Environmental Risk Assessment

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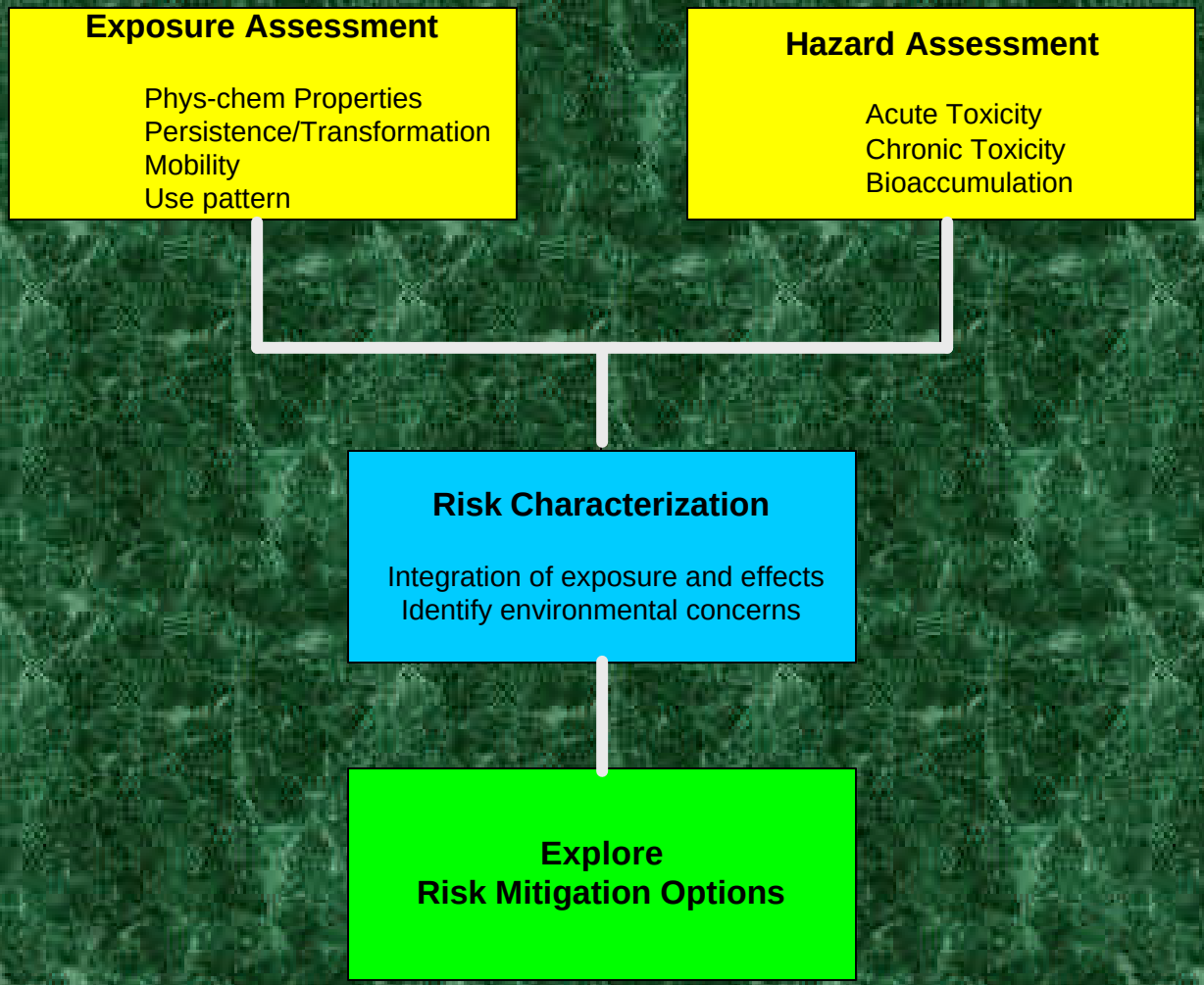
Overview:
Risk Assessment Framework



Exposure Assessment

Physico-Chemical Properties

- Summary:
  - Solubility in water
  - Vapour pressure
    - Henry's Law Constant
  - Octanol/water partition coefficient (K_{ow})
  - Dissociation constant (pK_a)
  - UV-visible adsorption spectrum

Analytical Methodology

- Soil (R)
- Sediment (R)
- Water (R)
- Biota (R)

Abiotic Transformation

- Hydrolysis (R)
- Phototransformation
  - Soil (R)
  - Water (R)
  - Air (CR)

Biotransformation
(20-30°C)

- Soil
  - Aerobic (R)
  - Anaerobic (flooded) (CR)
- Water
  - Aerobic (R)
  - Aerobic water/sediment (CR)
  - Anaerobic sediment/water (R)

Mobility

- Adsorption/desorption

Or

- Soil column leaching

Or

- Soil thin layer chromatography (R)

- Volatilization (CR)

NAFTA Technical Working Group on Pesticides

- Harmonization of Data Requirements and Test Protocols for Pesticide Registration

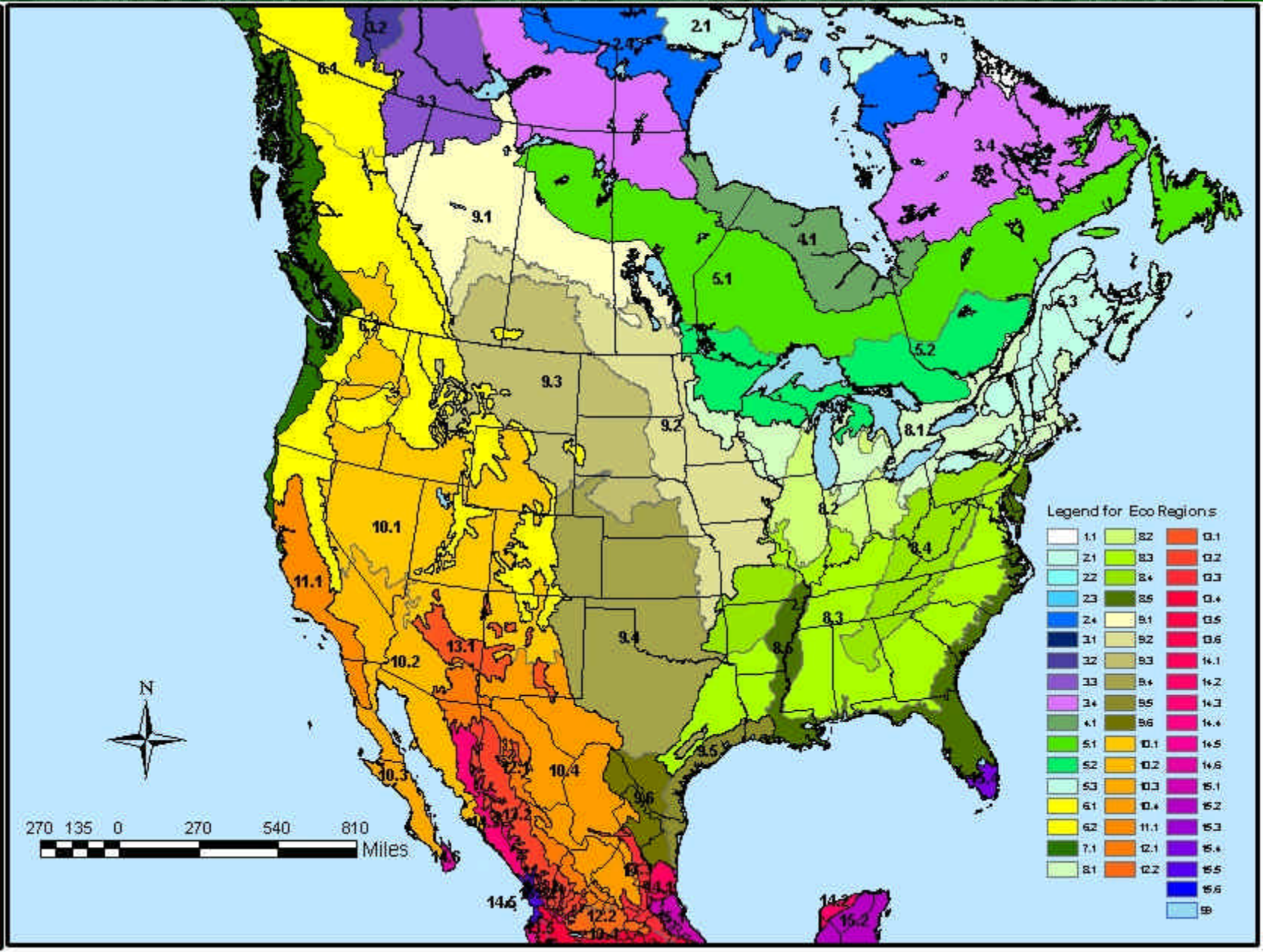
Field Dissipation –Terrestrial (R)

- Demonstrate fate and mobility at sites that are representative of areas of use in Canada

PMRA/U.S. EPA Workshop on Pesticide Field Dissipation Study Guidelines

- e.g., Number of field study sites/site selection criteria
- Ecoregions

North American EcoRegions



Field Dissipation – Aquatic (CR)

Exposure Assessment

- Determine:
  - Concentration and persistence of pesticide in different environmental media
  - Concentration to which non-targets exposed
  - Duration of exposure

Estimated Environmental Concentrations (EECs) in SOIL:

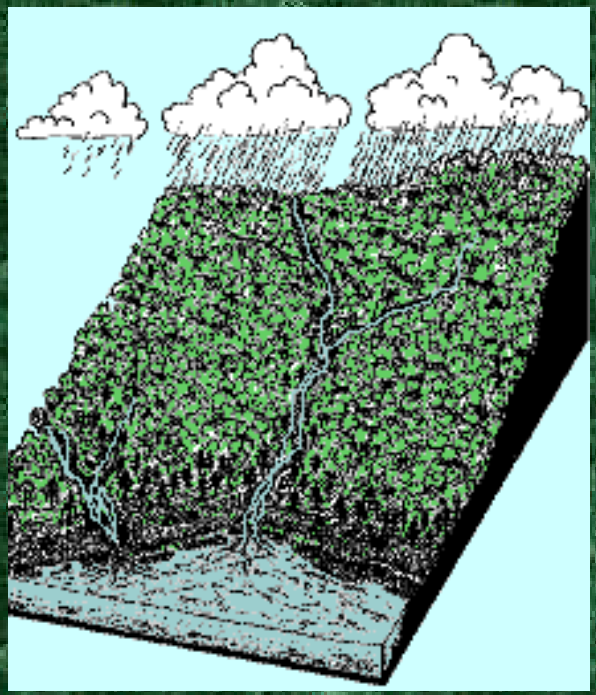
- g ai/kg soil (15 cm depth)

Estimated Environmental Concentrations (EECs) in WATER:

- g ai/L water (30 cm depth – agriculture)

EAD Water Modeling Group

- Determine EEC's in drinking water supplies
- PRZM/EXAMS
- LEACHM
- Develop Canadian scenarios for estimation of EEC's in surface waters & ground water



Other Estimates of Exposure:

- Honeybees and other beneficial terrestrial invertebrates
  - Labeled application rates

Estimated Environmental Concentrations (EECs) in FOOD:

- Birds and mammals
- Dosages consumed in contaminated food items estimated using Hoerger and Kenaga (1972) nomogram and modifications by Fletcher et al. (1994)

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For a given application rate, calculate concentration on vegetation and other food sources

Name of pesticide or ai >>>> **Acetamiprid**

ENTER application rate >>>> **428.4 g ai/ha**

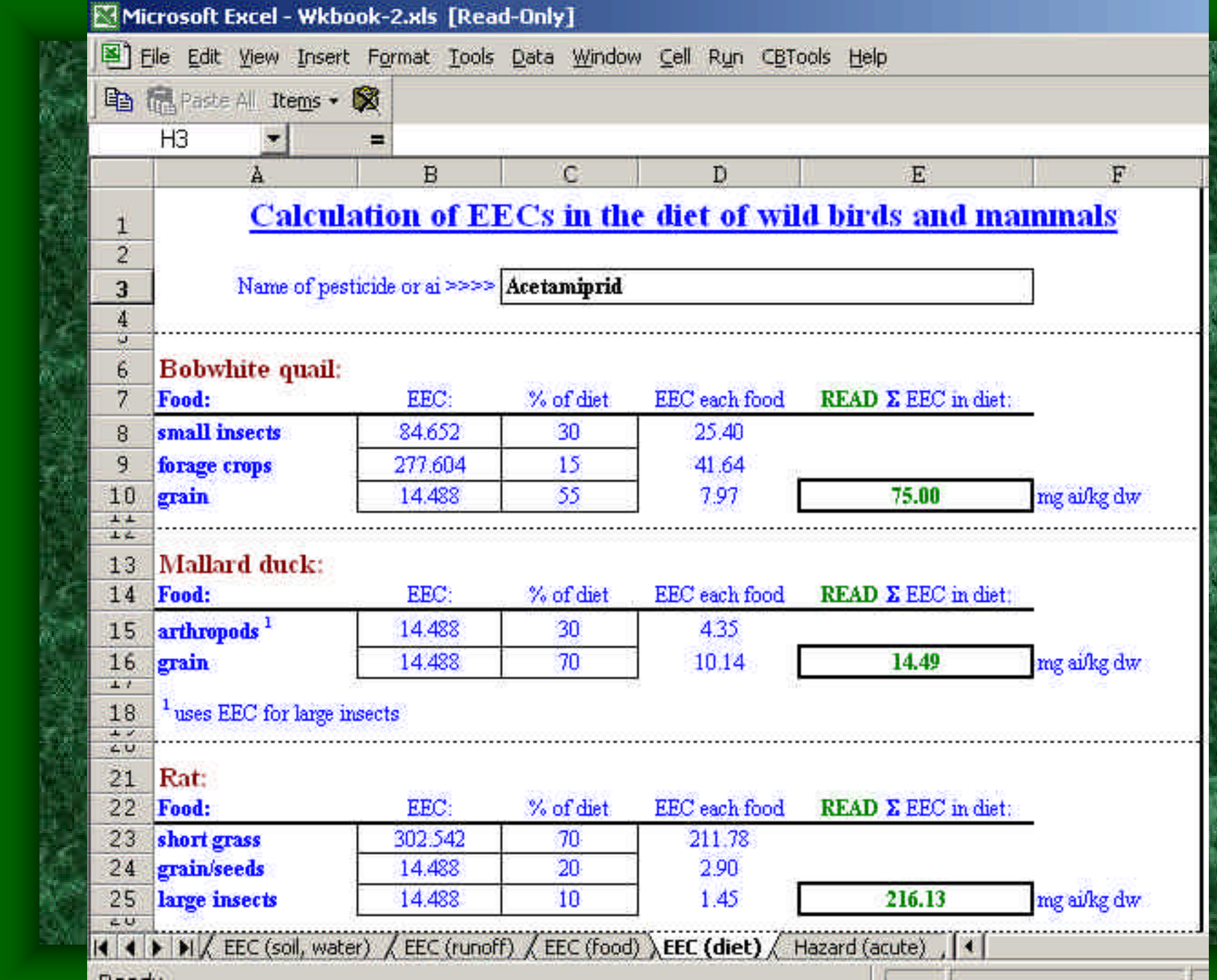
Environmental Compartment	Concentration fresh weight (mg ai/kg)	fresh/dry weight ratios	READ **Concentration dry weight (mg ai/kg)**
short range grass	91.6795	3.3	**302.5424**
leaves and leafy crops	47.9806	11	**527.7871**
long grass	41.9831	4.4	**184.7257**
forage crops	51.4082	5.4	**277.6043**
small insects	22.2768	3.8	**84.6517**
pods with seeds	4.5839	3.9	**17.8771**
large insects	3.8128	3.8	**14.4885**
grain and seeds	3.8128	3.8	**14.4885**
fruit	5.7406	7.6	**43.6282**

NOTES:

1. Results should be quoted to **no more than** 3 significant figures.
2. EECs based on correlations in Hoerger and Kenaga (1972) and Kenaga (1973), and modified according to Fletcher et al. (1994)

EEC (soil, water) | EEC (runoff) | **EEC (food)** | EEC (diet) | Hazard (acute)

Ready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Calculation of EECs in the diet of wild birds and mammals
Name of pesticide or ai >>>> Acetamiprid
Bobwhite quail:
Food: EEC: % of diet EEC each food READ Σ EEC in diet:
small insects 84.652 30 25.40
forage crops 277.604 15 41.64
grain 14.488 55 7.97
75.00 mg ai/kg dw
Mallard duck:
Food: EEC: % of diet EEC each food READ Σ EEC in diet:
arthropods [1] 14.488 30 4.35
grain 14.488 70 10.14
14.49 mg ai/kg dw
[1] uses EEC for large insects
Rat:
Food: EEC: % of diet EEC each food READ Σ EEC in diet:
short grass 302.542 70 211.78
grain/seeds 14.488 20 2.90
large insects 14.488 10 1.45
216.13 mg ai/kg dw
EEC (soil, water) EEC (runoff) EEC (food) EEC (diet) Hazard (acute)

Hazard Assessment – Characterization of Ecological Effects

Hazard Assessment

- Based on accepted protocols with surrogate test species (acute and/or chronic)
- Determination of effects endpoints and dose response (e.g., LD_{50}, NOEC, EC_{25})
- Identify sensitive organisms and predict adverse effect(s) on non-target organisms

Non-Target Terrestrial Organisms

Mammals

- Mammalian toxicology studies reviewed by HED

Birds:
Anas platyrhynchos - mallard

Colinus virginianus
- bobwhite quail

Reproduction

Earthworm - *Lumbricus terrestris*

Apis mellifera – honey bee

Predators and Parasites - *Trichogramma* – parasitic wasp

Hippodamia convergens – Lady Bird Beetle, adult

Lady Bird Beetle larvae

Chrysoperla rufilabris - Lacewing larvae

Orius sp. - Minute Pirate Bug

Poecilus sp. - ground beetle

Terrestrial Vascular Plants (R)

Non-Target Aquatic Organisms

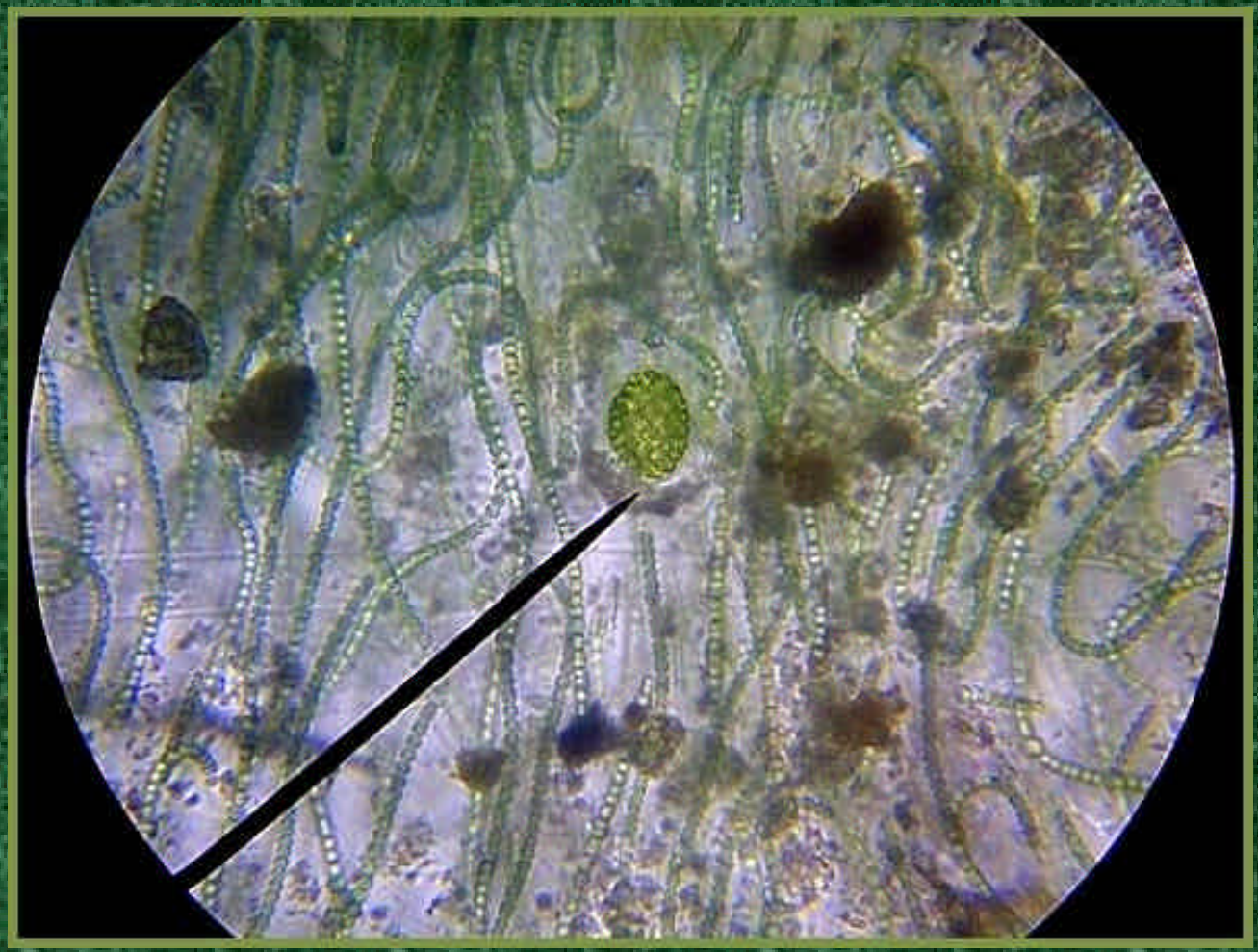
Daphnia magna – Freshwater Crustacean

Warm Water Fish – *Lepomis macrochirus* - Bluegill Sunfish

Cold Water Fish - *Oncorhynchus mykiss* - Rainbow Trout

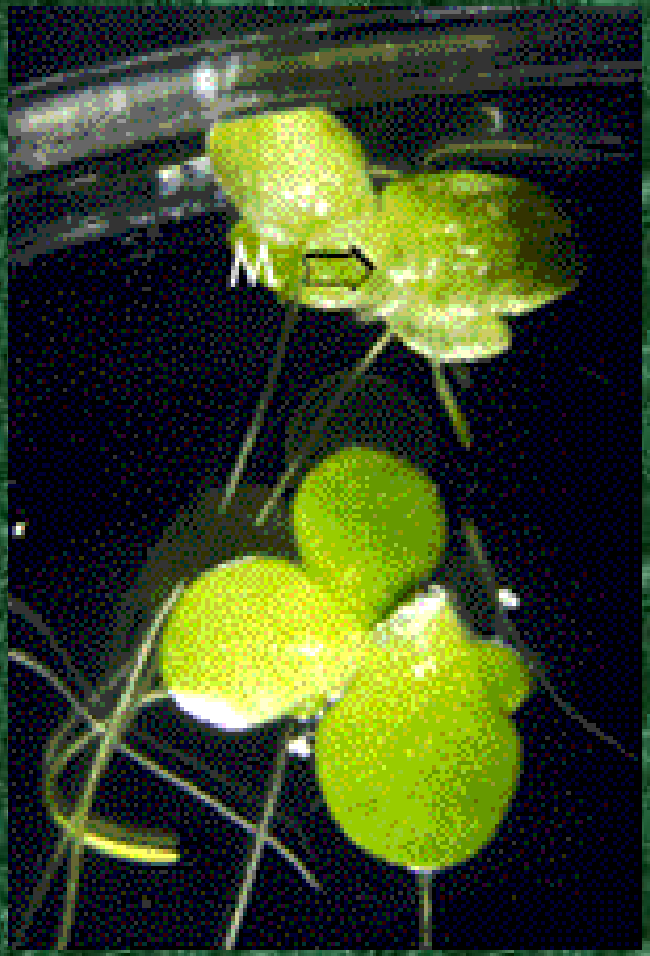
Freshwater Algae – 3 Species *Selenastrum capricornutum* – Green Alga

Anabaena sp. - Blue-green Alga



Aquatic Vascular Plant
Lemna gibba

- Floating aquatic macrophyte



Marine, Estuarine Organisms (CR)

- Acute crustacean
- Mollusk embryo larvae **OR** shell deposition
- Chronic (mollusk or crustacean)
- Algae
- Fish
  - Acute
  - Salinity challenge

Risk Characterization

Risk Characterization

- Exposure:
  - Expected Environmental Concentration (EEC)
  - Use Pattern
- Effects:
  - Most sensitive test species from each group
  - No-Observable-Effect Concentration (NOEC **or** 0.1 x LC_{50})

Risk Characterization (cont'd)

- Tier I: Deterministic
  - Risk Quotient (RQ) = [EEC / Toxicity Endpoint]
  - (where toxicity endpoint is NOEC, NOEL **or** 0.1 x EC_{50}, LC_{50})
    - RQ greater than 1 indicates environmental concern may exist
    - RQ less than 1 indicates margin of safety

Risk Characterization, Acute Toxicity – Birds and Mammals

- Use EEC in diet, body weight, food consumption, and toxicity endpoints to determine –
- Number of days of intake of the a.i. by a wild bird/mammal equivalent to the dose that ellicited a response from the lab population.

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C9 = 0.05

	A	B	C	D	E
7	ENTER *species* tested >>		mallard		
8	ENTER citation (author, date) >>				
9	ENTER FC (food consumption, control group) >>		0.05 kg dw/ind/d		
10	ENTER BWI (body weight per individual, control group) >>		1.2 kg bw/ind		
11	ENTER EEC[1] (expected environmental conc.) >>		524 mg ai/kg dw		
12	ENTER LD_{50} >>		1000 mg ai/kg bw		
13	ENTER NOEL >>		200 mg ai/kg bw		
16	DI (daily intake) = [FC*EEC] >>		2.62E+01 mg ai/ind/d		
18	$LD_{50(ind)}$ = [LD_{50}*BWI] >>		1.20E+03 mg ai/ind		
20	$NOEL_{(ind)}$ = [NOEL*BWI] >>		2.40E+02 mg ai/ind		
22	The number of days[2] of intake of ai by a wild mallard				
23	equivalent to the dose administered by gavage that killed 50% of				
24	individuals in the lab population [$LD_{50(ind)}$ / DI] >>		4.58E+01 days		
26	Maximum number of days[2] of intake of ai by a wild mallard				
27	equivalent to the dose administered by gavage that had no-observable-				
28	effect on the lab population [$NOEL_{(ind)}$ / DI] >>		9.16E+00 days		

Hazard (acute) | Hazard (dietary, repro.) | Hazard (soil, aquatic) | Buffe

Probabilistic Risk Assessment

- Tier II and above:
  Refined Environmental Risk Assessment
  - Probabilistic risk assessment methodologies
  - Refined exposure assessments
  - Better characterize risks to non-target organisms
  - U.S. EPA

Risk Mitigation

Ground Buffer Zones

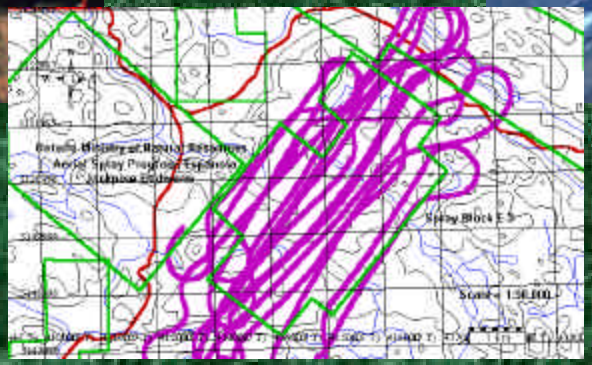
- Nordby and Skuterud 1972 (ground boom)
- Ganzelmeier et al. 1995 (airblast)

Buffer Zone Statements

- A buffer zone of **20 meters** (ground boom sprayer) or **30 meters** (air-blast/vineyard sprayer) is required from sensitive aquatic habitats
- Downwind

Aerial Buffer Zones

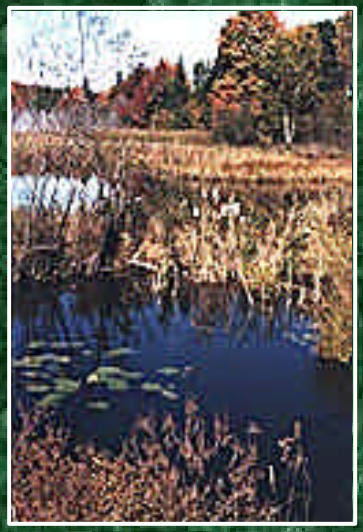
- AgDrift model
- FPT/PMRA Buffer Zone Working Group

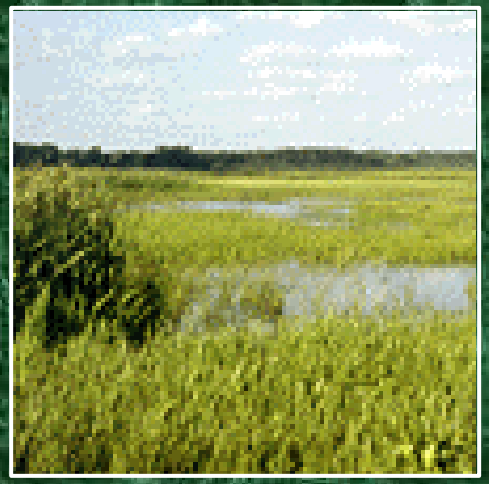


Other Risk Mitigation Options

- e.g., Decreased application rates (determined in conjunction with efficacy review)
- Reduce number of applications per season
- Precautionary label statements

To Protect the Environment





Questions