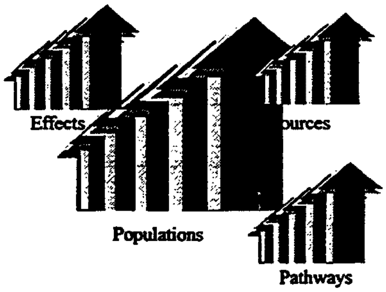
Define the Cumulative Risk Dimensions and Elements

- Develop a set of possible elements for each dimension (see Outline) with participants.
- Rank these elements in terms of data available, relevance to the RM goal, etc..
- Revisit these rankings as new data become available.

Cumulative Risk Dimensions and Elements Provide

- Definition of cumulative risk for the particular assessment.
- A record of what was considered, included and explicitly excluded from the analysis.
- The rationale for the these decisions.

Cumulative Risk Dimensions



Problem Formulation

- Iterative process for RA to develop hypotheses about why adverse effects might occur or have occurred.
- Determine the assessment endpoints- characteristics valued by society, and related to the management objective(s).
- Leads to a conceptual model.

Conceptual Models

- Show relationships between assessment endpoints and stressors.
- Reflects both scientific hypothesis and a rationale for accumulating risks from stressors affecting common receptors.

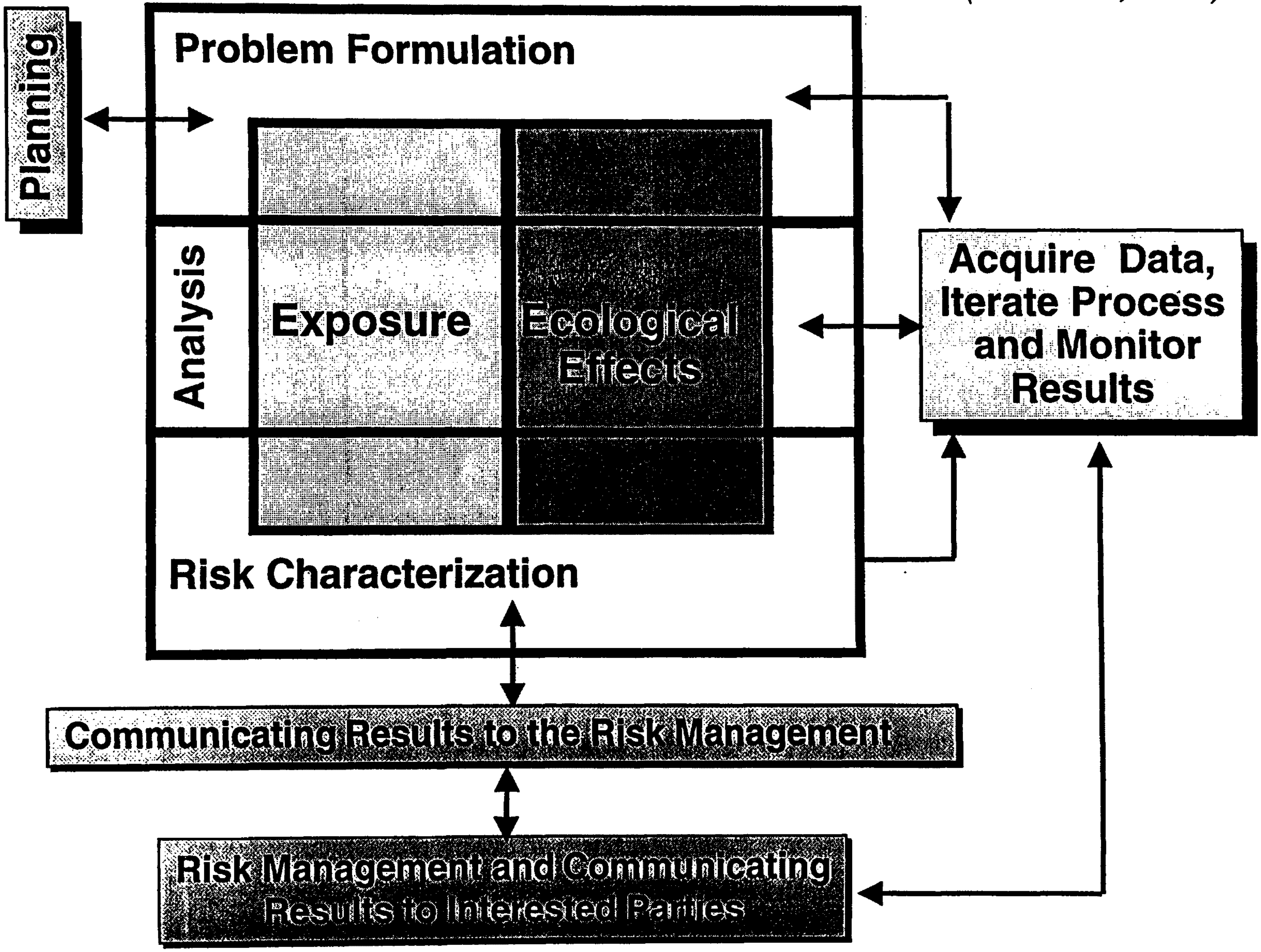
Problem Formulation:

Lessons from Ecological Risk Assessments

Mark A. Harwell and Jack Gentile

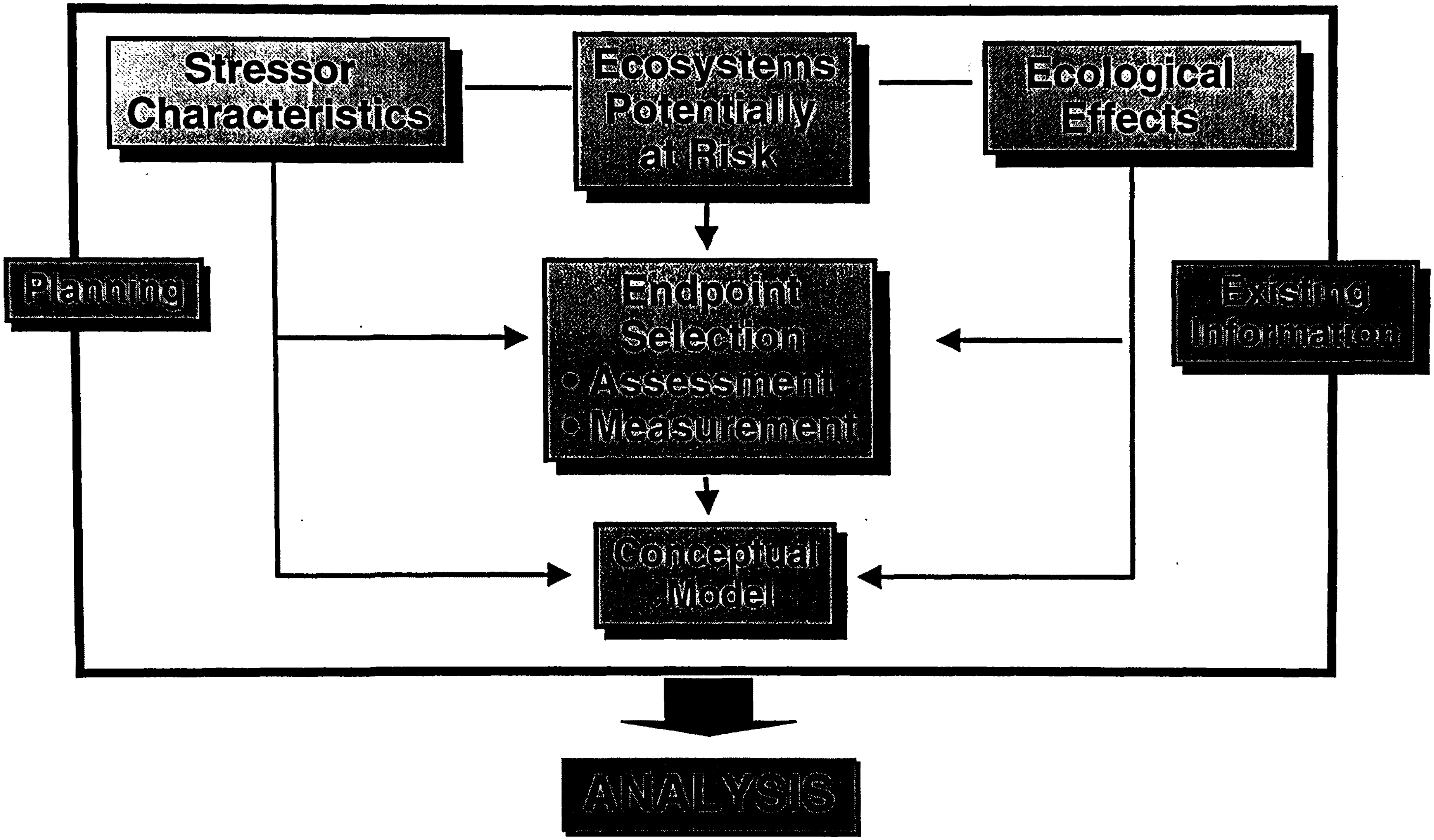
Framework for Ecological Risk Assessment

(EPA 1992, 1997)



Harwell Gentile & Associates, L.C.

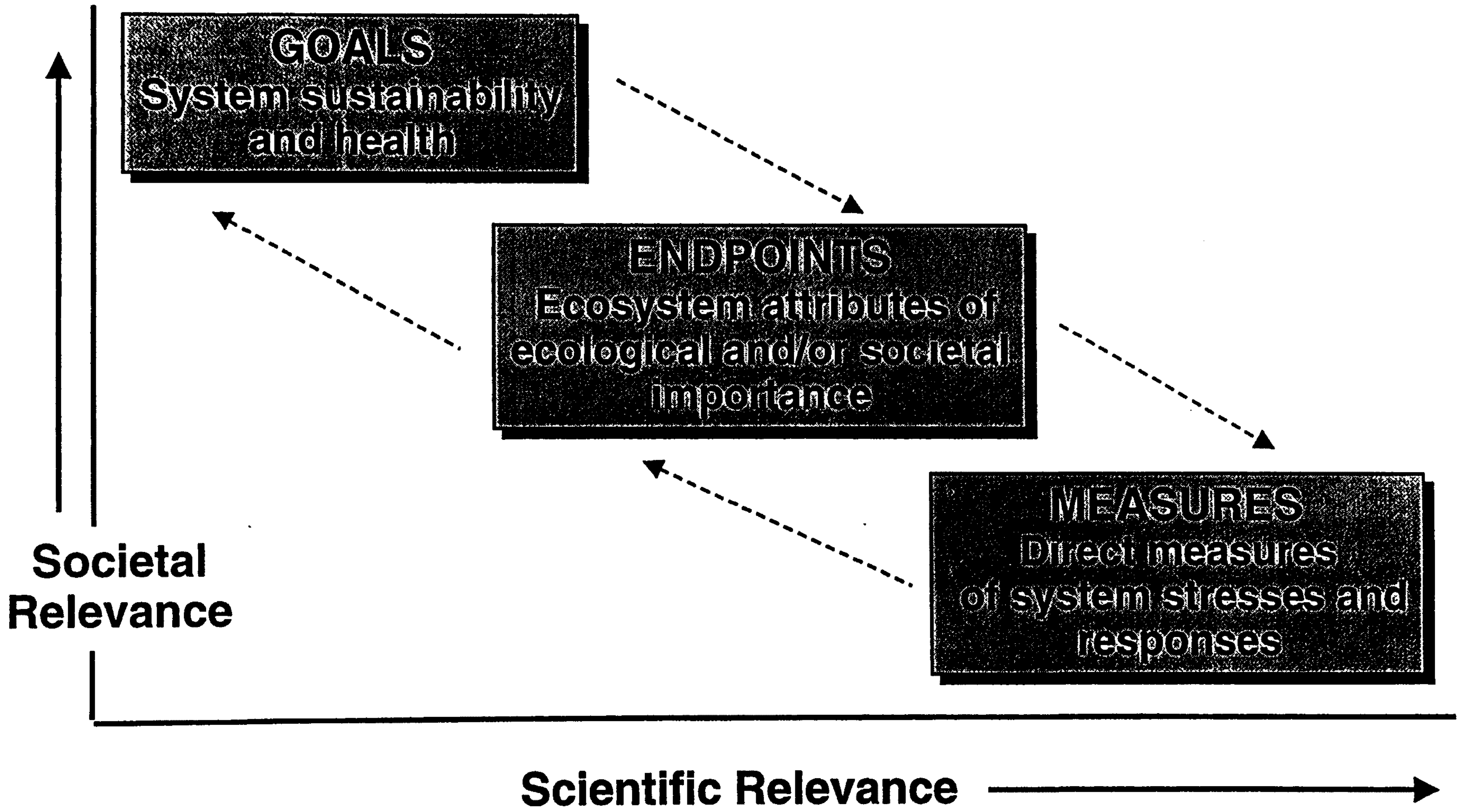
Problem Formulation



Harwell Gentile & Associates, L.C.

Relationship Between Societal Goals and Scientific Endpoints and Measures in Ecological Assessments

(Gentile and Harwell 1996)



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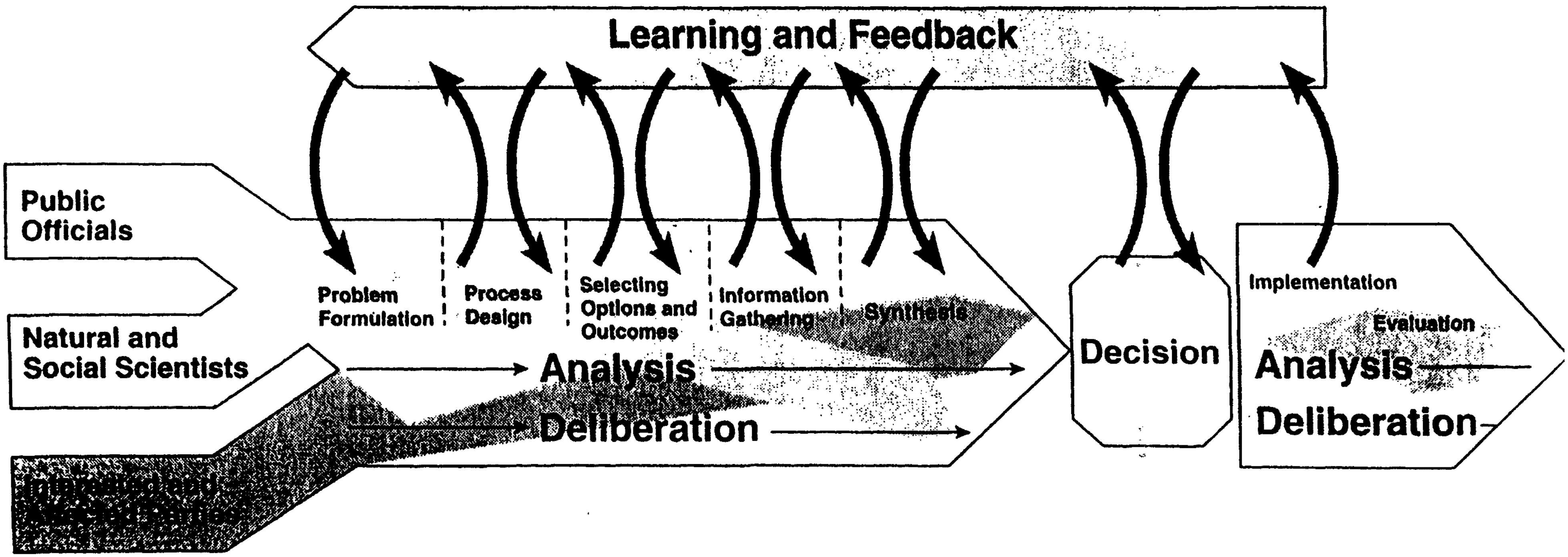


FIGURE 1-2. A schematic representation of the risk decision process.

CATEGORIES OF ECOLOGICAL ENDPOINTS

- HUMAN HEALTH CONCERNS
  - vectors for exposure to humans of diseases or toxics
- SPECIES-LEVEL ENDPOINTS

  societal importance
  - economic, aesthetic, recreational, nuisance, or endangered species

  ecological importance
  - interactions between species
  - habitat role
  - ecological role
  - trophic relationships
  - functional relationships
  - critical species
- COMMUNITY-LEVEL ENDPOINTS
  - food-web structure
  - species diversity of ecosystems
  - biotic diversity of ecosystems
- ECOSYSTEM-LEVEL ENDPOINTS
  - ecologically important processes
  - economically important processes
  - water quality
  - habitat quality
- LANDSCAPE-LEVEL ENDPOINTS
  - mosaic of ecosystem types
  - corridors for migration
  - spatial and temporal patterns of habitat
  - feedbacks to regional- and global-scale physical systems

Ecological Endpoints for Freshwater Marsh Ecosystems of South Florida

species-level endpoints

- *Spartina* spp. productivity
- *Muhly* productivity
- exotic species

community/ecosystem-level endpoints

- hydroperiod/water levels
- plant community structure
- upland succession
- biodiversity
- periphyton productivity
- water quality
  - nutrient/oligotrophic status
- feeding habitat for wading birds

landscape-level endpoints

- mosaic— spatial (physical distribution across landscape)
- mosaic— temporal (physical distribution across time)
- connectivity of habitats (e.g., with sawgrass)
- habitat fragmentation
- substrate dynamics
- stress response:
  - storm frequency
  - frost frequency
  - fire frequency/intensity

Cumulative Risk Elements

What are

The Questions ?

What are the relevant sources of stress?

What are the stressors of concern?

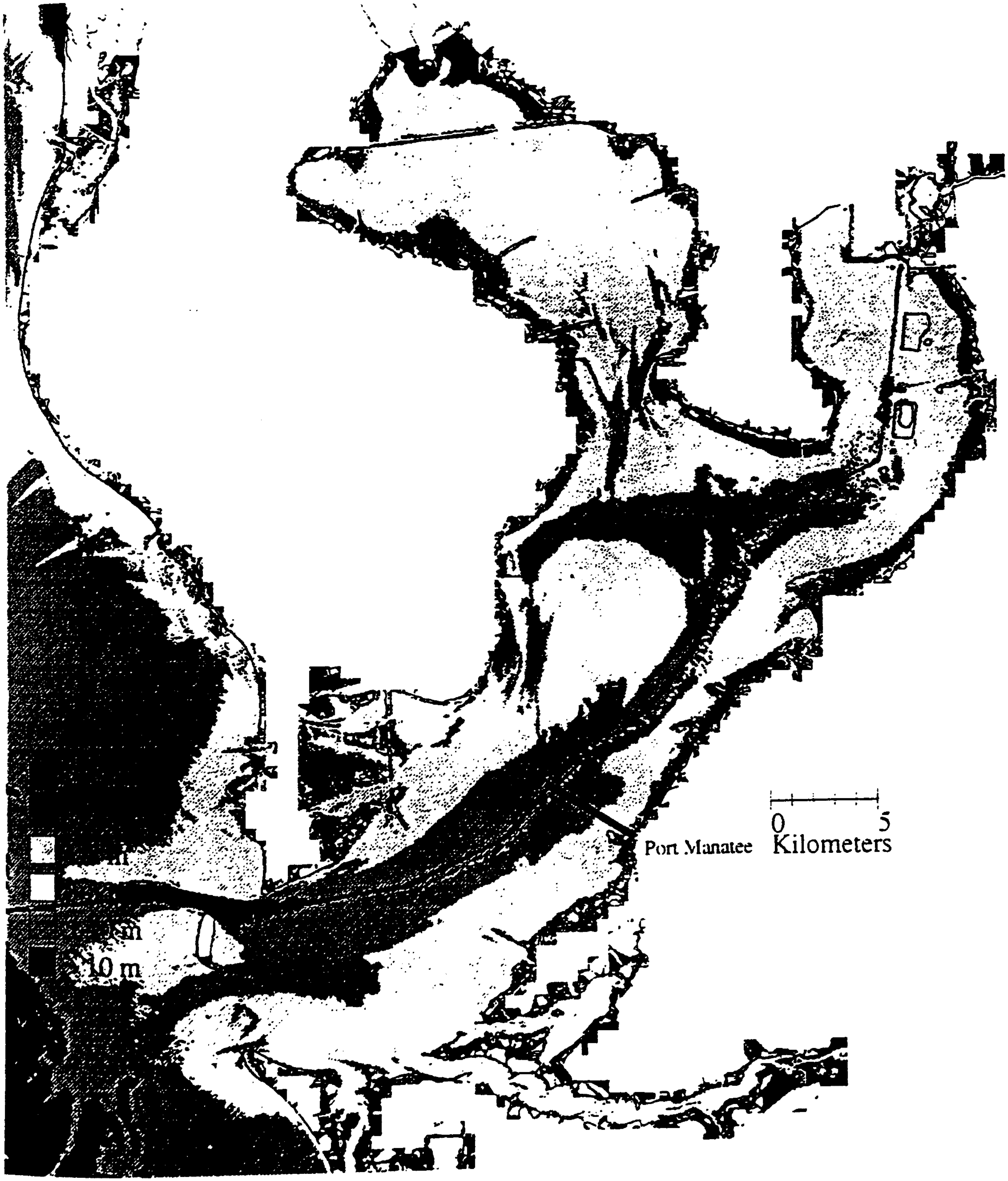
What are the relevant paths and routes of exposure?

Who and what are at risk?

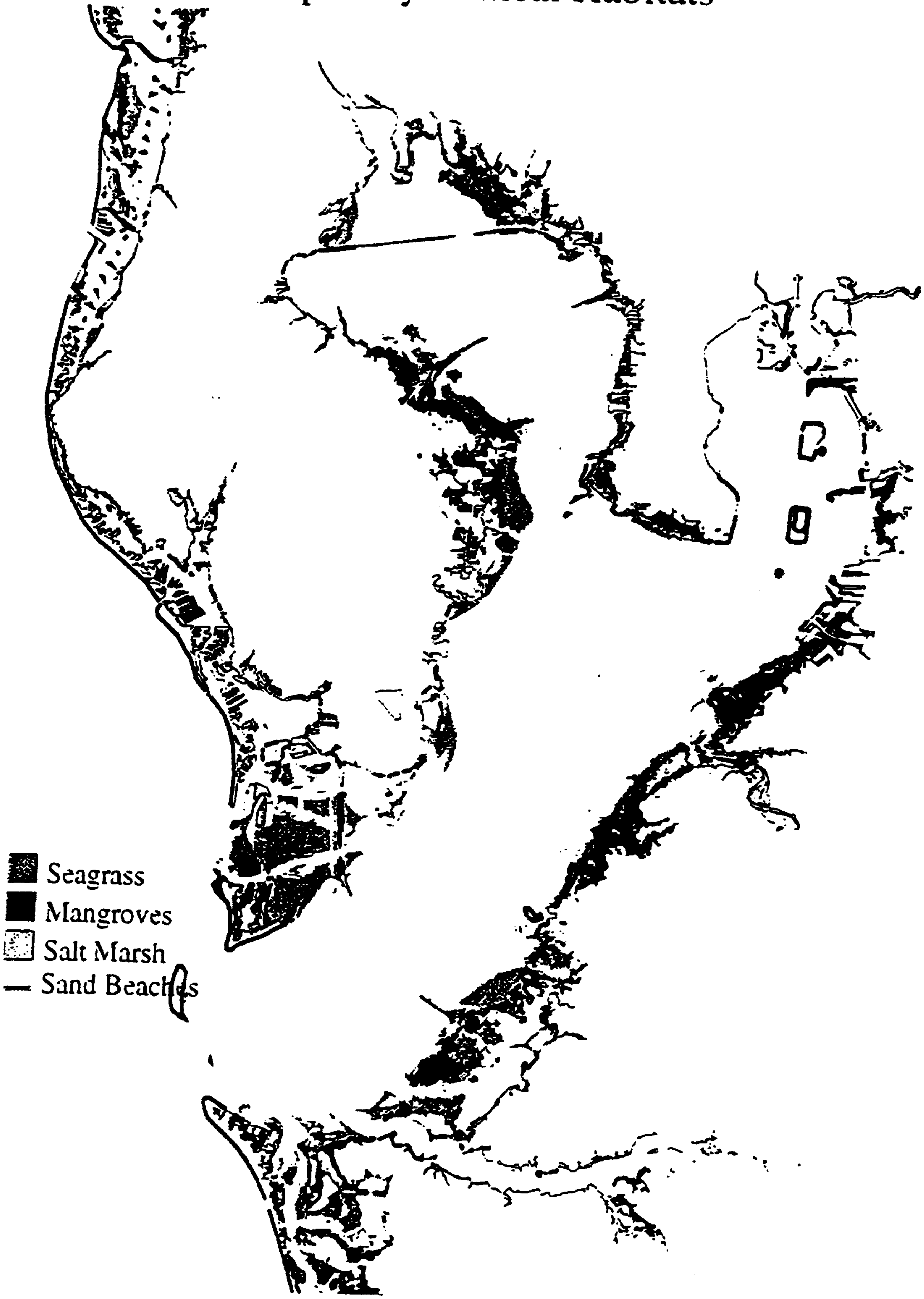
What are the health assessment endpoints?

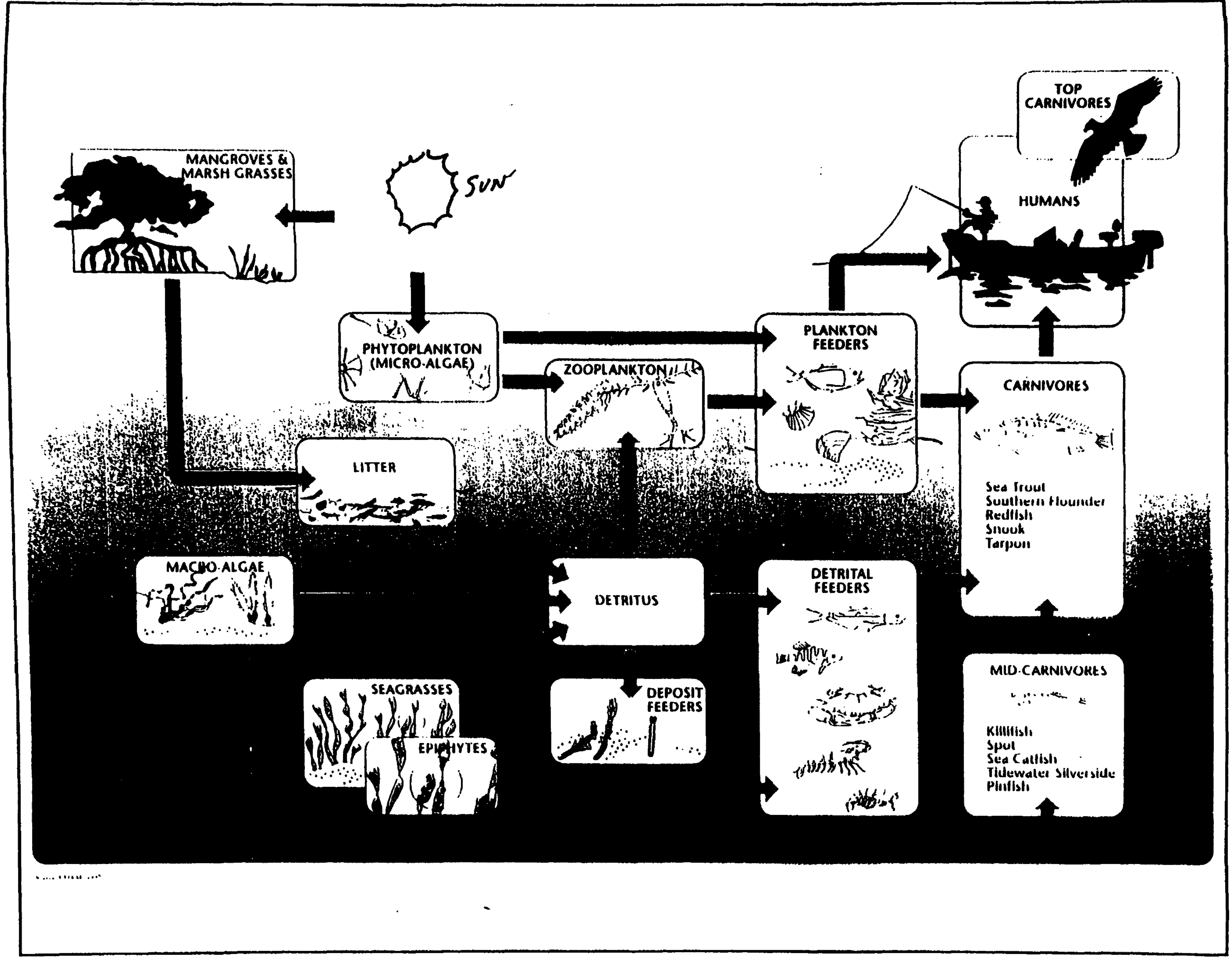
What are the ecological assessment endpoints?

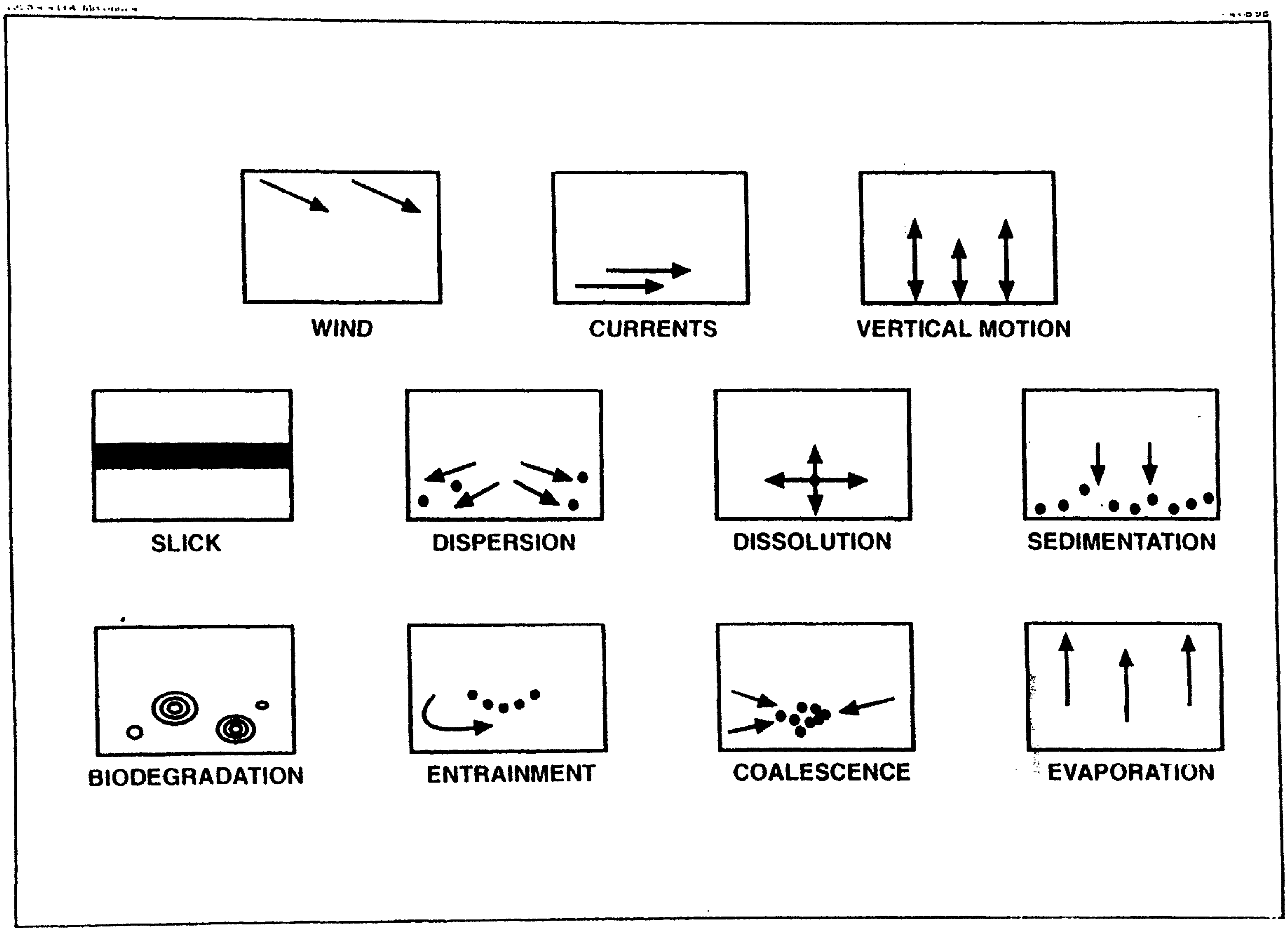
Tampa Bay Bathymetry



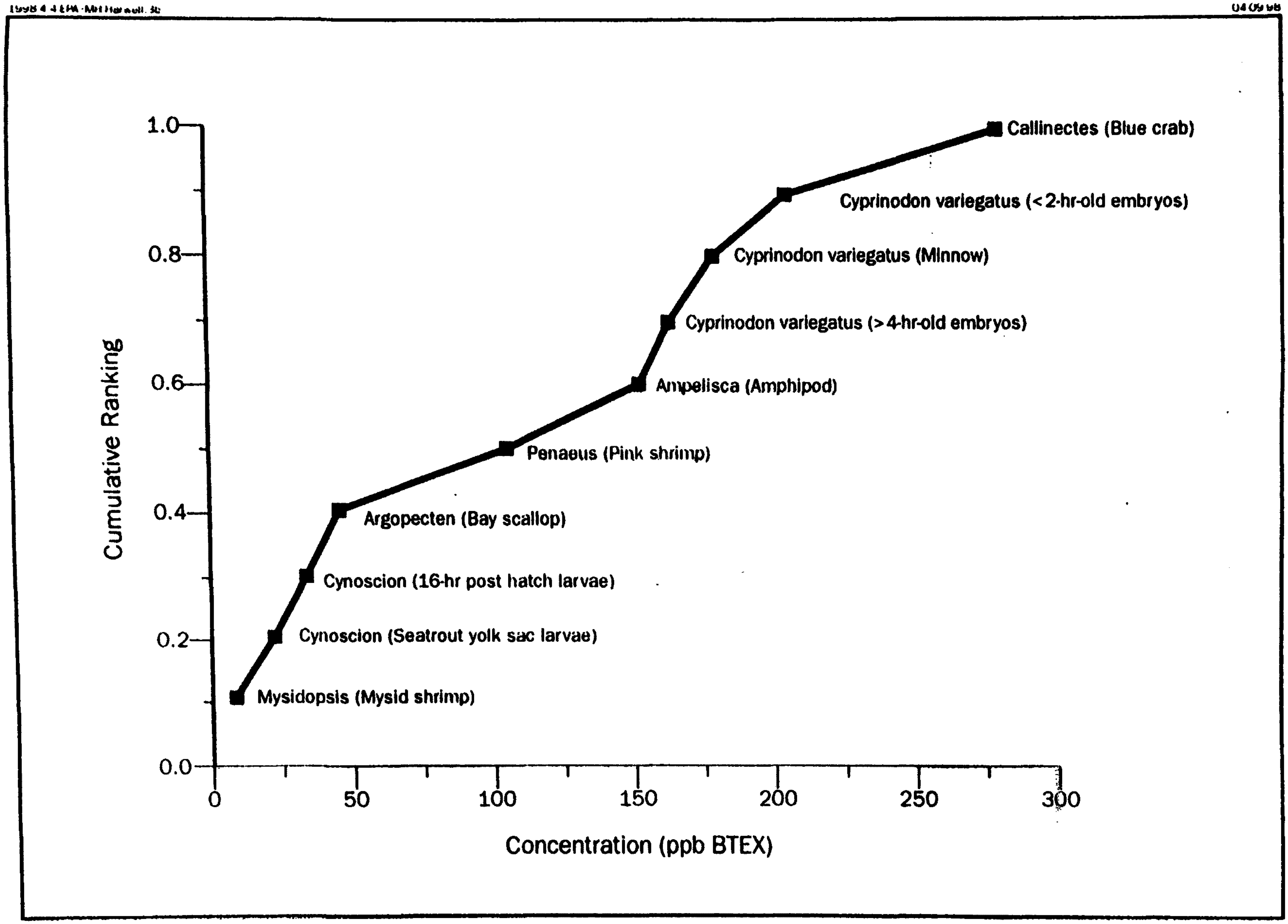
Tampa Bay Critical Habitats



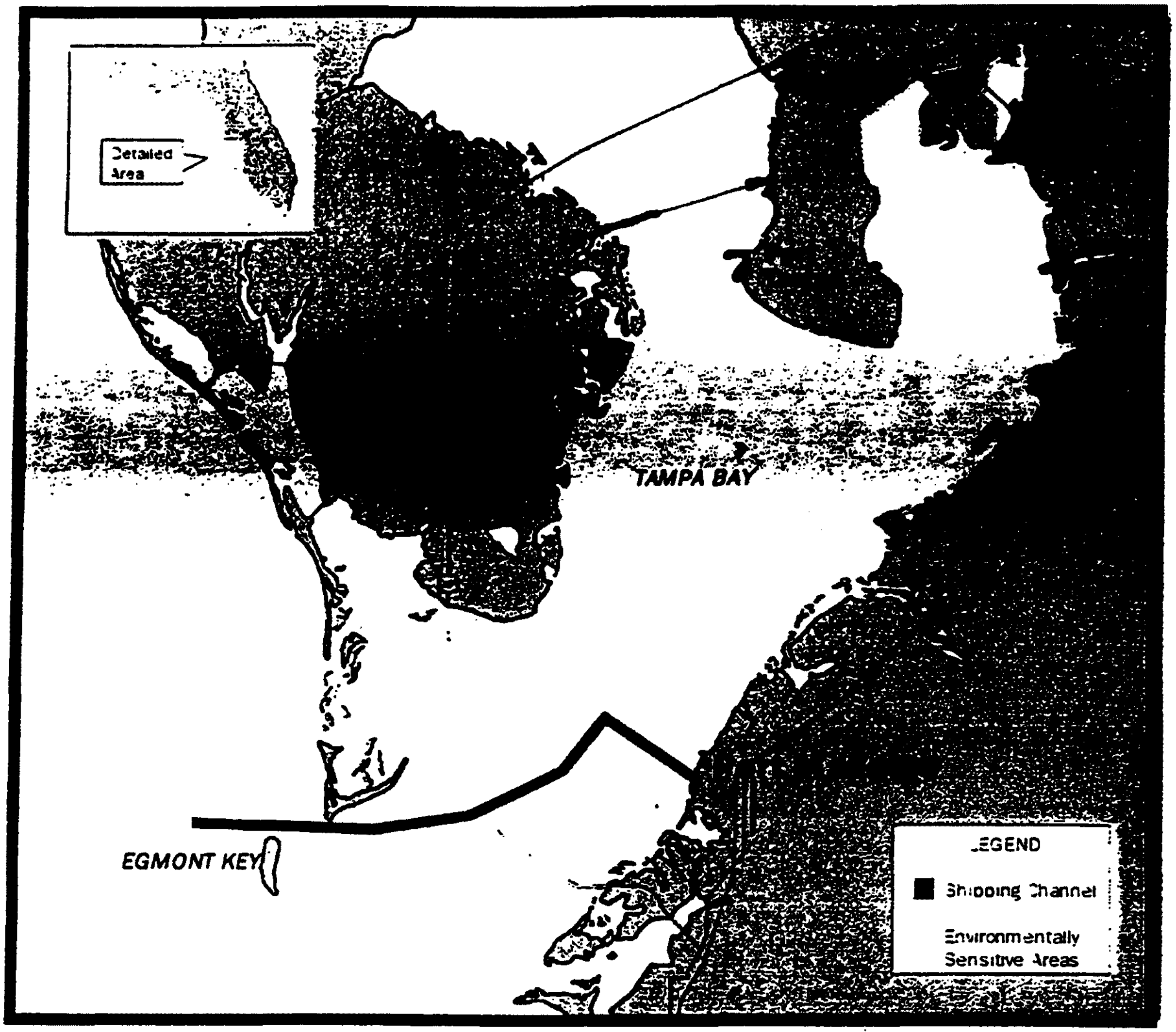

TOP CARNIVORES
MANGROVES & MARSH GRASSES
SUN
HUMANS
PHYTOPLANKTON (MICRO-ALGAE)
PLANKTON FEEDERS
ZOOPLANKTON
CARNIVORES
LITTER
Sea Trout
Southern Flounder
Redfish
Snook
Tarpon
MACRO-ALGAE
DETRITUS
DETRITAL FEEDERS
MID-CARNIVORES
SEAGRASSES
DEPOSIT FEEDERS
EPIPHYTES
Killifish
Spot
Sea Catfish
Tidewater Silverside
Pinfish



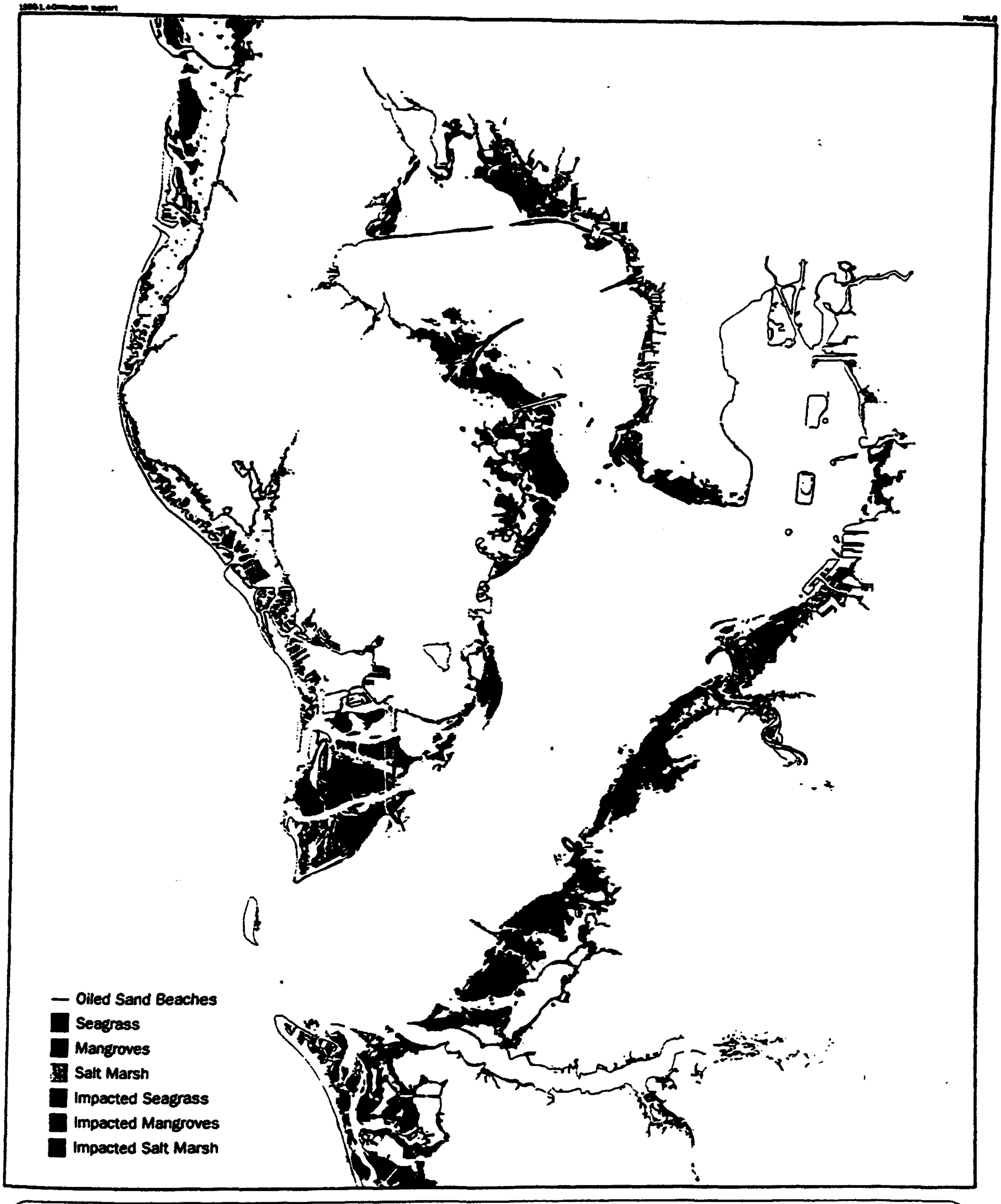
Physical Processes in Fate and Transport Models



Cumulative Distribution of Fuel Oil #6, Water Soluble Fraction Acute Toxicity Data



Shipping Navigation Channels to Port Manatee and Sensitive Environments in Tampa Bay



Impacted Shallow Water/Nursery Habitats (< 1/2m)
Adverse Condition Fuel Oil #6 Spill

Summary

- Define goals and objectives
- Establish spatial/temporal boundaries
- Identify sources, stressors, and pathways
- Define endpoints and measures
- Construct conceptual models
- Formulate stressor-response hypotheses
- Rank stressor-effects relationships

CONCEPTUAL MODEL DEVELOPMENT

JOHN H. GENTILE & MARK A. HARWELL

Harwell Gentile
& Associates, L.C.

Conceptual Models: Principles and Examples

Principles and rules

Format & structure

Watershed/habitat examples

RI/FS case study example

Harwell Gentile & Associates, L.C.

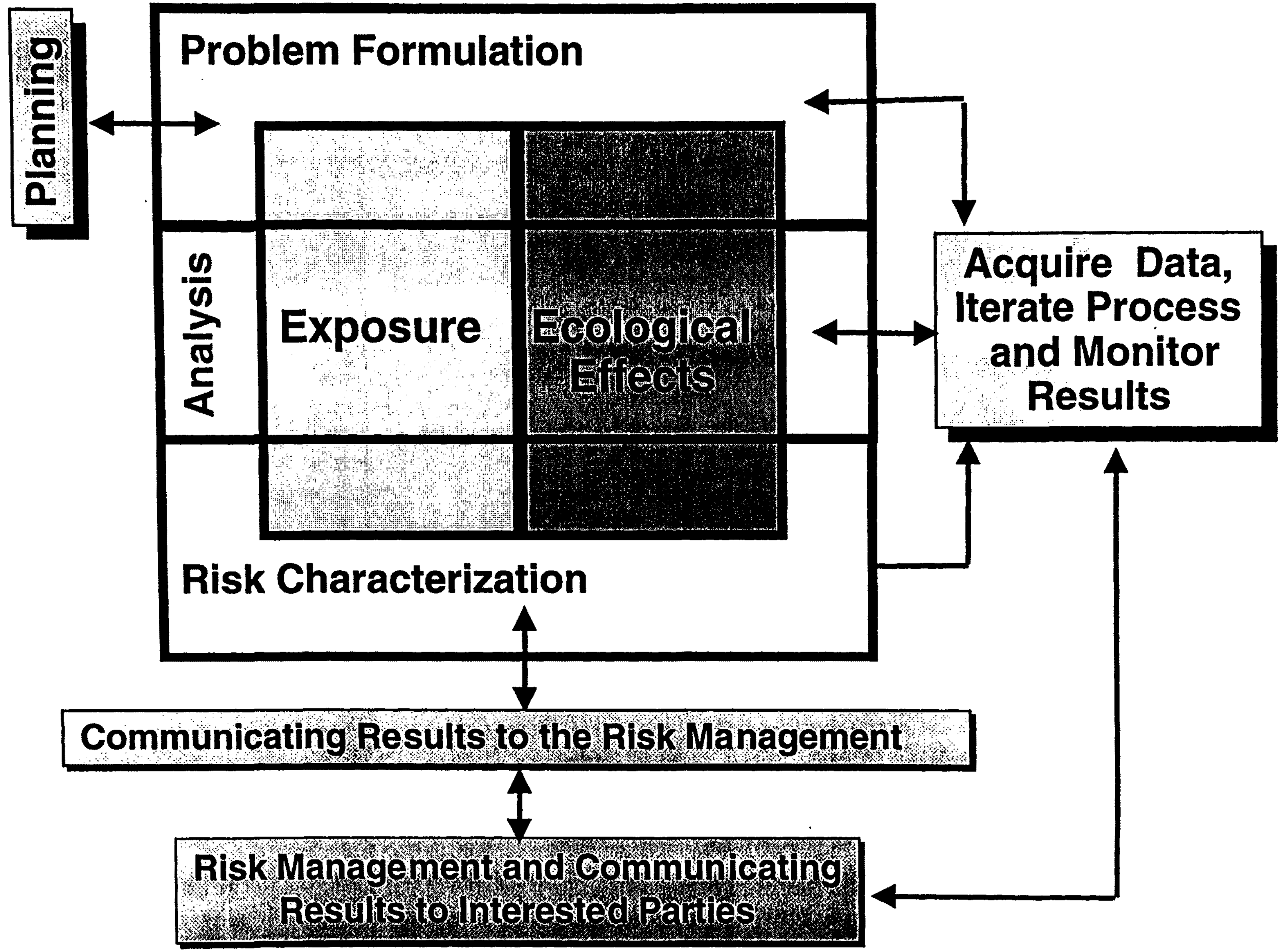
Conceptual Model Definition

A spatially explicit graphical or text description of the candidate causal linkages among sources, stressors, receptors and endpoints describing the spectrum of potential risks.

(EPA 1992, 1997)

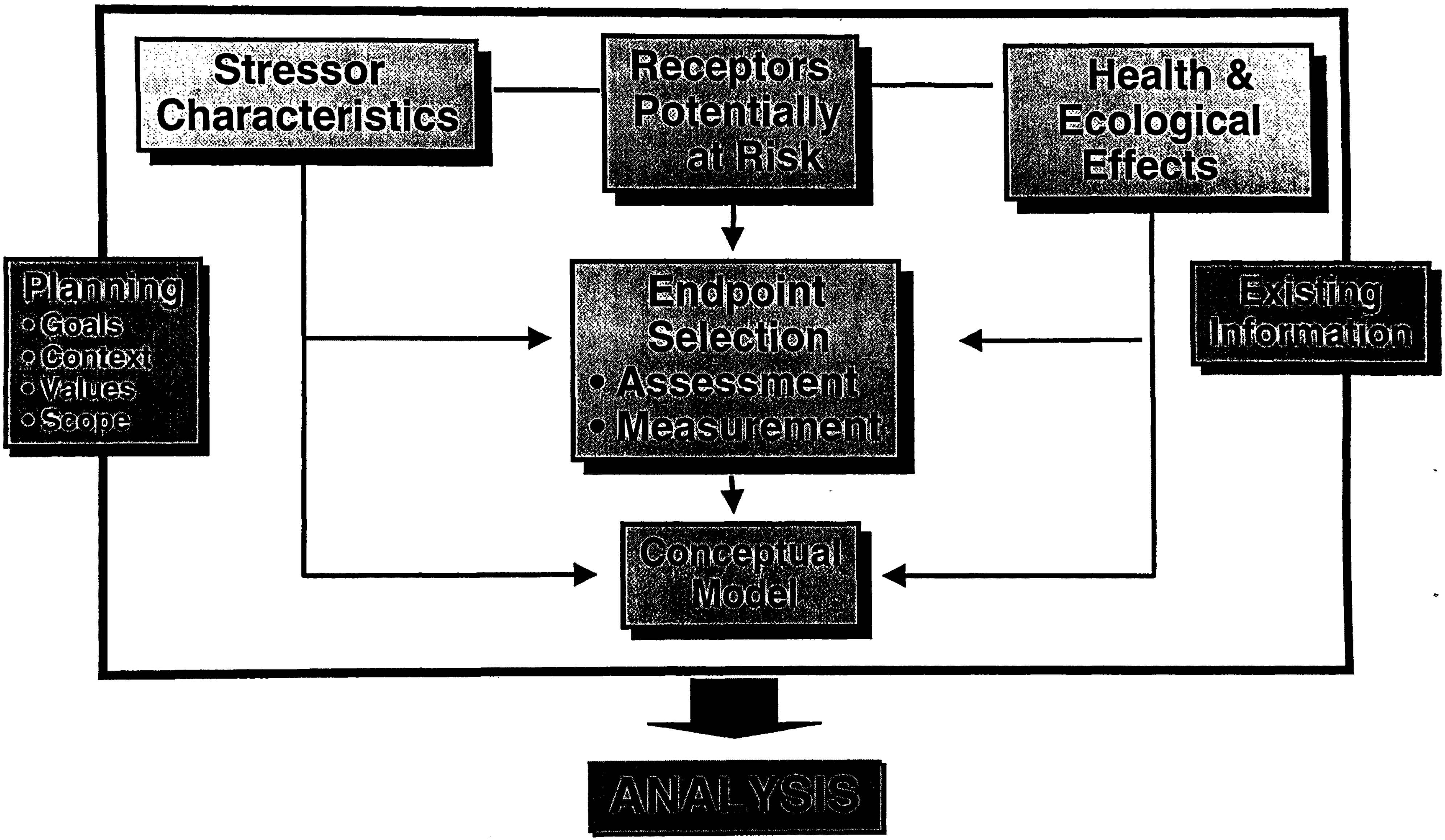
Framework for Ecological Risk Assessment

(EPA 1992, 1997)

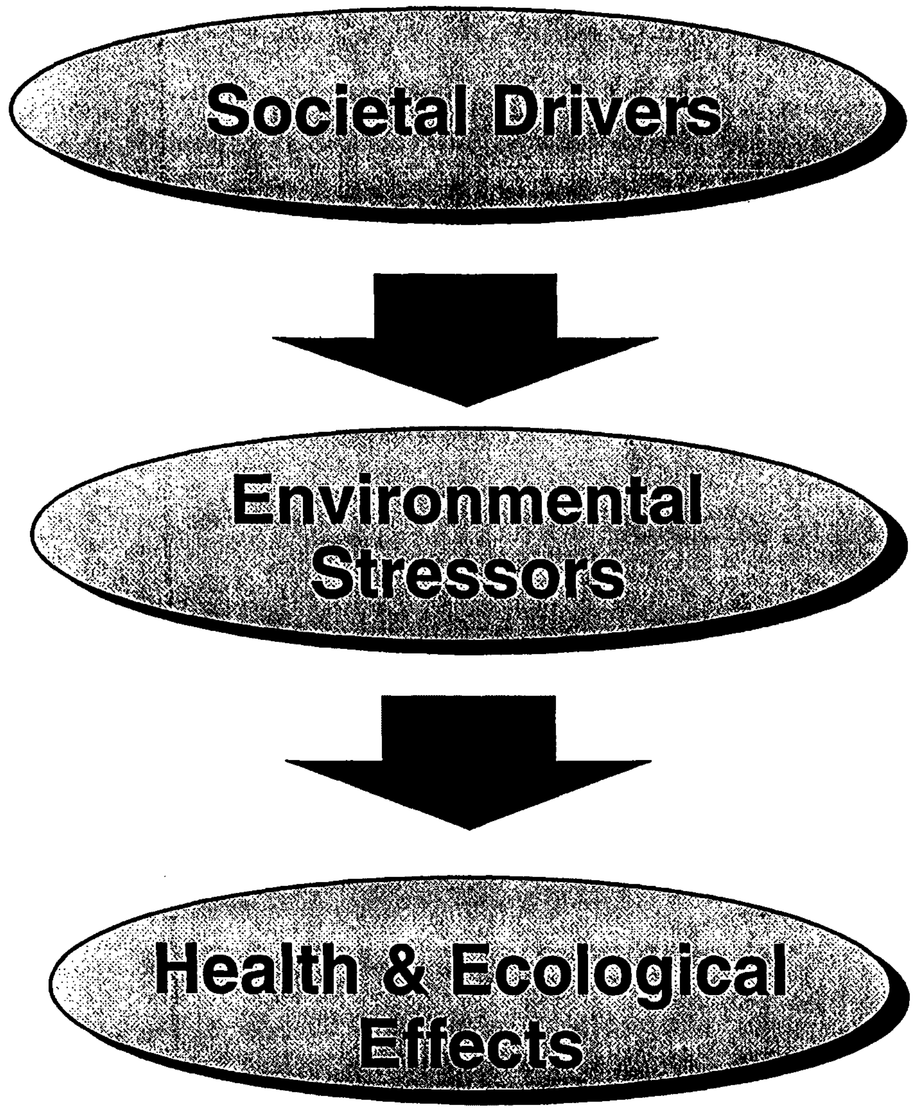


Harwell Gentile & Associates, L.C.

Problem Formulation



Driver-Stressor-Effects Linkages



Conceptual Model Benefits

- Provides explicit expression of the assumptions and understanding of the system
- Reduces the dimensionality of the problem
- Tool for learning, communicating, and consensus building
- Describes explicitly the linkages among sources, stress, and the ecological components at risk
- Template for generating testable risk hypotheses

Cumulative Risk Questions

What are the relevant sources of stress?

What are the stressors of concern?

What are the relevant paths and routes of exposure?

Who and what are at risk?

What are the health assessment endpoints?

What are the ecological assessment endpoints?

Conceptual Model Development

1. Define the goals and assessment context
2. Delineate scales and boundaries
3. Inventory land uses/activities
4. Describe the potential stresses and sources
5. Identify contaminant release mechanisms

Conceptual Model Development

6. Describe exposure pathways
7. Identify stressor - receptor co-occurrences
8. Identify health/ecological endpoints
9. Determine specific health/ecological measures
10. Develop a suite of risk hypotheses
11. Rank relative importance of potential risks

General Conceptual Model Format

Societal Drivers
(Landscape Activities)

⬇

System Stress

⬇

Stress Regime/Exposure Pathways

⬇

Disturbance/Stressor Co-occurrences with Receptors

⬇

Primary/Secondary Effects
(Proposed Causal Linkages)

⬇

Health/Ecological Endpoints

⬇

Measurements

Waqouit Bay Conceptual Model

EPA Watershed Case Study

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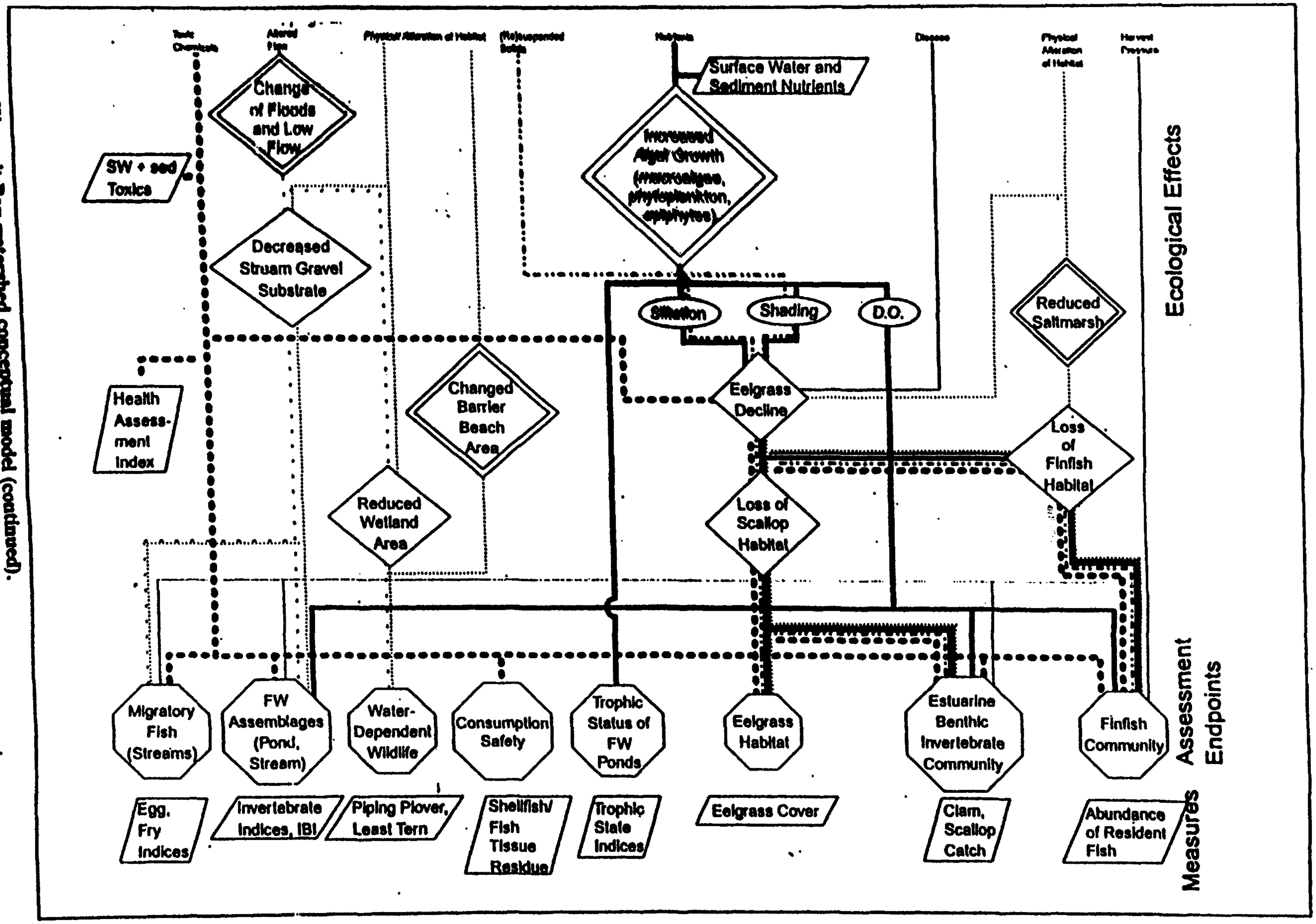
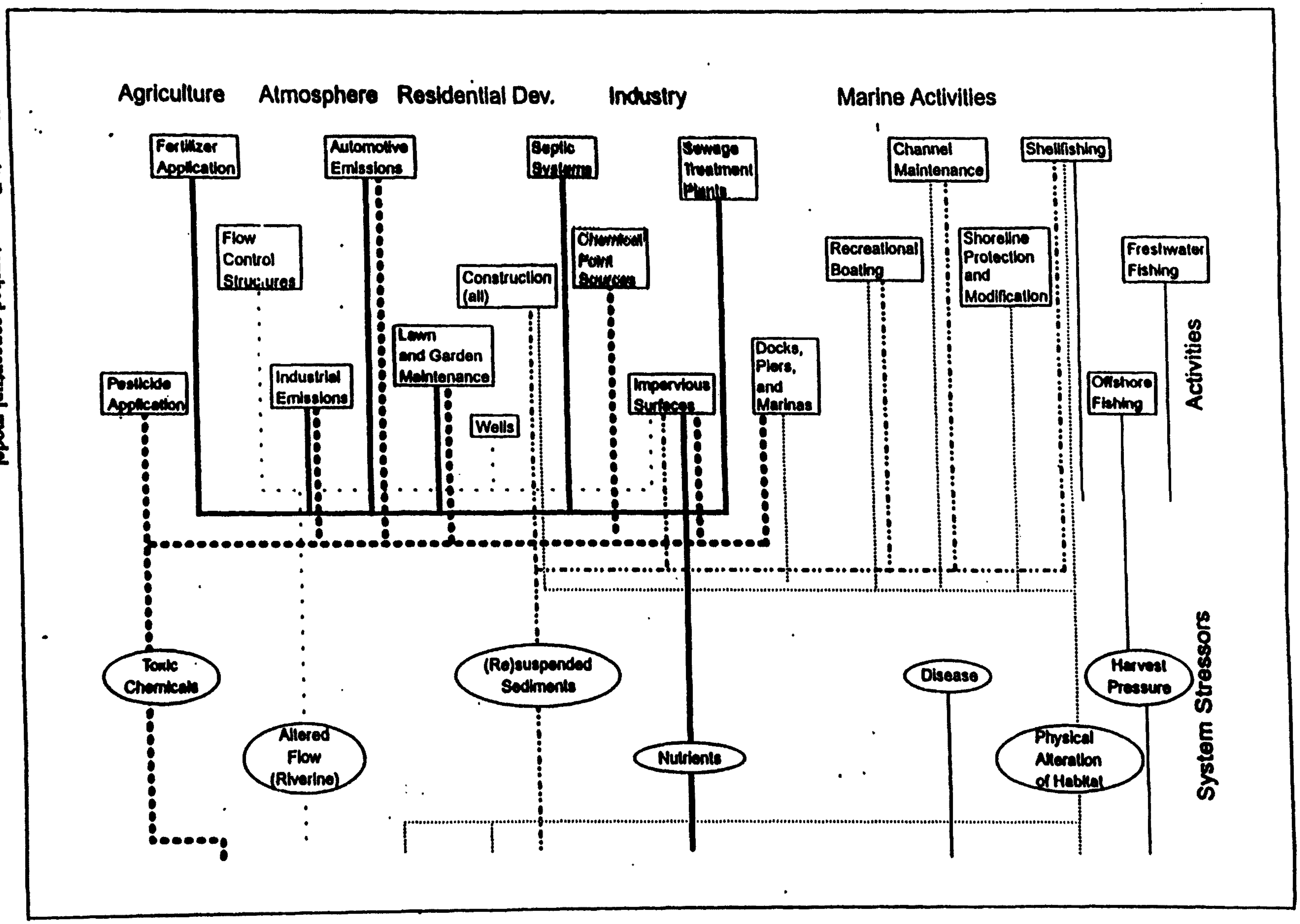


Figure 2. Waquoit Bay watershed conceptual model (continued).

Figure 2. Waquoit Bay watershed conceptual model.



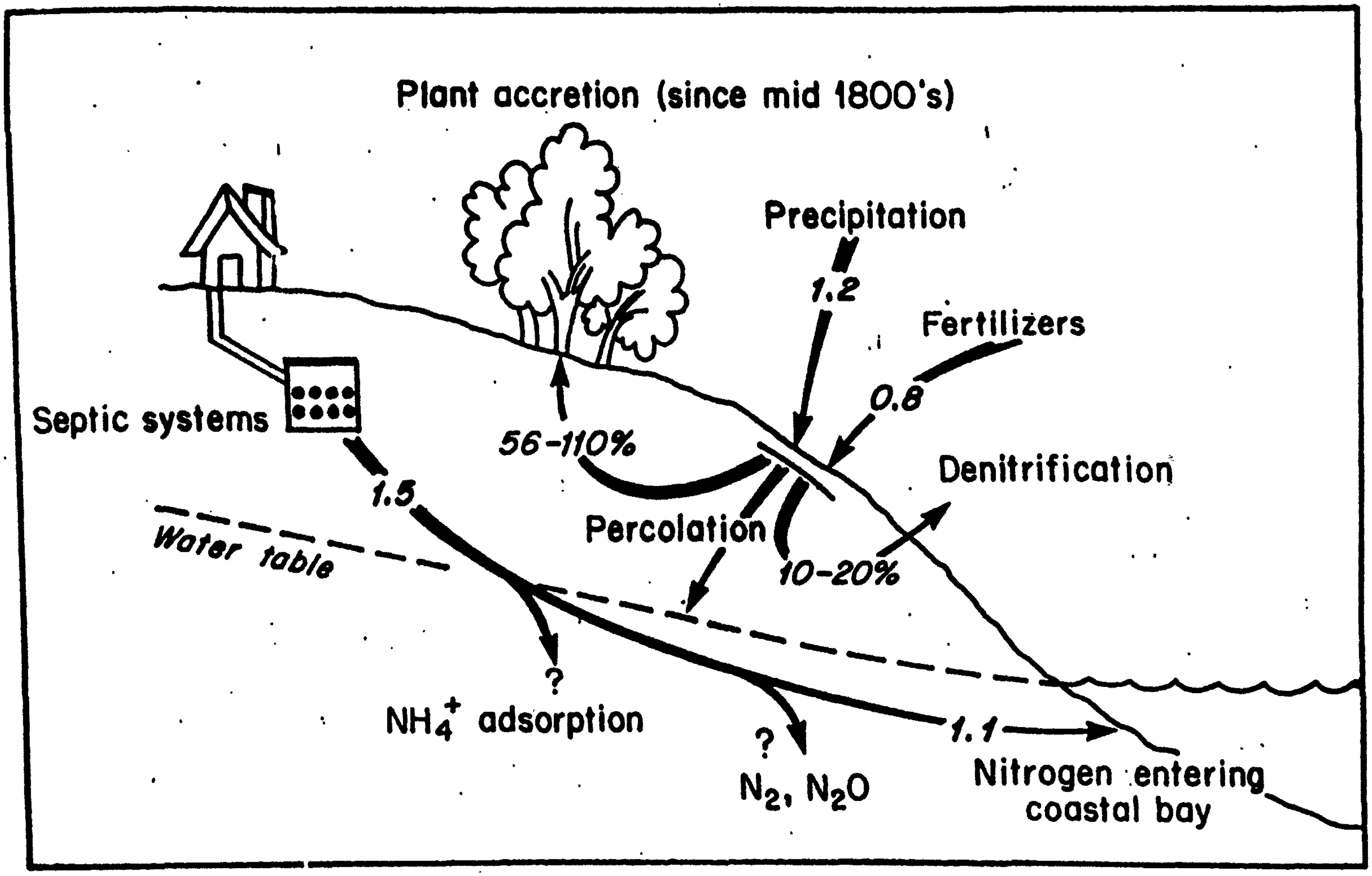


Figure E-5. Inputs and fate of nitrogen (mol N x 10^6 yr^{-1}) entering the watershed and traveling toward Buttermilk Bay near Waquoit Bay. Additional sources not shown are precipitation directly onto surface waters and onto impervious surfaces that are washed into surface waters. (Reprinted from "Couplings of Watersheds and Coastal Waters: Sources and Consequences of Nutrient Enrichment in Waquoit Bay, Massachusetts," by Valiela et al., published in *Estuaries*, December 1992, Vol. 15, No. 4, pp. 443-457, with permission from *Estuaries*. ©Estuarine Research Federation.)

South Florida/Everglades Case Study

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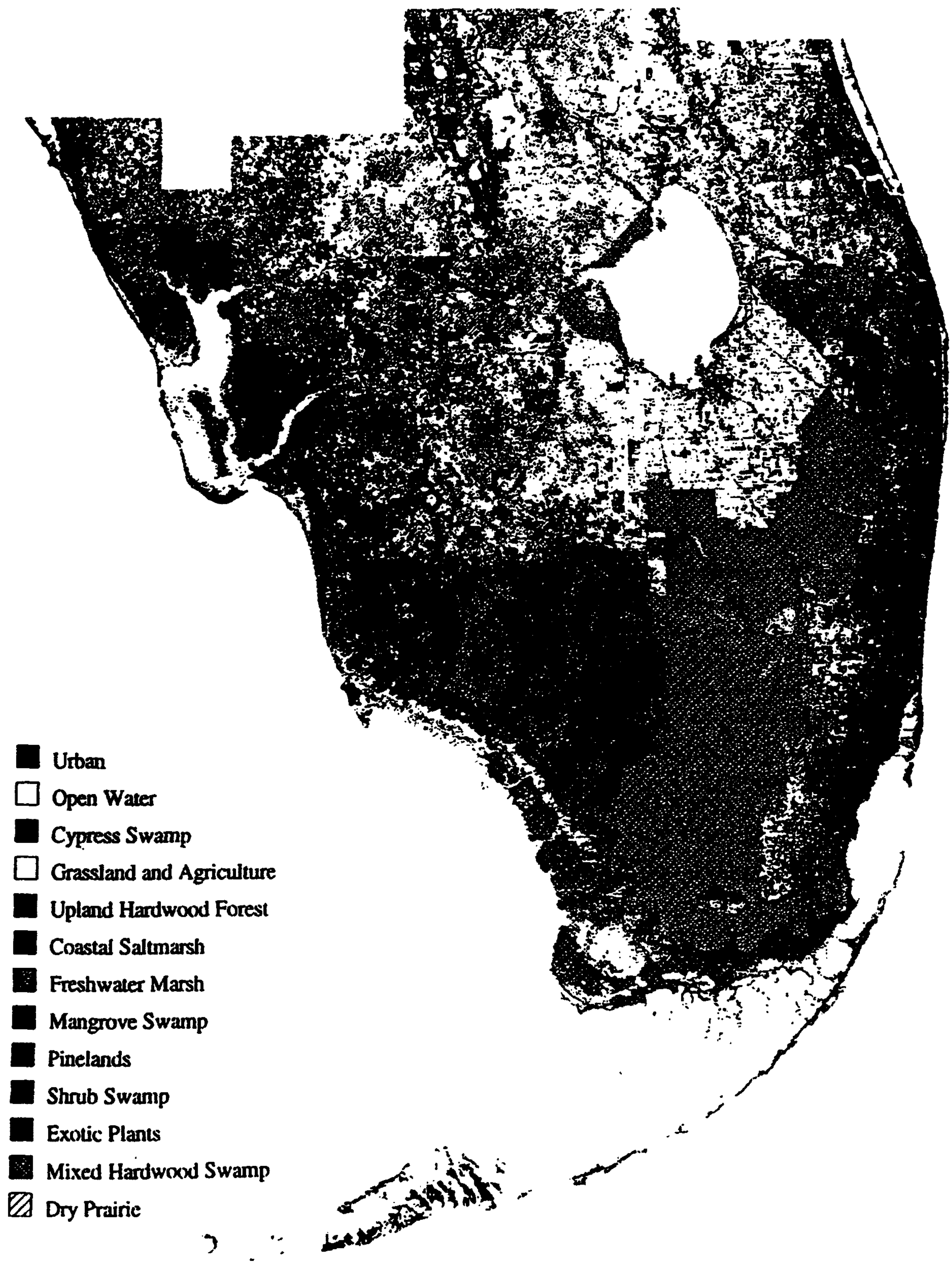
South Florida Regional Environments



Defining Spatial Boundaries:

Conceptual Model Landscape Units

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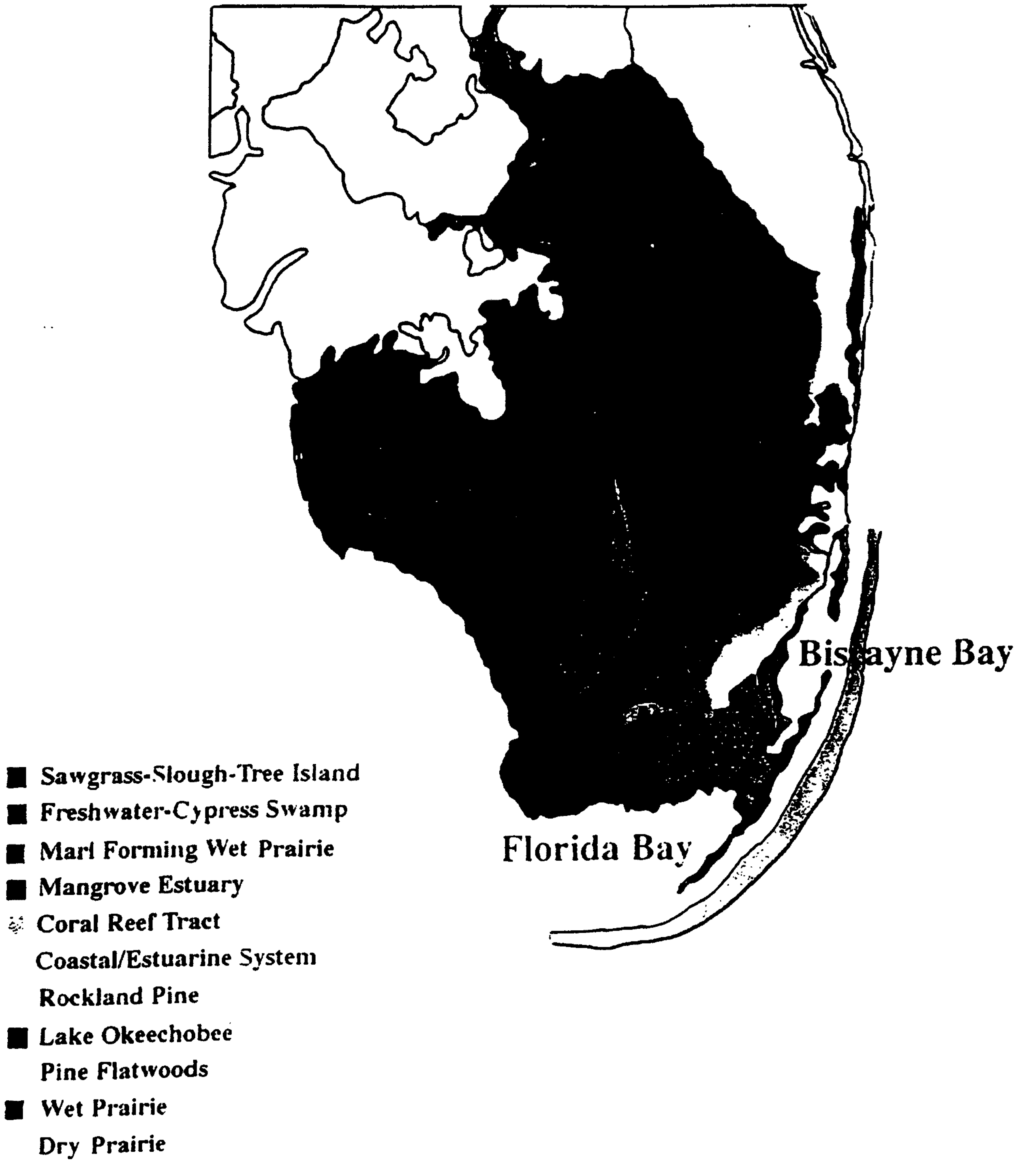
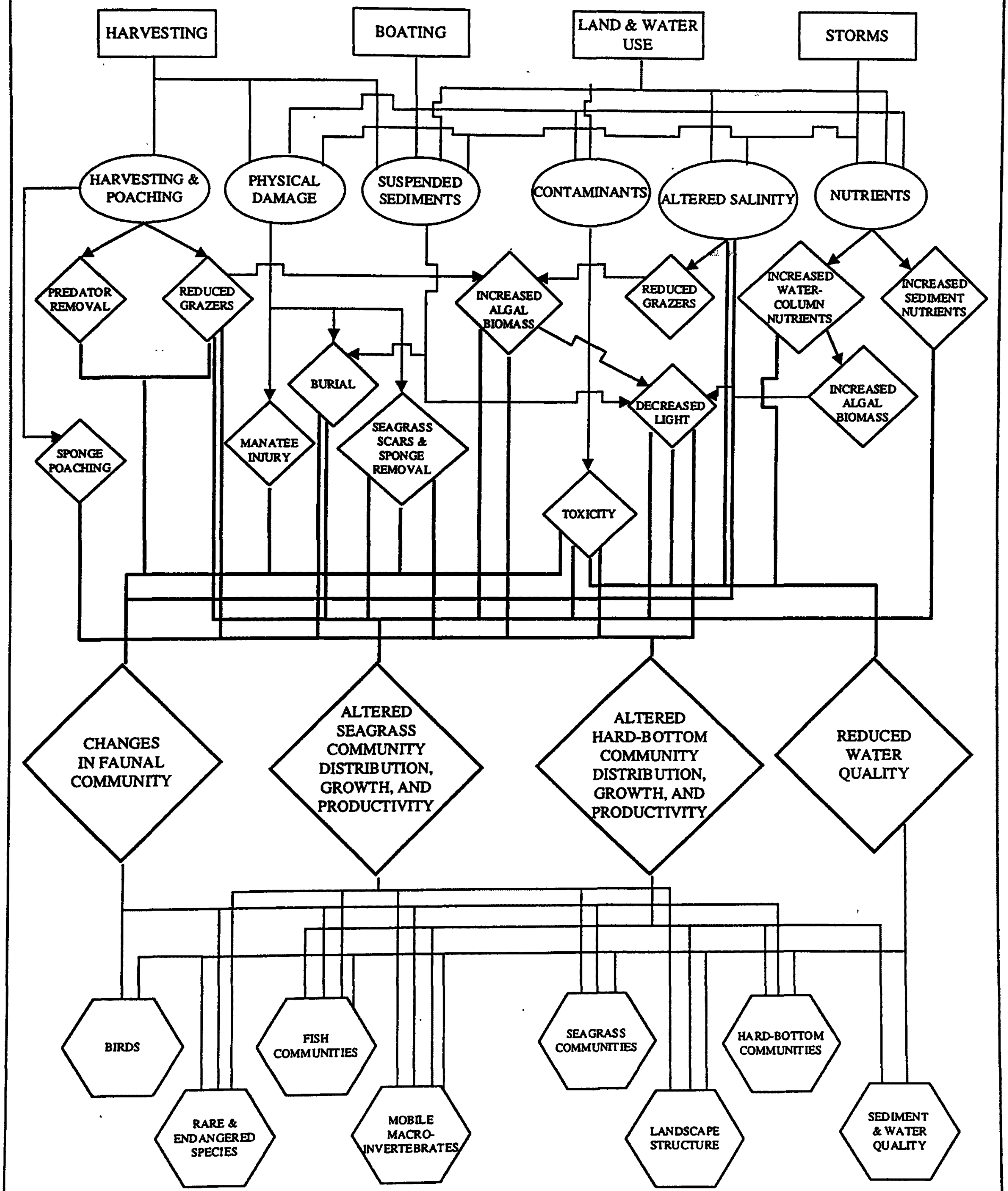

Biscayne Bay
Florida Bay
Sawgrass-Slough-Tree Island
Freshwater-Cypress Swamp
Marl Forming Wet Prairie
Mangrove Estuary
Coral Reef Tract
Coastal/Estuarine System
Rockland Pine
Lake Okeechobee
Pine Flatwoods
Wet Prairie
Dry Prairie

Biscayne Bay Conceptual Model

Biscayne Bay Conceptual Model



Decision Support Methods

- Best Professional Judgement (BPJ)
- Delphi Method (Linstone and Turoff, 1975)
- Analytical Hierarchy Process (Saaty, 1990)
- Fuzzy Set Theory (Zadeh, 1965, Harris et al. 1994)
- Vital Issues Process (Engi and Glicken, 1995)
- EPA/SAB Integrated Risk Project

Summary

- Define goals and objectives
- Establish spatial/temporal boundaries
- Identify sources, stressors, and pathways
- Define receptors, endpoints and measures
- Construct conceptual models
- Formulate stressor-response hypotheses
- Rank stressor-effects relationships

RI/FS Conceptual Site Models:

Chemical Stressor Model
Physical Stressor Model
Human Health Effects Model

Harwell Gentile
& Associates, L.C.

RI/FS Conceptual Model Format

Inputs

↓

Release Mechanisms (Primary /Secondary)

↓

Affected Media/Secondary Sources

↓

Exposure Routes

↓

Receptors and Systems @ Risk

↓

Primary/Secondary Health/Ecological Effects

↓

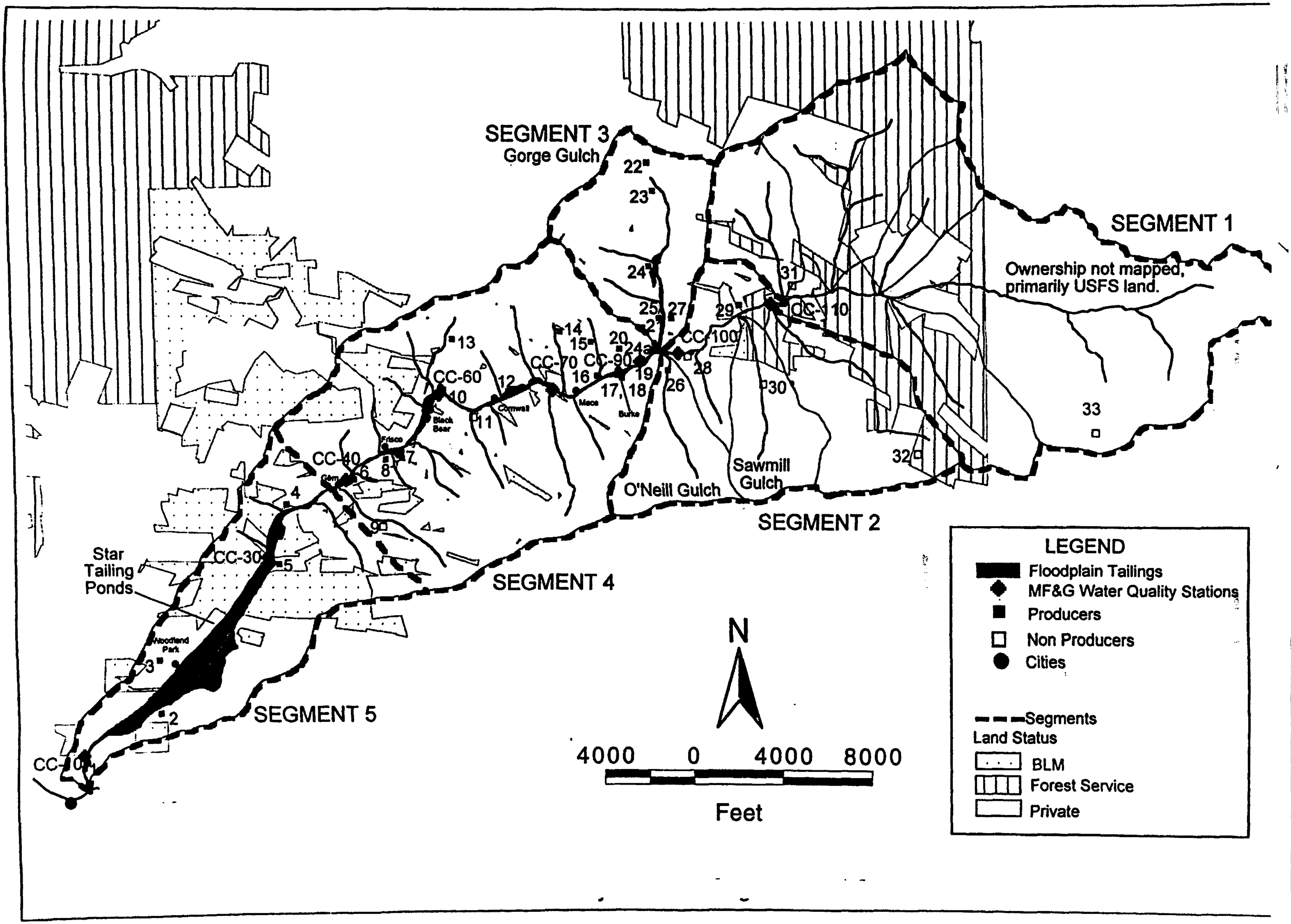
Health/ Ecological Endpoints

↓

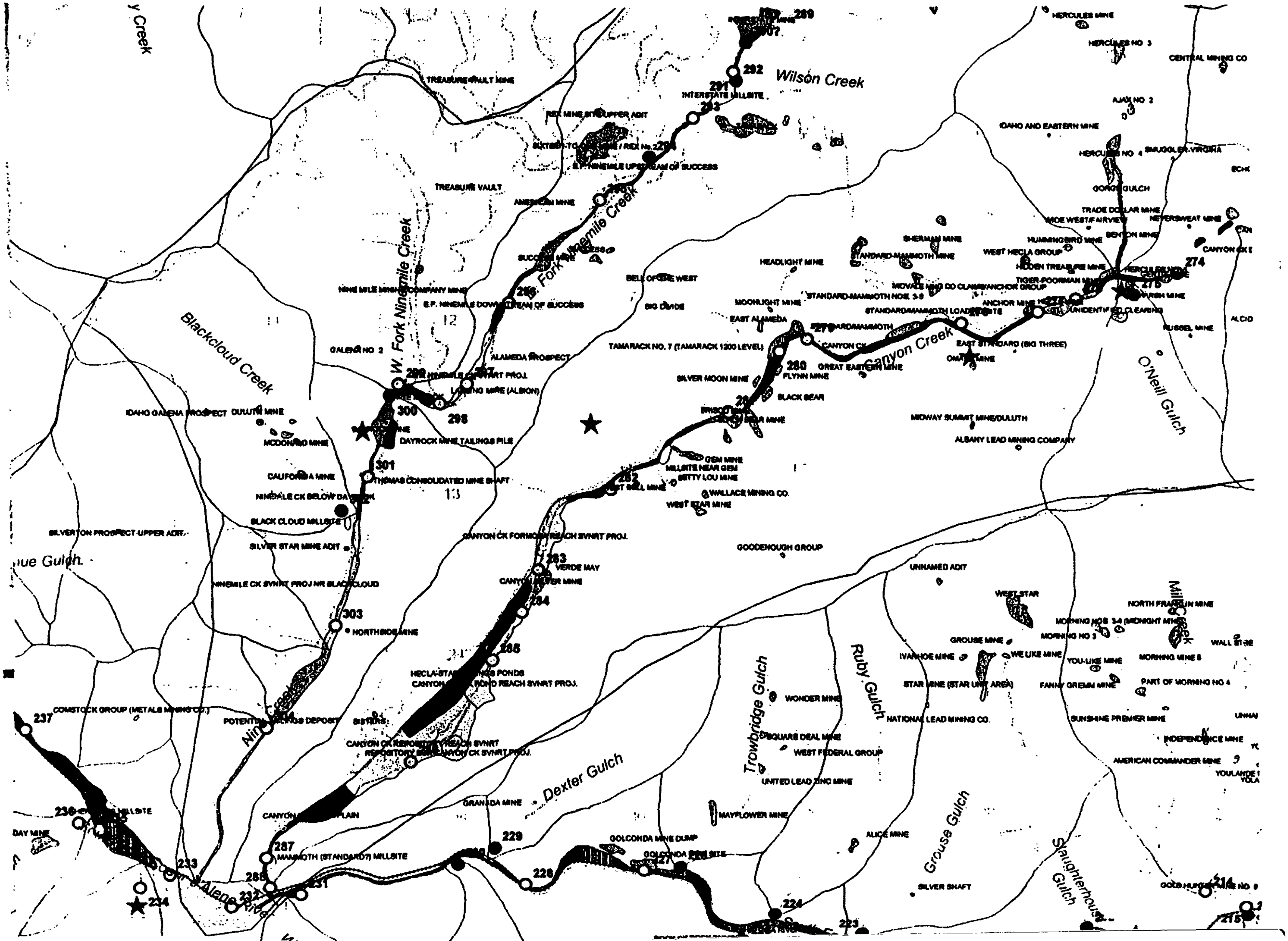
Measures

RI/FS Site Boundaries, Sources, and Stressors

Geography and Topography
Definine Spatially Explicit Sub-basins
Source and Stressor Characterization



SEGMENT 3
Gorge Gulch
SEGMENT 1
Ownership not mapped, primarily USFS land.
SEGMENT 2
SEGMENT 4
SEGMENT 5
O'Neill Gulch
Sawmill Gulch
Star Tailing Ponds
CC-10
CC-30
CC-40
CC-60
CC-70
CC-90
CC-100
CC-110
Frisco
Black Bear
Cornwall
Mace
Burke
Gem
Woodland Park
4000 0 4000 8000
Feet
N
LEGEND
Floodplain Tailings
MF&G Water Quality Stations
Producers
Non Producers
Cities
Segments
Land Status
BLM
Forest Service
Private



Wilson Creek
INTERSTATE MILLSITE
TREASURE VAULT MINE
TREASURE VAULT
AMERICAN MINE
E.F. NINEMILE UPSTREAM OF SUCCESS
E.F. NINEMILE DOWNSTREAM OF SUCCESS
NINE MILE MINING COMPANY MINE
W. Fork Ninemile Creek
Blackcloud Creek
GALENA NO 2
ALAMEDA PROSPECT
LOOKING MINE (ALBION)
IDAHO GALENA PROSPECT
DULUTH MINE
MCDONALD MINE
DAYROCK MINE TAILINGS PILE
CALIFORNIA MINE
THOMAS CONSOLIDATED MINE SHAFT
BLACK CLOUD MILLSITE
SILVERTON PROSPECT-UPPER ADIT
SILVER STAR MINE ADIT
NINEMILE CK SVNRT PROJ NR BLACKCLOUD
NORTHSIDE MINE
COMSTOCK GROUP (METALS MINING CO.)
POTENTIAL TAILINGS DEPOSIT
BELL OF THE WEST
BIG DIVIDE
HEADLIGHT MINE
SHERMAN MINE
STANDARD-MAMMOTH MINE
STANDARD-MAMMOTH NOS 3-9
STANDARD-MAMMOTH LOADING SITE
MOONLIGHT MINE
EAST ALAMEDA
TAMARACK NO. 7 (TAMARACK 1200 LEVEL)
SILVER MOON MINE
FLYNN MINE
BLACK BEAR
GREAT EASTERN MINE
Canyon Creek
EAST STANDARD (BIG THREE)
OMAHA MINE
MIDWAY SUMMIT MINE/DULUTH
ALBANY LEAD MINING COMPANY
GEM MINE
MILLSITE NEAR GEM
BETTY LOU MINE
WALLACE MINING CO.
WEST STAR MINE
CANYON CK FORMOSA REACH SVNRT PROJ.
GOODENOUGH GROUP
VERDE MAY
HECLA-STAR TAILINGS PONDS
CANYON CK REPOSITORY REACH SVNRT
CANYON CK SVNRT PROJ.
GRANADA MINE
Dexter Gulch
MAMMOTH (STANDARD?) MILLSITE
GOLCONDA MINE DUMP
GOLCONDA MINE SITE
HERCULES MINE
HERCULES NO 3
CENTRAL MINING CO
AJAX NO 2
IDAHO AND EASTERN MINE
HERCULES NO 4
SMUGGLER-VIRGINIA
GORGE GULCH
TRADE DOLLAR MINE
HIDDEN TREASURE MINE
TIGER-POORMAN MINE
HUMMINGBIRD MINE
WEST HECLA GROUP
NEVERSWEAT MINE
BENTON MINE
ANCHOR MINE
UNIDENTIFIED CLEARING
RUSSEL MINE
O'Neill Gulch
UNNAMED ADIT
WEST STAR
NORTH FRANKLIN MINE
Mill Creek
GROUSE MINE
IVANHOE MINE
WE LIKE MINE
YOU-LIKE MINE
MORNING MINE 6
STAR MINE (STAR UNIT AREA)
FANNY GREMM MINE
PART OF MORNING NO 4
Trowbridge Gulch
Ruby Gulch
WONDER MINE
NATIONAL LEAD MINING CO.
SUNSHINE PREMIER MINE
SQUARE DEAL MINE
WEST FEDERAL GROUP
INDEPENDENCE MINE
AMERICAN COMMANDER MINE
UNITED LEAD ZINC MINE
MAYFLOWER MINE
ALICE MINE
Grouse Gulch
Slaughterhouse Gulch
SILVER SHAFT
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RI/FS Ecological Conceptual Site Models

Chemical Process Model

Physical Process Model

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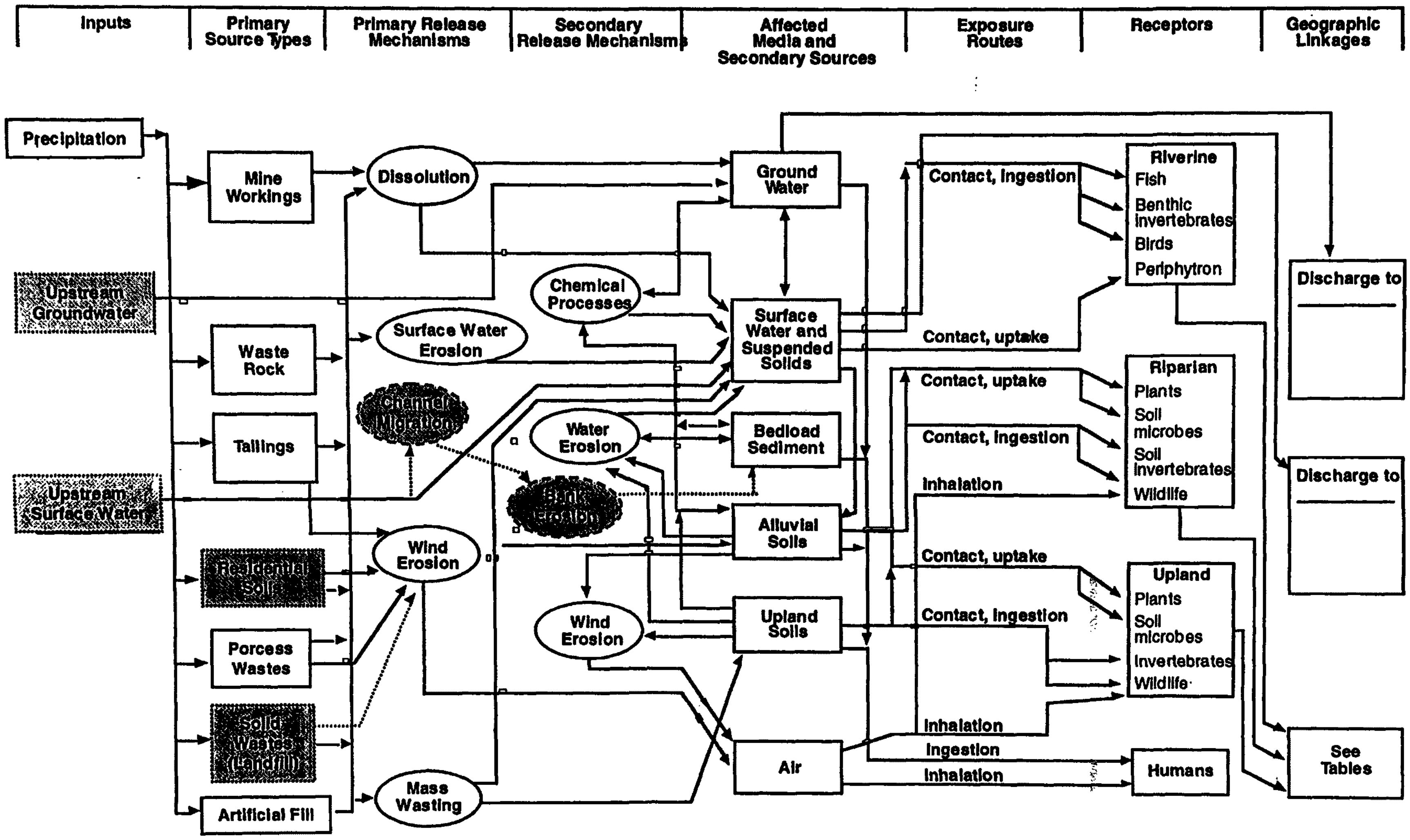
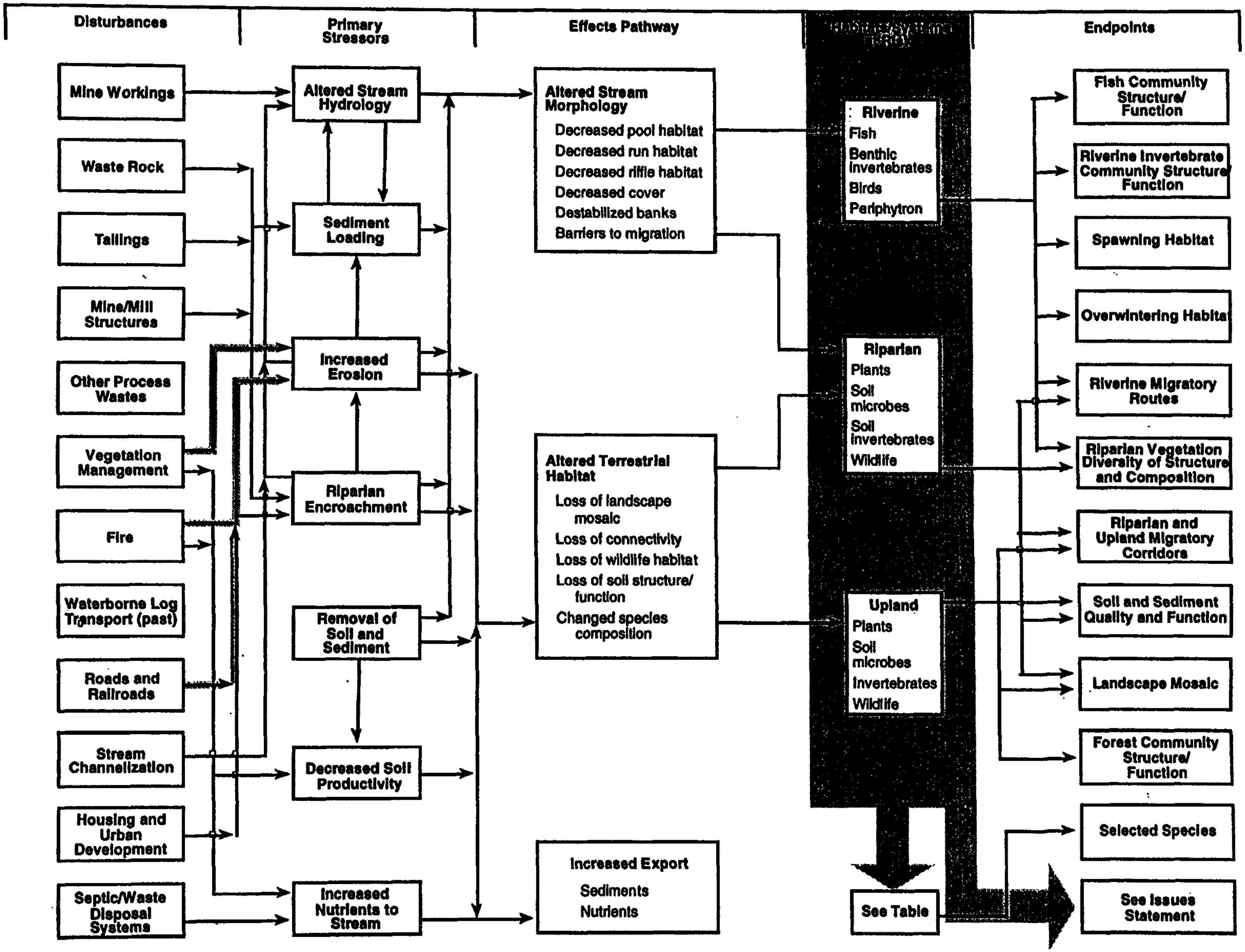


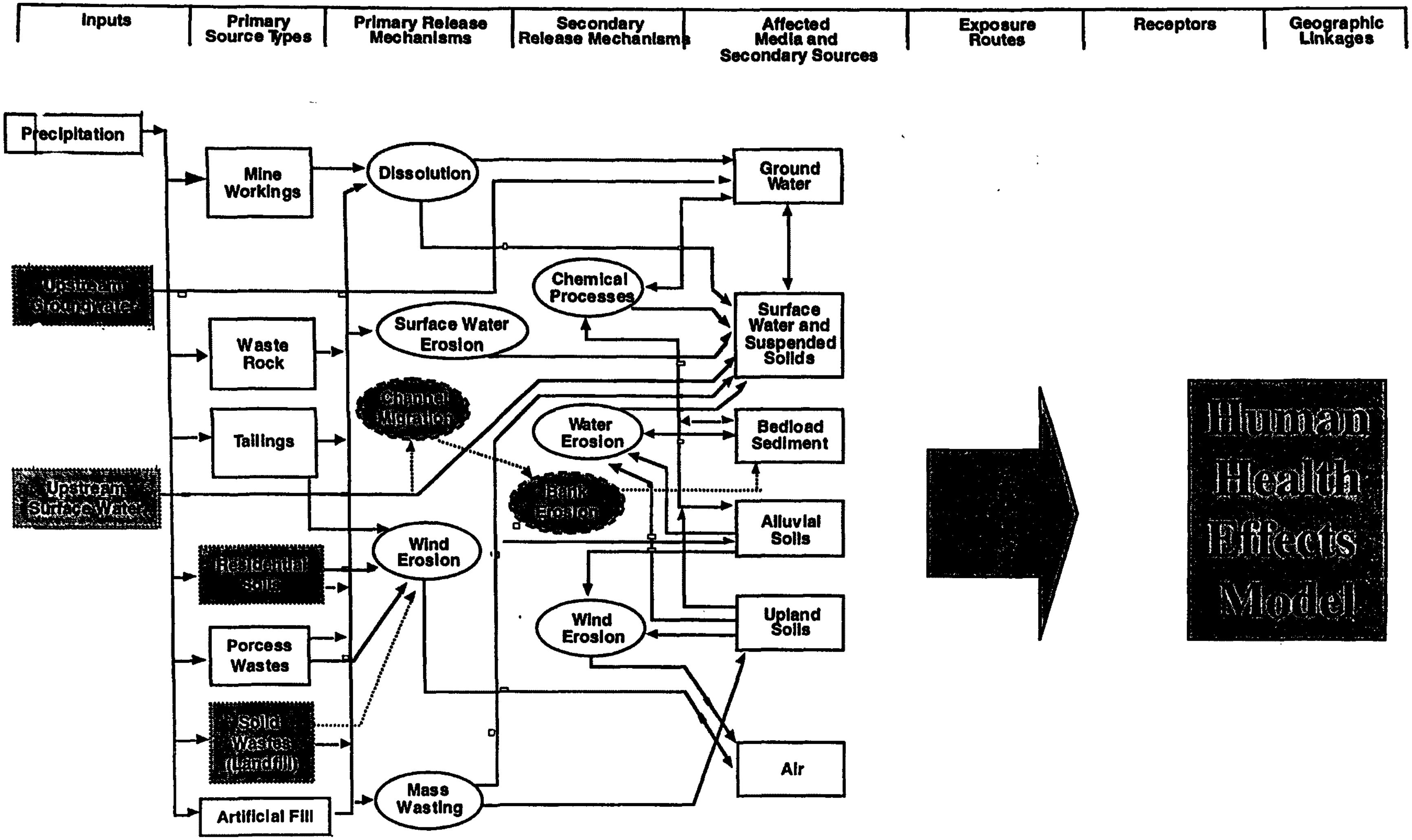
Preliminary Process Model



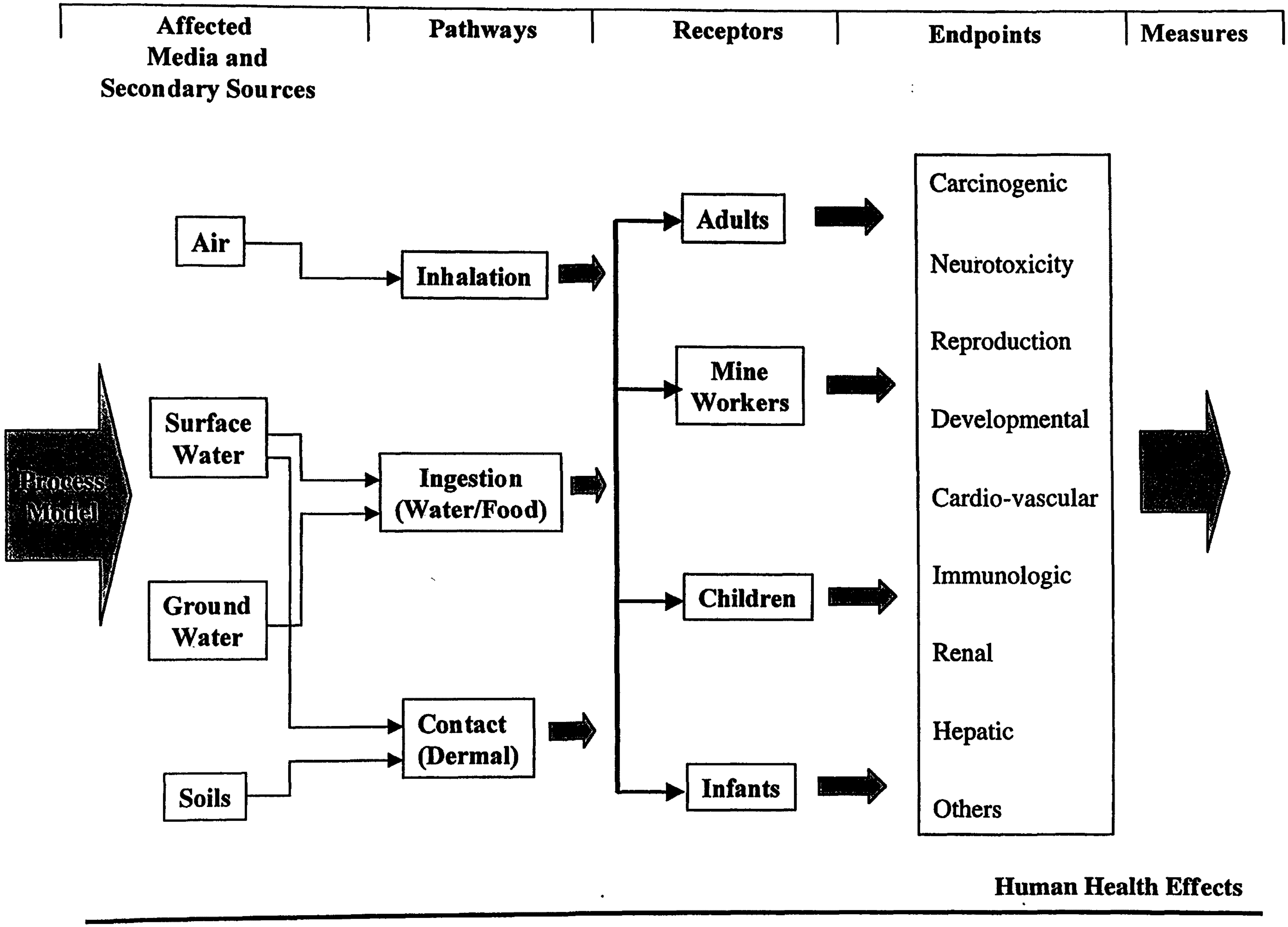
Physical Stressors CSM

RI/FS Health Effects Conceptual Model

Harwell Gentile
& Associates, L.C.



Preliminary Process Model


Affected Media and Secondary Sources
Pathways
Receptors
Endpoints
Measures
Process Model
Air
Surface Water
Ground Water
Soils
Inhalation
Ingestion (Water/Food)
Contact (Dermal)
Adults
Mine Workers
Children
Infants
Carcinogenic
Neurotoxicity
Reproduction
Developmental
Cardio-vascular
Immunologic
Renal
Hepatic
Others
Human Health Effects

Summary

- Define goals and objectives
- Establish spatial/temporal boundaries
- Identify sources, stressors, and pathways
- Define endpoints and measures
- Construct conceptual models
- Formulate stressor-response hypotheses
- Rank stressor-effects relationships

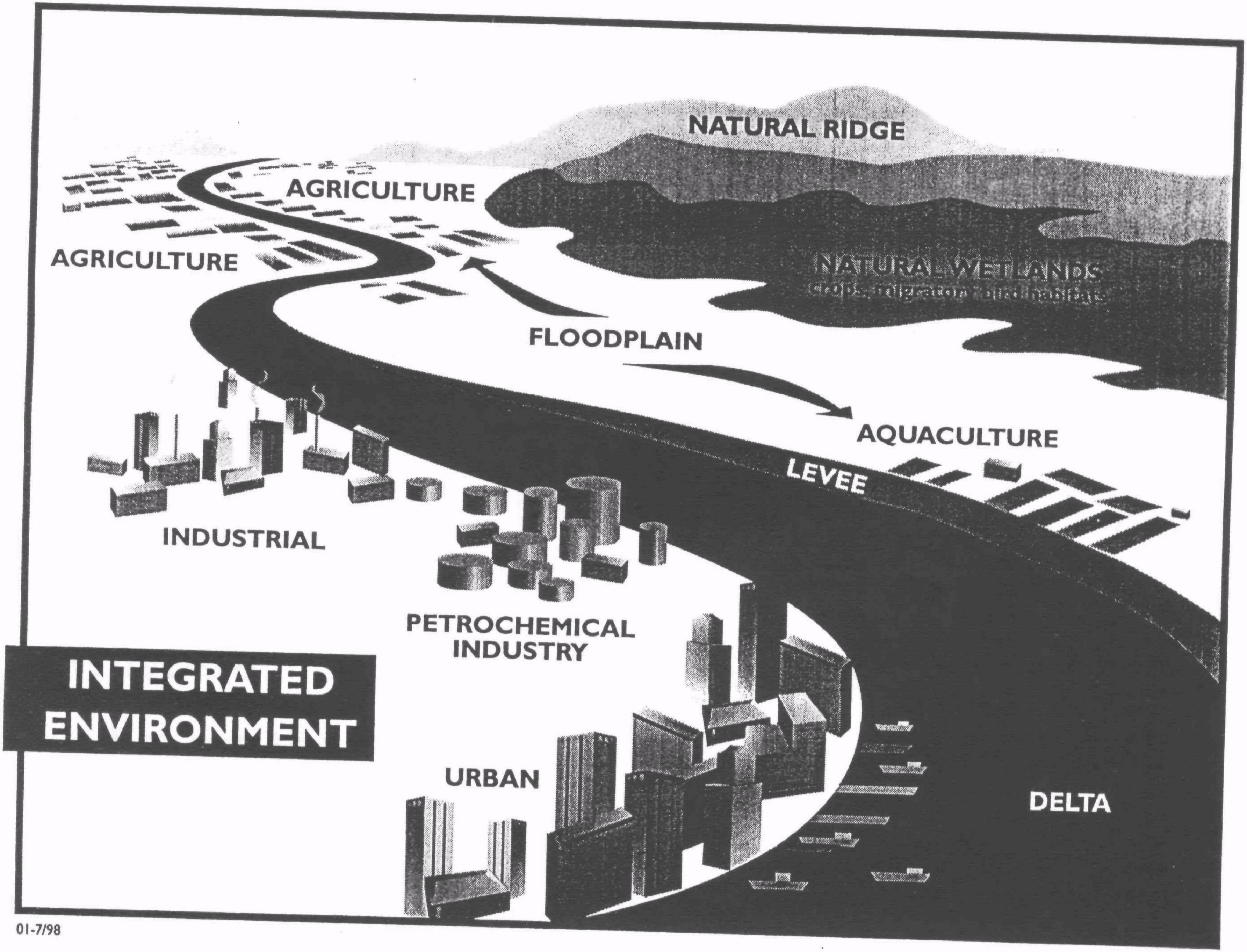
Appendix E. Hypothetical Model Exercise

HYPOTHETICAL CASE EXAMPLE FOR CUMULATIVE RISK

The Scenario

The area of concern is a regional environment consisting of the lower reaches of a major river system, its associated floodplain, wetland, and estuarine ecological systems, a highly engineered water management system, and a nearby urban population of 1 million people. The river system drains a large area with extensive agricultural production; agricultural runoff adds significantly to the river's already high load of suspended solids and turbidity. The river has very high levels of nutrients, but because of the high turbidity (which lowers primary productivity) eutrophication does not occur until the water reaches the estuary. The river also receives high levels of pesticides and organic chemicals from non-point agricultural sources, point source discharges from a fertilizer plant , and an extensive petrochemical industry with a variety of discharges. Alongside the river is a levee built for flood control, and beyond that artificial levee is a floodplain with a natural ridge some distance beyond. In between the two levees are natural wetlands, which are being rapidly converted to open water systems because of the interference with the natural sedimentation processes historically associated with floods. Further, some wetlands have been converted to agricultural use and others have been converted to aquaculture (oysters and catfish ponds). The remaining wetlands and croplands provide important habitat for migratory birds because the area is located on a major flyway. Near the mouth of the river is an urban area, which contributes significant discharges from storm water, municipal waste treatment facilities, and surface runoff. The river opens into a delta at the estuary. Off shore is a growing hypoxic area, resulting from the eutrophication of the estuarine waters because of excessive nutrient inputs, high secondary productivity, and consequent depletion of dissolved oxygen.

The human populations of the area include workers in the agricultural and chemical industries, who have high exposures to pesticides and toxic chemicals; a general urban population with a high incidence of bladder cancer (4 times the national rate); and a sensitive population of asthmatics, elderly, etc. exposed to high levels of particulates. Other ecological and/or human health issues include high lead levels in sediments; bioconcentration of chemicals in fish and in fish-eating birds.


NATURAL RIDGE
AGRICULTURE
AGRICULTURE
NATURAL WETLANDS
FLOODPLAIN
AQUACULTURE
LEVEE
INDUSTRIAL
PETROCHEMICAL INDUSTRY
INTEGRATED ENVIRONMENT
URBAN
DELTA

01-7/98

Cumulative Risk Questions

What are the relevant sources of stress?

What are the stressors of concern?

What are the relevant paths and routes of exposure?

Who and what are at risk?

What are the health assessment endpoints?

What are the ecological assessment endpoints?

Cumulative Risk Elements

What are

The Questions ?

What are the relevant sources of stress?

What are the stressors of concern?

What are the relevant paths and routes of exposure?

Who and what are at risk?

What are the health assessment endpoints?

What are the ecological assessment endpoints?

Cumulative Risk Elements

What are

Sources ?

Single Source

- point sources: industrial discharges, waste sites
- non-point sources: automobiles, agriculture
- natural sources: floods,hurricanes, fires

Multi-sources

- combinations of those above

Cumulative Risk Elements

What are **Stressors ?**

Chemical

- toxic metals and organics
- nutrients

Physical

- habitat alteration, floods, fires
- climate: precipitation, temperature, etc.

Biological

- pathogens, disease
- exotic/invasive species

Societal

- economic
- psychological

Cumulative Risk Elements

What are

Exposure Pathways ?

- Air
- Surface water
- Groundwater
- Soils/sediments
- Solid waste
- Food
- Non-food products

Cumulative Risk Elements

What are

Single Species Routes ?

Ingestion - food and water

Dermal - absorption and active uptake

Inhalation - includes gaseous exchange

Non-dietary ingestion - hand-to-mouth behavior

Cumulative Risk Elements

What are

Community/Ecosystem Routes ?

Direct contact or ingestion without accumulation

Bioaccumulation

Biomagnification

Vector transfer - parasites, pathogens, etc.

Cumulative Risk Elements

What are

Receptor Categories @ Risk?

Human

- Individuals
- General Population: distribution or estimation of central tendency and high end exposure
- Population subgroups: highly exposed subgroup (e.g., age, gender) and highly sensitive subgroups (e.g., age gender, pre-existing conditions)

Cumulative Risk Elements

What are

Receptor Categories @ Risk?

Ecological

- Individuals
- Populations
- Communities
- Ecosystems/Habitats

Landscapes/Regions

- Watersheds
- Regional scale ecosystems

Cumulative Risk Elements

What are **Human Health Endpoints?**

- Carcinogenic
- Neurotoxicological
- Reproductive Dysfunction
- Developmental
- Cardio-vascular
- Immunologic
- Renal
- Hepatic
- Others

Cumulative Risk Elements

What are

Ecological Endpoints ?

Species: growth, survival, reproduction, habitat role

Population: long-term growth, sustainability, resiliency, etc

Community: biotic and species diversity, richness, trophic structure, etc.

Ecosystem: structure, function, services, water quality, habitat quality etc.

Landscape: habitat mosaic, connectivity, spatial-temporal habitat patterns

Appendix F. Case Study Results from the Break Out Sessions

(Brainstorming, lists of dimensions, ranking and priorities and preliminary linkages and conceptual models)

I. CCRI

Presenter: Carole Braverman, Region V
Facilitator: Mark Harwell, University of Miami

Chicago Cumulative Risk Initiative Case Study–November 12, 13, 1998
(Transcription from Hand-Written Notes on Charts, not in any particular order)

At Risk Populations–Human Health

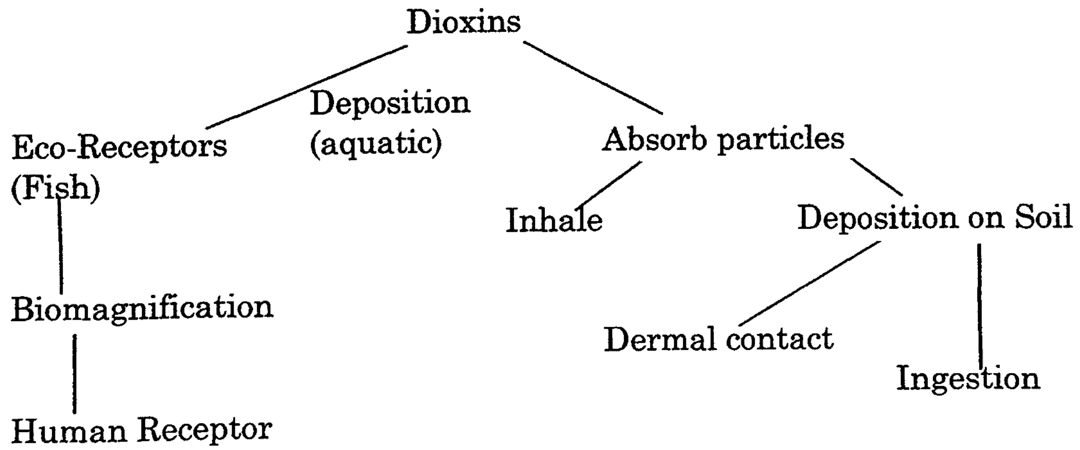
General Population
Children (pre-school)
Elderly
Pregnant females
Asthmatics
Immuno-Suppressed
Sickle Cell Anemics/Genetic predisposition
Economics/Cultural: subpopulations

<u>Exposure population</u>
Industrial workers
Proximity to point sources
Economic&Cultural > subpopulation
Children
Smokers
2nd Hand smoke pop.
Confined populations

Stressors (air)

Particulates	Mercury, PCBs, Dioxin
Bio-Aerosols Lead	
Ozone	Cadmium
PAHs	Chromium
Toxic Organics	Noise/vibration
Benzene	Other Toxics
Metals	Flammables/Explosives
NOx and SOx	Endocrine Disruptors
Odor	Pesticides

Pathway Breakout



CCRI
Goals and Objectives

1. Understand environmental conditions of Cook and Lake County (Air quality current focus) better

2. Use understanding as basis for:
   -(future) permitting decisions
   - communication with stakeholders

3. Determining societal goals in region

4. Determining if multiple contaminant sources are in COMPLIANCE (to result in healthy environment)

SPATIAL/TEMPORAL Boundaries

1. Political boundary: Cook Co. (IL) and Lake Co. (IN)

Endpoints: Human Health

Cancer—
   Childhood leukemia
   Lung cancer
   Breast Cancer
   Other Cancers

Non-cancer–

Asthma	Developmental
COPD	Cardio-Vascular
Birth Defects	Acute Effects
Neurological	Reproductive Disorders
Immunological	Behavioral Effects

Human Health and Ecological Risk Assessment

SOURCES (Air)

- Steel Mills
- Oil Refineries
- Incinerators
- WWTP
- Mfg. Plants
- Small Point Sources
- Recycling (Metals)
- Indoor Air
- Background sources
- Asbestos
- Land mgt. burning
- Landfills
- Chemical Plants
- Power Generation Plants
- Airports
- Mobile
- Pesticides (lawn/golf pest control)
- Lake Michigan

Endpoint - Eco

	Lake (Aquatic)	UrbanHabitat	AG	
			Tall grass Prairie	Migratory birds
			Dunes	Forest Preserves
Species	carp	Neotropical Birds	Karner blue butterfly	Amphibians Deer Tree health
Community				Maintain biodiversity
Ecosystem			Decomposition Processes	Air filtering
Landscape				

SOURCES	**STRESSORS**	**ENDPOINTS**
	Toxics:	Human:
Steel mills	organics	Cancer: leukemia, lung, breast,
Mfg. plants	Pesticides	Other
Small point sources	PCB/Dioxin	Respiratory :COPD, asthma
Indoor air	PAH	Dev./Reprod./Birth Defects
Mobile	Benzene	Neuro./Behav.
Incinerators	Endocrine Disruptors	Cardio-Vascular
Agriculture		Immune
	Inorganics:	
	Metals: Pb, Hg, Cr, Cd	Eco:
	Particulates	
	Noise	Neotropical Birds
	Odor	Tree Health
	Ozone/NOx/SOx	Biodiversity
		Deer

(Pathways presented below)

Sources	**Stressors**	Endpoints
Incinerators	End. Disruptors	
Agriculture		
Incinerators	Odor	
Mfg. plants		
Indoor air		
Mobile		
Agriculture		

Sources	Stressors	Endpoints
		(Human)
Steel mills Incinerators Mfg. plants	Particulates	
Agriculture	Pesticides	Cancer Dev./Reprod./BD Neuro/Behav. Immune
Incincerators Indoor air Mobile	PAH	
Mfg. plants	PCB/Dioxin	Cancer Neuro/Behav Immune
Steel mills Mfg. plants Indoor air	Metals	
		ECO
Mfg. plants Small pt sources Mobile	Ozone/NOx/SOx	Tree Health Biodiversity
	Noise	Neotropical birds Tree health Biodiversity Deer

Pentachlorophenol-Assigned Participants
Presenter: Nader Elkassabany and Wanda Jacobs, Office Pesticide Programs
Facilitator: Jack Gentile, University of Miami

B. Pentachlorophenol

Presentation of case on PCP

Milestones
used only for wood preservation, 1987

Working with PMRA--NAFTA
Doing work sharing with work plan dividing up tasks
Eco, human health etc. So won't duplicate work

Regulated under other laws

STAKEHOLDERS are industry, trade assoc., public , environmental groups

? Ho w do you mediate differences--No set formula (Karen Mc); senior management and public ultimate determiners; strong impetus to agree based on NAFTA

Chemistry
Usage--25 products registered for use
Hazard ID
-B2 carcinogen
-microcontaminants important; used TEFs and TEQs used to set criteria
Environmental Hazards
-limited eco effects; relying on ORD and contractor support--will be qualitative assessments
Human Exposure Scenarios
Human Exposure Pathways
Environ. Exp Pathway
Issues/Uncertainties

? Any indication of unintentional dietary exposure (beddding shavings used in hog farms); swine showed PCP residues (Karen Mc)--Wanda--some people using railroad ties for gardening; Should be considered in conceptual model development? Canada requiring accountability for bedding source--not sure how big problem; no requirement for putting wood into RCRA site in Canada. and the US

Process for breakout group--id sources, stressors, pathways, endpoints; start inclusively could go outside PCP; broaden conceptual model to include microcontaminants (perhaps 2nd model)

Do PCP and if time do microcontaminants

What about alternative--creosote, CCA--looking at relative risk assess.; may more relevant to look across agents to evaluate relative toxicity; be careful not to eliminate less toxic material;

What are expectations? Jack
Tutorial, how to apply
PCP with contaminants (Karen's preference)

CR Risk Elements--the Questions

Potential Sources-PCP and microcontaminants
(Karen--looking at overall contribution to dioxin contamination in environment)

-wood treatment plants
-manufacturing
-disposal: landfill sites/recycled-re-dimensioned/incineration
-in-use/service: utility poles(soil), marine dock pilings (aquatic), residential (decks/outdoor only),
residential (indoor)

Stressors

- PCP
-furans/dioxins (lump because can evaluate with TEFs
-hexachlorobenzenes (HCB)
(stressors must be in contact with receptors)

Pathways of exposure--eco and human health

? Is psychological legitimate stressor (stress)--yes; relates to contaminants; could put on human side; however, not part of US thinking at this time but is in Canada--will put in as endpoint.

-runoff onto surface water
- ground water
- soil,
- air (volatilization)
-dietary
-treated wood

Routes of exposure
-ingestion

-contact
-inhalation

Review of approaches from yesterday/RI/FS model--1)Aggregate in how stressors move through environment together (process approach), 2) Waquoit Bay approach--sources at top, stressors at bottom, then stressor-driven analysis

Biscayne Bay model--little simpler approach; major sources at top, stressors sources, pathways, major habitats impacted (freshwater stream communities, etc.); develop broad pathways and put in detail; suggest to build simply but capture major issues; look in more detail later on

Need to flesh major habitats of concern and then pick the endpoints

Major Receptor Habitats/classes impacted
-terrestrial community/soils (unsure if available in plants--may be thru air deposition)
-streams/waterbody
-estuarine
-marine
-human: 1) occupational: workers in plant, utility pole workers, handlers,
2) residential (adults, children)

(Conceptual models are accompanied by extensive text--Jack)

Receptor Habitats:	Endpoints: PCP	Dioxin/Furans	HCB
Terrestrial:	Floral diversity -acute effect	NA	NA
Soils:	Earthworms Microbes Invertebrate community	Birds (earthworms) Mammals(voles, moles) Raptors (subreceptor) Habitat quality	
Freshwater:	Fish community Invertebrates	Fish/fishing Mammals (mink, otters) Raptors(birds, waterfowl) Water quality	
Marine:	Benthic invert. Comm.	Same	

Fish/bottom feeders Shellfish
plants

Occupational: Teratogenicity
Cancer, renal, stress
Genotoxicity, subchronic

Residential: developmental
neurotoxicity

Next step rough out conceptual model using Biscayne Bay model (flip charts)

Manufacturing Water treatment. Transportation Disposal Poles Pilings Residential

....

PCP Dioxins/Furans HCB

terrestrial Soils fresh water marine occupational residential

(Flora diversity)
passerine birdsearthworm pop

voles

hawks

....

(see hand written graphic)

Might be useful to look at receptor hits for manufacturing; do ranking of sources to receptors-Jack

Manufacturing

terrestrial (runoff)
marine (effluent/spill, air deposition?)
occupational (inhalation, ingestion, dermal)
residential (stack emissions)
fresh water (effluent/spill, runoff)
soils (runoff, leaching)

Wood treatment

contaminated soils (runoff)
fresh water (runoff/effluent)
marine (runoff/effluent)--geographic (east coast primarily)
occupational (dermal, ingestion, inhalation?)

Transportation (tanker truck on road)

soils
fresh water
occupational

Disposal (landfills)

soils
fresh water

Poles

soils
occupational
residential

Pilings

marine

Miscellaneous (wood/homes)--replaces residential

residential

....

Ranking exercise for human pathways and environmental pathways/routes of exposure was performed at the first practicum and was used in this exercise (see tables at the end of discussion). Ranked for each source not across sources.

Environmental Pathways/routes of exposure

(Secondary routes were identified to wildlife but didn't identify links to human life (in analysis) 2 hooks)

Process for breakout group--identify sources, stressors, pathways, endpoints; start inclusively could go outside PCP; broaden conceptual model to include microcontaminants (perhaps 2nd model). The group agreed to focus first on PCP and if time do microcontaminants.

What about alternatives--creosote, CCA--looking at relative risk assess.; may more relevant to look across agents to evaluate relative toxicity; be careful not to eliminate less toxic material;

The expectations were that this case would serve as a tutorial on how to apply the guidance to the risk assessment of this case.

Cumulative Risk Elements--the Questions

Potential Sources-PCP and microcontaminants.
(Karen--looking at overall contribution to dioxin contamination in environment)

-wood treatment plants
-manufacturing
-disposal: landfill sites/recycled-redimensioned/incineration
-in-use/service: utility poles(soil), marine dock pilings (aquatic), residential (decks/outdoor only),
residential (indoor)

Stressors

- PCP
-furans/dioxins (lump because can evaluate with TEFs
-hexachlorobenzenes (HCB)
(stressors must be in contact with receptors)

Pathways of exposure--eco and human health

? Is psychological legitimate stressor (stress)--yes; relates to contaminants; could put on human side; however, not part of US thinking at this time but is in Canada--will put in as endpt.

-runoff onto surface water
- ground water
- soil,
- air (volatilization)
-dietary

-treated wood

Routes of exposure
-ingestion
-contact
-inhalation

Review of approaches from yesterday/RI/FS model--1)Aggregate in how stressors move through environment together (process approach), 2) Waquoit Bay approach--sources at top, stressors at bottom, then stressor-driven analysis

Biscayne Bay model--little simpler approach; major sources at top, stressors sources, pathways, major habitats impacted (freshwater stream communities, etc.); develop broad pathways and put in detail; suggest to build simply but capture major issues; look in more detail later on

Need to flesh major habitats of concern and then pick the Endpoints

Major Receptor Habitats/classes impacted
-terrestrial community/soils (unsure if available in plants--may be thru air deposition)
-streams/waterbody
-estuarine
-marine
-human: 1) occupational: workers in plant, utility pole workers, handlers,
2) residential (adults, children)

(Conceptual models are accompanied by extensive text--Jack)

Receptor Habitats:	Endpoints: PCP	Dioxin/Furans	HCB
Terrestrial:	Floral diversity -acute effect	NA	NA
Soils:	Earthworms Microbes Invertebrate community	Birds (earthworms) Mammals(voles, moles) Raptors (subreceptor) Habitat quality	
Freshwater:	Fish community Invertebrates	Fish/fishing Mammals (mink, otters)	

		Raptors(birds, waterfowl) Water quality
Marine:	Benthic invert. Comm. Fish/bottom feeders plants	Same Shellfish
Occupational:	Teratogenicity Cancer, renal, stress Genotoxicity, subchronic	
Residential:	developmental neurotoxicity	

Next step rough out conceptual model using Biscayne Bay model (flip charts)

Manufacturing H20 trmt. Transportation Disposal Poles Pilings Residential

....

PCP Dioxins/Furans HCB

terrestrial Soils fresh water marine occupational residential

(Flora diversity)
passerine birdsearthworm pop

voles

hawks

....

Might be useful to look at receptor hits for manufacturing; do ranking of sources to receptors-Jack

Manufacturing

terrestrial (runoff)
marine (effluent/spill, air deposition?)
occupational (inhalation, ingestion, dermal)
residential (stack emissions)
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soils (runoff, leaching)

Wood treatment

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soils
fresh water
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Disposal (landfills)

soils
fresh water

Poles

soils
occupational
residential

Pilings
marine
Miscellaneous (wood/homes)--replaces residential
residential
....

Ranking exercise (human pathways)

Management Goal: Review HDWPs in sequential order; then do comparative risk analysis.
> Review wood preservatives as a class
> Assess each class individually
> Revisit each class as a group/cumulative risk/comparative risk

Planning Process: Use pentachlorophenol as a model/template.

To Build a Matrix:

Point/Non-point?
Health/Ecological?
Pathways: human/eco?

HUMAN	ECOLOGICAL	SOURCES
Occupational	Aquatic	Manufacturing
Accidental (L)*	Spill	Transport [of chemicals and logs]
Occupational (H)*	Aquatic (L)	Wood Preservative Facility
Occupational (L)	Soil (L)	Utility Poles [localized]
Occupational (RCRA)	Aquatic (H)	Disposal of Treated Poles [consumer misuse]
Children (L) (?)		Residential Uses (e.g., decks)
(L)	Soil (L)	Fences
(L)	Aquatic	Pilings, Piers, Docks
Residential Occupational	Soil/Water (H)	Remedial Ground line Treatment
(L)	(L)	Farm buildings/Industrial buildings

*L=Low, H=High

Action: Enhance dialog between OP/AD and ORD: e.e., exposure pathways and toxicology. Need to assume "partners" are providing appropriate information.

Air Emissions: Gene Crumpler from Kelly Rienert at workshop.

Pathways

Human Pathways/Routes of Exposure

SOURCE	DERMAL	INHALATION	INGESTION
Manufacturing	High	Low	Low
Transportation			
Wood Preservative Facility	High	Medium	Low
Utility Poles	Low	Low	Low
Disposal of Treated Poles	Low (RCRA Issue)	Low	Low

Residential Uses/ subpopulation-children	Medium - children	Low	Medium
Fences	Low	Low	Low
Pilings, Piers, Docks	Low (N/A)	Low	Low
Remedial Ground line treatment			
a. Occupational	Low	Low	Low
b. Residential	High	Low	High
Farm Buildings/Industrial Buildings	Low	Low	Low

<u>Human Health Endpoints</u>

> Liver
> Carcinogenicity
> Immunotoxicity
> Endocrine Disruption
> Kidney
> Neurotoxicity
> Developmental Toxicity (Teratogenicity)

Environmental Pathways/Routes of Exposure

SOURCE	DERMAL	INHALATION	INGESTION
Manufacturing	Low?	Low?	High
Transportation - Parked			
Wood Preservative Facility	Low	Low	Low
Utility Poles	Low	Medium?	Medium?
Disposal of Treated Poles	Low (RCRA Issue)	Low	Low
Residential Uses/ subpopulation-children	Low	Low	Low
Fences	Low	Medium?	Medium?
Pilings, Piers, Docks	Low	Medium	High
Remedial Ground line treatment			

a. Occupational	Low	Medium	Low
b. Residential	Low	Medium	Low
Farm Buildings/Industrial Buildings	Low	Low	Low

Environmental Endpoints

A. Aquatic Organisms	**Mortality**	**Reproduction**
> Fish	✓	✓
> Invertebrates	✓	✓
> Aquatic Plants	✓	
B. Terrestrial Organisms		
> Bird	✓	
> Mammals	✓	✓
> Invertebrates- need receptor for analysis/ scoping		

III. Concentrated Animal Feeding Operations
Presenter: Gerald Carney, Region VI, Dallas, TX
Facilitator: Larry Reed, Superfund, Ed Bender, OSP, Washington, DC

Preliminary comments and questions on scope and background
Needed to clarify that the Cumulative Risk Index Analysis was a screening process, which used GIS data, being applied to a Concentrated Animal Feeding Operation,
Initially there was some confusion over the sources within a CAFO
The terminology of stressor needed a bit of clarification.
There were human health, quality of life and human welfare issues associated with CAFOs
watershed impact seems like good approach
what is cum risk aspect- either an addition of stressors to a watershed or siting of multiple facilities.
odor and disease were main human effects; can capture as economic loss as well as risk.

List of factors for each dimension of the CAFO project

<u>Assessment End points</u>
-Sustainable natural grassland prairie ....
-biodiversity (richness, evenness)
Plant Communities
Wildlife communities
Sport and recreational fish and their habitats
Maintain a designated stream use for the water shed or stream segment
Habitats which may contain endangered species

<u>Stressors</u>
Turbidity
Nitrate-nitrogen (ammonia)
Nitrite-nitrogen
Phosphorus (phosphate)
Sulfur (hydrogen sulfide, sulfides)

Aerosol chemicals
Noise
Dust, particulates
Odor (also considered as an effect)
Pathogens
Attractive nuisance to waterfowl
Pesticides
Drugs and antibiotics
Waste feed

Manure
Road Deterioration/construction and maintenance
Water quantity (groundwater withdrawal, water table draw down)
Increased traffic
Higher taxes

Sources

One or more CAFOs within a watershed
-lagoon
-barns
-land application system
-trucks

Other sources within the watershed which contribute similar stressors
-Expansion of other farms
-Urban areas looking for growth and higher land use
-Federal facilities
-Industry-particularly oil and petroleum exploration in Texas setting.
-Septic tanks and drain fields
-POTWs

Measurement end points

1. Fish, invertebrates, aquatic community
-water quality measurements
-water borne pathogens
-algal populations, abundance and diversity, photosynthetic indices....
-endocrine disruptors

2. Terrestrial ecosystem (prairie)
-number of birds vs. control areas (literature for screening
-endangered species, other special species (presence, absence, abundance)

3. Human health
-incidence of disease, self-reported
-medical survey data (screening)
-complaints to local and state doctors and health service, police, firm and rescue
-could address EJ health (Indian reservations for example)

Effects

Siltation
Loss of water clarity
Anoxia
Odors causing anxiety and stress
land-use changes
algal blooms-eutrophication of lentic waters
aesthetics
met-hemoglobanemia from nitrites in water supply
headaches, dizziness, nausea
fish flesh tainting
Inability to urban/suburbanize (residential development foreclosed)
Fish effects of silt
Traffic accidents
Spills of materials
Water quality damage
Road deterioration
Habitat fragmentation due to new and wider roads
Wetlands dry up
Disease to humans and domestic and wild animals.

The group focused on nutrients and toxic effects on the watershed, habitat degradation and loss for the uplands, and nuisance (e.g., odor, flies, and increased traffic) and land-use commitments as effects of concern to humans. The group was not aware of any studies on human disease or other human health effects related to these CAFOs. Several people noted that this is the kind of issue that sparks a lot of public interest and concern, but that most federal agencies and state agencies are powerless to address. Region VI is using the NPDES permit process to set some conditions on these facilities, however, this discussion shows that it is far more that can and should be considered than the traditional limitations placed on sewage treatment facilities.

The group also discussed how this might be used to communicate the nature of the problem and the issues of greatest concern to the public. The process of planning and scoping was very helpful to open up the thinking of the participants and share experiences they had about related problems and approaches. The group found that several stressors caused multiple effects, e.g., ammonia as a nutrient for algae and being toxic to fish.

The group put together a preliminary diagram of the dimensions of the risk assessment, but the linkages were not completed.

The role of stakeholders in the screening process was unclear. In some instances, this type of analysis was prompted by public requests for assistance or review.

Appendix G. Comments and Suggestions from Participants

Comments on Chicago Colloquium

Most useful:

1. Outline of conceptual model and planning and scoping. Practice in the breakout sessions.

2. Seeing this from the ecological standpoint and a human health perspective.

3. Breakout session case studies to flesh out the guidance and conceptual models.

4. The examples presented on the first day and the working experience in the break-out session were the most useful.

5. The format was excellent, concepts, hypothetical case and the real case study. Good balance between into. Lectures, walk-through, and break out exercises.

6. Glad the discussion was not limited to existing data.

7. The advance materials were very helpful background. They articulated the main themes of human health and ecological risk assessments and the problems of merging them into a cumulative risk assessment.

Aspects to change:

1. Seems like first day could be done more quickly, get to the discussion of the hypothetical earlier, let the detailed diagram be shown later, at least to some extent.

2. I would not change any aspect, but I probably would add to them when holding future practicums.

3. The connection to cumulative risk was unclear and the presentations were almost too basic.

4. The hypothetical needed more basic facts and foundation regarding the proposed action site.

5. Add an analytical component to address conceptual models and rankings.

6. Offer more ideas on how to merge ecological and human health risks into one cumulative risk assessment. Explain the differences.

7. Some examples of human health risk assessment would be useful.

8. Make more time for the case study evaluation.

9. Separate ecological risk and health risk to avoid confusion about the terminology. Once people have gone through the process it would be easier to join the disciplines.

Recommendations to strengthen the discussions and practicum:

1. Move to hypothetical earlier in presentation.

2. Add information on tools for diagram drawing and GIS

3. Add expert on human health and examples of human health cumulative risk assessment to the introduction.

4. From a regulatory point of view, the practicum needs to strengthen the areas where no data are available to determine potential exposure. Next what happens when the model is complete- how is it converted to a numerical model.

5. Need to look more at how it applies to regulatory program and sites.

6. Need to go beyond scoping/planning/conceptual models.

7. Unclear how ranking individual stressors fits into true cumulative perspective.

8. Take environmental justice into account. Continue to emphasize stakeholder (interested and affected parties) involvement at the problem formulation stage.

9. Make more time to explain and work with the conceptual models (the breakout sessions helped). Perhaps have software that could draw a conceptual model.

10. More discussion of stressor-endpoint ranking exercise. Demonstrate software for producing conceptual models.

11. Add extra day for to flesh out and apply the model in the case studies.

12. Identify issues up-front: 1) program level use of the exercises and 2) spatial scope for the analysis.

13. Make the handout maps and charts clearer.

Case Studies

1. The case study was useful in serving as an example of developing a conceptual model as well it is of direct interest since re-evaluation of PCP is currently in progress.

2. Not sure that cumulative risk assessment is the correct term for what we did.

3. Look at cumulative risk and compare what drives risk (i.e., scientific methods) with community pressures and politics and economics.

4. CCRI is a good example of a case that has intense public interest.

5. Discriminate between incremental and aggregate cumulative risk.

Appendix H. Draft Conceptual Model

PCP Human Health Conceptual Model