

EPA Pesticide Ecological Risk Assessment Methods



ECS 3119 – Pesticides and Fish & Wildlife Resources

Problem Formulation

- FIFRA: no unreasonable adverse effect
- ESA: not likely to adversely affect
- FIFRA: problem formulation largely prescribed (assessment endpoints, conceptual model, analysis plan)
- ESA: problem formulation involves species specific considerations

Evaluation Procedure for Ecological Risk Assessment

- Assumes risk is a function of toxicity and exposure
- Risk Quotient (RQ) =
Exposure /Toxicity
Endpoint
- RQ compared to levels of concern (LOC's)

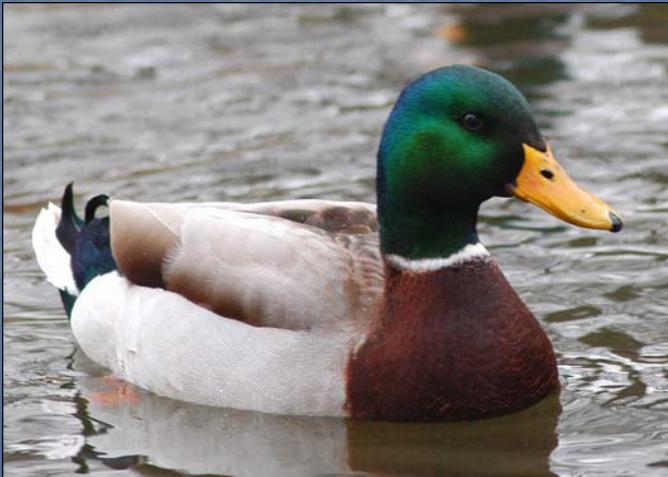


Which Chemical Poses the Greatest Risk?

- Chemical A:
 - Fish LC₅₀ = 4 ppb
 - Exposure = 0.5 ppb
 - **Risk = 0.5/4 = 0.12**
- Chemical B:
 - Fish LC₅₀ = 4 ppm
 - Exposure = 5 ppm
 - **Risk = 5/4 = 1.25**



RISK = Exposure / Effects



EPA OPP Pesticide Data Requirements

- Tiered approach
- Studies can be conditionally required (CR) or required (R)
- Requirements to conduct studies based on:
 - Intended use (agriculture (food vs. non-food), silviculture, greenhouse, aquatic)
 - Toxicity
 - Environmental fate

Toxicity Tests

Terrestrial Animals

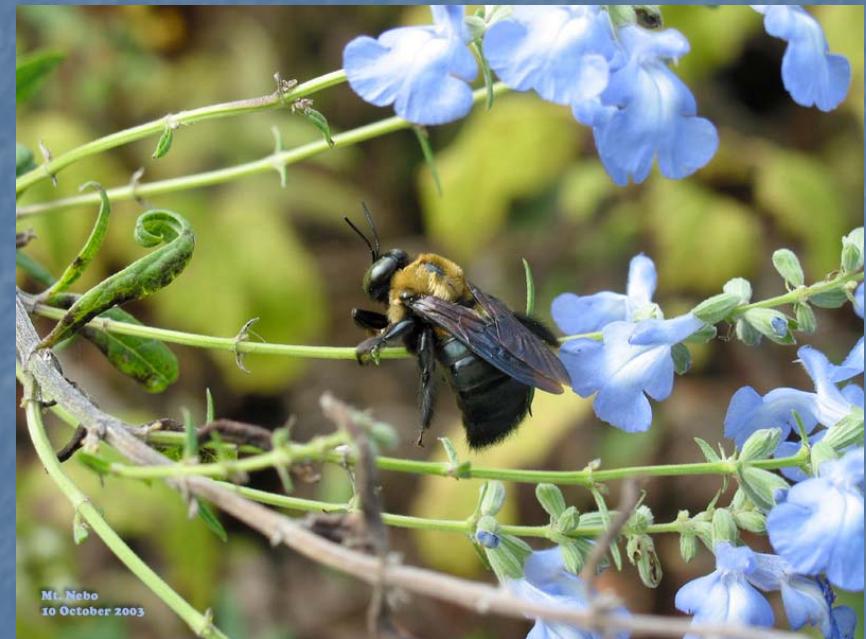
Test	Species	Exposure	Endpoint
LD50	Bobwhite/ Mallard	Single oral	Mortality
LC50	Bobwhite/ Mallard	5-d Dietary	Mortality
Repro.	Bobwhite/ Mallard	10-wk Dietary	LOEC, NOEC

Toxicity Tests: Aquatic Animals

Test	Species	Exposure	Endpoint
LC50	Rainbow, bluegill, sheepshead	96 h	Mortality
LC50	Daphnia, mysid, eastern oyster	48-96 h	Mortality
ELS	Fathead, Rainbow, Sheepshead	30-100 d	LOEC, NOEC
Life Cycle	Daphnia, mysid, fish spp.	21-300 d	LOEC, NOEC

Toxicity Tests: Terrestrial Invertebrate

- Honey bee
 - Acute oral LD50
 - Acute contact LD50
 - Residue studies LD50



Toxicity Test: Plants

- Aquatic plants
 - Blue-green and green algae (EC50)
 - Marine and freshwater diatom (EC50)
 - Duckweed (EC50)
- Terrestrial plants (EC25, NOEC)
 - Six dicots and four monocots (crops)
 - Root-shoot length, weight, visual

New Data Requirements for Pesticides

- 40 CFR Parts 152 and 158
 - Effective December 2007
- New data requirements for conventional, microbial and biochemical pesticides
- Justification:
 - Updating the 1984 requirements
 - Reorganizing part 158 to improve usability
 - Improve scientific basis for pesticide registration decisions

Revised Data Requirements for Avian/Reptile Toxicity Studies

- Avian oral toxicity studies
 - Add passerine species (red-winged blackbird) or other acceptable species
 - Case-by-case for typical end use products (TEP) avian testing
- Expand use patterns that could require simulated or actual field testing
- Avian reproduction testing required for most uses
- Consideration of reptile testing protocols

Revised Data Requirements for Aquatic Toxicity Studies

- Require one or two fish spp. for pesticides used indoors and in greenhouses
- Change CR for marine and chronic testing to required for most uses
- CR acute/chronic sediment toxicity studies
 - Based on partitioning and half life
 - Acute: <10 days; Chronic: >10 days

Revised Data Requirements for Honeybee Toxicity Studies

- Honeybee acute contact toxicity
 - Change from CR to required for all uses
- Honeybee toxicity of residues on foliage
 - Required for TEP when $LD50 < 11 \mu\text{g/L}$ and the use pattern demonstrates exposure
 - Previously required when $LD50 < 1 \mu\text{g/L}$

Typical End-Use Product and Degradate Testing

- Toxicity/Environmental data for TEP/Degradates
 - TEP required for all terrestrial plant testing
 - TEP/Degradate testing conditionally required for aquatic animals
 - Based on use pattern, toxicity, residues



Fat pocketbook mussel



Gopher tortoise

Human Health Toxicity Studies

- Rat oral toxicity
- 2 generation chronic rat
- 90-day sub-chronic rat
- Inhalation (rat/mouse)
- Dermal (rabbit)
- Formulation toxicity studies

Other Sources of Toxicity Information

- Open Literature
 - Peer reviewed
 - Other government agencies
- Internet Sources
 - Chemical-related search engines
- EPA-OPP "One-liner" ecotoxicity and environmental fate database

Other Sources of Toxicity Information

- Registrant generated test to satisfy registration requirements for other countries
 - OECD Studies:
 - Beneficial arthropods
 - Soil microorganisms
 - Formulation/mixture studies
 - Metabolite studies





RISK = Exposure / Effects



Laboratory Environmental Fate Studies

- Aerobic Soil Metabolism - rate of degradation by soil microorganisms
- Hydrolysis - chemical reaction with water forming new molecule (often pH dependent)
- Aqueous Photolysis - breakdown of molecules in water through the absorption of light
- Aerobic and Anaerobic Aquatic Metabolism - rate of metabolism in aqueous environment with and without oxygen.
- Kd and Koc - rate of soil adsorption

Field Environmental Fate Studies

- Field Dissipation - evaluate pesticide mobility, degradation and dissipation under actual use conditions
 - agricultural, aquatic, forestry
- Field Volatility - evaluate pesticide movement when volatilization is concern
- Dislodgeable residue

Chemical/Physical Studies

- Vapor pressure - measure of a chemicals volatility
- Solubility - measure of ability to dissolve in a solvent (water)
- Henry's Law Constant - ratio of vapor pressure to water solubility
- Octanol-water partition coefficient (Kow) - ratio of partitioning in octanol to water

EPA-OPP Exposure Analysis

- Terrestrial:
 - T-REX Residue Model
 - Monitoring Data
- Aquatic:
 - GENEEC
 - PRZM/EXAMS
 - Monitoring Data
- Terrestrial/Aquatic:
 - AgDrift



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Pesticide Use Characterization

- Type of formulation (granule, WP, EC)
- Application rates and crops
- Geographic limitations
- Application method and timing
- Application frequency, intervals and # of applications

Kenaga/Fletcher Nomogram

- Dietary exposure model for liquid applications
- Determines maximum and median concentrations on various food items
- Residue based on application rate and structure of plant/insect
- Residues independent of application method

Model Validation

- Published results comparing field data and Kenaga data
- Short range grass, long grass, leafy crops, and pods values were comparable
- Forage crops and fruit values lower than those reported in literature
- Model modified by EPA OPP to incorporate results from paper

T-REX Input Variables

- Application rate:
 - Liquid applications
 - In furrow/row/bands: row width, spacing, % incorporated
- # of applications
- Application interval
- Half life of active ingredient
- Simulation length
- Avian/mammalian toxicity data

Granular, Bait, and Treated Seed Exposure Applications

- In-furrow, drill, or shanked applications assume 1% of granules, bait or seed unincorporated
- Incorporated banded treatments assume 15% material unincorporated
- Broadcast treatment w/o incorporation assumes 100% of granules, bait, seed unincorporated

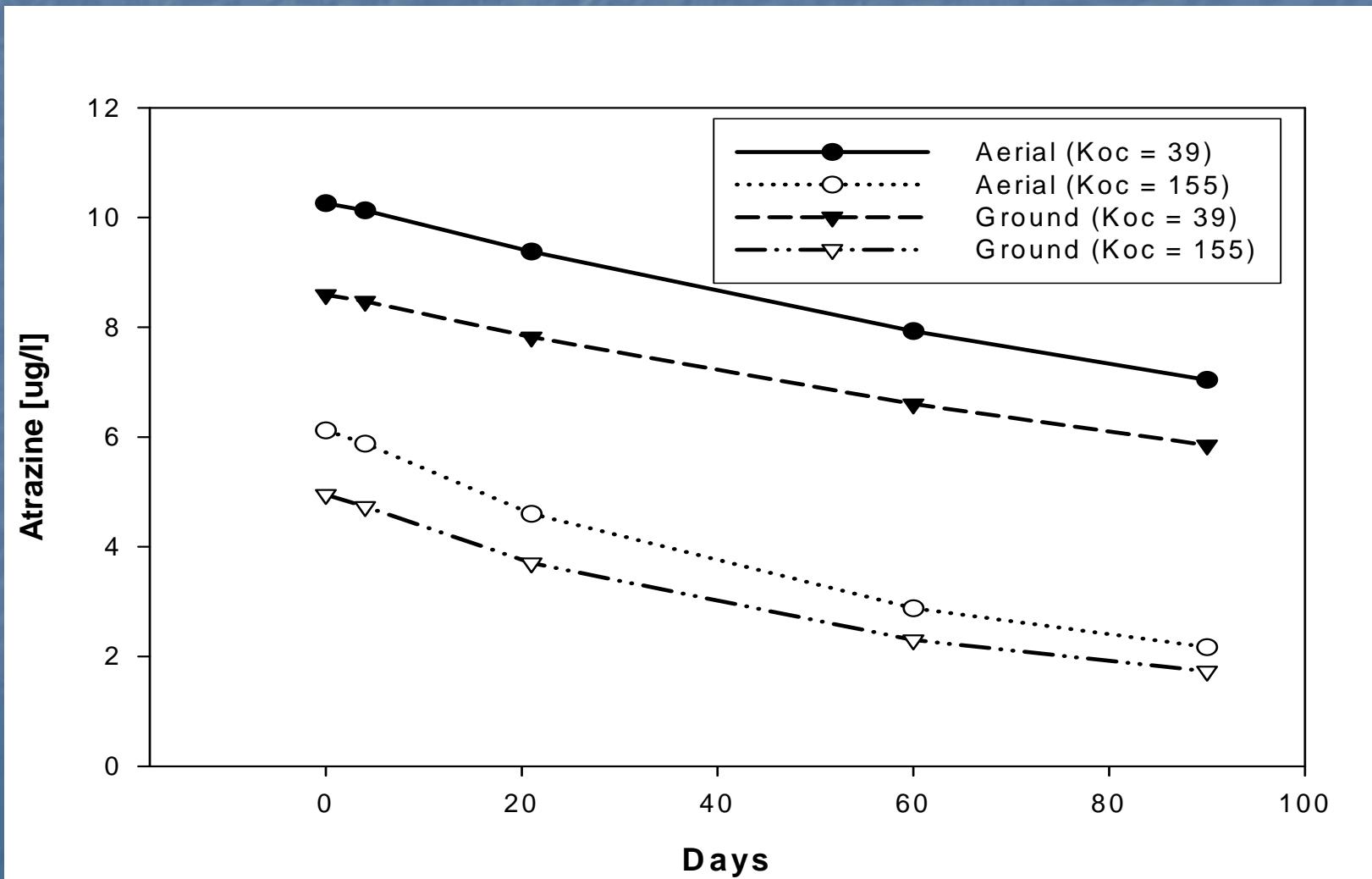
Terrestrial Plant Exposure Analysis

- TerrPlant 1.2.2
- Runoff based on solubility
- Drift based on standard assumptions for ground (1%) and aerial (5%) applications
- Scenario based on runoff from 1-ha to adjacent hectare for terrestrial plants
- Scenario based on runoff from 10-ha to adjacent hectare for semi-aquatic plants

GENEEC2 Input Parameters

- Application Rate
- Koc
- Application Method
- # of applications
- Application Interval
- Depth of Incorporation
- Aerobic Aquatic Metabolism
- Solubility
- Aquatic Photolysis
- Hydrolysis
- Aerobic Soil Metabolism

Effect of Application Method and Koc on Atrazine GENEEC2 EEC's



GENEEC2 Aquatic Screening Model Assumptions

- Applications occur on a 10-ha field that drains into a 1-ha pond 2-m in depth
- No buffer between the pond and treated field
- Runoff is from a single six inch rainfall event over a 24-hour period
- Soil type is considered a high runoff soil
- Drift contribution:
 - Based on contributions from AgDrift

AgDrift Model Summary

- Model based on field and wind tunnel studies to determine drift from different application methods
- Simulates ground, orchard air blast and aerial applications
- Predicts off-site terrestrial and aquatic concentrations into standard or user-defined waterbodies

Factors that affect drift

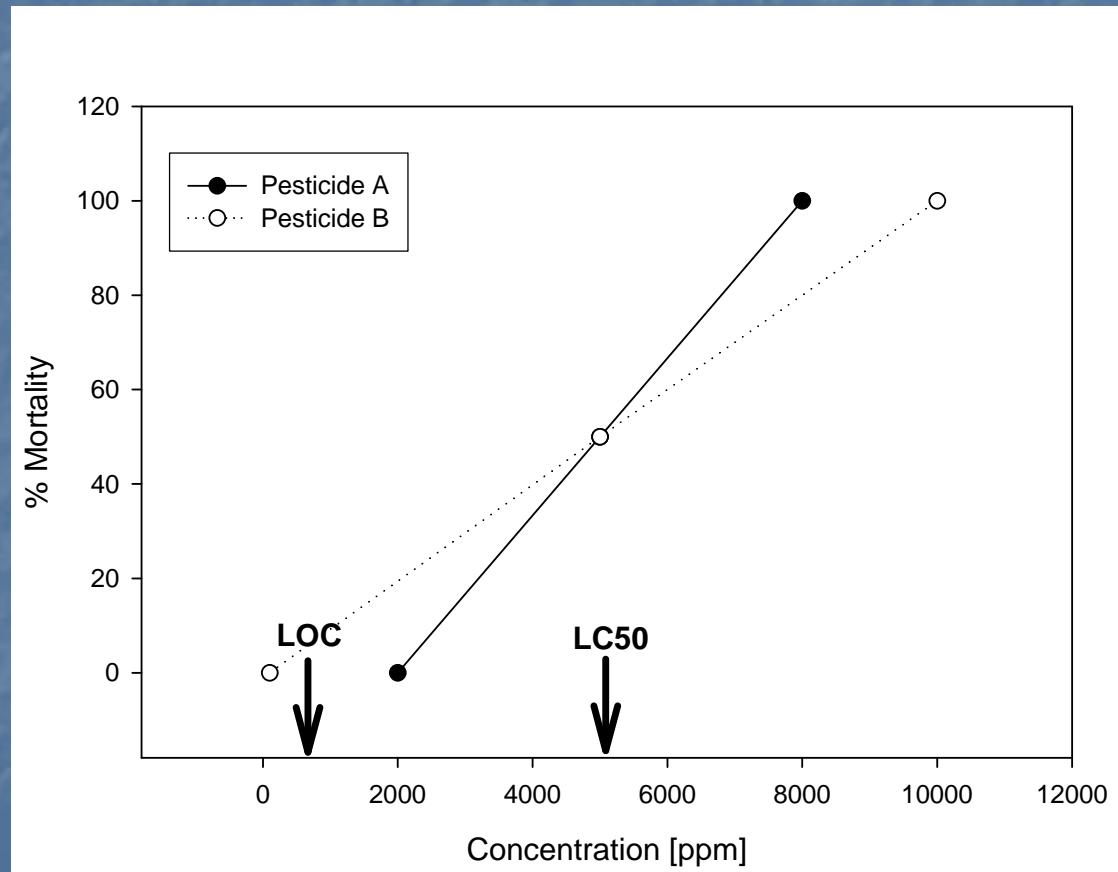
- Droplet size distribution
- Wind speed/direction
- Release height
- Application method
- Environmental factors (temperature, humidity)

EPA OPP Risk Assessment Methods

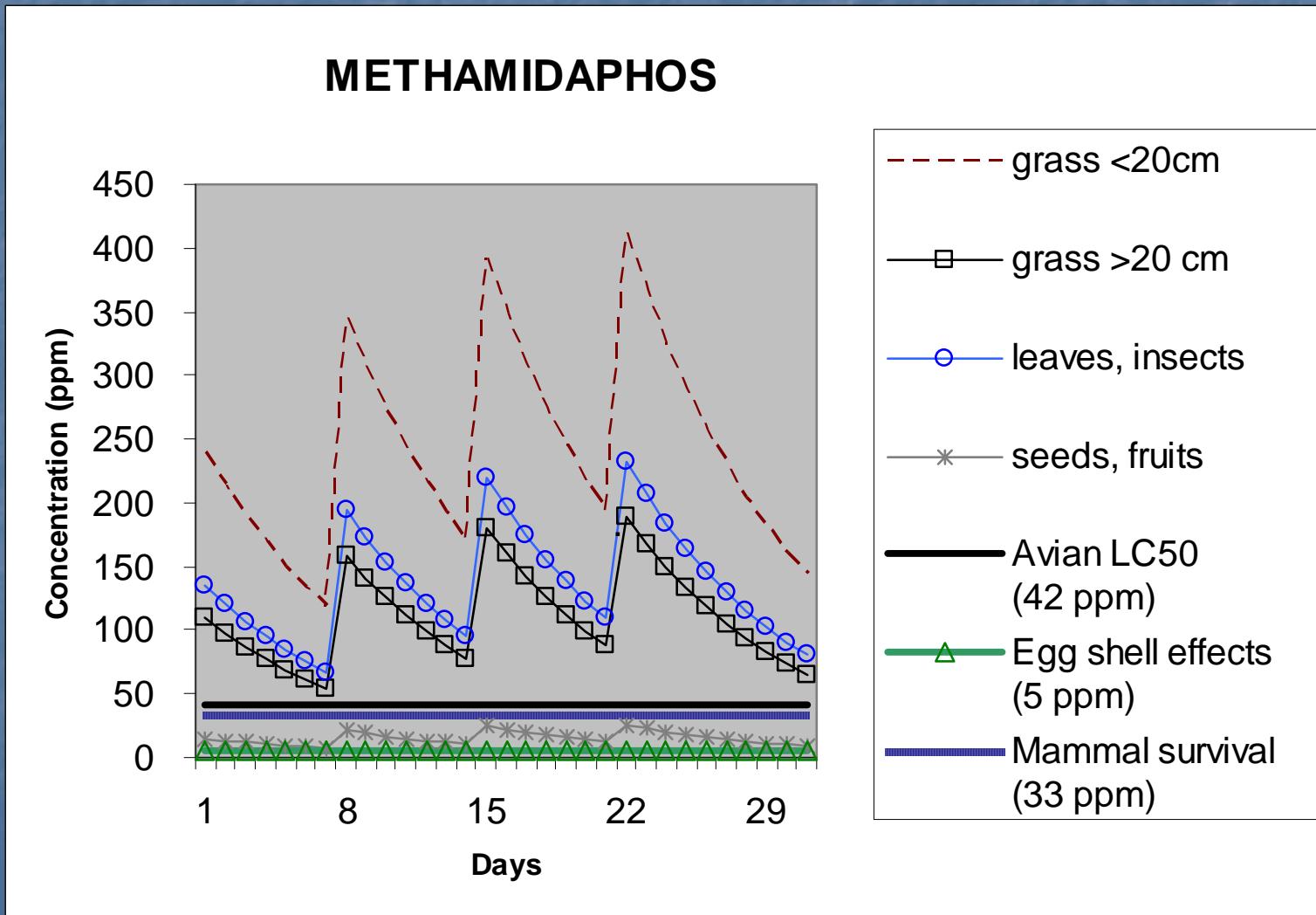
Risk Presumption for Direct Effects to Terrestrial Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC/LC50 or LD50/ft ²	0.5
Acute Restricted Use	EEC/LC50 or LD50/ft ²	0.2
Acute Endangered Species	EEC/LC50 or LD50/ft ²	0.1
Chronic RQ	EEC/NOEC	1

LOC and Dose Response



Nomogram Results for Multiple Insecticide Applications



Risk Presumption for Direct Effects to Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic RQ	EEC/NOEC	1

Risk Presumption for Direct Effects to Terrestrial Plants

Risk Presumption	RQ	LOC
Terrestrial and semiaquatic plants		
Acute high risk	EEC/EC25	1
Acute ES	EEC/NOEC	1
Aquatic plants		
Acute high risk	EEC/EC50	1
Acute ES	EEC/NOEC	1

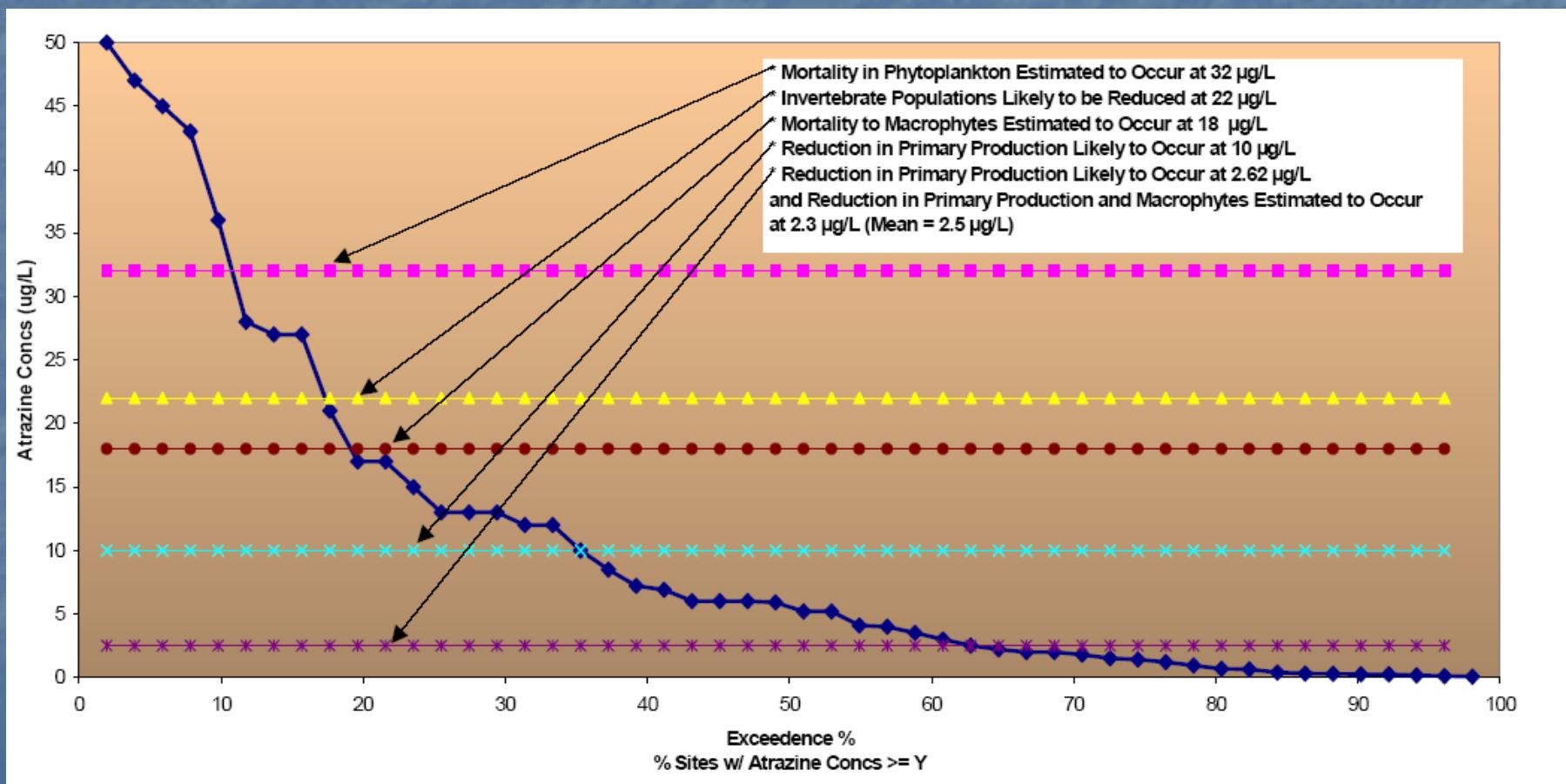
Indirect Effects Characterization for Animal Taxonomic Groups

- If $RQ < ES$ LOCs: Assumption is no indirect effects to listed species
- If $RQ > ES$ LOCs:
 - Acute:
 - Dose response relationship
 - Further evaluate geographical and temporal exposure
 - Chronic:
 - Evaluate nature of endpoint and species profile
 - Further evaluate geographical and temporal exposure

Exceedance of LOCs in the Screening Assessment

- Request additional effects data
- Request additional environmental fate data
 - Ex. aerobic aquatic metabolism, foliar dissipation
- Use higher tier modeling/monitoring to refine exposure analysis
- Probabilistic risk assessment
- Conduct species specific risk assessment

USGS Mid-Western Stream Sampling for 1995 Post-Application Atrazine Concentrations for 50 streams



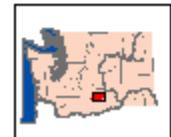
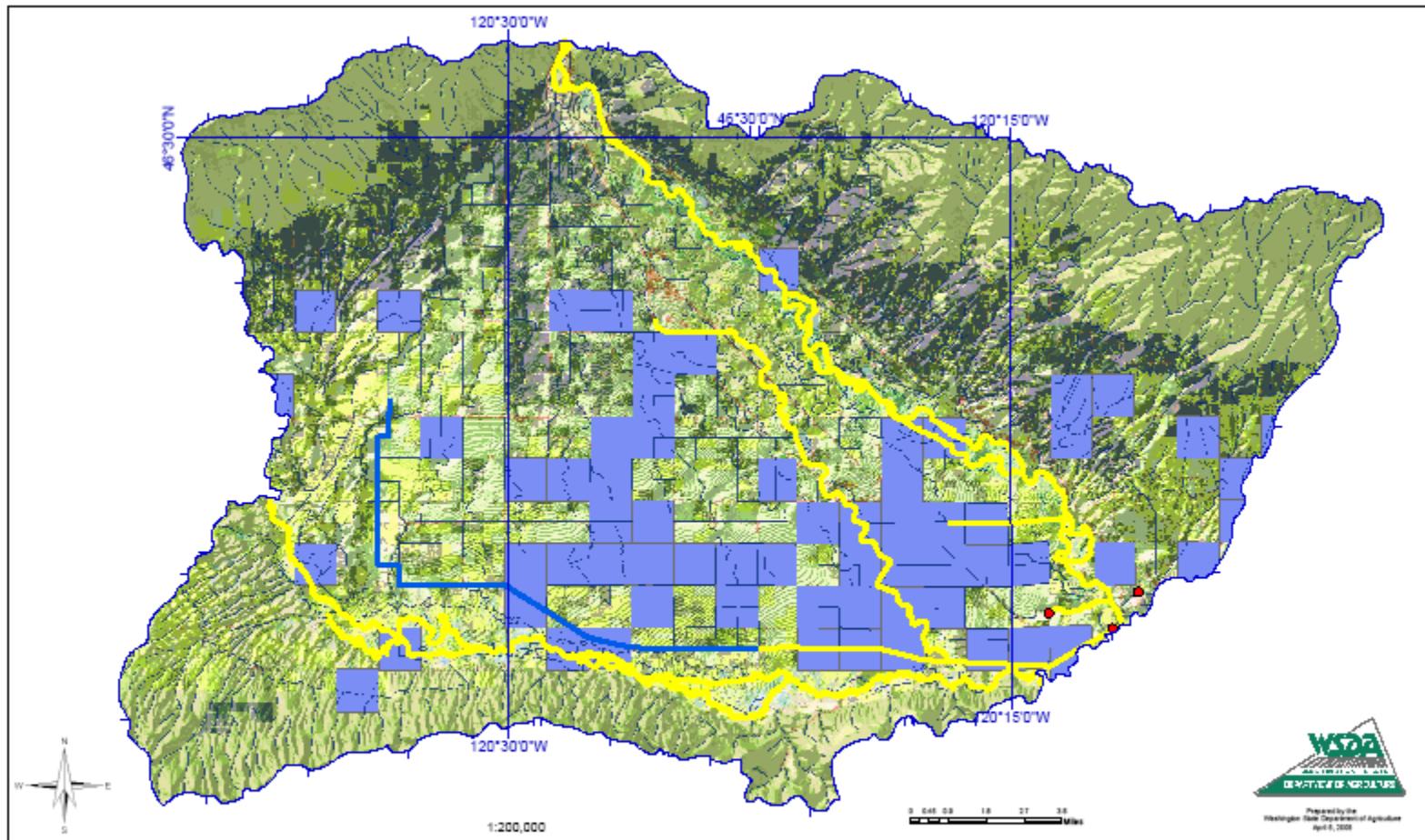
Information Used in Species-Specific and Habitat Specific Assessments

- Co-occurrence of commodities and listed species
 - LOCATE database
 - FIFRA Endangered Species Task Force (FESTF)
- Biological requirements and habits of listed species
 - Service documents (ie recovery plans, listing rules)
- Refined exposure estimates/monitoring data
- Geographic features that preclude exposure
- Incident information
- Local use practices

HUC 170300304

Washington State
Middle Columbia Steelhead, Metolachlor-treated Crops and Metolachlor detections (1995-2005)

Lower Toppenish Creek Watershed



* NOAA Fisheries: Federal Register, Vol. 70, No. 24, Feb. 7, 2005.

Risk Mitigation for Fish and Wildlife

- Eliminate use on specific crop
- Buffer zones
- Time of application
- Application method and rates
- Number of applications
- Spray drift best management practices