National Pesticide Program

Ecological Risk Assessments: Status and Challenges

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Environmental Fate and Effects Division
Office of Pesticide Programs
US Environmental Protection Agency

Pesticide Regulation -- Overview

- For environmental effects, EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act
- Under FIFRA, EPA may approve a pesticide if its use will not “cause unreasonable adverse effects on the environment”
- Risks to wildlife, aquatic life, habitat
- Statute requires balancing risks and benefits
- Ensure regulatory actions consistent with the Endangered Species Act

National Pesticide Program -- Overview

- Gateway to pesticide market; sales over $11 B/year
- Over 5,000 regulatory decisions annually
- Approximately 1,100 active ingredients and 19,000 products (agricultural chemicals, anti-microbial and consumer products, inert ingredients).
- Evaluation of new pesticides and reevaluation of existing pesticides on regular, statutory schedules

National Pesticide Program

- Large number of chemicals to review
- Many potential adverse outcomes over space, time, and levels of biological organization
- Finite resources and statutory timeframes
- Use of best available data; availability/quality of data varies extensively
- Scientifically sound, transparent, and timely

Ecological Risk Assessment Methods for Pesticides

Agency's Ecological Risk Assessment Guidelines

- Defining the assessment issues
- Regulatory decisions and uncertainty

Best available ecotoxicological data

- Species extrapolation
- Dose-response interpretation

Population/community-based responses from pesticide exposure

- Ecological relevancy of toxicological endpoints

Explicit analyses

- Spatial and temporal resolution of exposure and effects
- Pesticide risk projections in the context of habitat quality

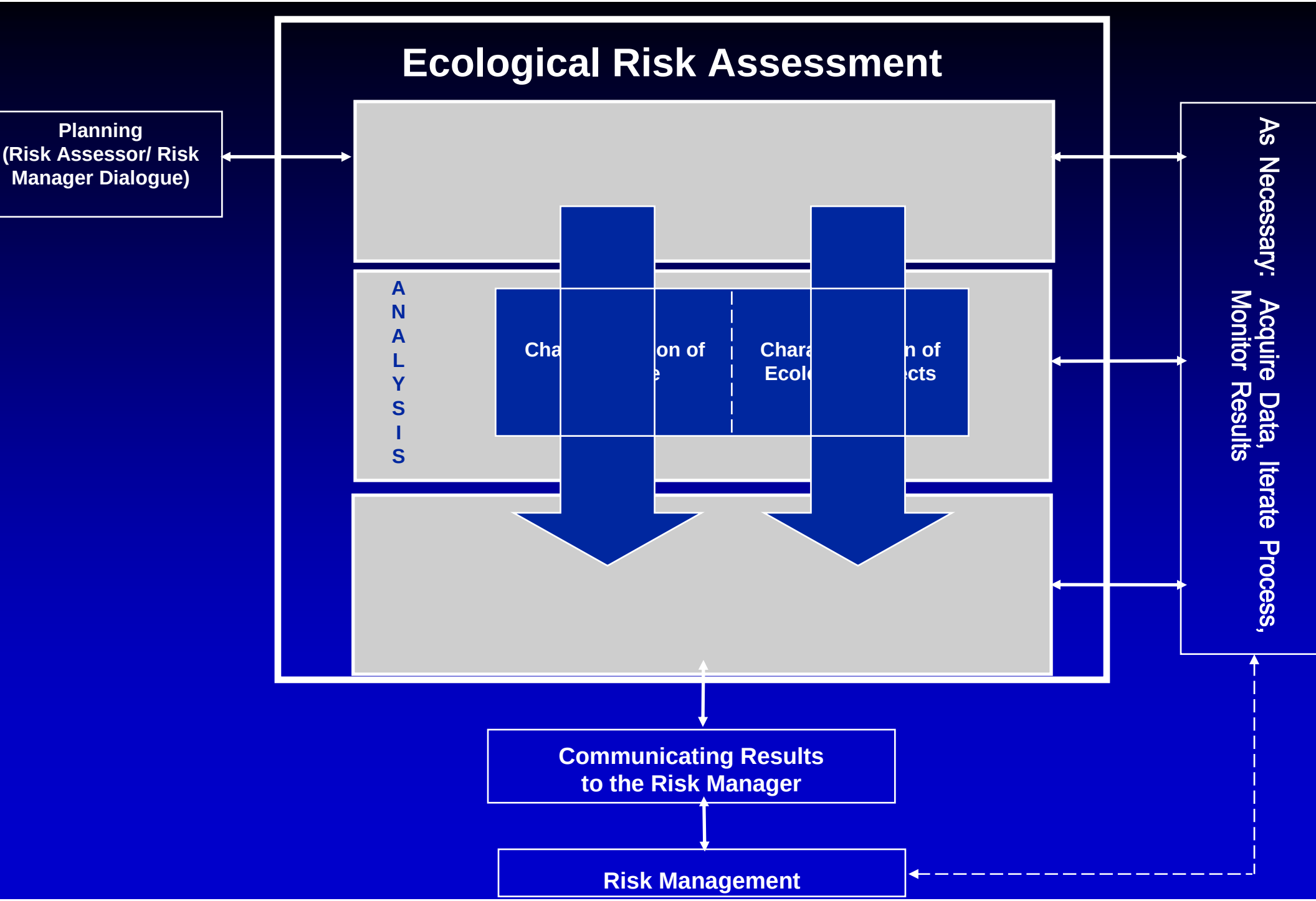
Ecological Risk Assessment Methods for Pesticides

Detailed description of current deterministic methods and approaches to assess risks for non-listed and listed species and their critical habitat at:

http://www.epa.gov/espp/consultation/ecorisk-overview.pdf

Compendium of probabilistic methods and models under development:

http://www.epa.gov/oppefed1/ecorisk/index.htm


Ecological Risk Assessment
Planning
(Risk Assessor/ Risk
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As Necessary: Acquire Data, Iterate Process,
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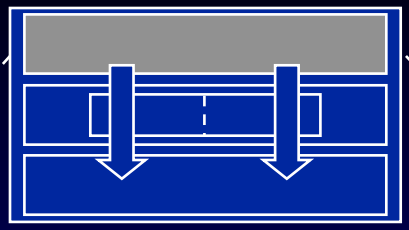


PROBLEM FORMULATION

ANALYSIS

RISK CHARACTERIZATION

PROBLEM FORMULATION

Planning (Risk Assessor/ Risk Manager Dialogue)

Integrate Available Information

Source and Exposure Characteristics

Ecosystem Potentially at Risk

Ecological Effects

Assessment Endpoints

Conceptual Model

Analysis Plan

As Necessary: Acquire Data, Iterate Process, Monitor Results

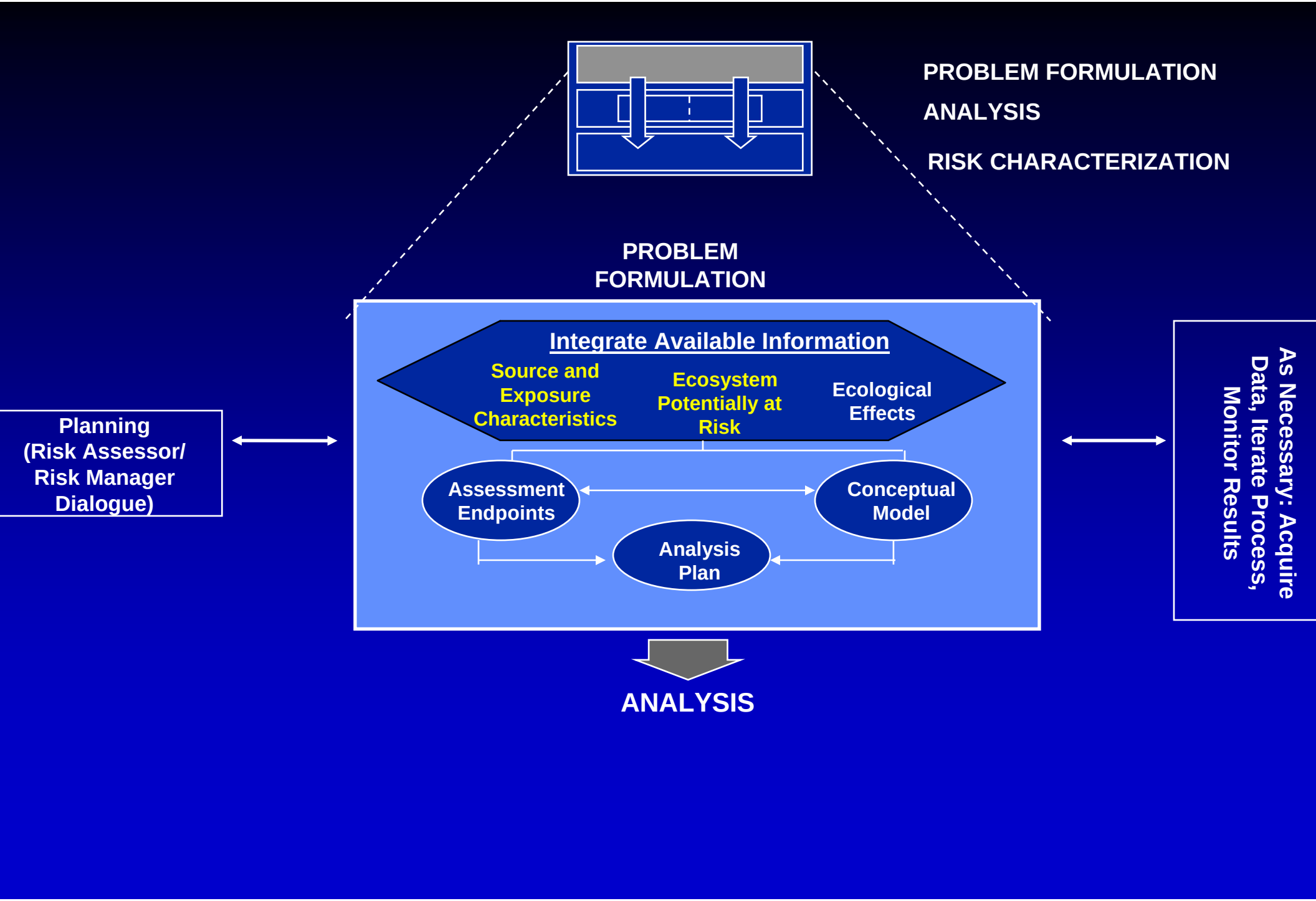
ANALYSIS

Problem Formulation: Source Information

- **The product labels are legal documents defining:**
  - **Potential use sites (*e.g.*, specific crops)**
  - **Maximum use rates**
  - **Minimum application intervals**
  - **Allowable application methods, *etc.***

Problem Formulation: Exposure Characteristics

- Hydrolysis
- Photodegradation
- Aerobic Soil Metabolism
- Anaerobic Soil Metabolism
- Aerobic/Anaerobic Aquatic Metabolism
- Leaching-Adsorption/Desorption
- Laboratory Volatility
- Field Volatility
- Field Dissipation
- Accumulation in Fish
- Bioaccumulation in Aquatic Non-Target Organisms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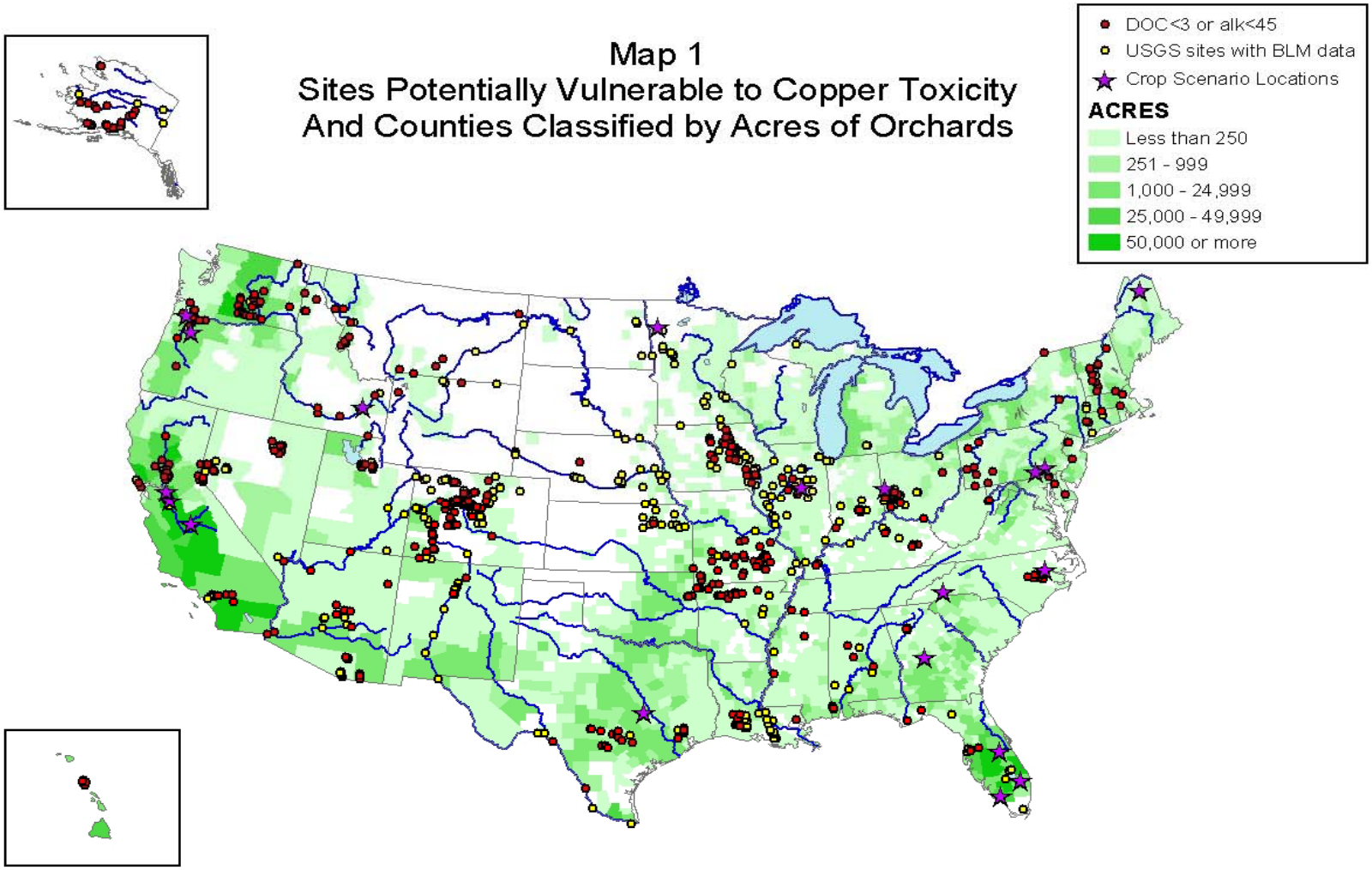

Coppers Assessment
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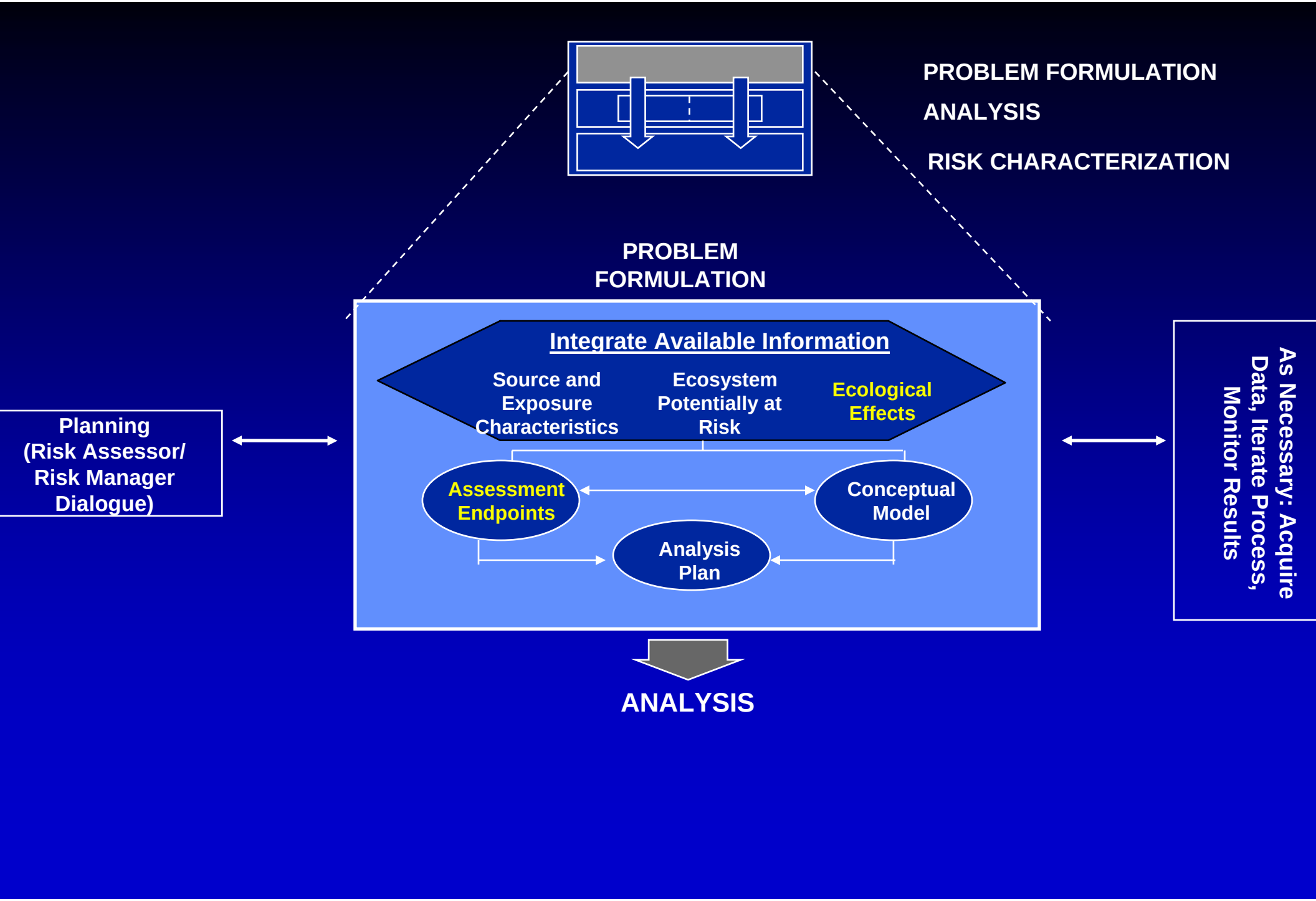
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Problem Formulation: Effects Characteristics

- Available information on toxic effects to invertebrates, fish, birds, mammals, and plants is evaluated based on data quality and documented
  - Part 158 data requirements
  - Open literature data obtained from EPA's ECOTOX database at:

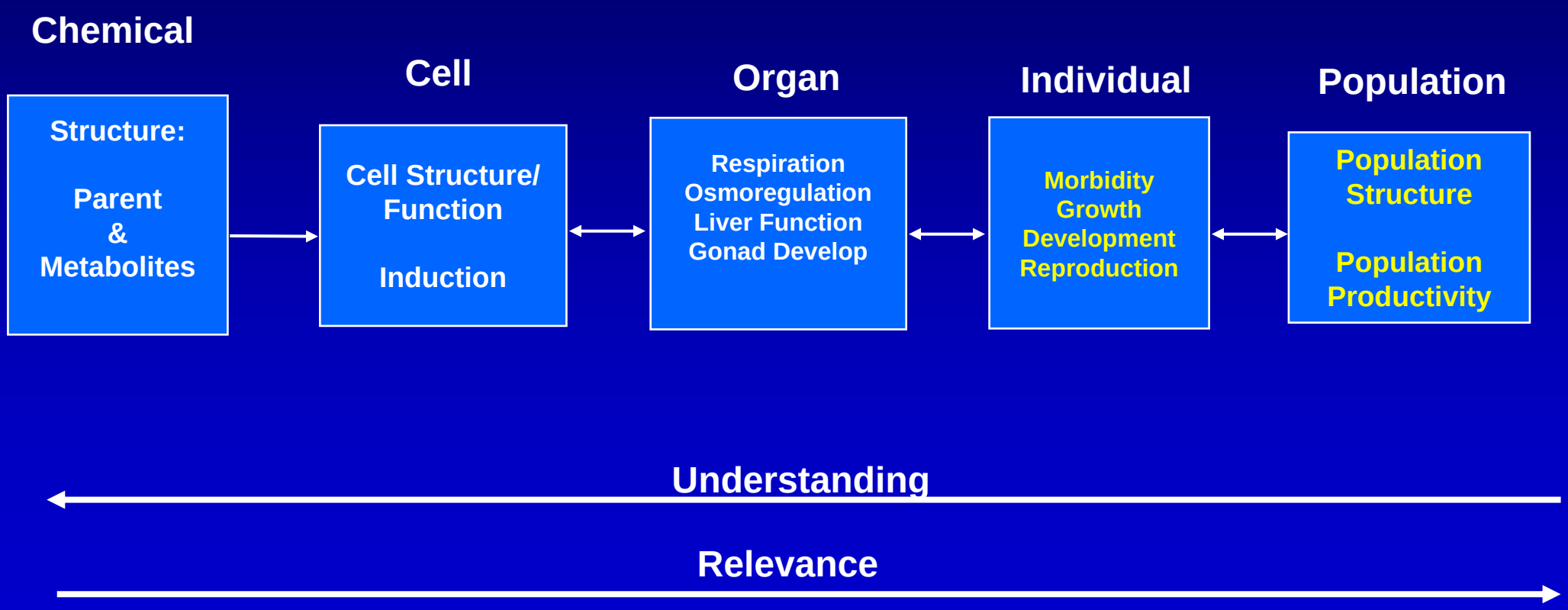
    http://www.epa.gov/ecotox/

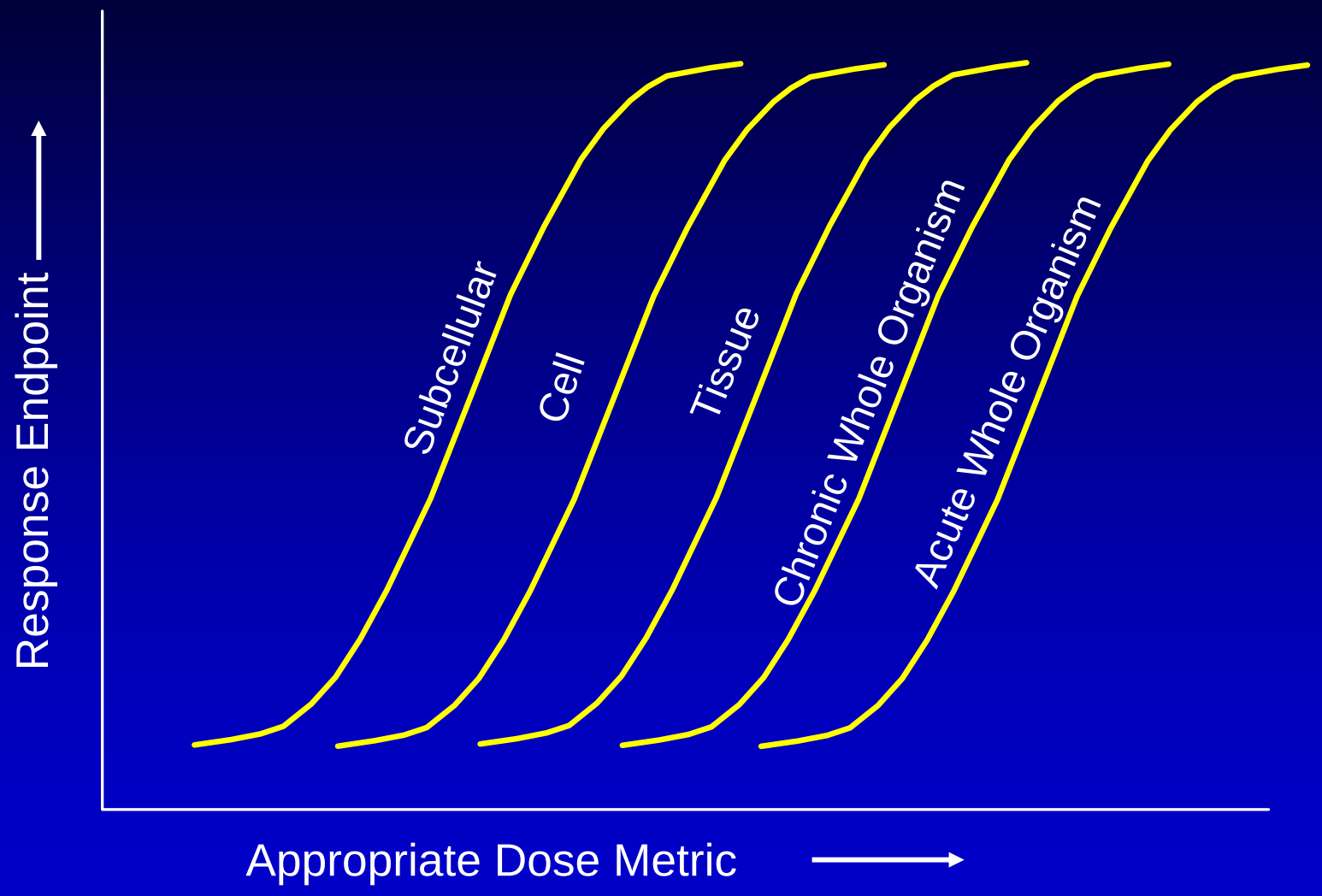
  - FIFRA 6(a)(2) data

Assessment Endpoints for Salmonids

- Individual fish survival, growth, and reproduction
- Integrity of the habitat
  - Food
  - Cover
  - Water quality
  - Stream stability

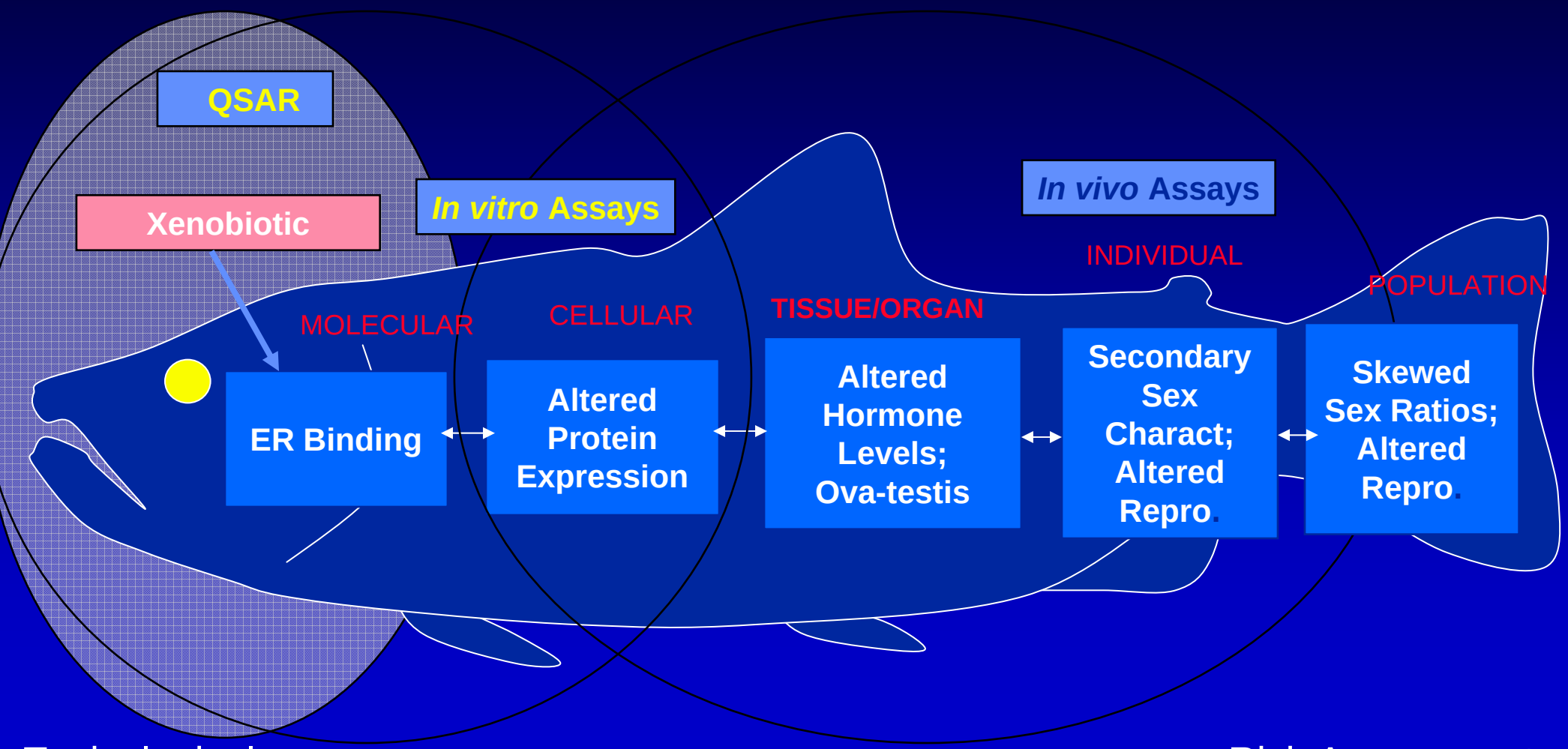
Linkage and Focus Across Levels of Biological Organization



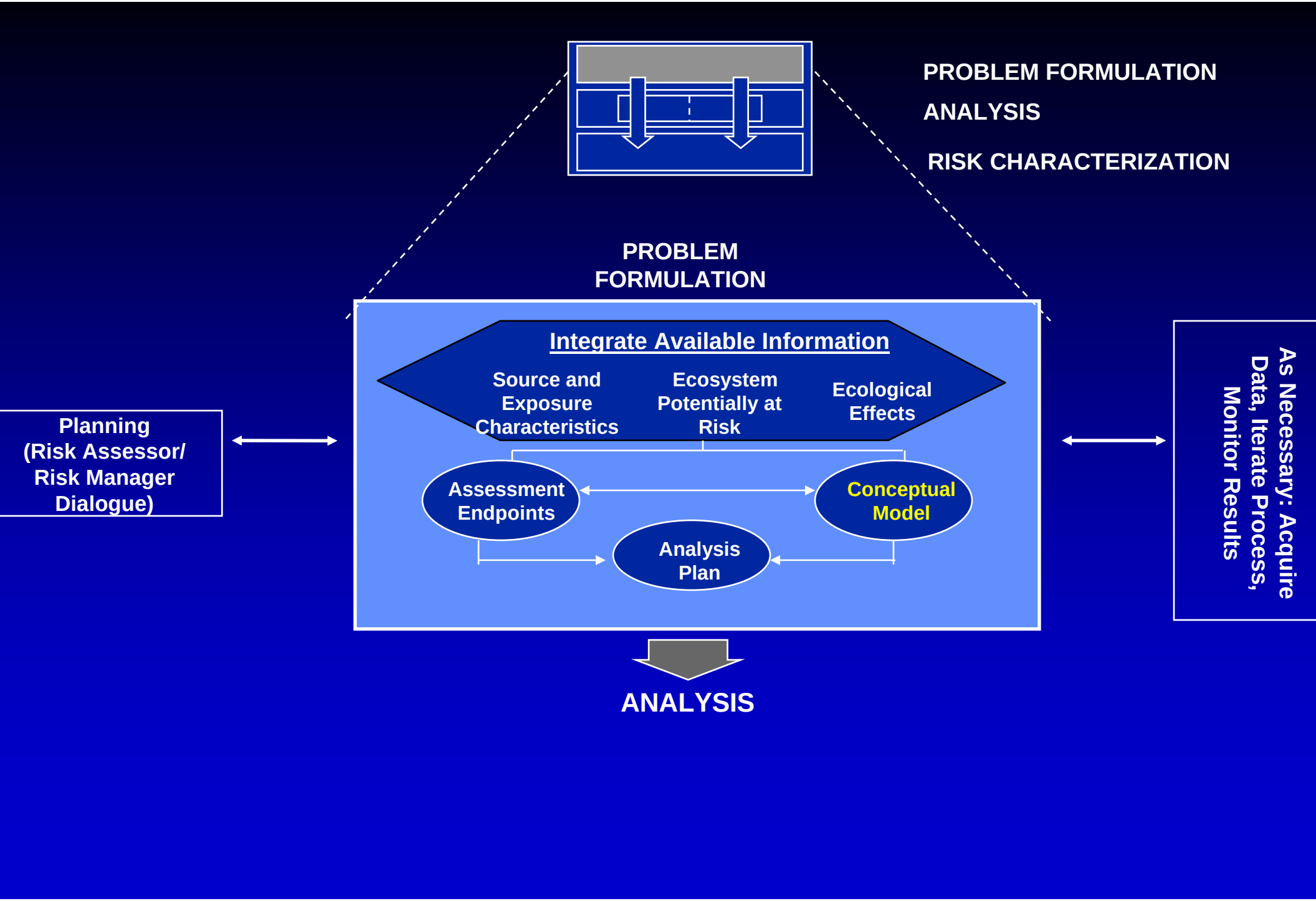

Response Endpoint
Subcellular
Cell
Tissue
Chronic Whole Organism
Acute Whole Organism
Appropriate Dose Metric

Defining Toxicity Pathways Across Levels of Biological Organization:

Example - Direct Chemical Binding to ER



Toxicological Understanding ⟷ Risk Assessment Relevance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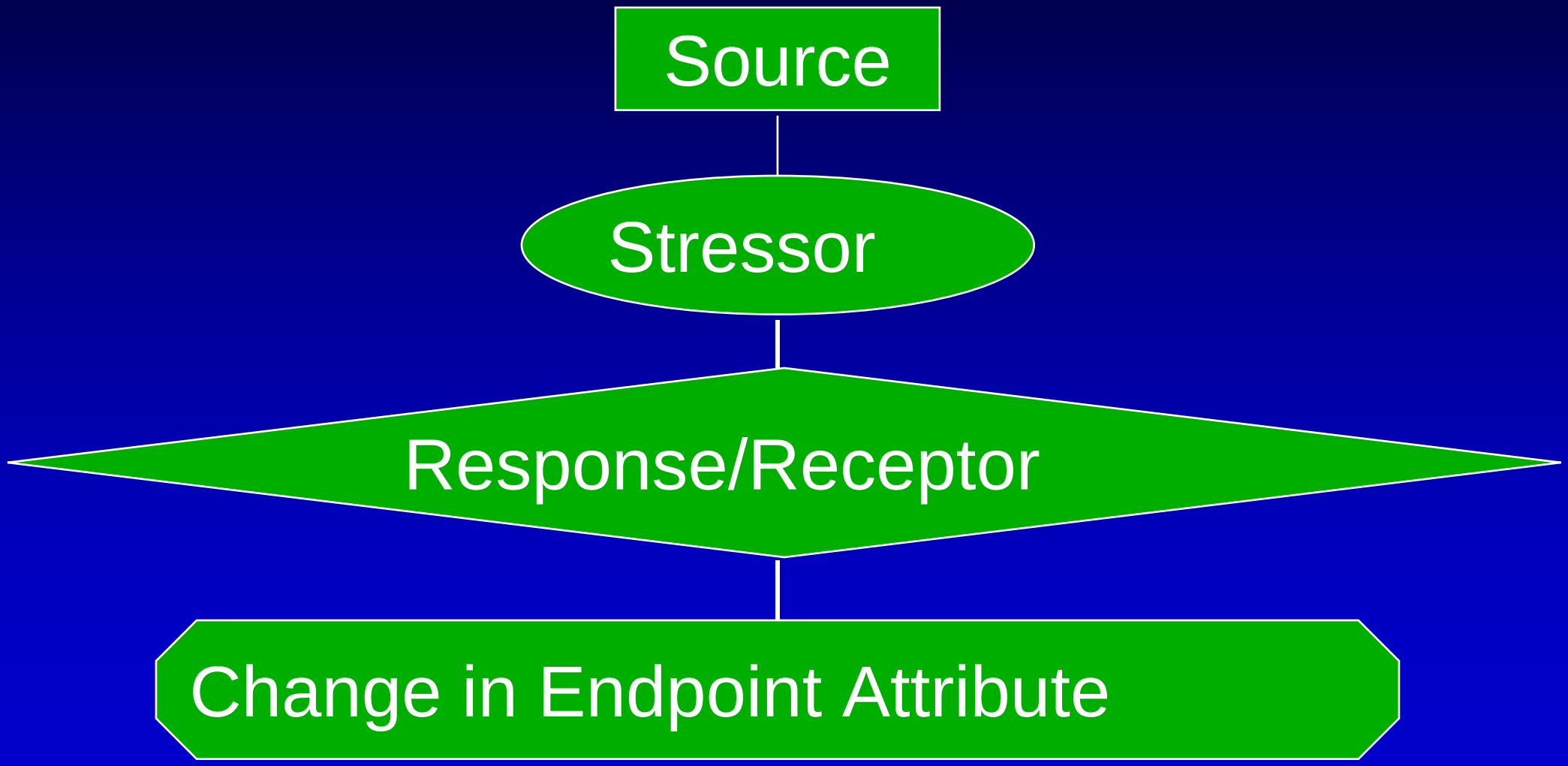
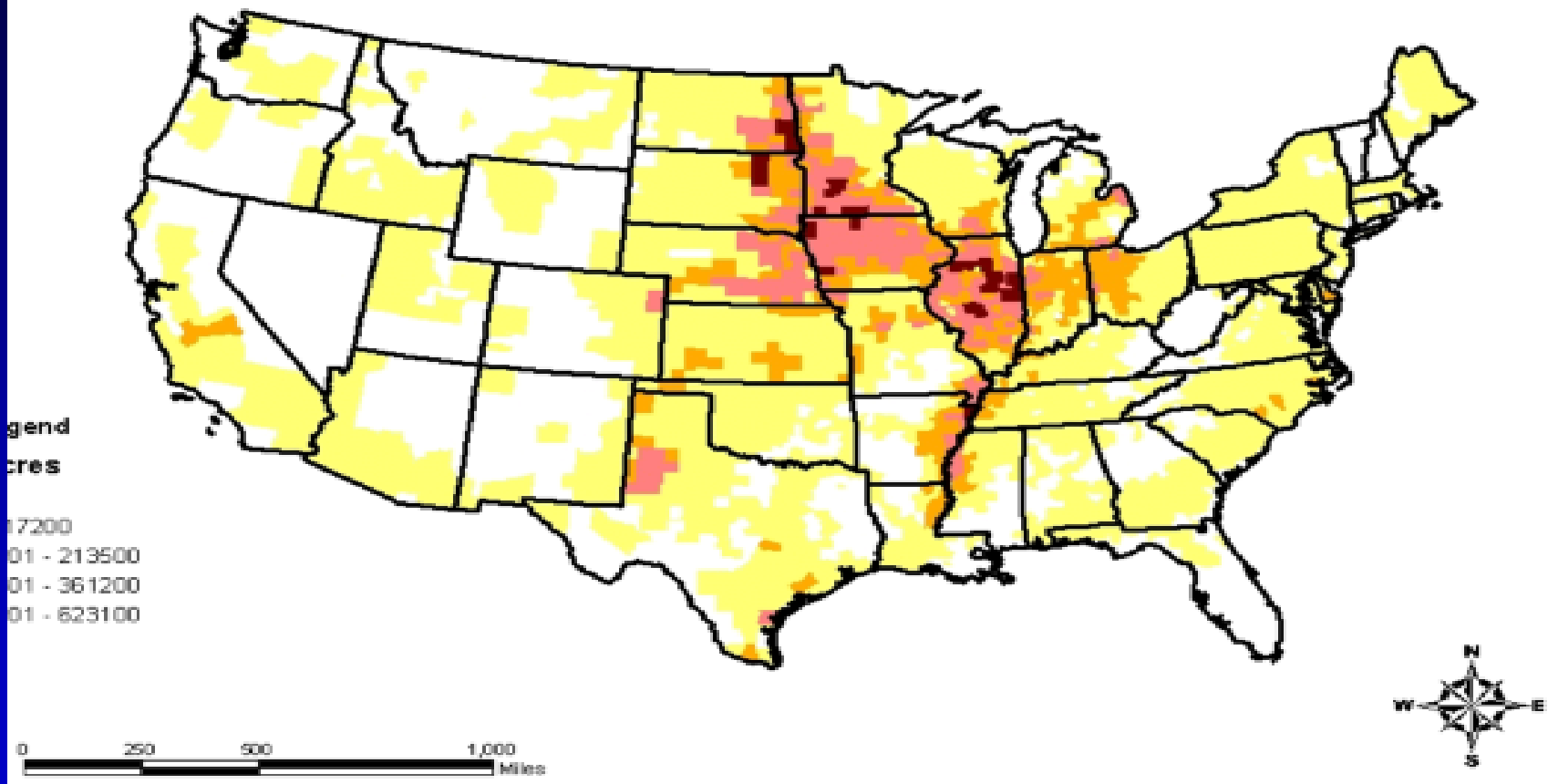
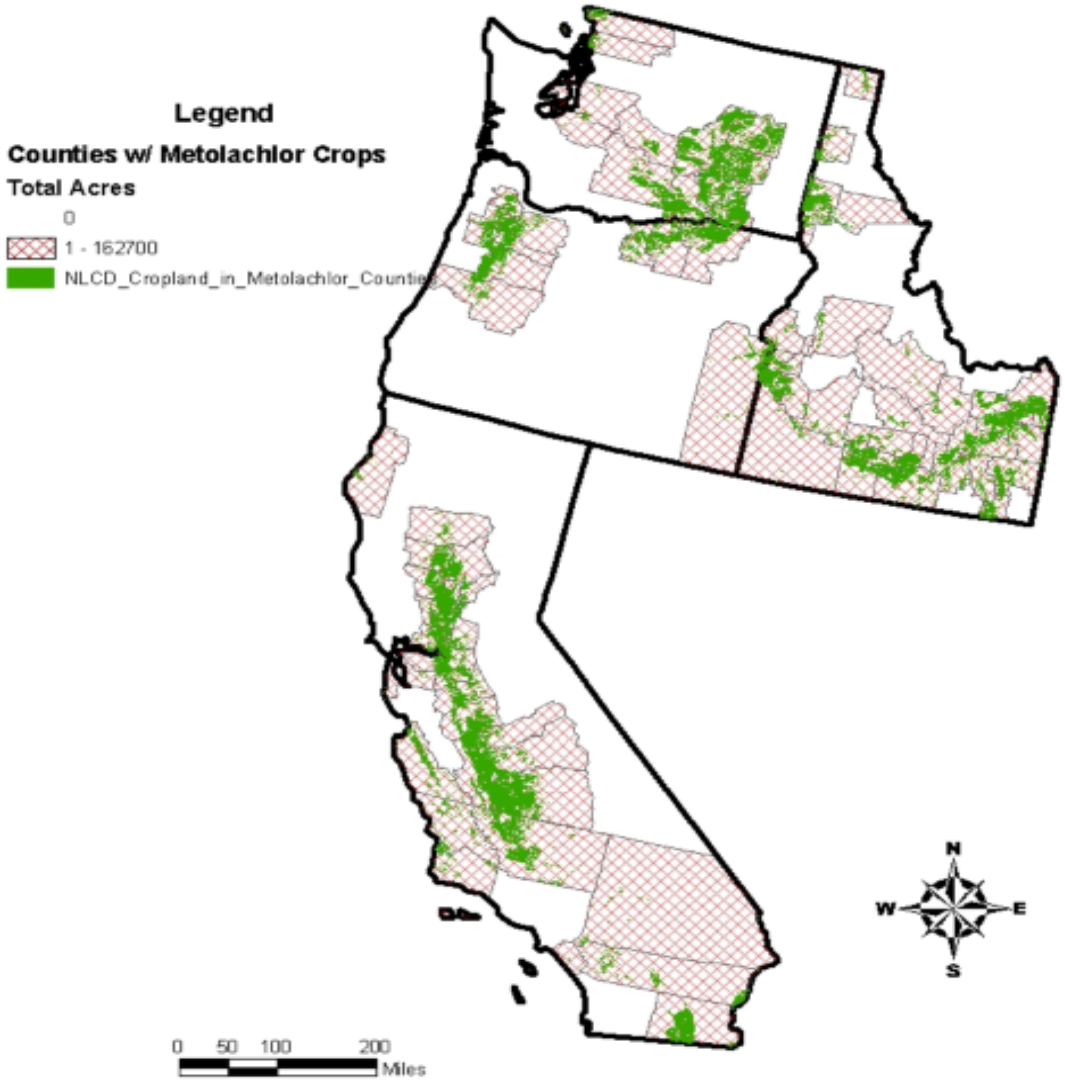
Conceptual Model - Diagram



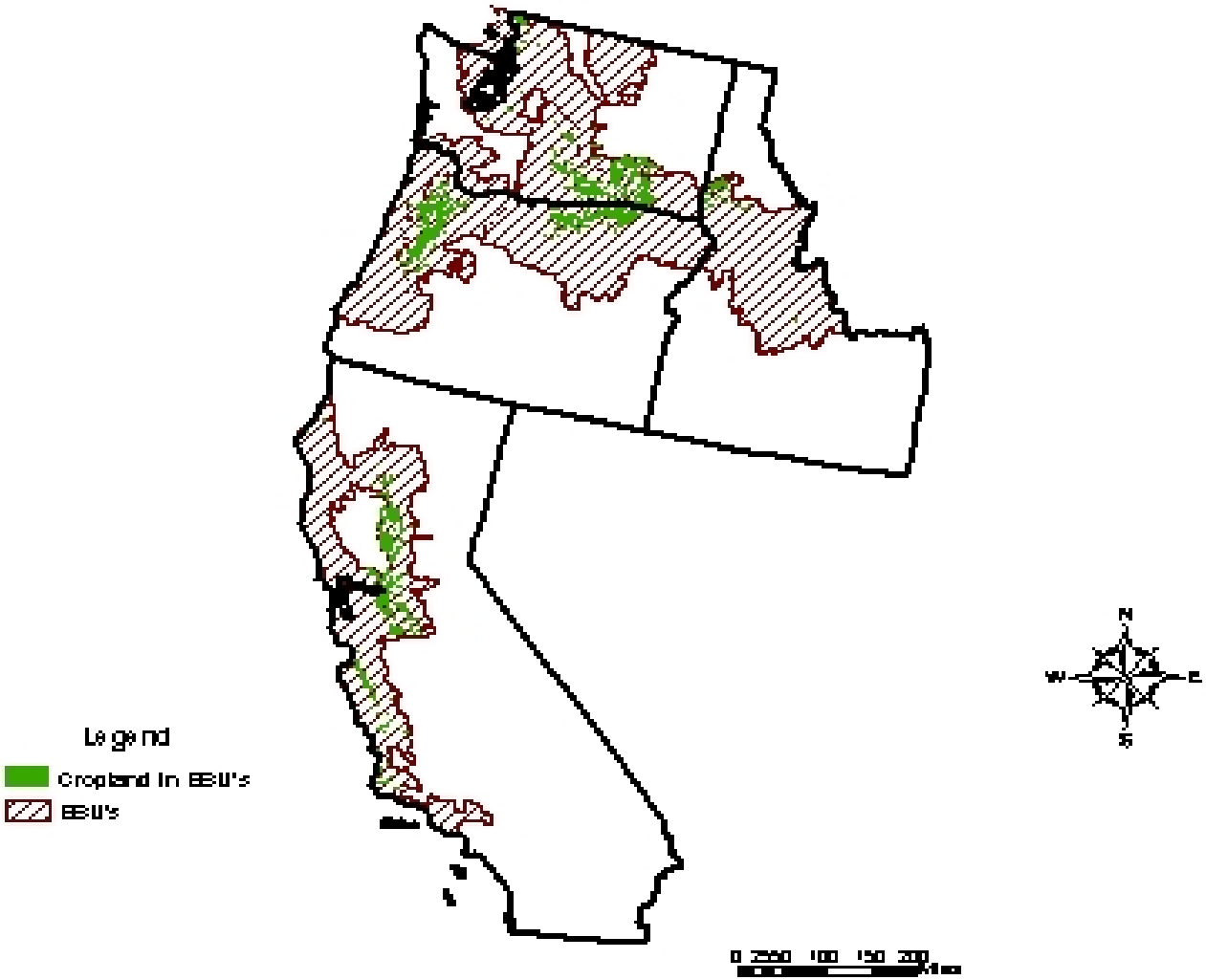
National Extent of Crop Acreage on Which Racemic Metolachlor is Registered for Use



NLCD Cropland in Counties in the Pacific Northwest with Crops Registered for Use with Racemic Metolachlor



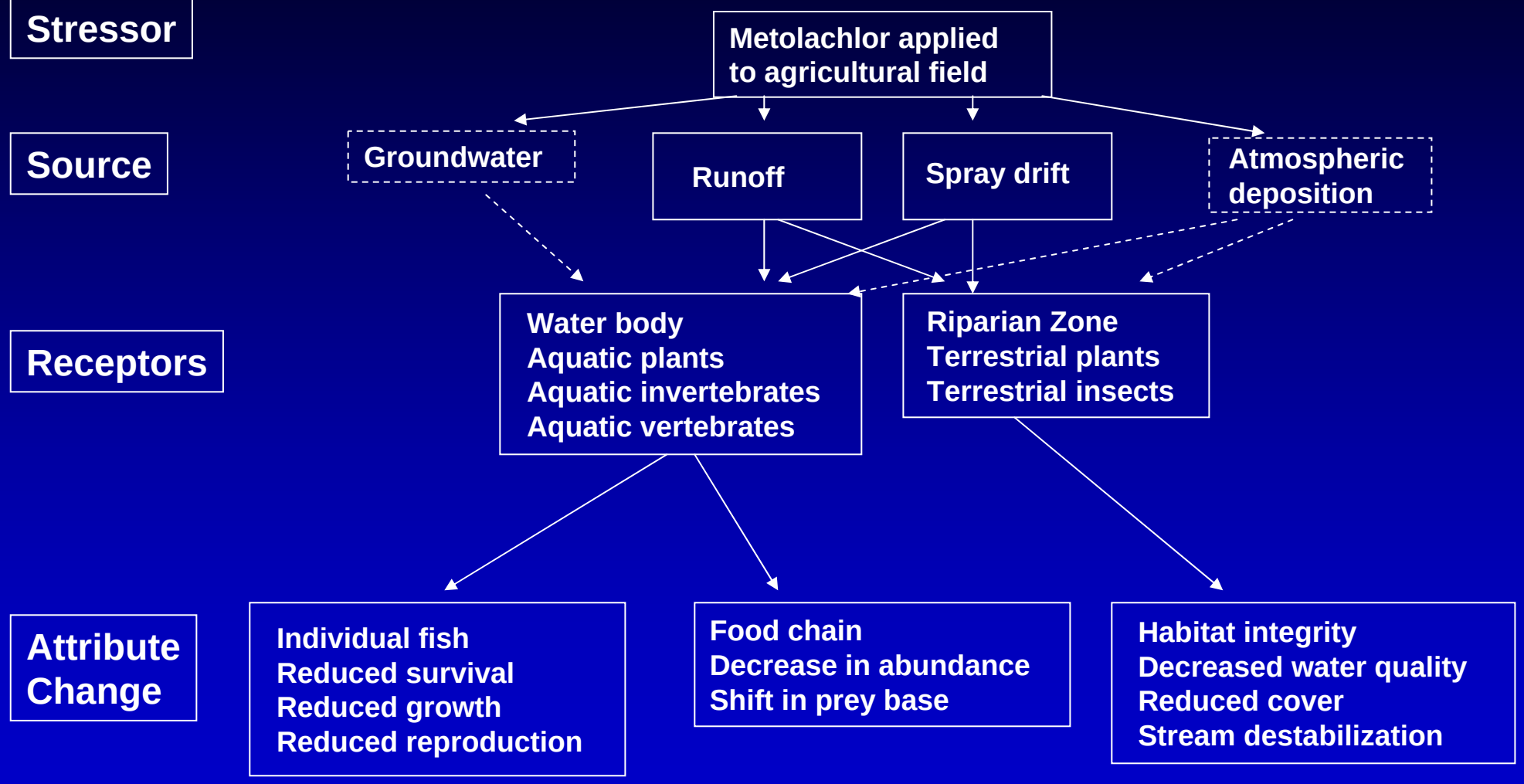
NLCD Cropland Relative to ESUs in the Pacific Northwest

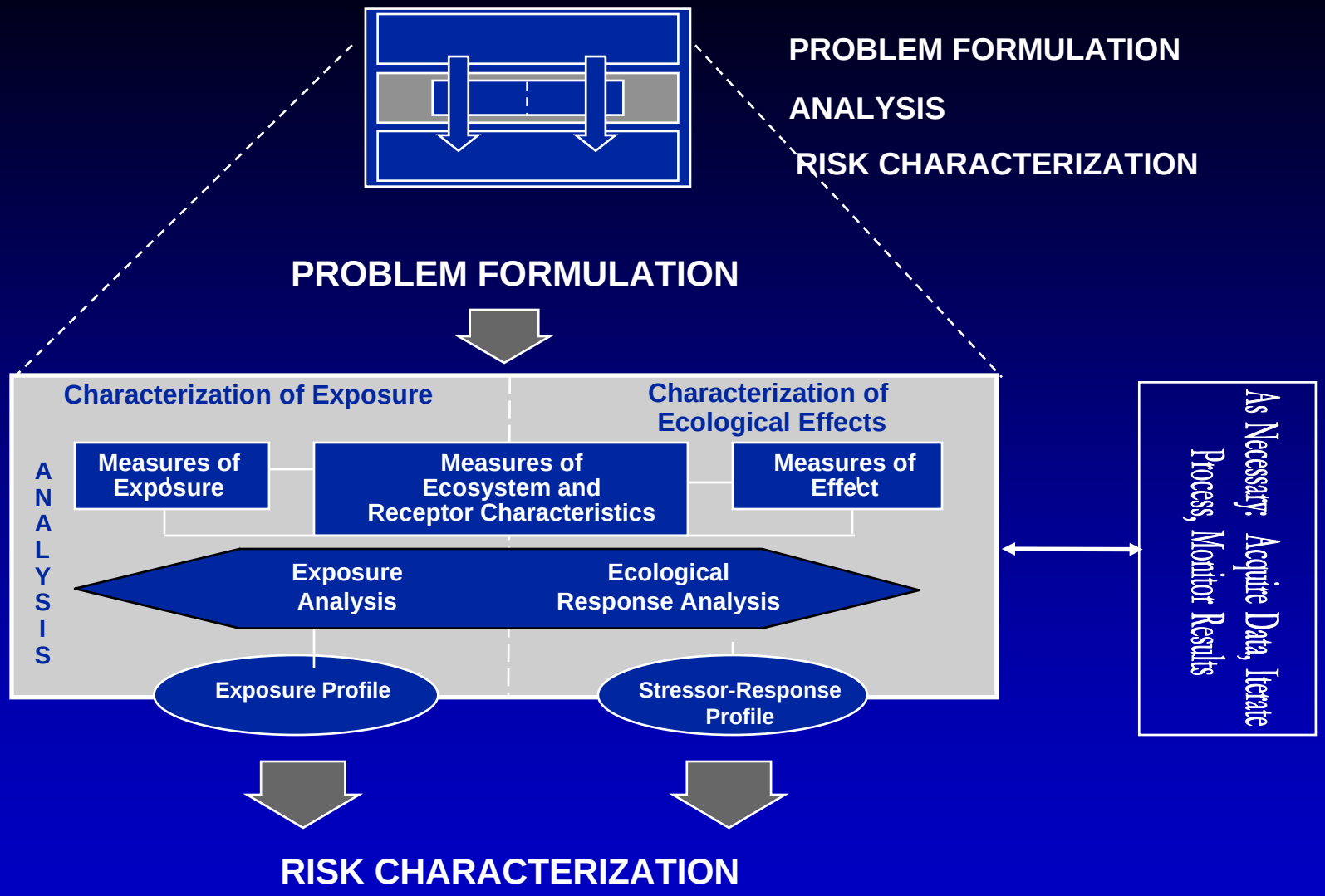


Metolachlor Risk Hypotheses

- Metolachlor may affect salmonids directly by reducing individual fish survival, growth, or reproduction.
- Metolachlor may affect salmonids indirectly by adversely modifying the food web.
- Metolachlor may affect salmonids indirectly by adversely modifying the habitat.

Conceptual Model for Metolachlor Risk Assessment




PROBLEM FORMULATION
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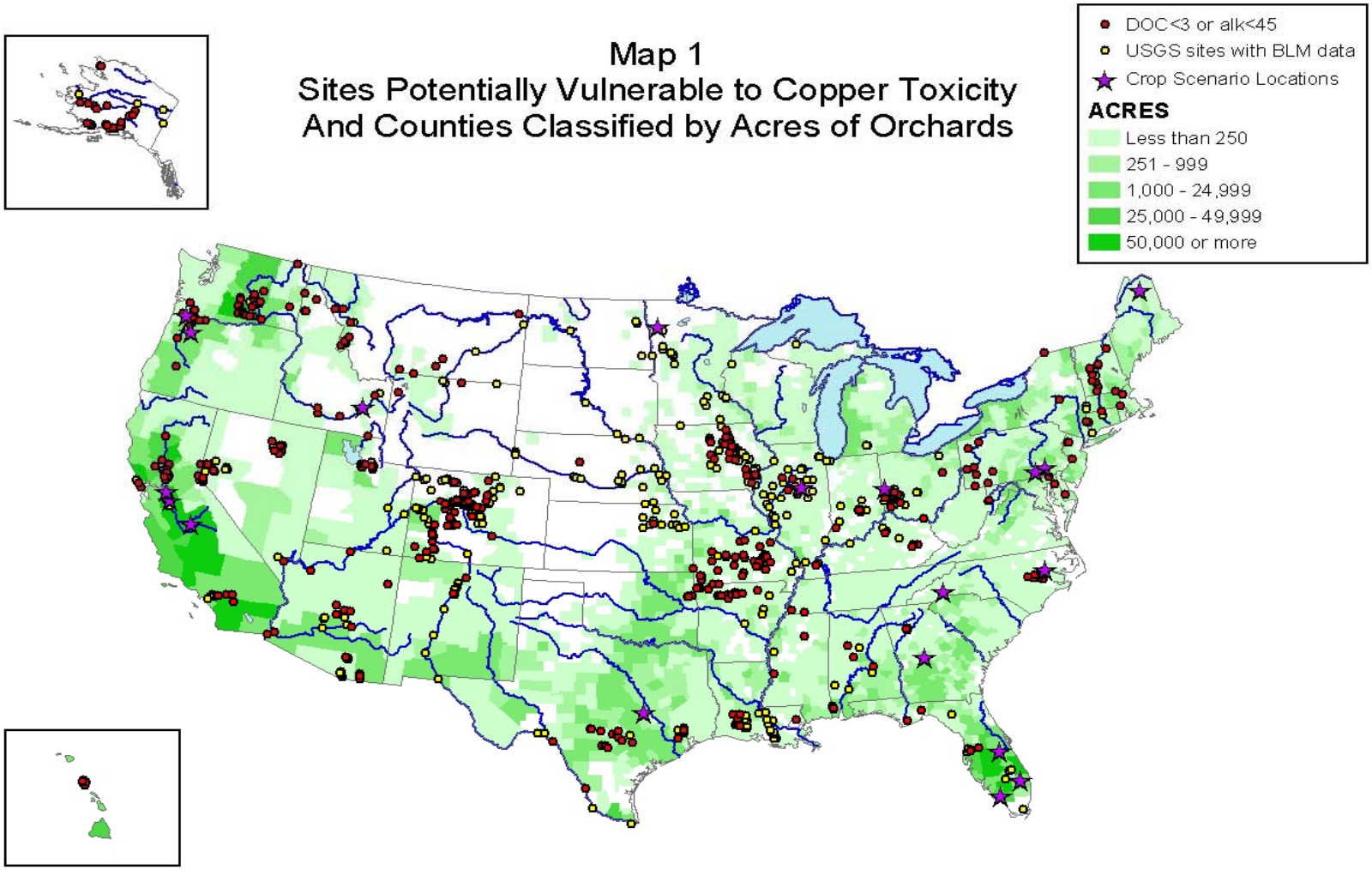
PROBLEM FORMULATION
Characterization of Exposure
Characterization of Ecological Effects
ANALYSIS
Measures of Exposure
Measures of Ecosystem and Receptor Characteristics
Measures of Effect
Exposure Analysis
Ecological Response Analysis
Exposure Profile
Stressor-Response Profile
As Necessary, Acquire Data, Iterate Process, Monitor Results
RISK CHARACTERIZATION



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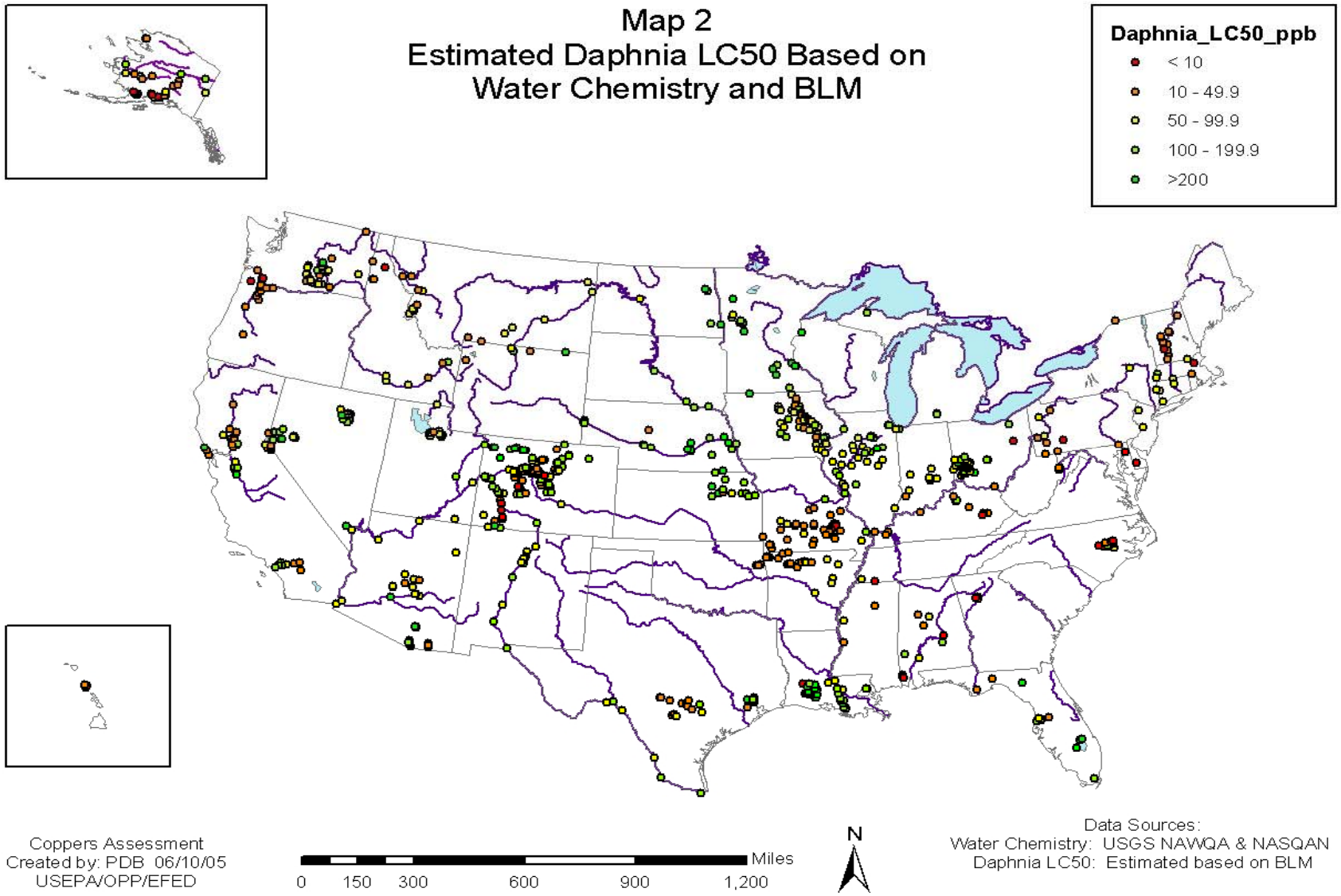
Map 2
Estimated Daphnia LC50 Based on
Water Chemistry and BLM
Daphnia_LC50_ppb
< 10
10 - 49.9
50 - 99.9
100 - 199.9
>200
Coppers Assessment
Created by: PDB 06/10/05
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0 150 300 600 900 1,200
Miles
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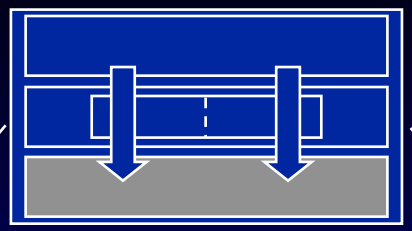


PROBLEM FORMULATION

ANALYSIS

RISK CHARACTERIZATION

ANALYSIS

Risk Estimation

Risk Description

Communicating Results to the Risk Manager

Risk Management

As Necessary: Acquire Data, Iterate Process, Monitor Results

Risk Characterization:
Risk Estimation

- Risk quotients (RQs): ratios of estimated exposures and effects
- RQs compared with Levels of Concern (LOC), the criteria used to indicate potential risk
- Direct and indirect effects; habitat modification

Deterministic and 'Probabilistic' Approaches

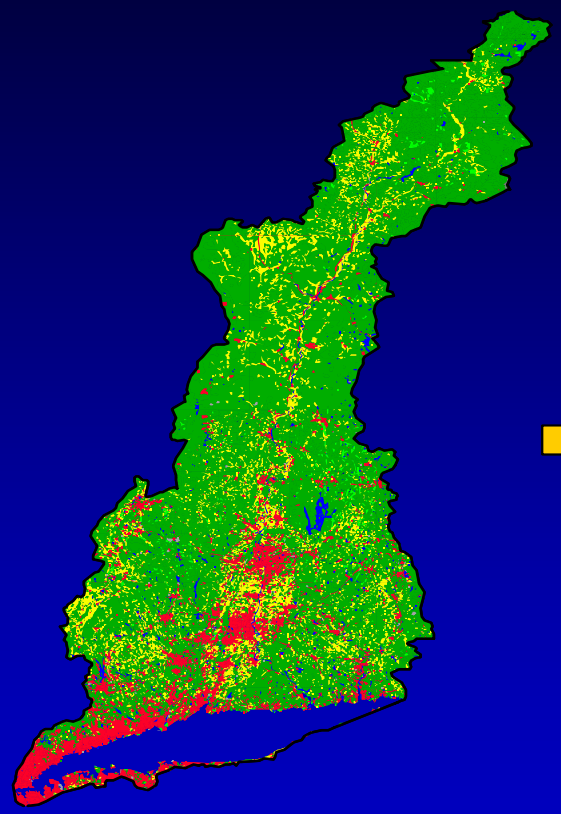
Deterministic Process

- **Exposure is a point estimate selected to be an expected conservative level from a distribution**
- **Effects endpoint is the LD50/LC50**
- **Effects uses lowest LD50/LC50 from species tested**
- **Assessment process is division of exposure estimate by effects endpoint**
- **Output is a single number**

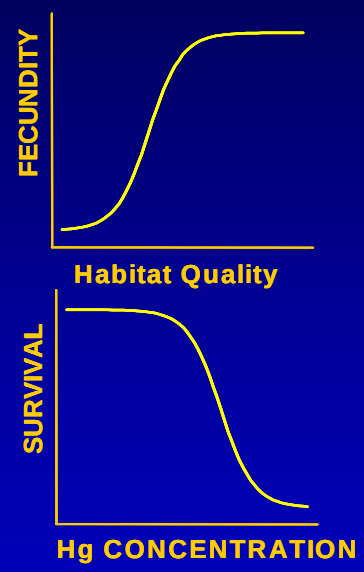
'Probabilistic' Process

- **Exposure varies with variable inputs; entire distribution of exposure values is considered**
- **Effects considers entire dose-response relationship to account for variability in sensitivity among individuals**
- **Effects estimates interspecies variability in sensitivity; uses scenarios to express uncertainty about sensitivity of a given species**
- **Assessment is integration of exposure distribution with entire dose response curves**
- **Output is a distribution of the probability and magnitude of adverse effects**

Risk Description: Conceptual Model



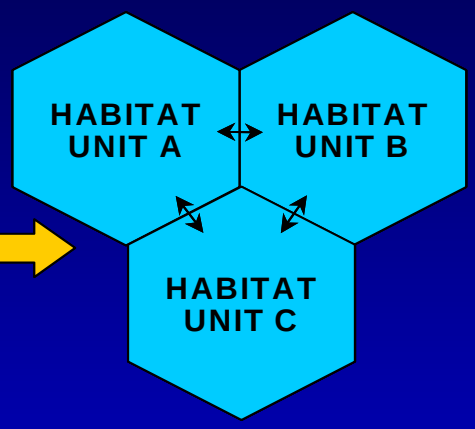
GIS-referenced habitat & exposure data



exposure-response habitat-response relationships

$$n_{t+1} = A n_t$$

population models

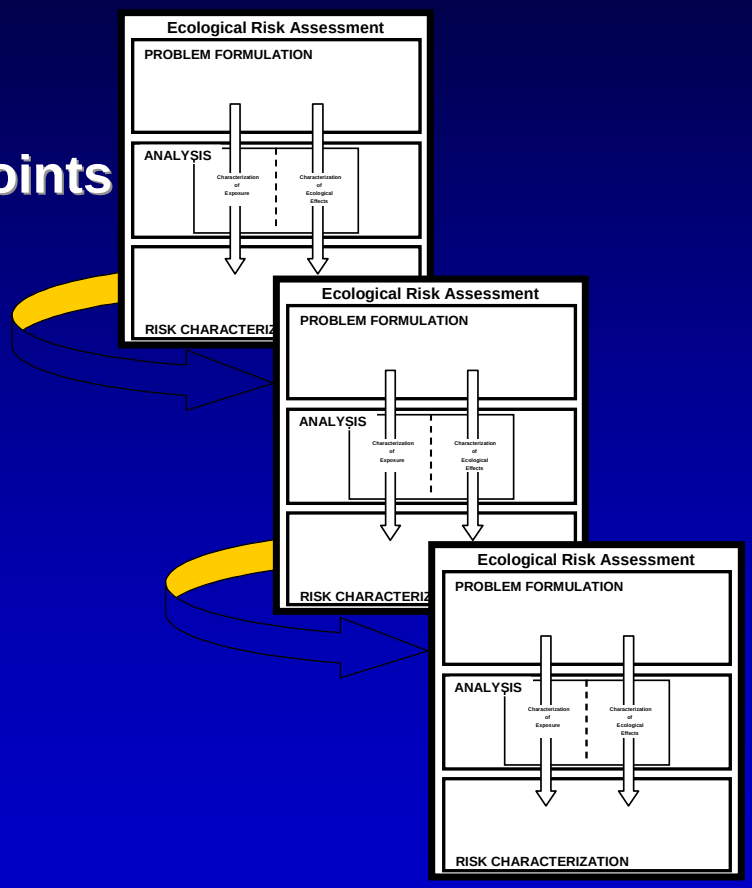


spatially-explicit models

Tiered Assessment Process

Assessment Uncertainties and Risk Management Decisions

Low spatial
and temporal resolution
General assessment endpoints
Deterministic



Site-specific resolution
Species/habitat-specific endpoints
Probabilistic

The Tiered Process

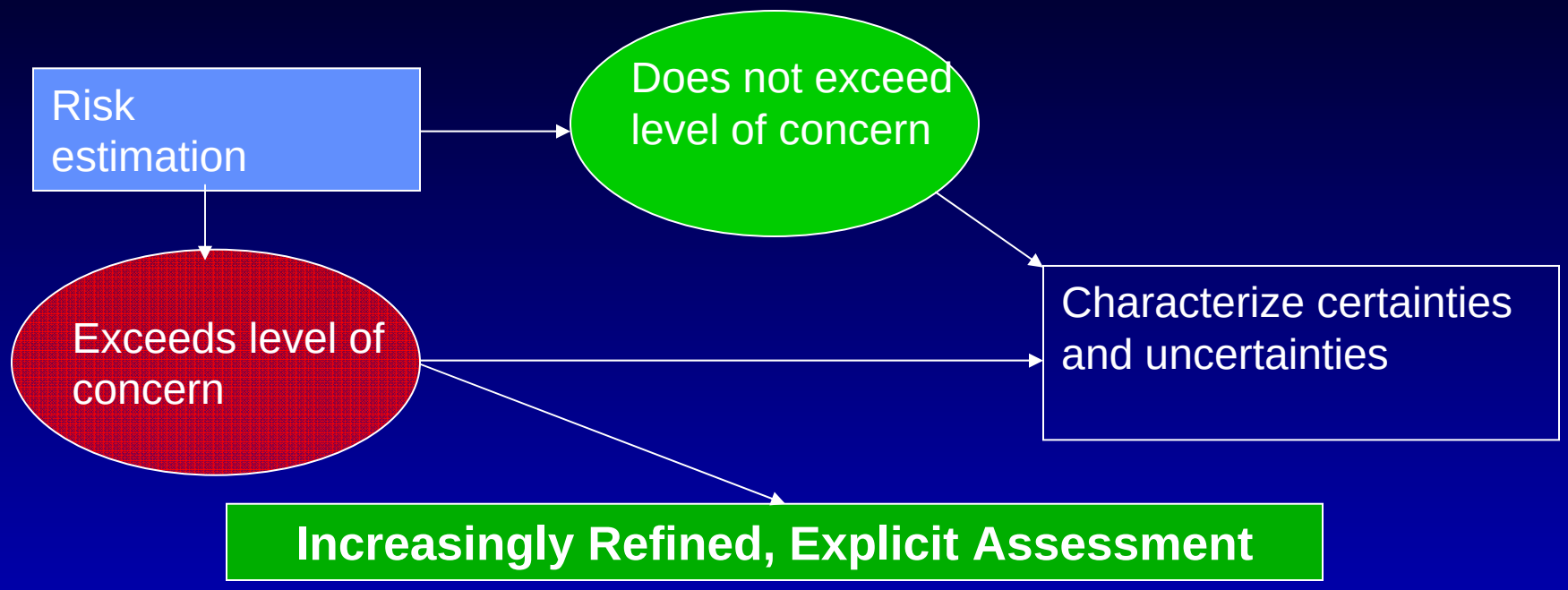
- Resolution of ecosystems potentially at risk

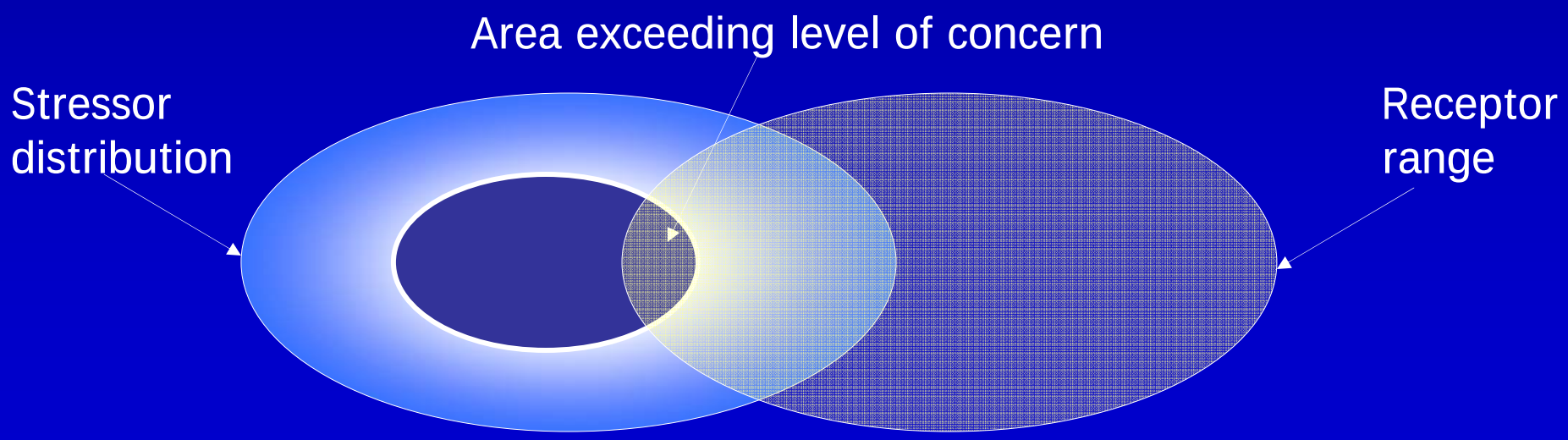
  -- key abiotic factors related to the pesticide fate and transport

  --geographic boundaries of pesticide use

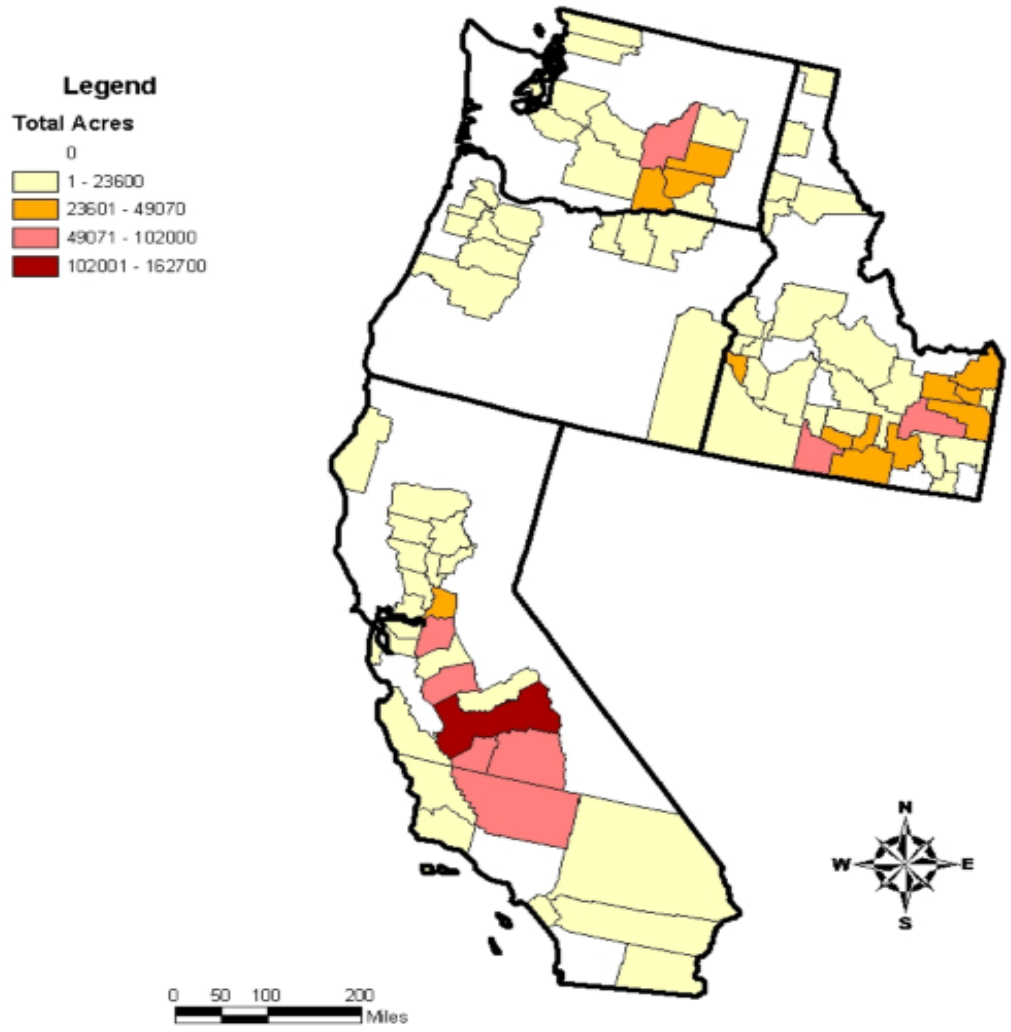
  --boundaries of habitats and their quality, functionality

Iterative Process to Assess Species, Habitats Potentially at Risk





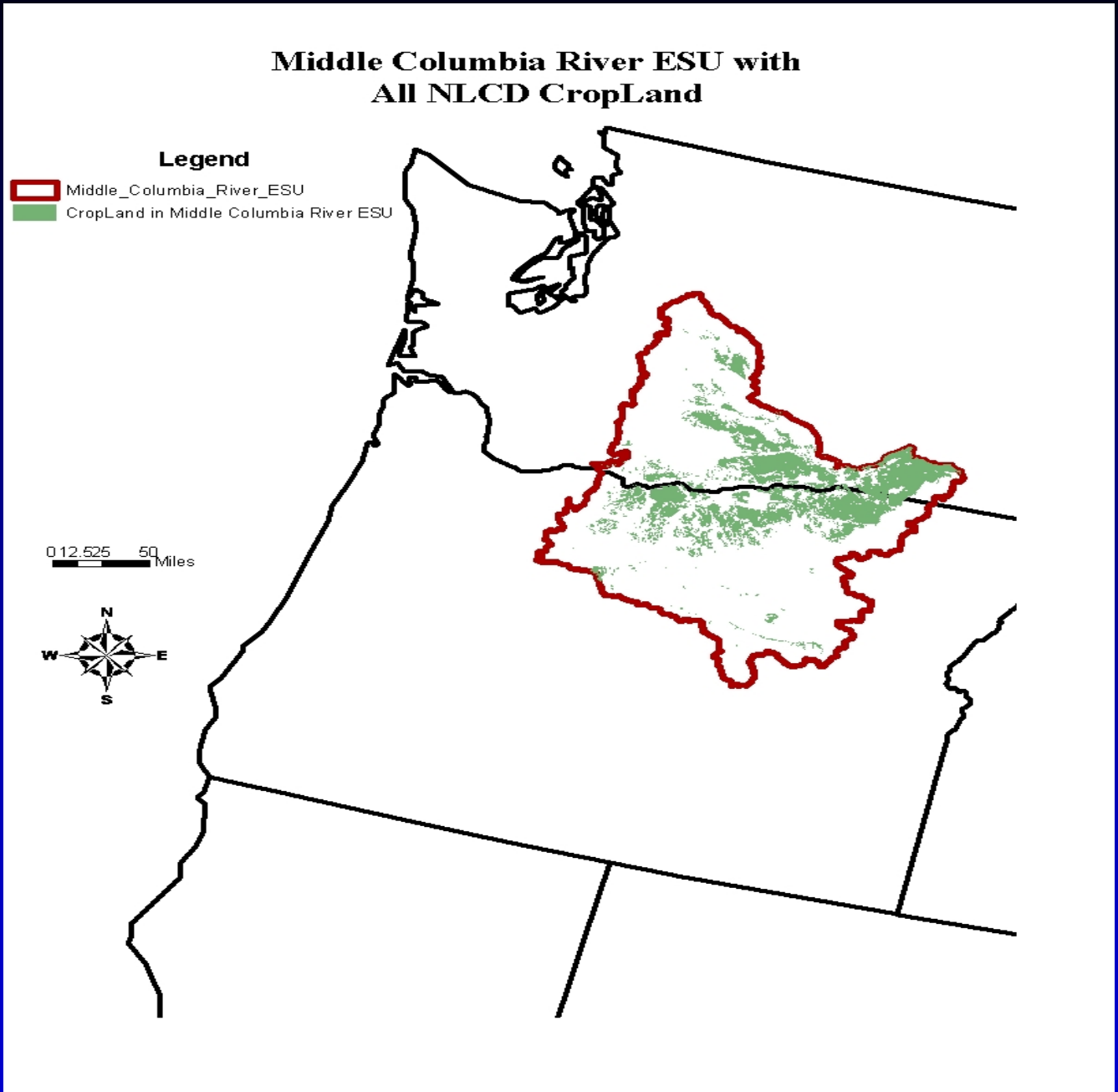
Counties in the Pacific Northwest with Crop Acreage for Which Racemic Metolachlor has Registered Uses



Identifying Potential Action Area

Stressor range:

- Ag Census acres, Cropland area



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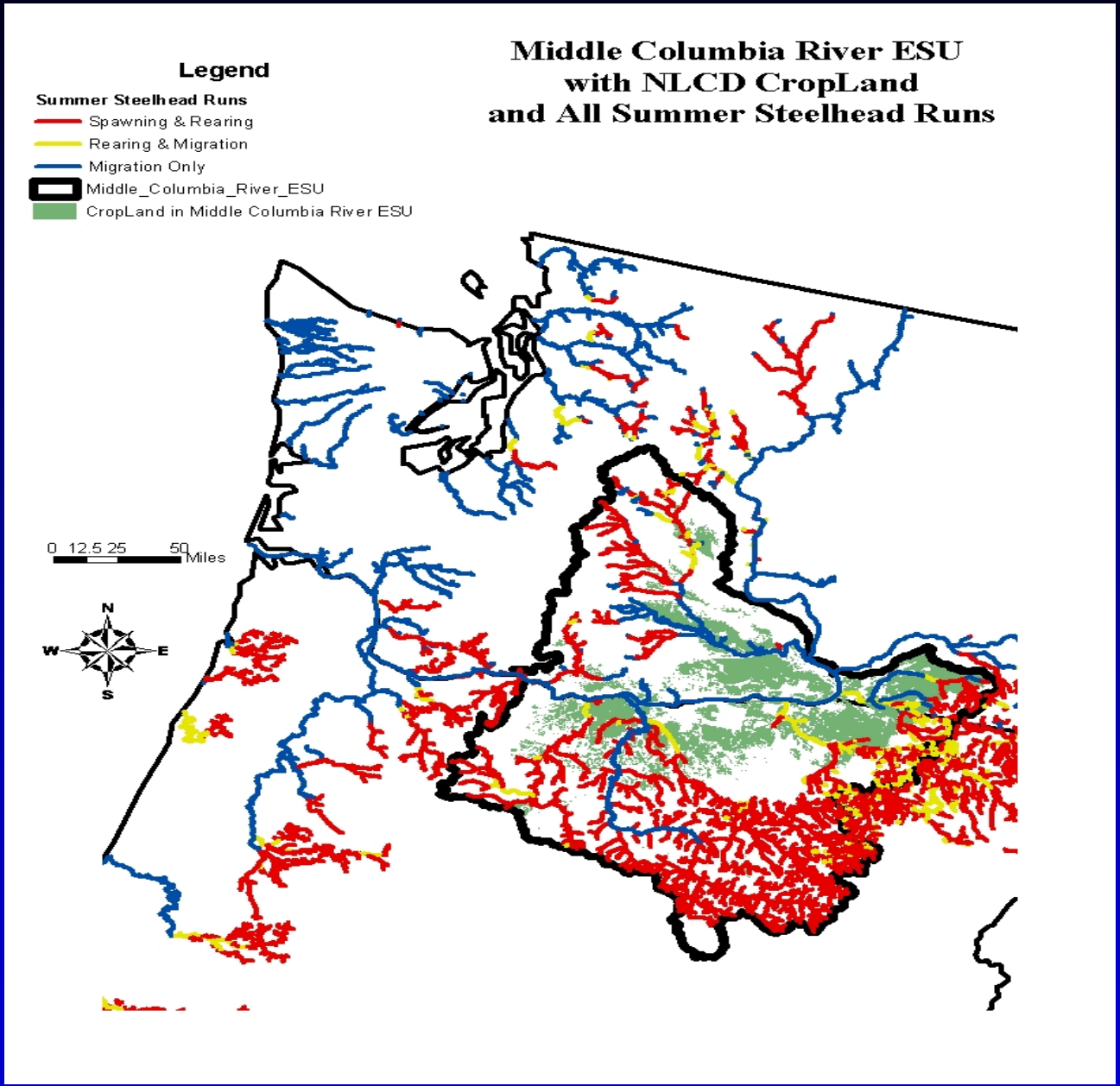
Receptor range:

ESUs, stream segments (summer steelhead runs)



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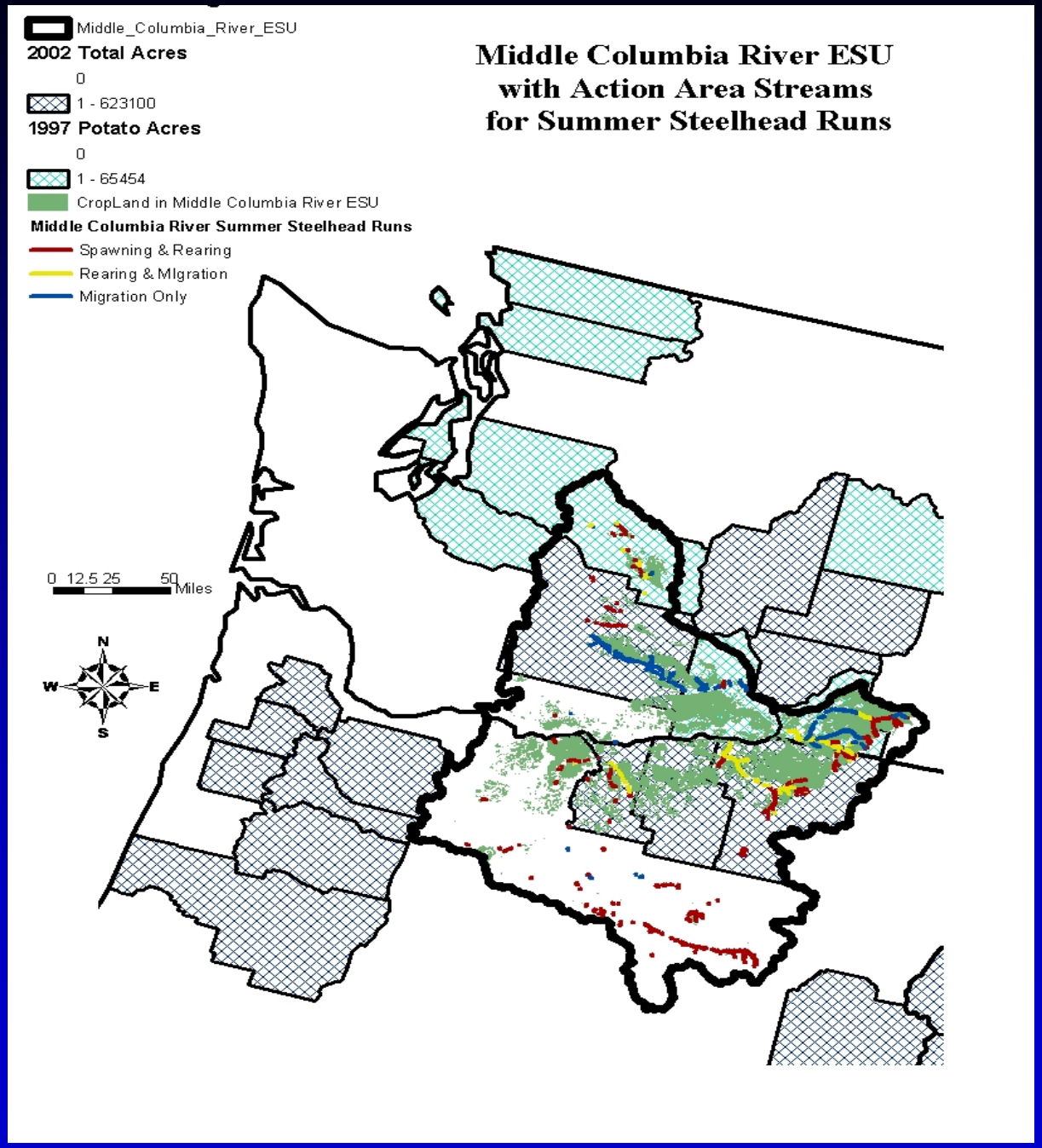
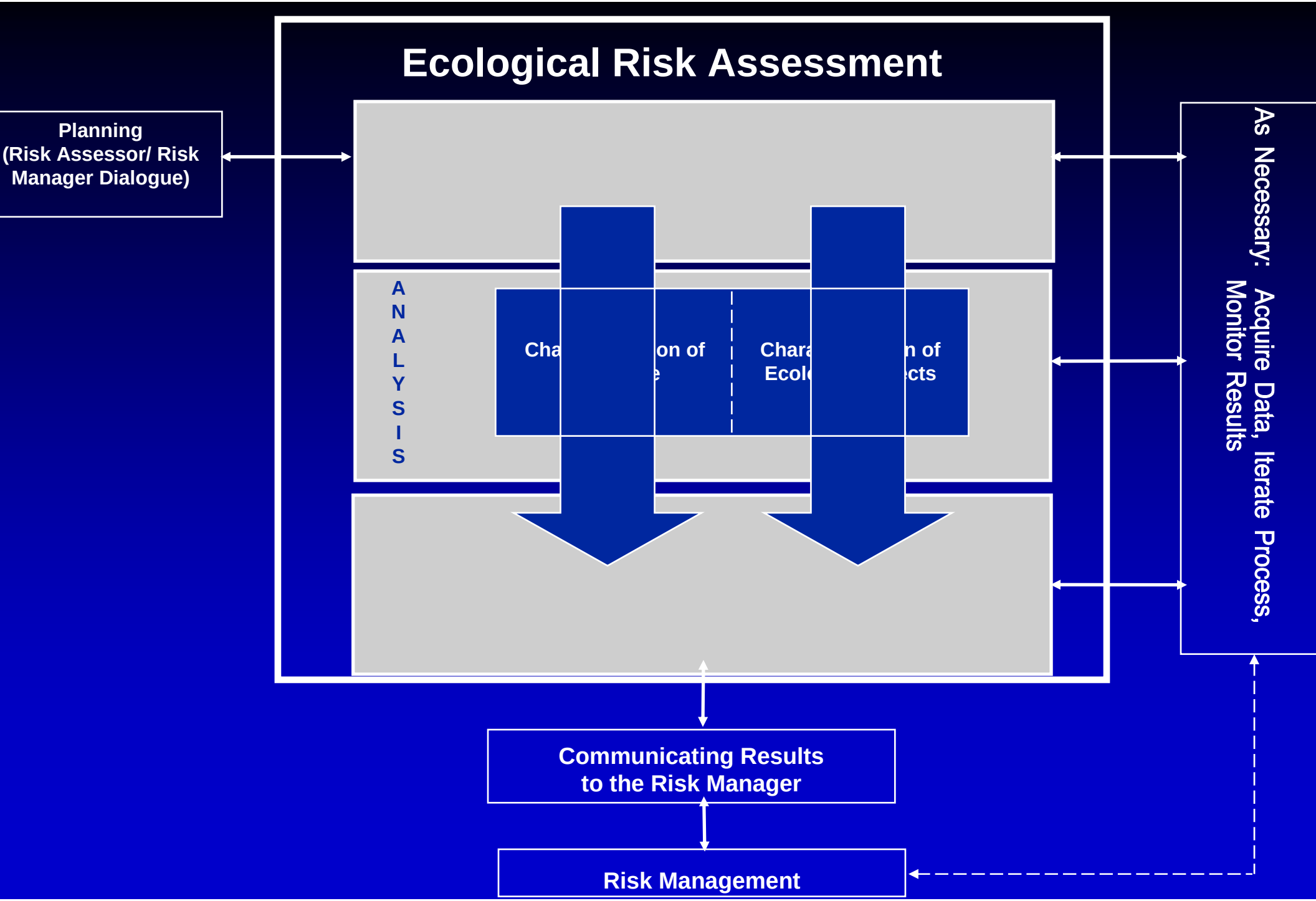
Intersecting Stressor and Receptor ranges

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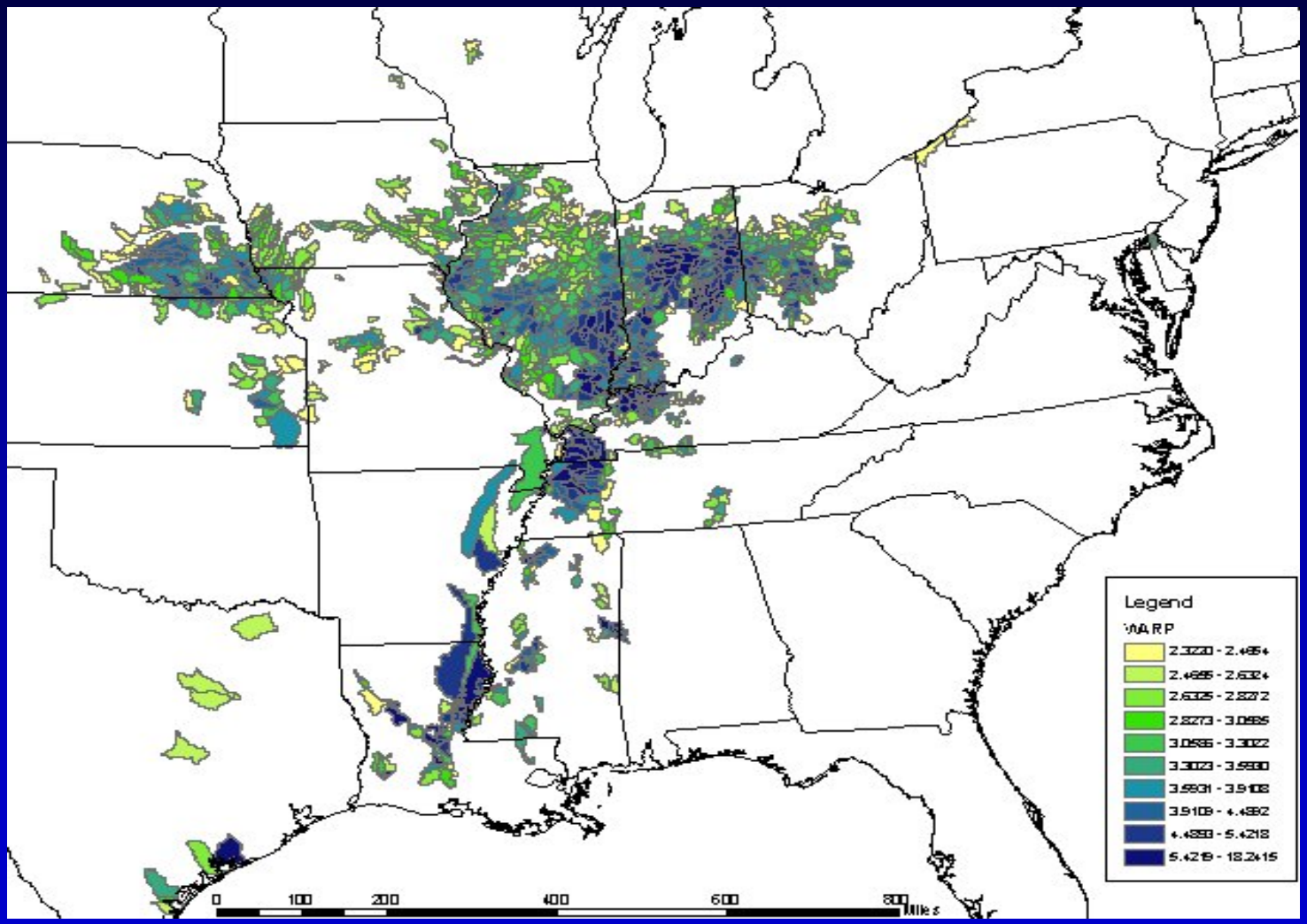
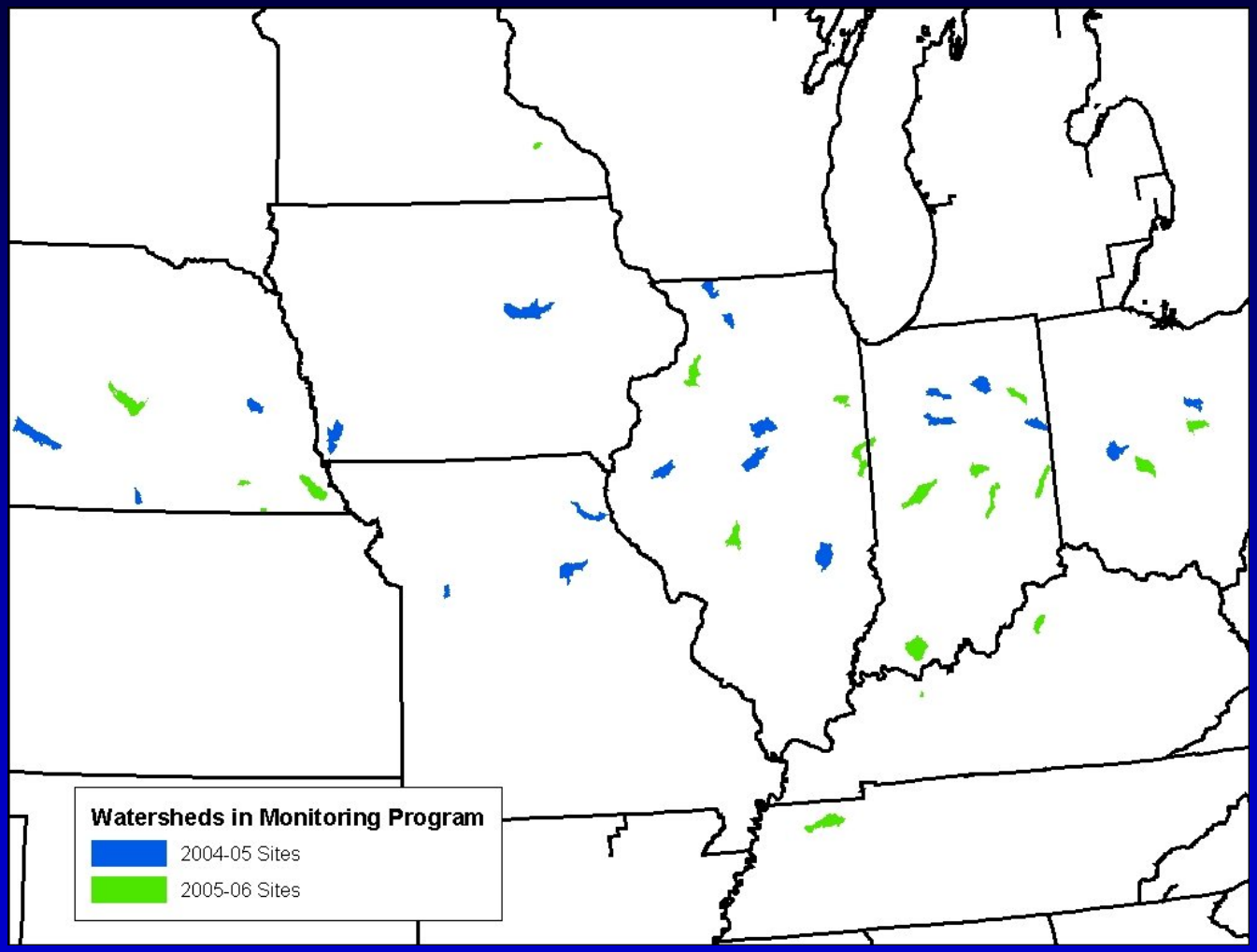
Monitoring as a Condition of Re-registration

- GIS data and spatial modeling used to identify vulnerable watersheds
- Harmonize methods and programs between FIFRA and CWA

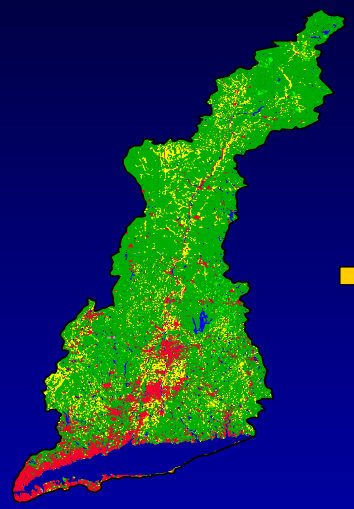


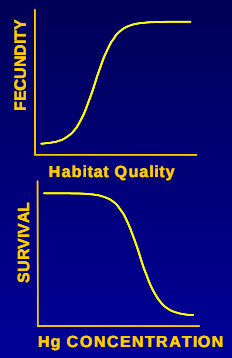
Statistically-Representative Sampling

- Random stratified sampling design for specific watershed (ORD-EMAP)

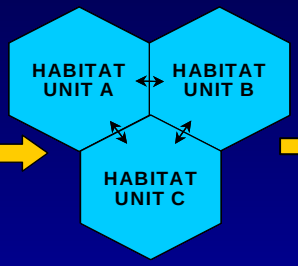


Building Capacity for Explicit Risk Assessments





$$n_{t+1} = An_t$$



OUTCOME:
Efficient-effective site-specific risk assessments

- Habitat/Biota Distribution Data Layers
- Chemical Data Layers
- Habitat-Species Response
- Chemical, Species Dose-Response Data and Models
- Species Physiology Data
- Population Models
- Demographic Data
- Life History Data
- Spatial Models

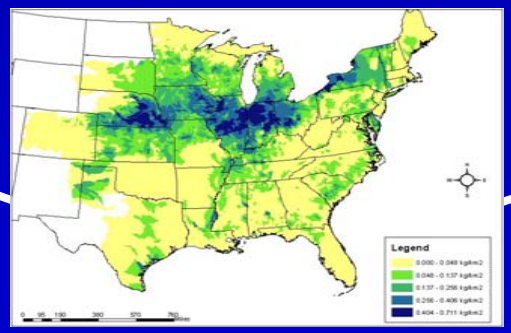
Setting Environmental Management Goals

Given current or projected land use, what is the 'ecological potential'?

Use Attainment Environmental Management Option Building

→

SPATIALLY, TEMPORALLY EXPLICIT ECOLOGICAL RISK ASSESSMENTS

→

OUTCOME: SPATIALLY, TEMPORALLY EXPLICIT RISK MANAGEMENT DECISIONS