Limitations and Uncertainty of Risk Assessment

(a.k.a. “All models are wrong, some are useful”)

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ECS 3119 – Pesticides and Fish & Wildlife Resources
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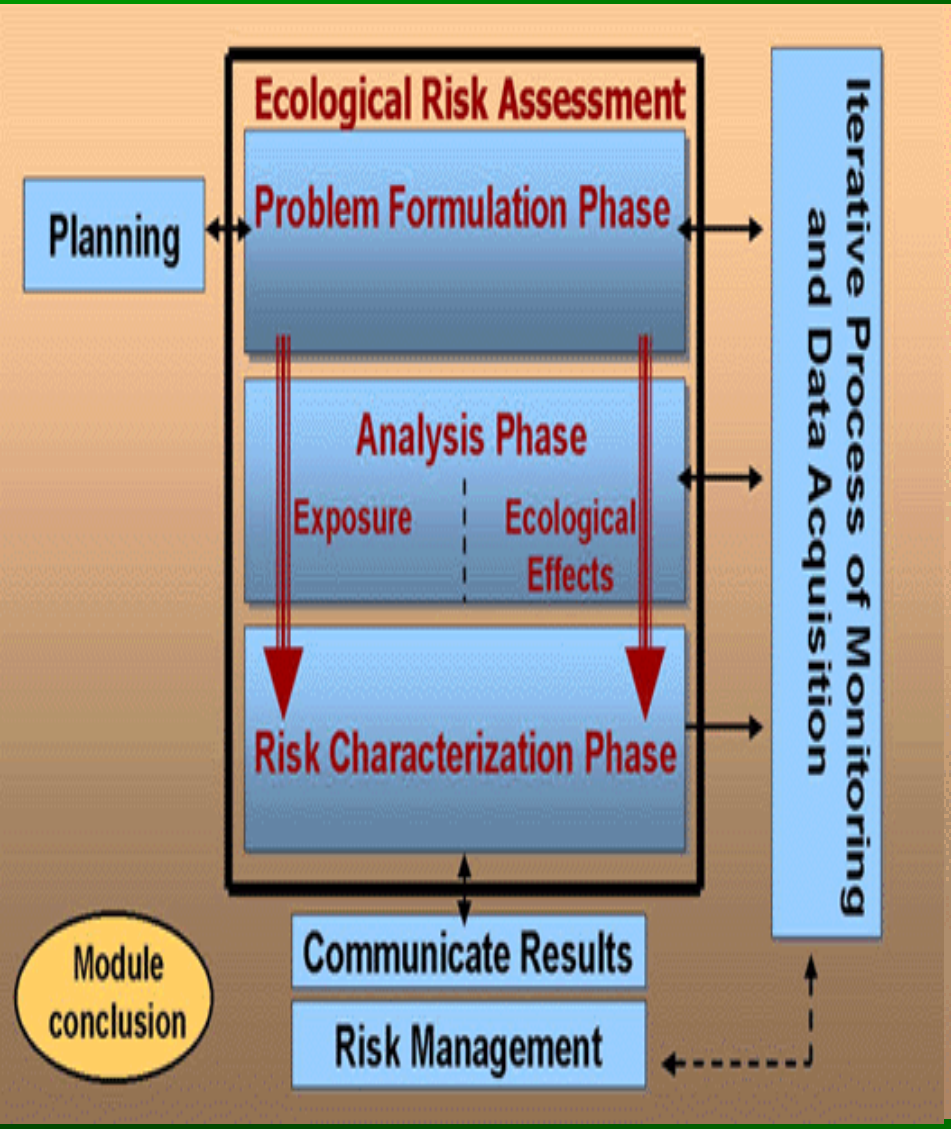
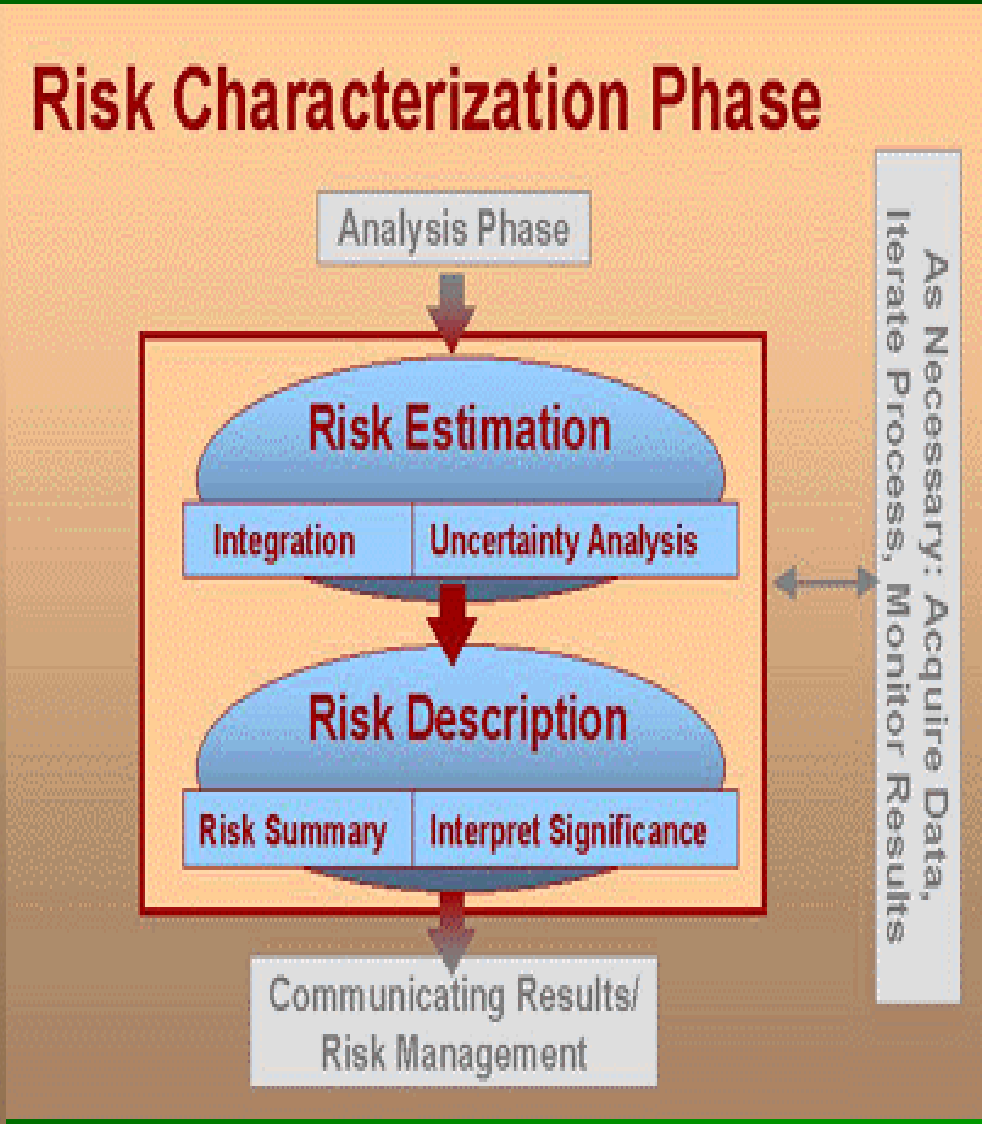
Risk Assessment & Characterization





Ecological Risk Assessment

What is risk?

The probability of an adverse effect to an ecological entity

What is ecological risk assessment?

The determination of the probability that an adverse effect will result from a defined exposure (NRC 1993)

Variability refers to observed differences attributable to ***true heterogeneity*** or diversity in a population or exposure parameter.

Examples of variability:

- physiological variation
- genetic differences
- nutritional status
- size
- feeding rates
- environmental conditions

Variability is usually not reducible by further measurement or study (but can be better characterized).

Uncertainty refers to a lack of information about specific factors, parameters, or models.

Example of uncertainty:

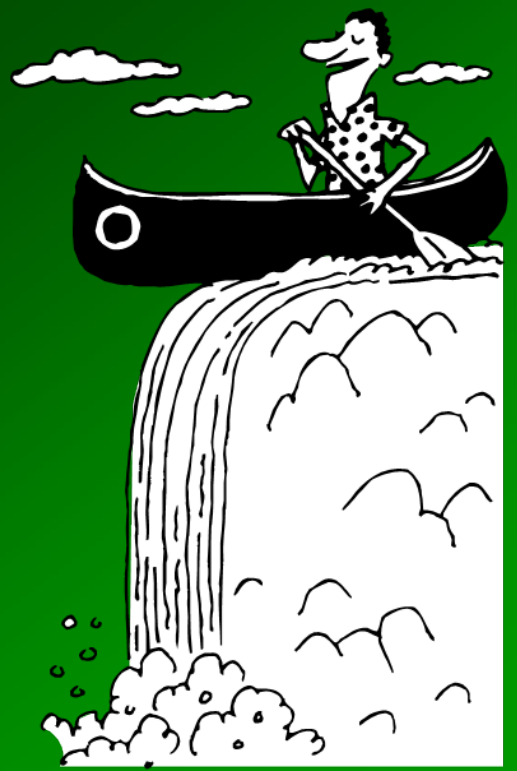
- concentration in the environment ("dose")
- duration of the "dose"

Uncertainty includes:

- *parameter uncertainty* (measurement errors, sampling errors, systematic errors),
- *model uncertainty* (uncertainty due to necessary simplification of real-world processes, miss-specification of the model structure, model misuse, use of inappropriate surrogates)
- *scenario uncertainty* (descriptive errors, aggregation errors, errors in professional judgment, incomplete analysis)

Ignorance

Ignorance refers to being destitute of knowledge or the lack of knowledge.



The Screening Level Assessment

Advantages

- "The principal advantages of the quotient method are that it is simple and quick to use and risk assessors and managers are familiar with its application. It provides an efficient, *inexpensive means of identifying high- or low-risk situations* that can allow risk management decisions to be made without the need for further information."

(U.S. EPA, 1998 Guidelines for Ecological Risk Assessment)

Current Method of Addressing Uncertainty in Ecological Risk Assessments

- Many of the uncertainties associated with effects analysis are not addressed in a typical section 3 registration package
  - Formulated product, mixtures, and degradates (all)

- EPA uses a screening process that utilizes upper bound estimates for exposure as well as uncertainty factors in the ERA process

History of Uncertainty Factors

- Originally established in 1945
- Convenient to use in the absence of data
- Have changed little over time
- Designed to be used until data were generated
- Have become a crutch

Use of Uncertainty Factors/Levels of Concern in Risk Assessments

- *Proposed UF for endangered/non-endangered species:*
  - Species w/n genus: 10
  - Genus w/n family: 30
  - Families w/n order: 60
  - Orders w/n class: 100
  - Classes w/n phylum: 1000
  - T&E species: 20

Source: Calabrese and Baldwin, 1993. Performing Ecological Risk Assessments

UF Applied to Pesticide Risk Assessments

- *Using currently recommended UF results in impractical applications for pesticide risk assessments with T/E species (bull trout)*
  - Ex. Standard fish species (rainbow trout acute)

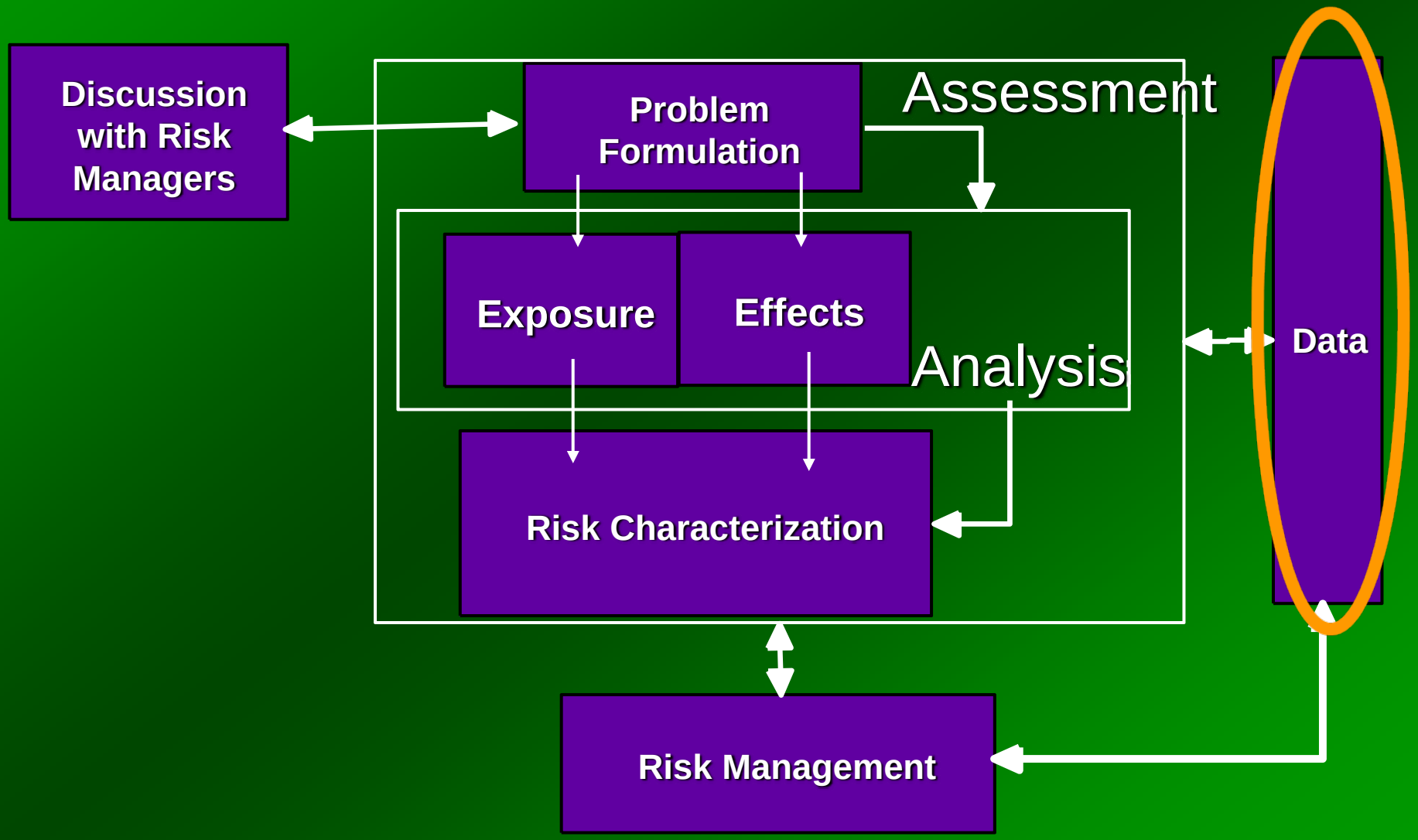
• Different genus w/n same family	30
• Acute lethality to chronic NOAEL	100
• T&E species	20
• Cumulative UF	60,000

Summary

- Risk assessment is ripe with both variability and associated uncertainty

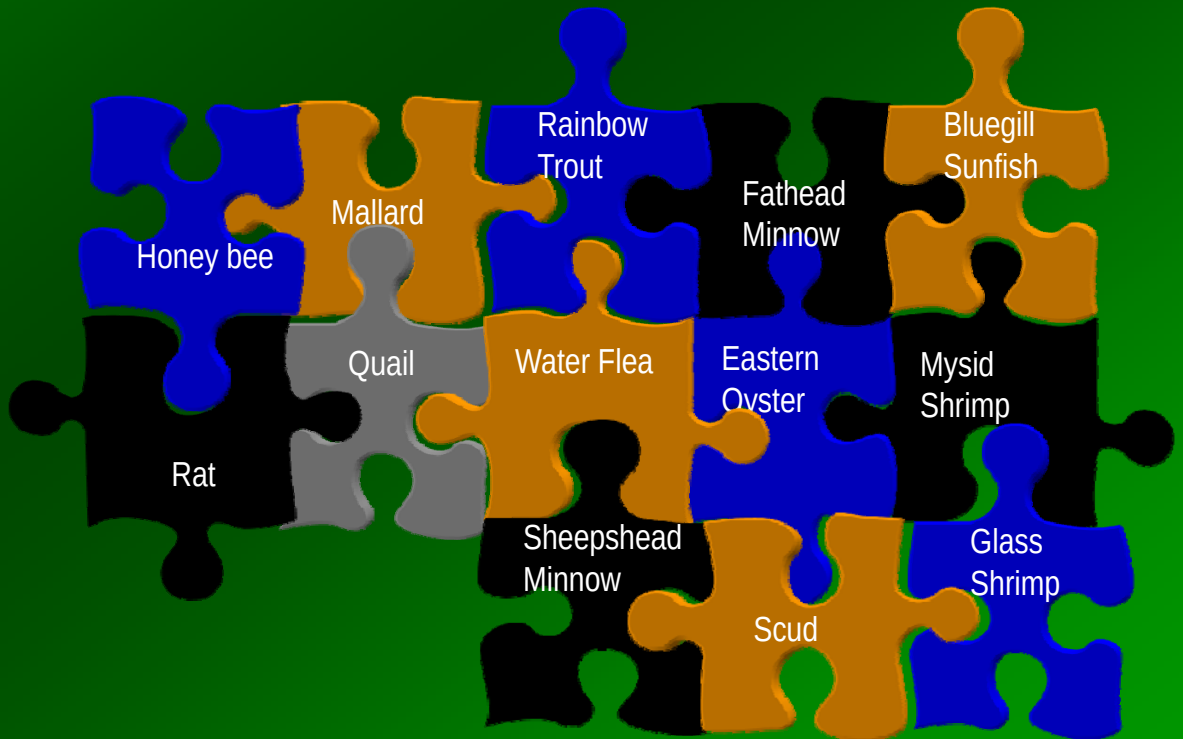
- ERA must go beyond the use of uncertainty factors and generate the data necessary to achieve T/E species conservation, population level effects, etc.

ERA Paradigm



Toxicity Data Requirements

- Tests required to evaluate effects on non-target (surrogate) organisms are arranged in hierarchical or tier system.



Types Of Ecological Data

- *Major taxa tested include:* algae, vascular plants, insects, crustaceans, mollusks, fishes, birds, & small mammals.

- *Important taxa that EPA generally has little or no data on include:* reptiles, amphibians, protozoans, sponges, coelenterates, and flat, round and segmented worms, fungi and numerous other plant groups

Number of Species Tested

Of the more than 1.3 million animal species known in the world, EPA generally has acute toxicity data on perhaps 15 species for new chemicals and perhaps 50 species for older chemicals. For herbicides, EPA may only have 15 tested species of plants.

This limited amount of data is used to predict toxicity levels (mortality generally) to a much larger number of potentially exposed species in a pesticide use site.

Some General Assumptions

- 15 species of plants are used to indicate sensitivity of entire plant kingdom
- 3 or 4 species of invertebrates are used to indicate sensitivity of 1 million species
- 1 insect specie to represent over 80,000
- 2 – 3 species of fish represent 22,000 fish and 4000 species of amphibians
- 2 species of bird represent 9000 species of birds and 6500 species of reptiles

Chronic Data Assumptions

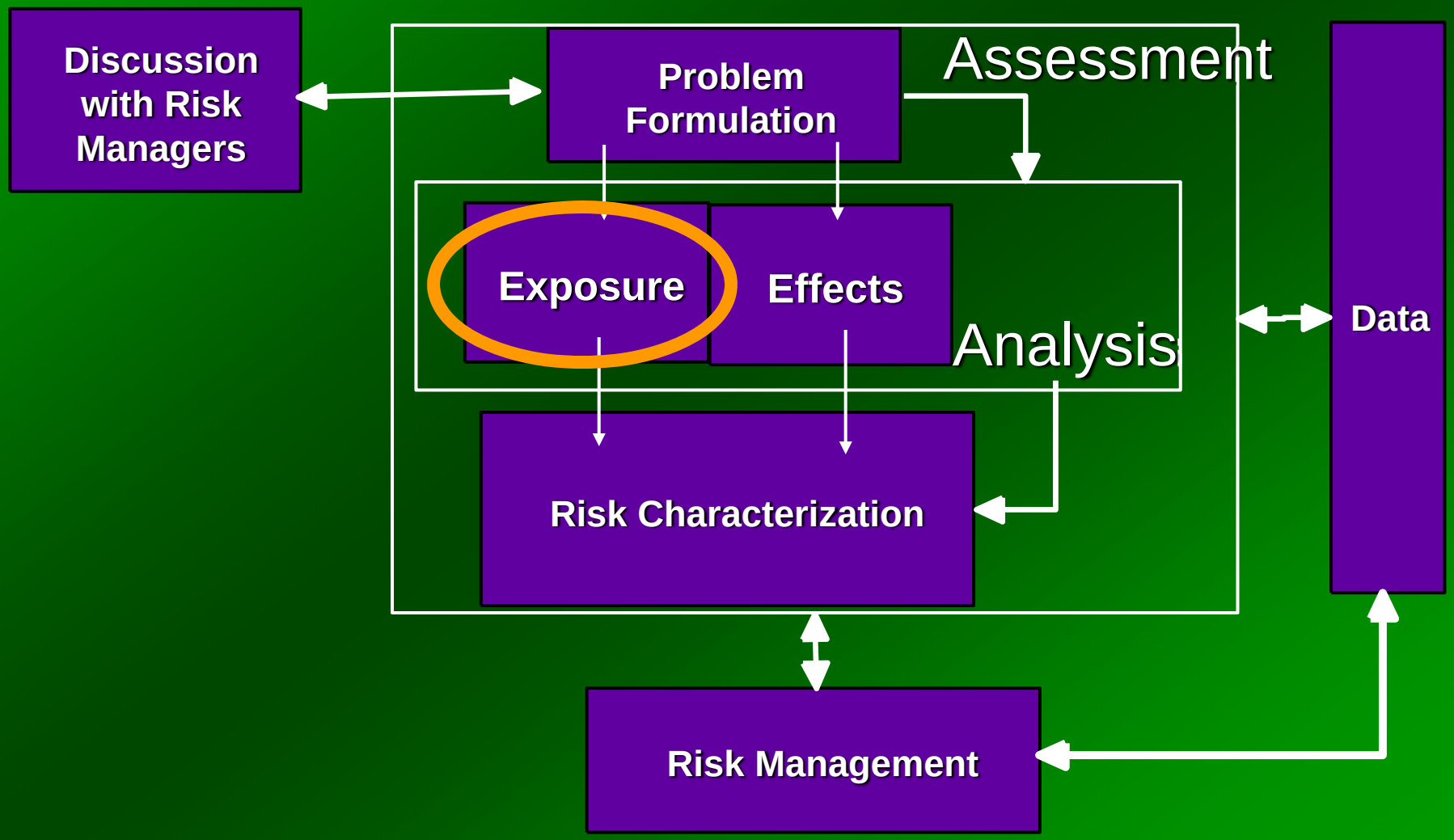
- 2 species of birds, 1 - 2 species of crustacea, and 1 – 2 species of fish to represent sublethal or chronic sensitivity of all species in these groups

- Limited number of chronic endpoints (generally growth and reproduction) are statistically analyzed under controlled laboratory conditions and may well overlook other potentially adverse chronic or sublethal effects

Data-related Uncertainty

- Interspecies extrapolations
- Extrapolation to listed/other species
- Simplification of food chain models
- Life history information
- Natural variability in ecosystems

ERA Paradigm



Application of Exposure Models

- Mathematical representation that corresponds to the understanding of the ecological system under review and the transport of pesticides to those systems
  - *various types of process models used to characterize risk*

Application of Exposure Models cont…

- Caution with the use of these models
  - Assumption driven
  - Robustness of the input data
  - Validation of output
  - May suggest a higher degree of certainty than is fitting

- *Remember…..*

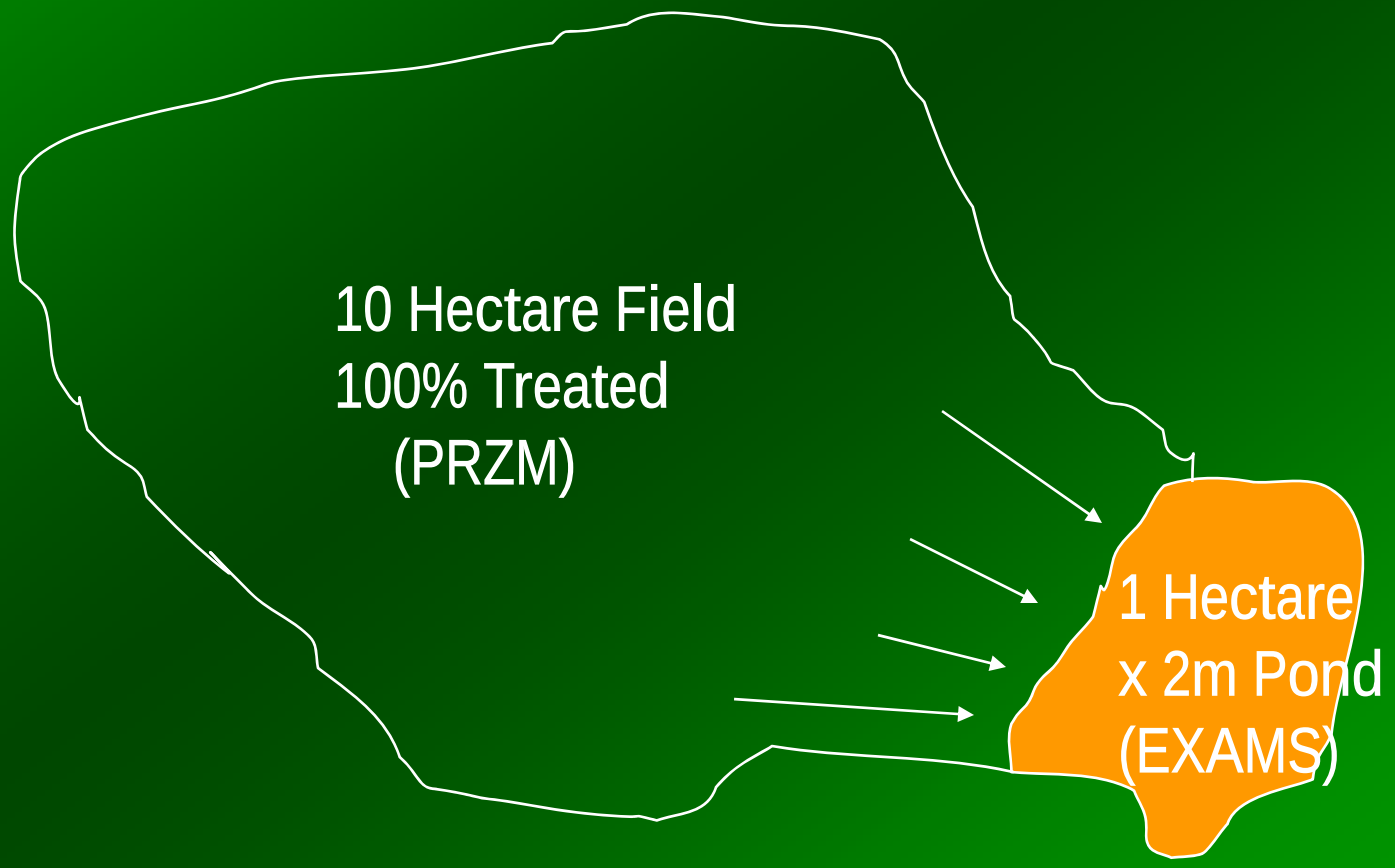
All models are wrong; some are useful!!

Wildlife Exposure:
What's Not Predicted/Considered Now

- Dermal exposure
- Inhalation exposure from sprays or dusts
- Drinking water exposure to on-site water sources
- Incidental soil ingestion exposures
- Possible higher residues at turn-abouts or overlapping swaths
- Drift residues from adjacent treated fields

These other routes and additional exposures are being investigated for use in future assessment strategies

Surface Water Modeling:
Eco Scenario



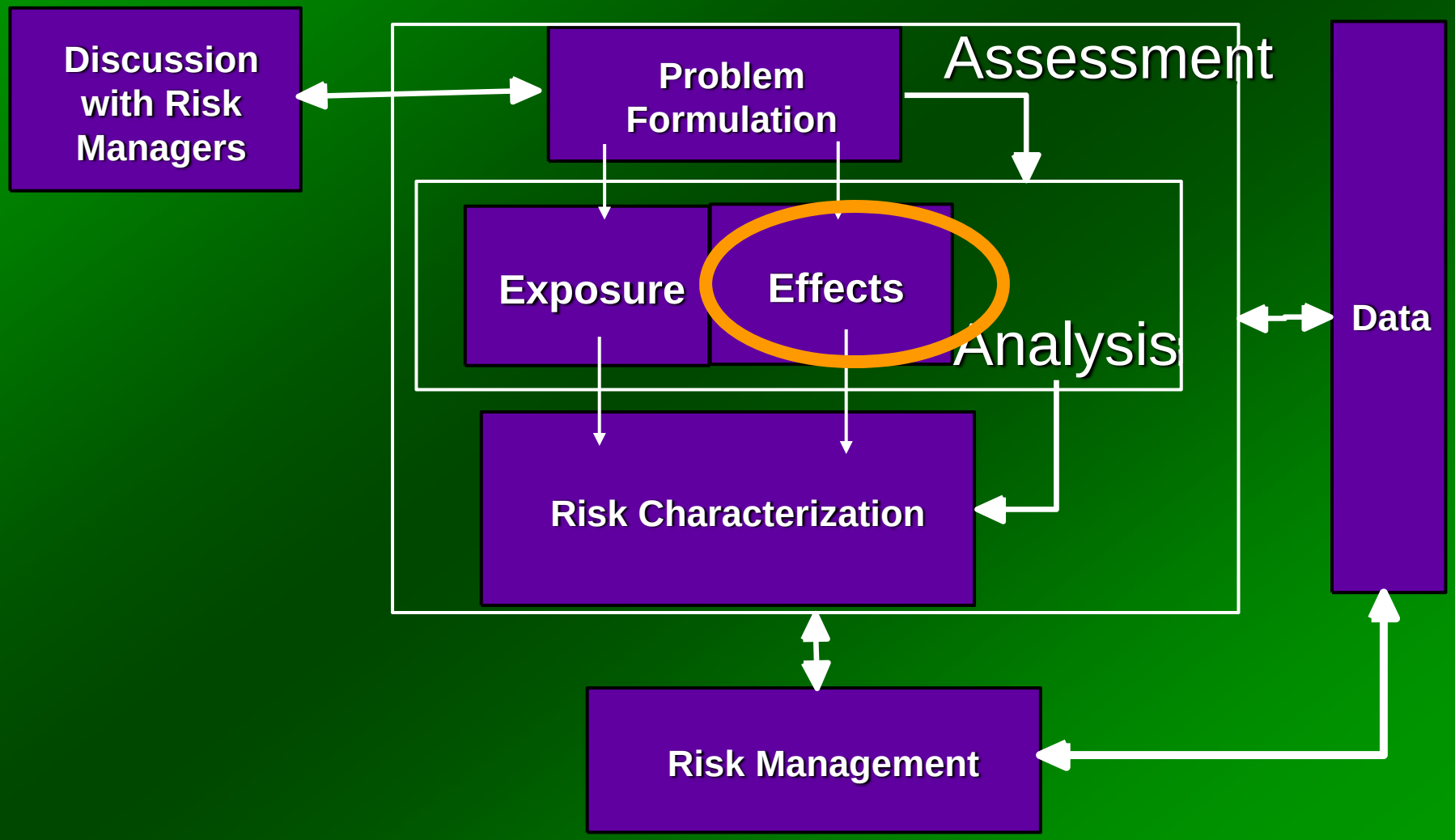
Characteristics Not Modeled For Aquatic Organism Exposure

- *In real life ponds probably exist with somewhat similar characteristics; however there are many habitats that are perhaps at higher or lower risk.*
  - Ponds with flush rates; static scenario assumed.
  - Watersheds larger than 10 hectares.
  - Depth usually increases toward center, therefore initial shoreline runoff values could be higher.

Aquatic Habitats That Need Further Study

- Stream habitats and behavior of pesticides in streams (rivers, creeks, etc.)
- Shallow marsh scenarios with heavy displacement by aquatic plants
- Saltwater marshes subject to tides
- Pesticide behavior in swamps, bogs, canals and other slow moving waters
- Urban streams fed by stormwater networks
- Vernal pools, puddles, etc.

ERA Paradigm



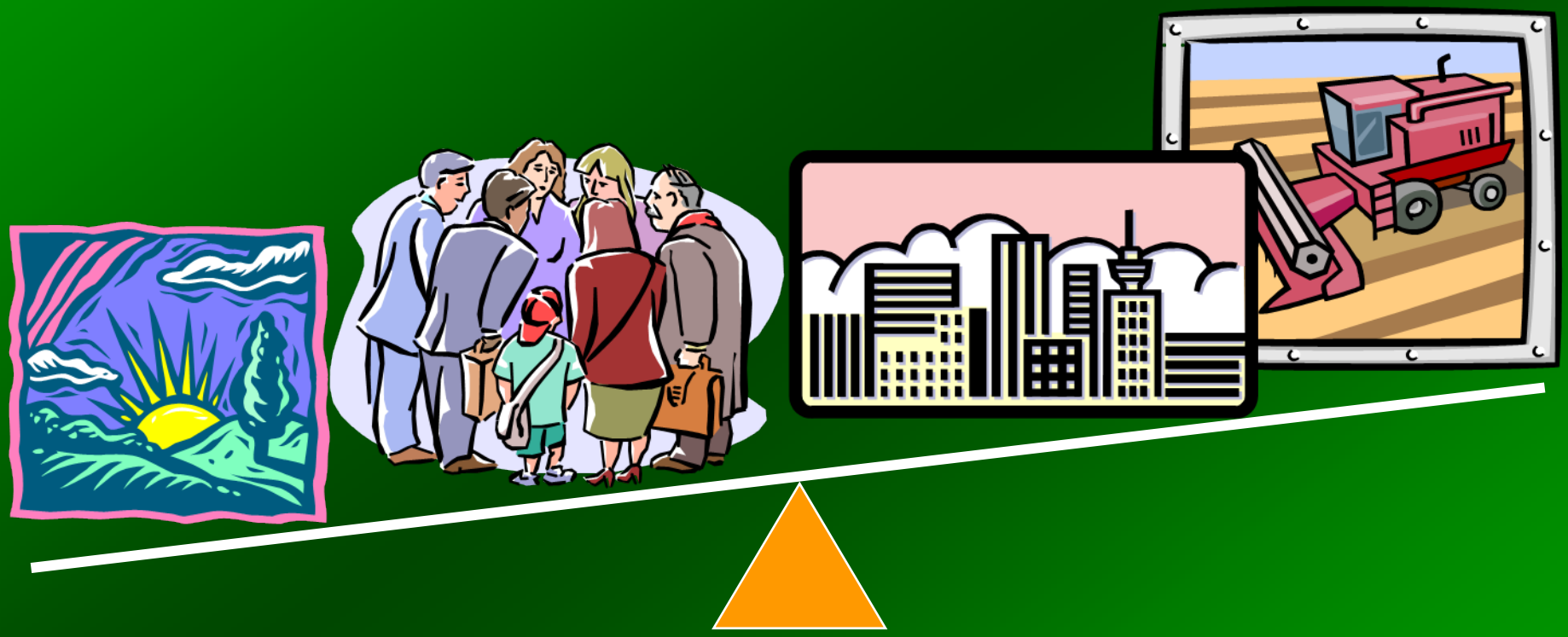
Areas of Uncertainty Associated with the Effects Analysis

- Degradation/metabolic products
- Formulated versus technical material
- Mixture effects
- Laboratory to field extrapolation
- Ecologically relevant endpoints based on the mechanism of action of the pesticide (sublethal effects)
- Concluding population persistence based on short term toxicity tests

Various Legal Authority Standards

ESA	CWA	FIFRA
-Preclude jeopardy -Minimize “take” -Conserve the species & their ecosystem	-Protection of 95% of the taxa… - Risk based approach	-No unreasonable adverse effects on the environment - Risk based
-Best Scientific & Commercial Data Available (benefit of the doubt to species)	-Promulgated standards and criteria	-Standard acute and chronic tox. tests & environmental fate data
-No destruction or adverse modification of critical habitat that affects the species	-No toxic chemicals in toxic amounts	-Prevent unreasonable effects on non/off-target species/sites

FIFRA Regulatory Decisions: Balancing Risks & Benefits



Major Sources of Scientific Uncertainty (Data Gaps)

Exposure/Effects

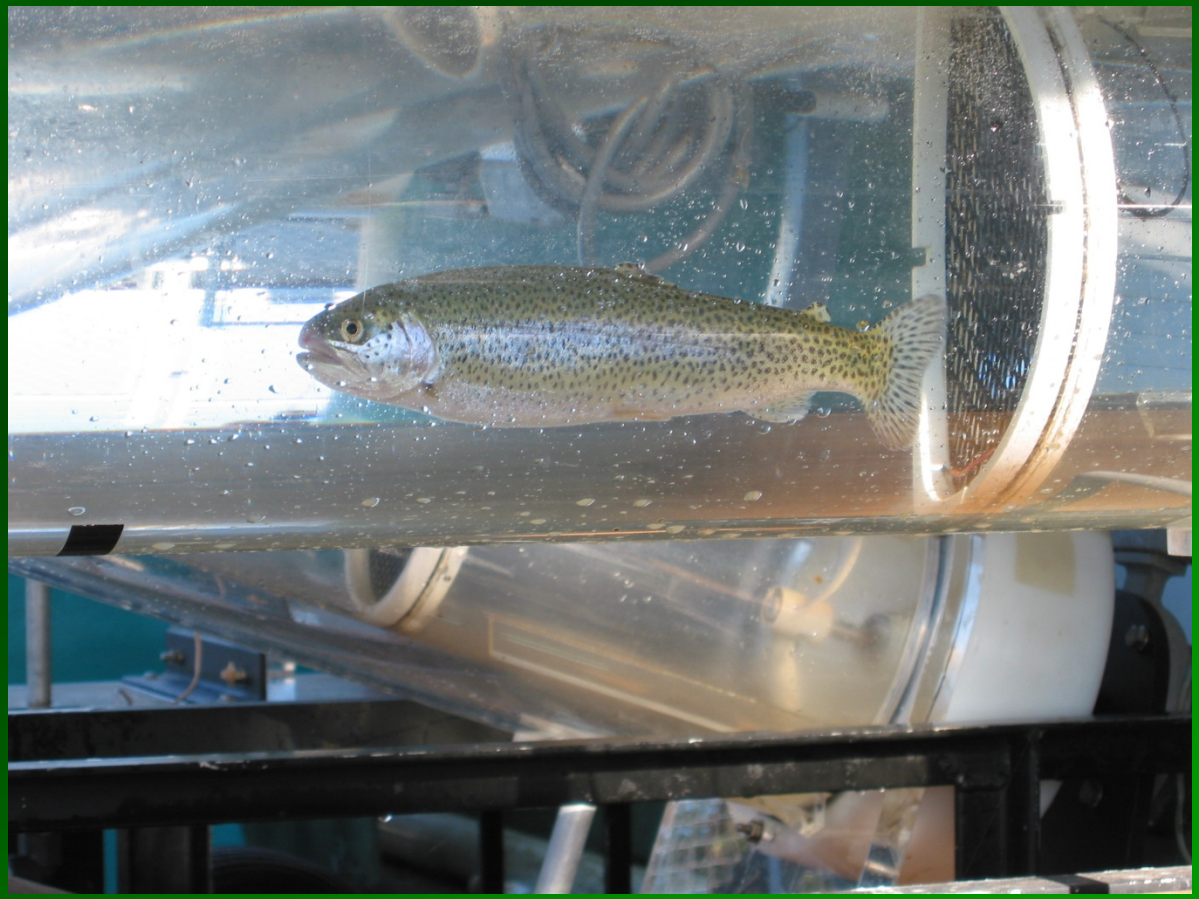
- Surfactants, Adjuvants, Inerts and Dyes
- Metabolites, Degradates & Mixtures
  - Additivity/Synergism/Antagonism
- Volatiles
- Pulses
- Other Exposure Pathways
  - Groundwater, Sediment, Dietary, etc.

T/E Specific Toxicological Data

- Surrogacy and Sub-lethal Endpoints

Uncertainty Example #1 Salmonid Issues in the Pacific Northwest

- Sublethal Effects – LOC Evaluation



LOC Evaluation when using lethality data for sub-lethal effects

$$\text{Risk Quotient} = \frac{\text{EEC}}{\text{Toxicity Endpoint}}$$

Assumptions:

EXPOSURE TYPE	SPECIES	RQ CRITERIA VALUE
Acute	non-T/E	<0.1
Acute	T/E	<0.05*
Chronic	non-T/E & T/E	<1.0

LOC Evaluation

- Diazinon LC_{50} for cutthroat trout = 1,700 μg/L
- Toxicological thresholds for diazinon in salmonids
  - 0.3 μg/L for reproductive dysfunction - Waring & Moore in Atlantic Salmon
  - 1.0 μg/L for olfactory diminution (predator avoidance, homing behavior, reproductive priming, etc.) – Scholz in Pacific Salmon

$$(RQ)0.05 = \frac{EEC}{1{,}700\mu g/L(LC50)}$$

EEC = 85μg/L

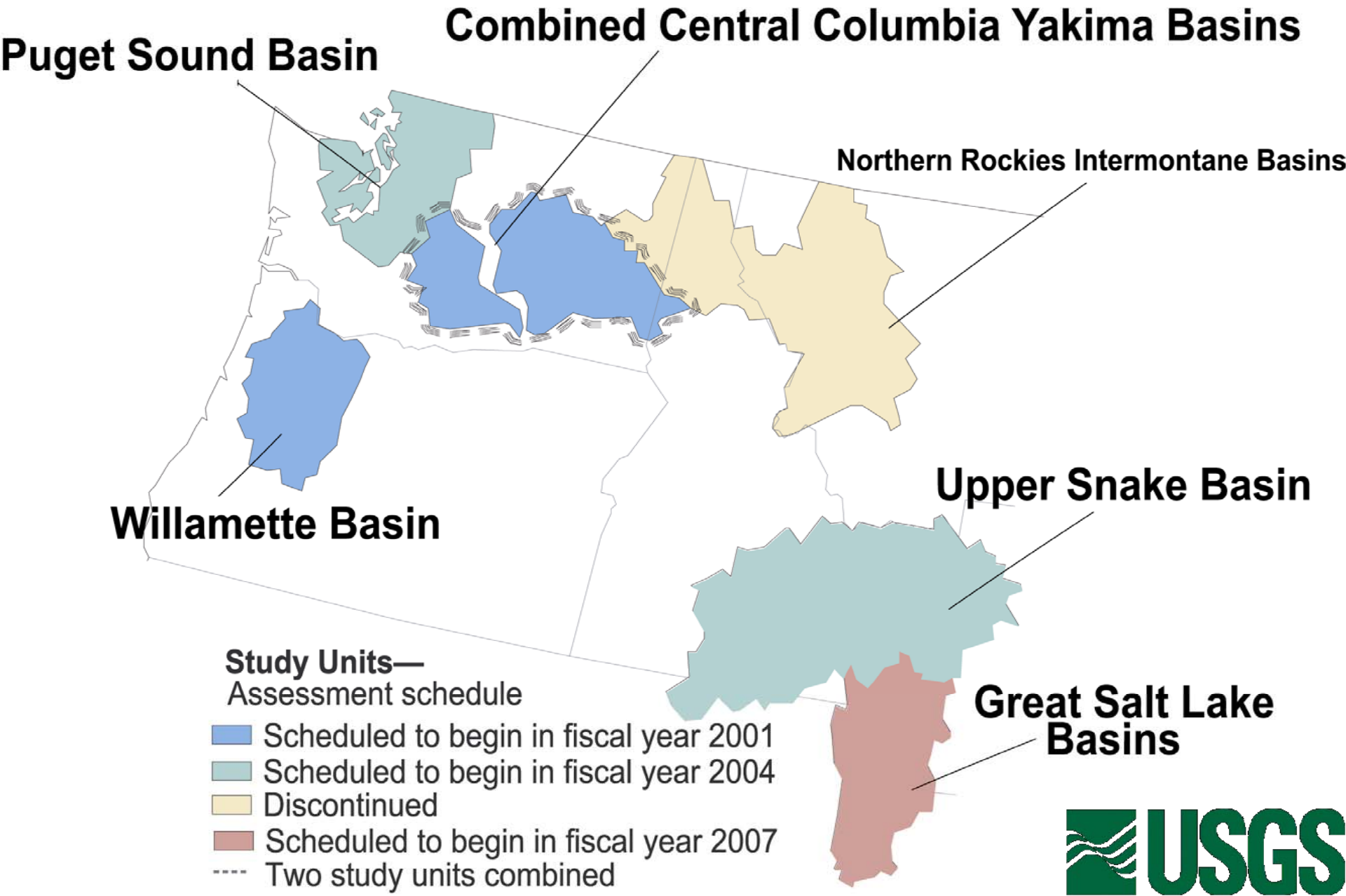
Thus, water concentrations would be 283 to 85 fold above sub-lethal thresholds for salmonids before BMPs would be implemented.

Uncertainty Example #2
Typical Problem - Mixtures

The disconnect between single-chemical aquatic life criteria and/or toxicological thresholds and actual ecological conditions in salmonid habitat.

The USGS' NAWQA program found that >50% of all surface water samples contain mixtures of five or more pesticides (USGS Circular 1225).

Pacific NW NAWQA 2001 to 2012 Sampling Schedule

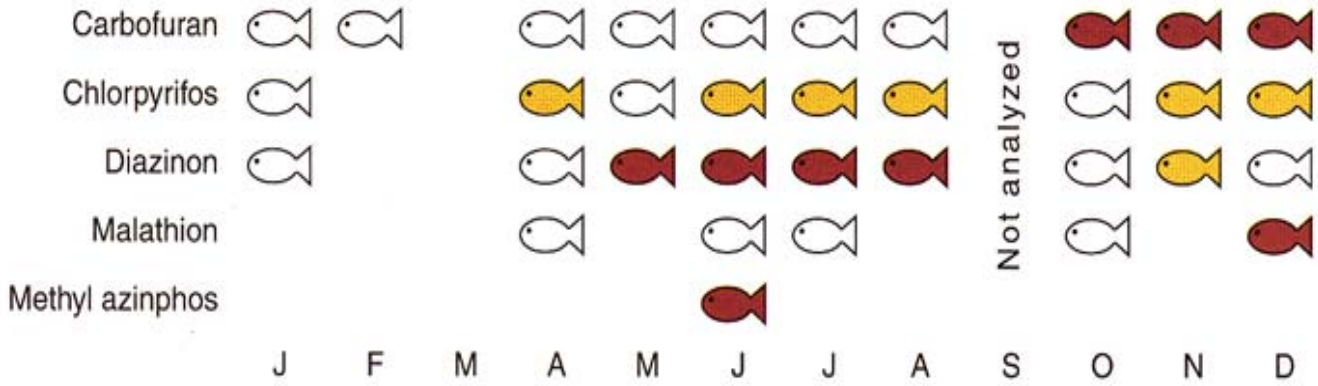


Pesticide Detections in Washington State Surface Waters

Pesticide Classification	Total Number of Pesticides Detected	Number of Pesticides Detected in Each Basin		
		Columbia Plateau*	Yakima*	Puget Sound*
Herbicides	56	38	22	26
Insecticides	41	18	35	7
Fungicides	1			1

*National Water Quality Assessment Program Basins

INSECTICIDES DETECTED IN WATER IN ZOLLNER CREEK, OREGON, 1993 AND 94



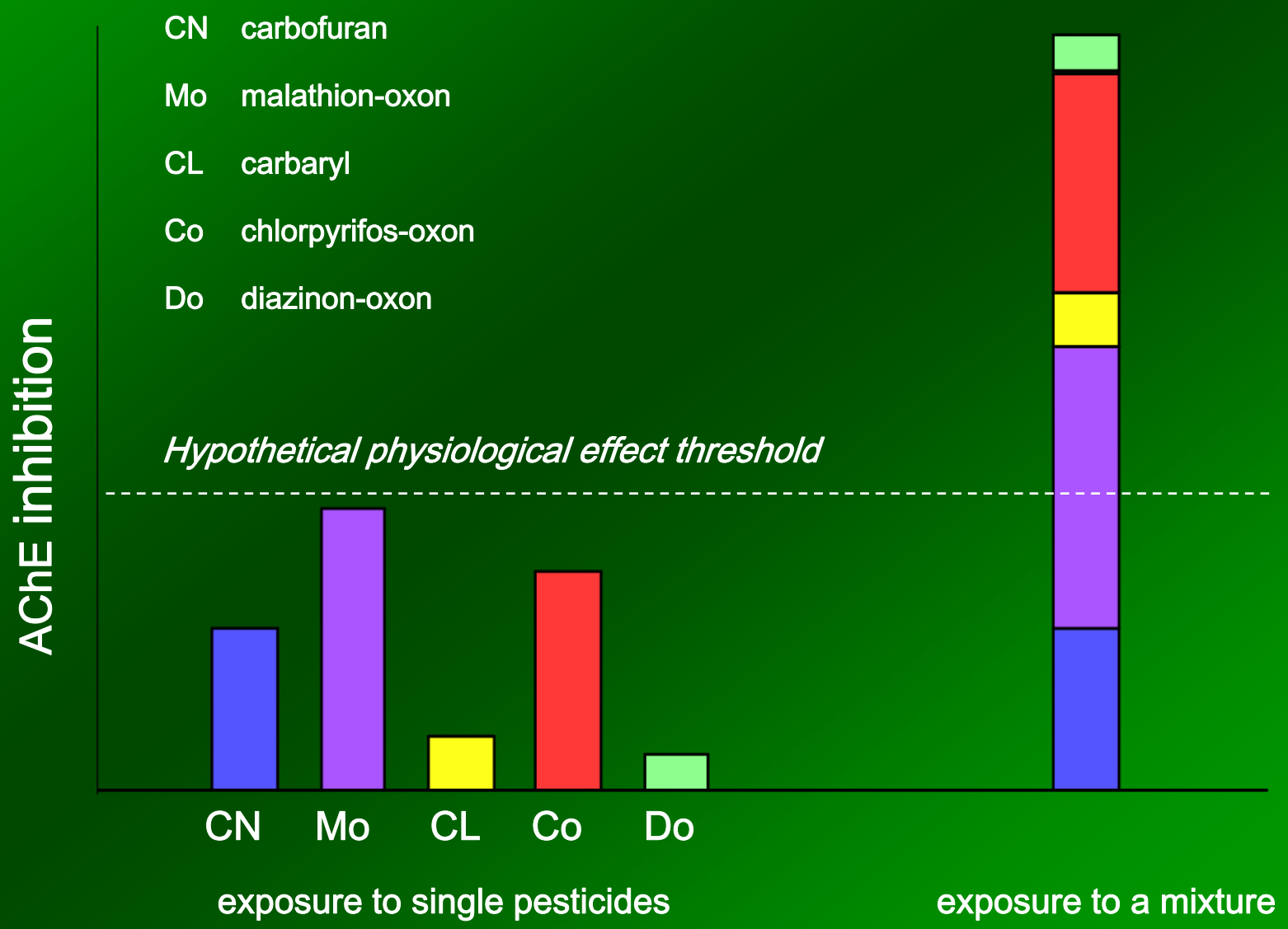
Detected

Approached aquatic-life guidelines

Exceeded aquatic-life guidelines

Zollner Creek in the Willamette Basin receives agricultural runoff from intensively irrigated crops, including row crops, grass, wheat, hops, nurseries, and orchards. A wide variety of insecticides was applied to these crops; the insecticides were transported to the creek by irrigation and stormwater runoff. One or more insecticides were found in most water samples collected during the 2-year period, and several approached or exceeded concentrations that may be harmful to aquatic life, sometimes accurring as mixtures.

Potential Neurobehavioral Toxicity of Mixtures



Other Limitations in Risk Assessment

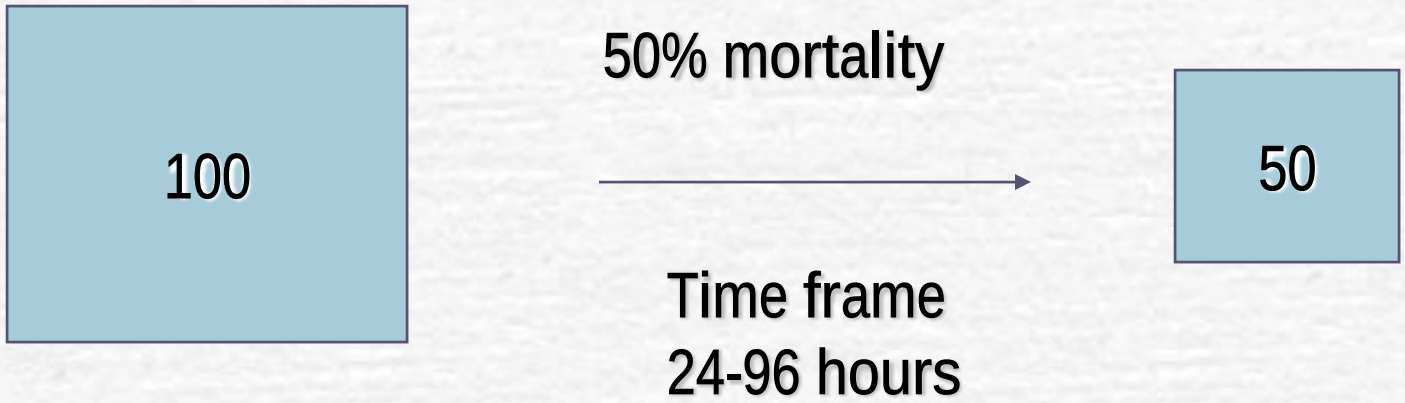
<u>Intraspecific variability</u>:

- Variability between individuals (sensitivity)
- Age and developmental stage (life history)
- Variation between studies with the same spp.
- Variation between species (surrogacy)

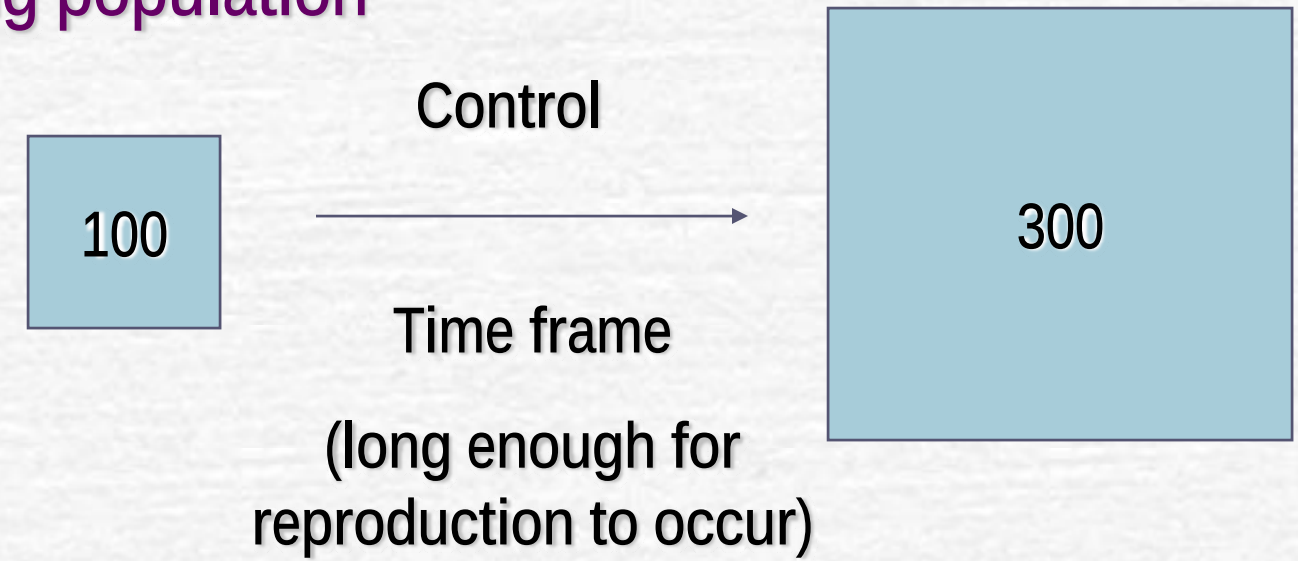
Individual
versus
Population-level effects

There appears to be a disconnect between what happens to individuals exposed to toxicants and what happens to populations

Starting population

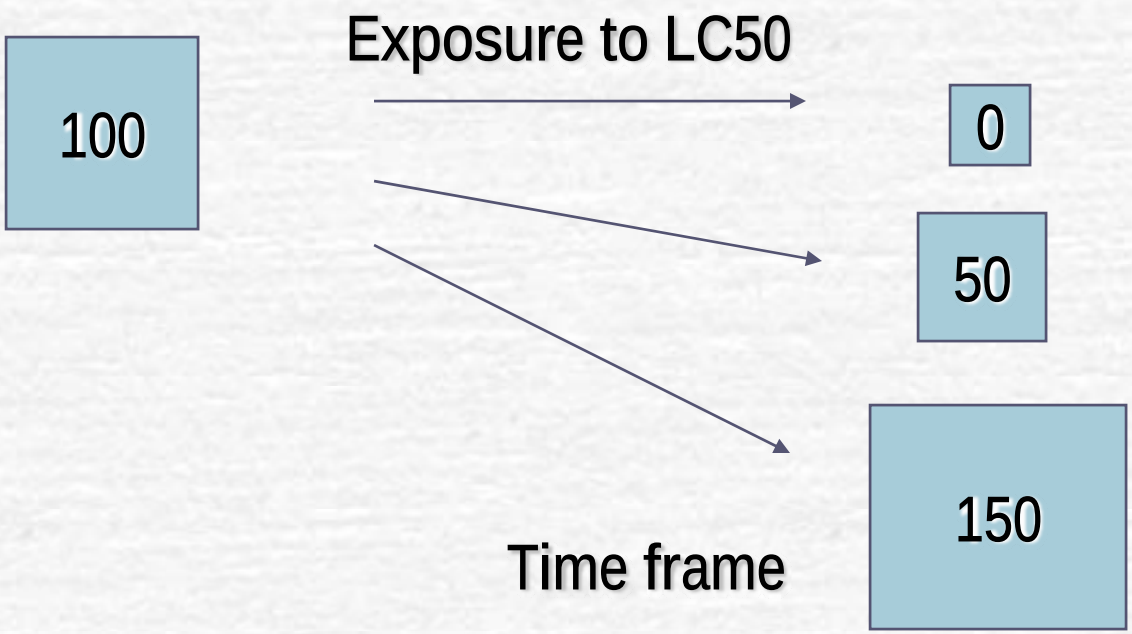


Starting population



Starting population

Some possible outcomes



Time frame

(long enough for reproduction to occur)

How can such different outcomes occur?

-Sublethal effects
-Population compensation

Types of sublethal effects

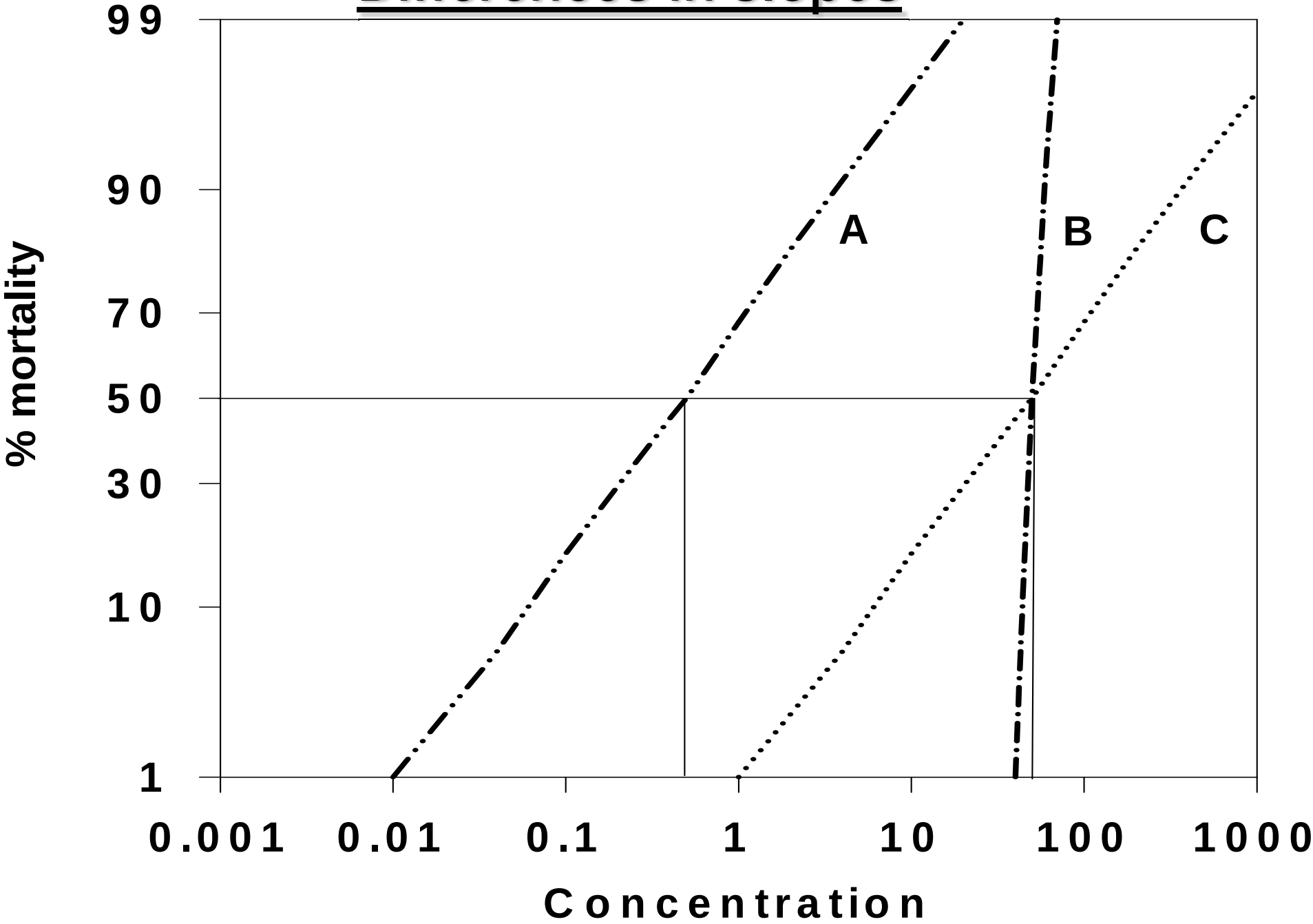
- Reduction in offspring
- Weight loss
- Reduction of life span
- Cancer
- Mutations
- Behavioral changes
- Sterility

Population Compensation

After a catastrophic event such as a major die-off, the survivors have more resources available to them and thus can produce more offspring

Problems with the use of the LC50 as a toxicity endpoint in risk assessment

Differences in slopes

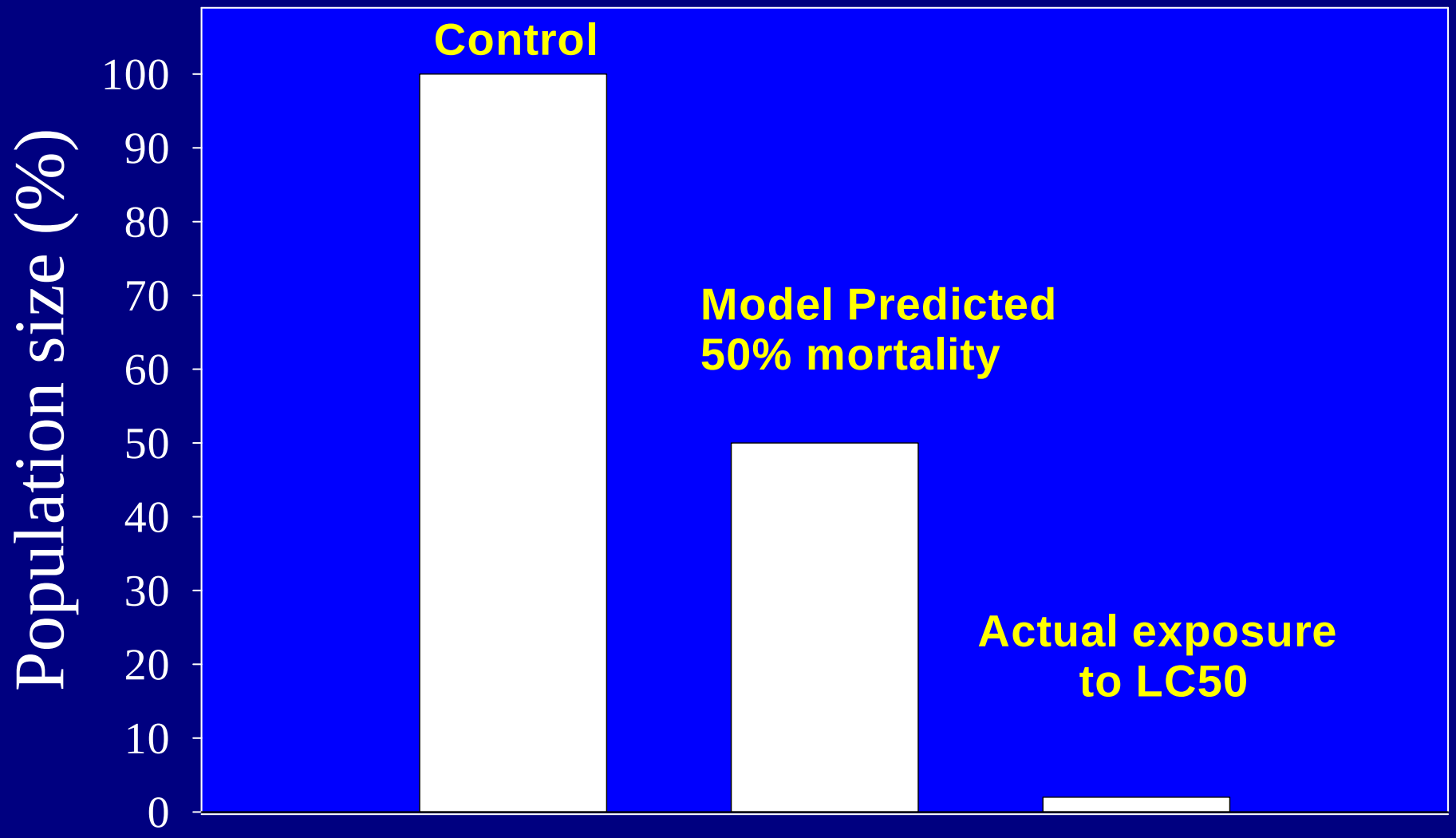


Examples of population outcomes after exposure to the nominal acute LC50

John Stark, PhD
Washington State University

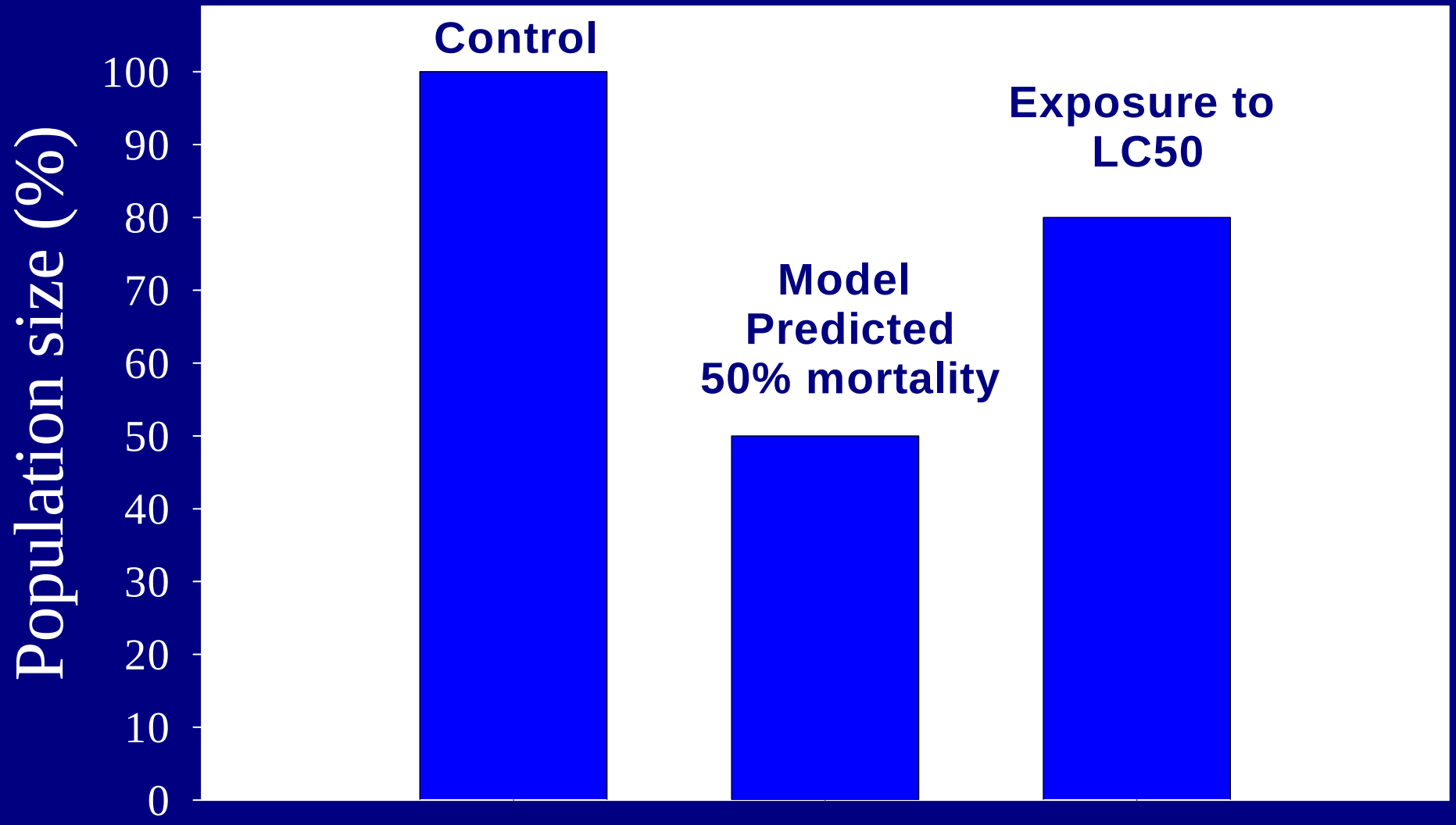
Sublethal Effects

C-7 Lady beetle exposed to Neemix



Population Compensation

Two spotted spider mites exposed to Avermectin for 16 days



Population size of *Daphnia pulex* 10 days after static non-renewal exposure to the 48 hour acute LC_{50} for several insecticides.

Treatment	Mean number of individuals ± SE	% of control
Control	285 ± 25	-
Actara	1.5 ± 1	0.5
Aphistar	82 ± 4	29
Diazinon	259 ± 28	91
Fipronil	118 ± 7	42
Fulfill	0 ± 0	0
Neemix	0 ± 0	0
Spinosad	0 ± 0	0

Most toxicological evaluations involve measurements of one or maybe two effects

However, exposure to chemicals can result in lethal and multiple sublethal effects

How do you measure the total effect of a chemical exposure?

Demographic Toxicology

Estimating effects of toxicants through the use of life tables

Demography

The study of populations and the processes that shape them (Pressat 1985)

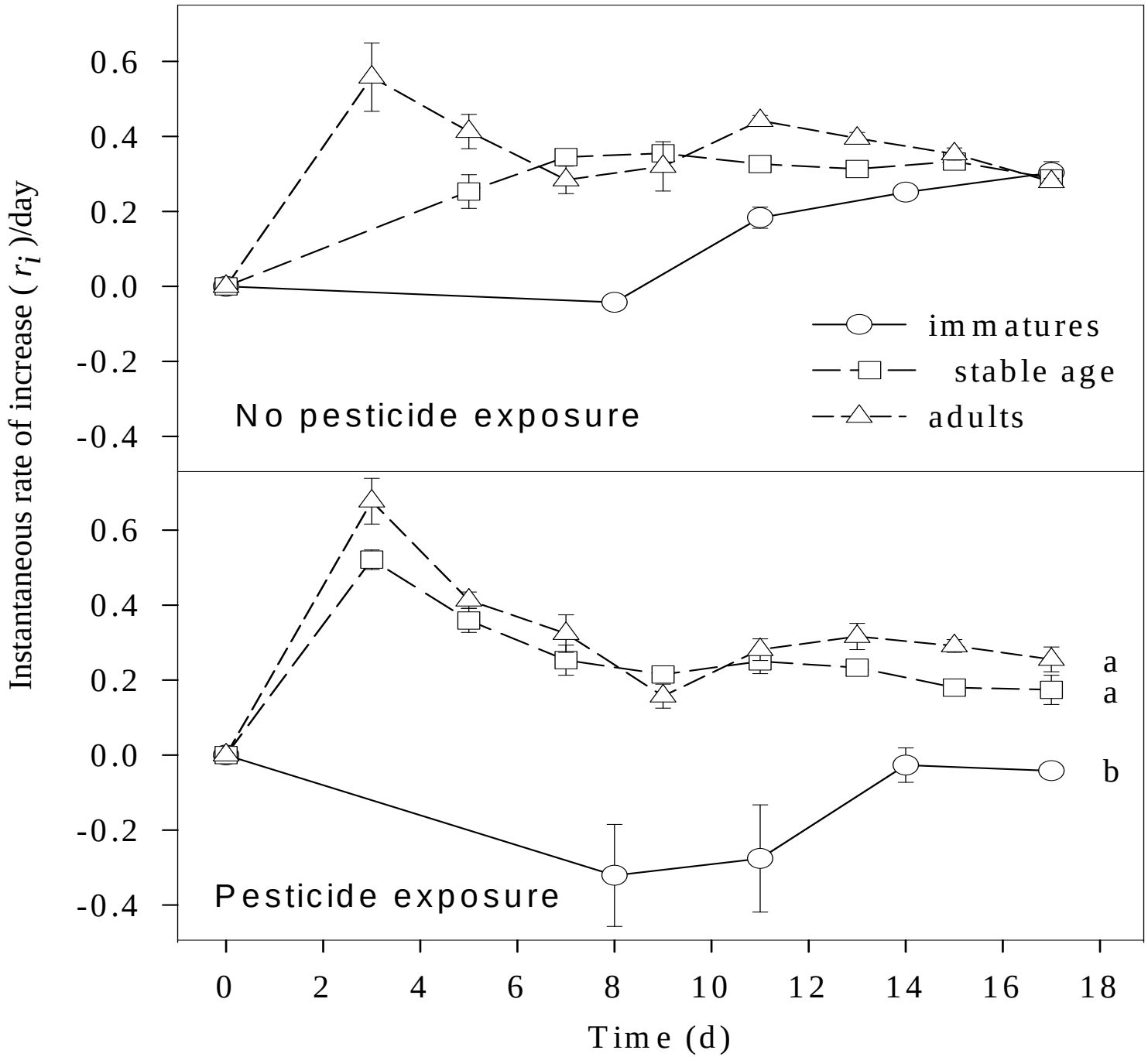
Population structure

Animal populations in nature often exist as a mixture of life stages and ages.

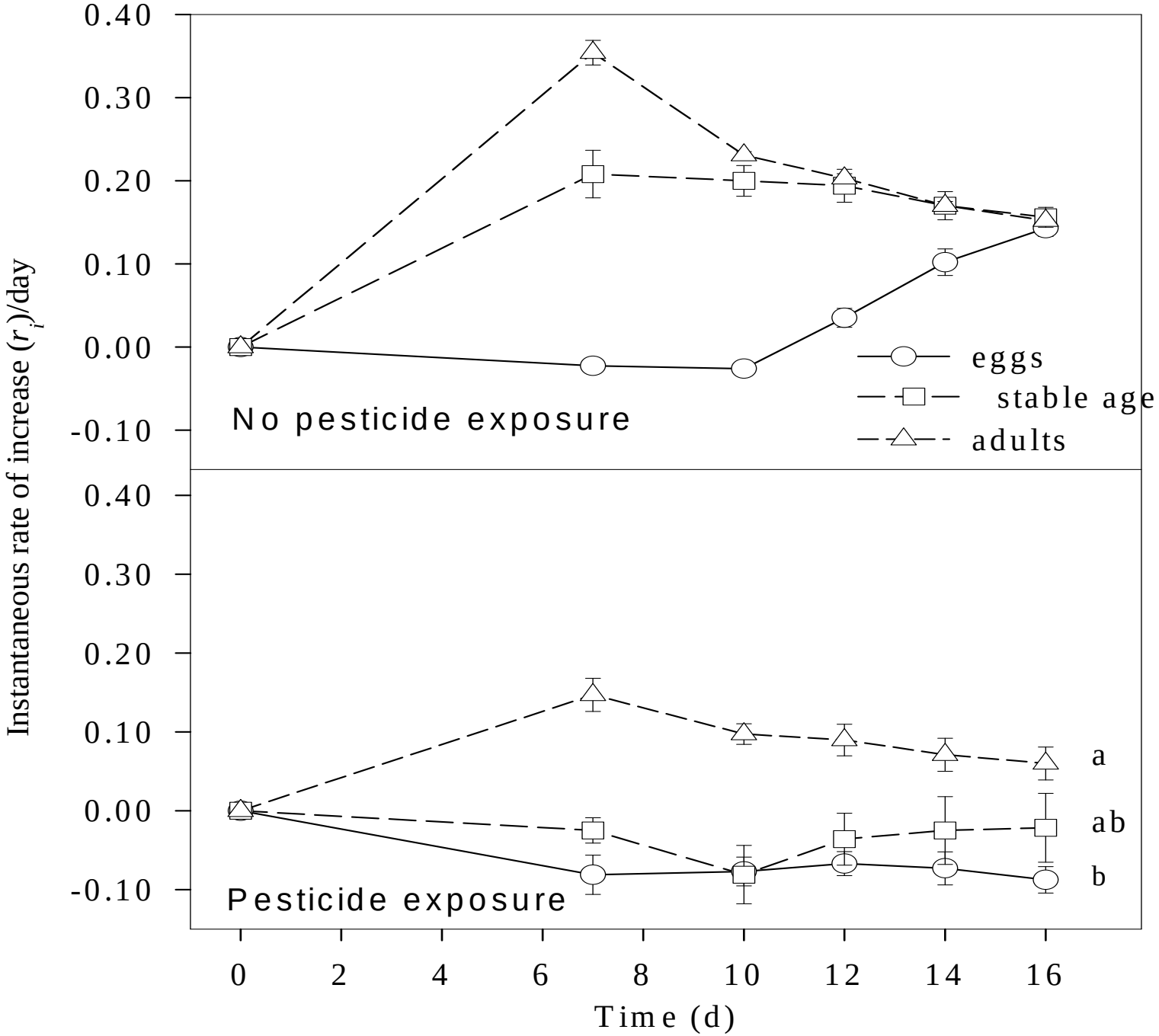
For example, there might be adults, newborns, juveniles, and elderly individuals in a population.

What influence, if any, does population structure play in terms of susceptibility of population to toxicants

Studies with pea aphids and neem


Instantaneous rate of increase (r_i)/day
0.6
0.4
0.2
0.0
-0.2
-0.4
immatures
stable age
adults
No pesticide exposure
Pesticide exposure
a
a
b
0
2
4
6
8
10
12
14
16
18
Time (d)

Studies with mites and dicofol


Instantaneous rate of increase (r_i)/day
0.40
0.30
0.20
0.10
0.00
-0.10
No pesticide exposure
eggs
stable age
adults
Pesticide exposure
a
ab
b
0
2
4
6
8
10
12
14
16
Time (d)

The LC50 plays a major role in ecological risk assessment

An underlying assumption of the LC_{50} is that the LC_{50} for one species can be directly compared to that for another species (surrogacy)

However, this assumption overlooks the fact that different species have different life history strategies and variables such as life span, time to first reproduction and number of offspring produced over a life-time.

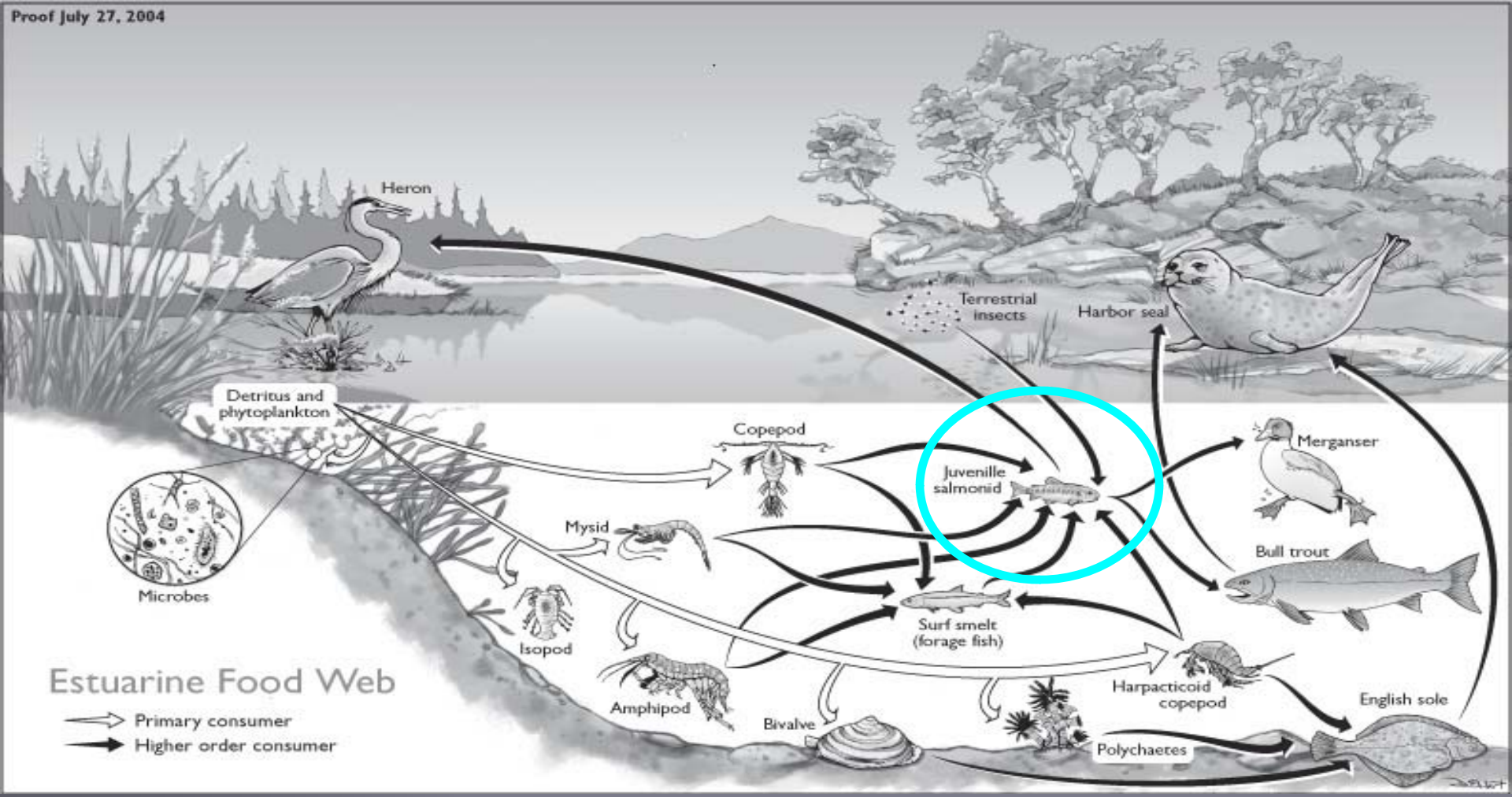
The rat-elephant hypothesis

Toxicity data for closely related species can be very different

Hypothesis: all species react to the same stress in the same way regardless of their life history strategies – i.e., 50% mortality or 50% reduction in offspring has the same effect on all species.

Conclusion: LC50 estimates are not comparable among species over longer periods of time than a few days because of differences in life history parameters

Simplistic measures of toxicity like the LC50 don’t tell us enough about the potential impacts that pesticides and other pollutants might have on non target organisms. To make progress we need to adopt more ecologically relevant measures of effect.



Pesticide formulation X indirectly affects salmonids by altering the prey availability at a critical life stage transition, juvenile ⟶ smolt. Smoltification is critical to seaward survival.

Questions?