
Frameworks for Risk Assessment: Global to Local
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Praguicidas e o Meio Ambiente
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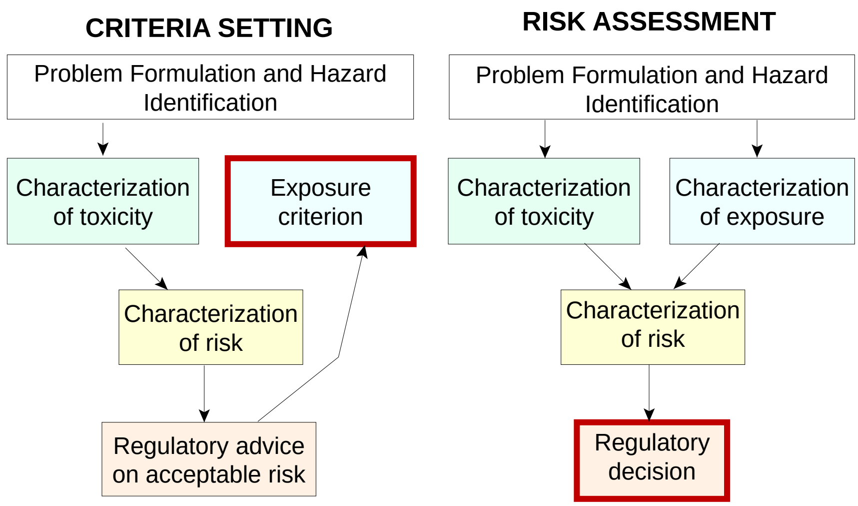
Uses of risk assessment

- All risk assessment methods are essentially similar
- But they may be used for different purposes
  - Environmental guidelines and criteria - *a priori* or prospective, inclusive of all situations
  - Exposures are known and their significance is being assessed - *a posteriori* or retrospective judgments, may be exclusive and not consider certain situations

Uses of risk assessment



Regulatory goals and protection goals

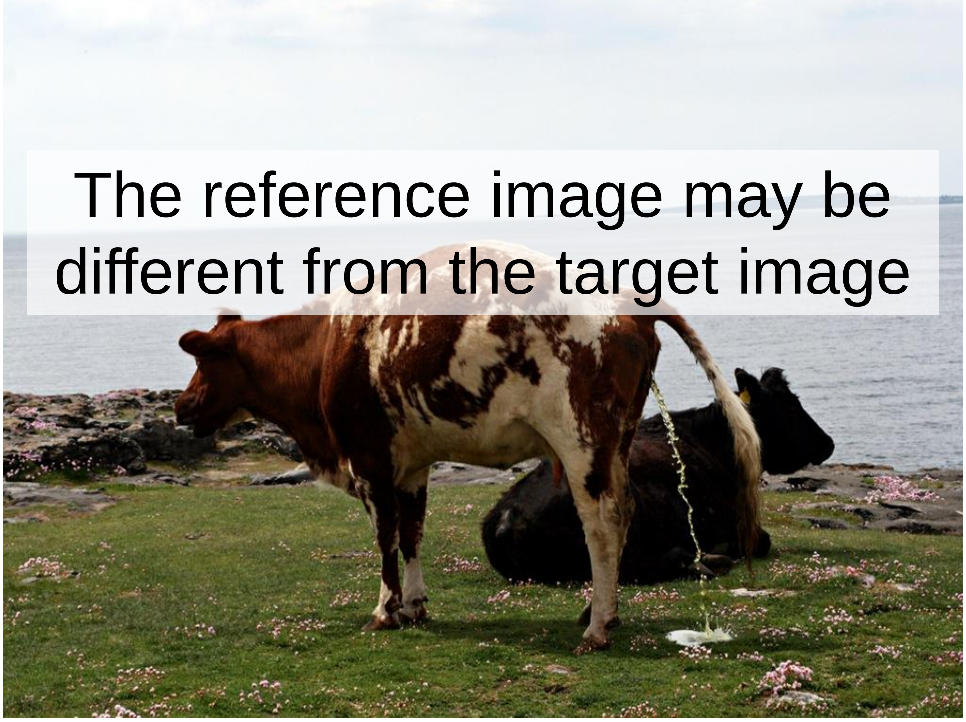
- Many jurisdictions have regulatory policy goals such as "environmental protection"
- However,
  - They are ambiguous or difficult to define or measure.
- But:
  - Protection goals are key to setting risk assessment endpoints.
  - You must know what you are trying to protect.

Sustainable ecosystem

- Ecosystems vary in space and time.
- In ecotoxicology, the concern is rarely for individual organisms but usually for populations and communities in their natural environment.
- Exceptions are individuals of wildlife populations valued by society or endangered species
- Intention is that populations and communities be sustained in the environment.
  - Protection from change, not just decreases.
  - Adverse ecosystem responses misperceived as always being negative.
  - Increases in populations or functional processes such as algal blooms may be just as deleterious in the ecosystem.

What do we protect

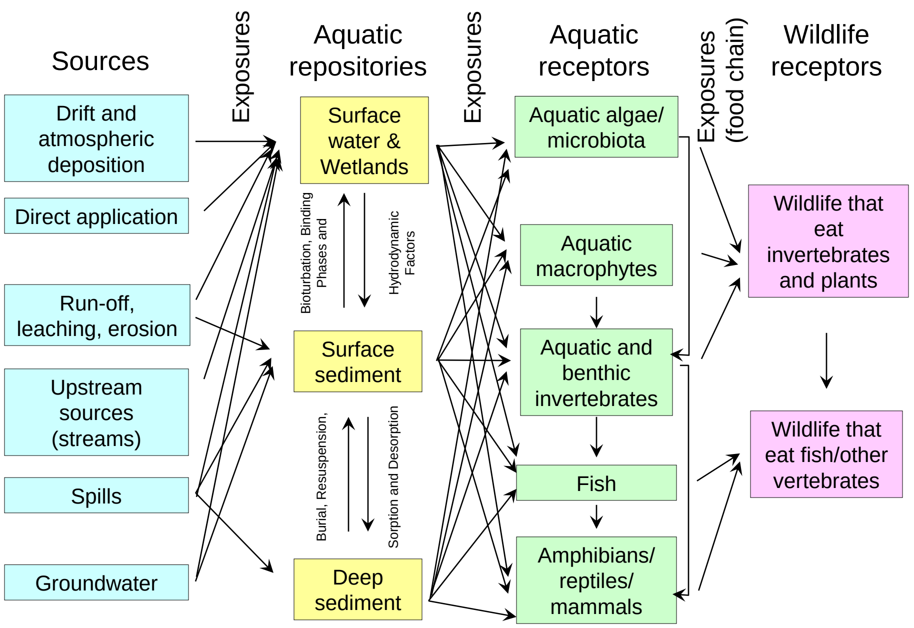
- Structure
  - Types of organisms present
  - Diversity
  - Abundance
- Function
  - The interaction of the population with other populations or the abiotic environment
  - Provision of ecosystem services such as: energy and nutrient flow, production of biomass, consumption of biomass, controlling the abundance of other (prey) species, feeding predators, processing organic detritus



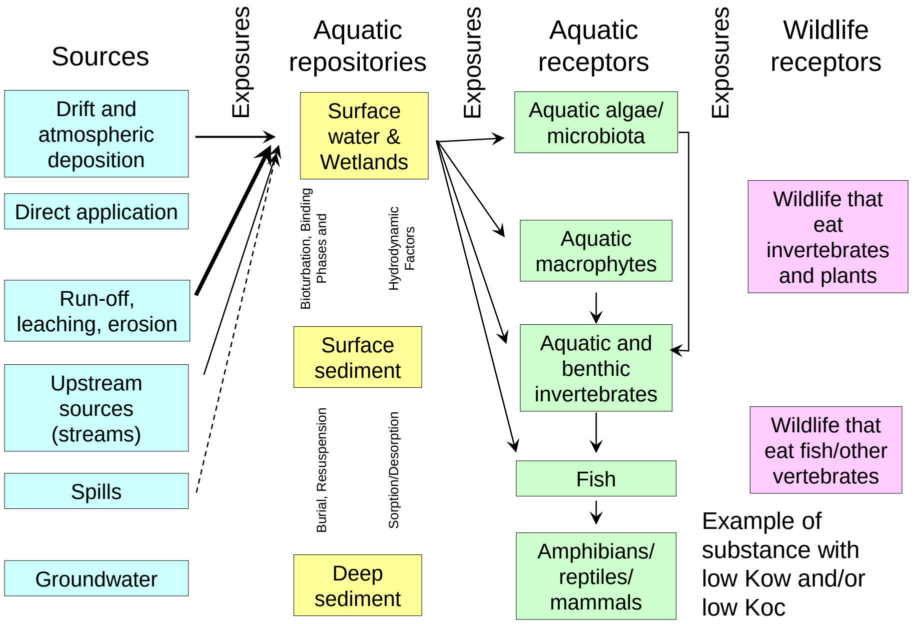
The conceptual model and risk hypotheses

- Development of working hypotheses as to how the stressor might affect components of the ecosystem
- Generic conceptual model
  - Useful as a check that you have not missed anything.
  - Eliminate what you do not need for the specific situation

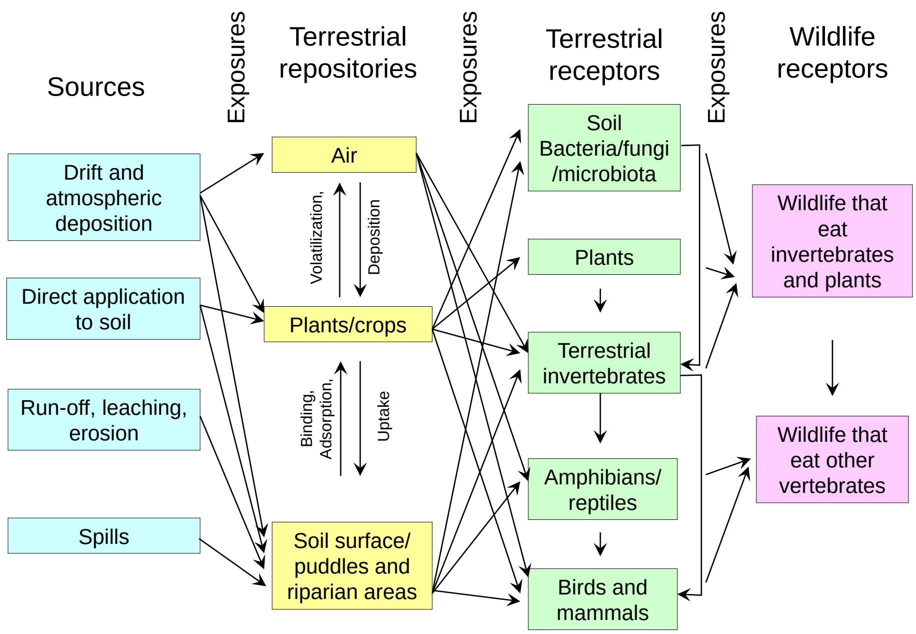
Generic model: Aquatic exposures



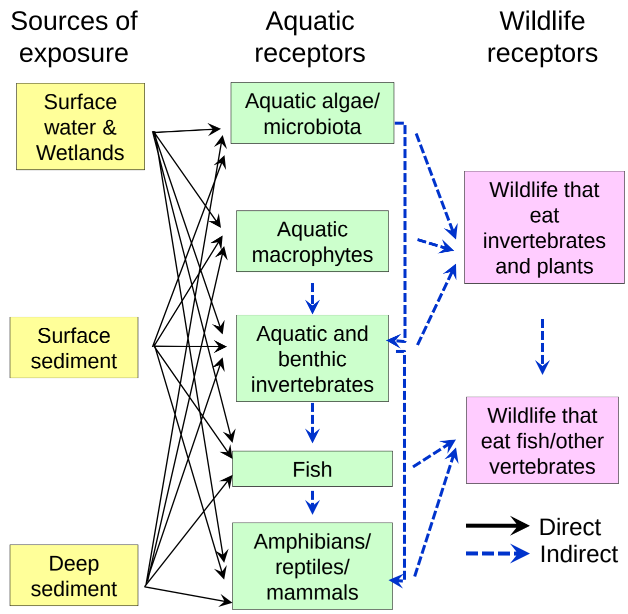
Specific model: Aquatic exposures



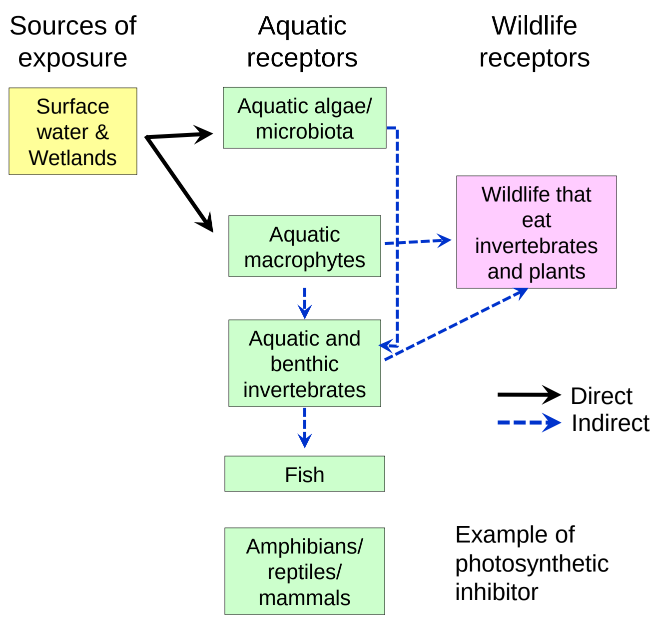
Generic model: Terrestrial exposures



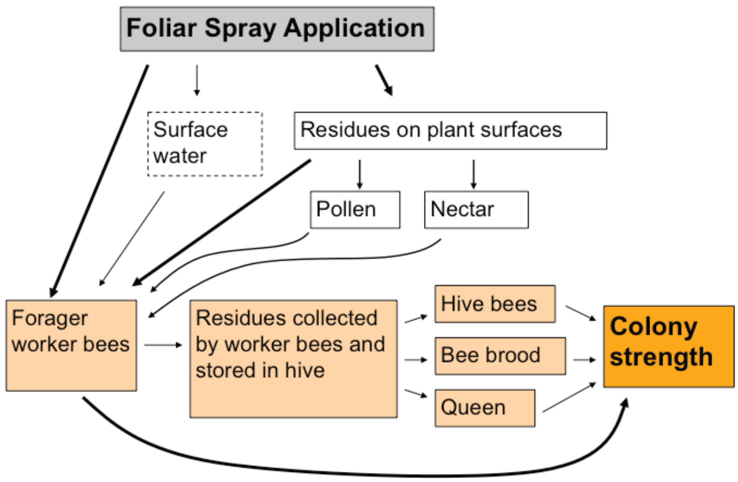
Generic model: Aquatic effect



Specific model: Aquatic effects



Specific model: Pollinators



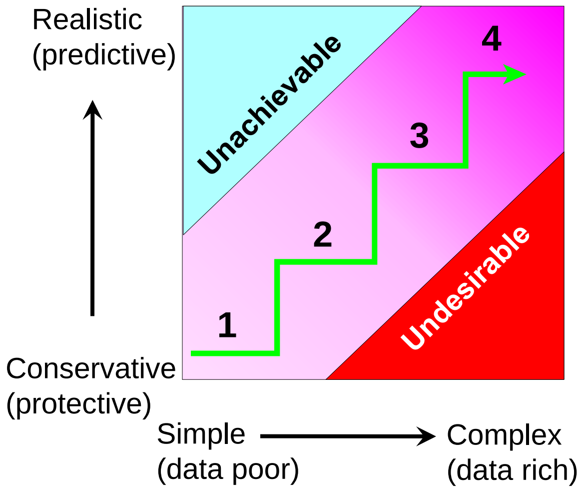
Fischer & Moriarty 2011 SETAC Pellston Workshop on Pesticide Risk Assessment for Pollinators

Risk hypotheses

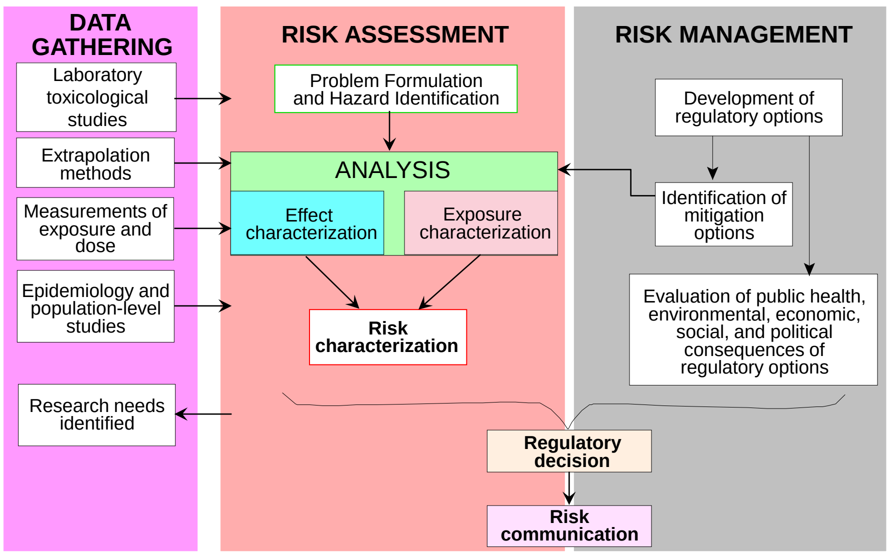
- Where will the exposures be?
- Duration and frequency of exposures?
- What organisms will be exposed?
- What will the exposure concentration be?
  - Deterministic:
    - Will the exposure exceed the LC50, NOEC of a single test species?
    - What proportion of the population of a test species will be affected
  - Probabilistic:
    - What proportion of species will experience an exceedence of their LC50 or NOEC?

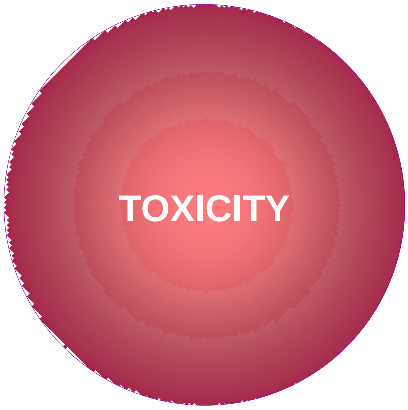
Tiered approach

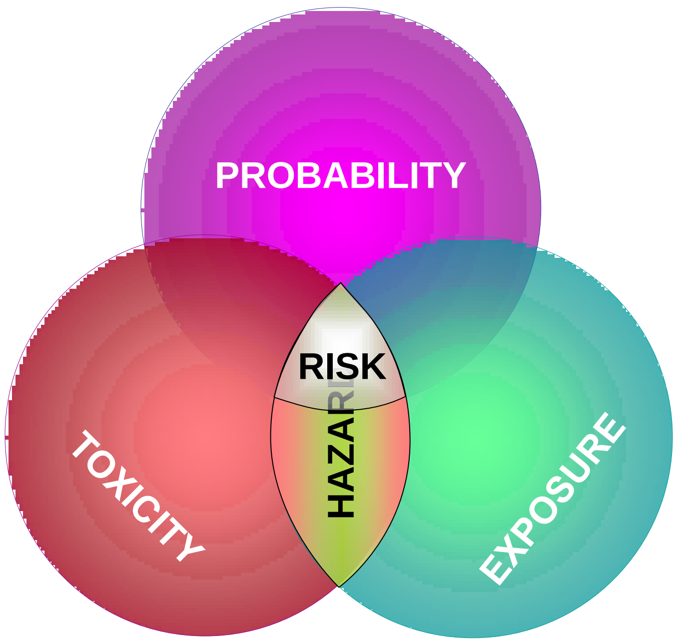
- Tiered process maximizes efficiency
- Achieve a desired and realistic level of protection with progressively more certainty



A generic framework




TOXICITY

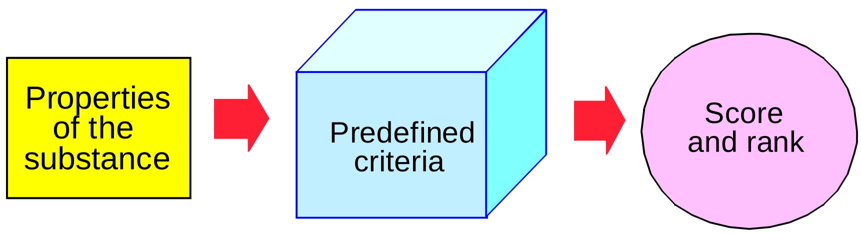

PROBABILITY
RISK
HAZARD
TOXICITY
EXPOSURE

The first tiers - scoring systems

- The POPs convention under the auspices of UNEP.
- Toxic Substances Control Act (TSCA) in the US
- The Priority Substances List (PSL) of Environment Canada has developed a set of criteria for selecting substances that are potentially hazardous to the environment.
- REACH program in the EU.

Scoring systems

- Use a predefined set of criteria for comparison.
- Property of the substance (biological, chemical, physical) is then assigned a score on the basis of the criteria.



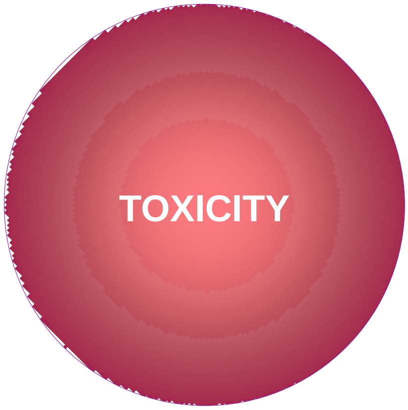
Scoring systems – example

Criteria for persistence (P) or very persistent (vP)	Criteria for bioaccumulative (B) or very bioaccumulative (vB)	Criteria for toxicity (T) POPs	Potential for long-range transport (LRT)
POP; P: Water: DT50 > 2 months Sediment: DT50 > 6 months Soil: DT50 > 6 months	**POP; B:** BCF > 5,000 or Log K_{OW} > 5 Other, e.g., very toxic or bioaccumulation in nontarget species	**POP; T:** No specific criteria other than "significant adverse effects" 2009/1107 EC	**POP; LRT:** Air: DT50 > 2 d or modeling or monitoring data which shows long-range transport
PBT; P: Marine water: t½ > 60 d; Fresh water t½ > 40 d Marine sediment: t½ >180 d Freshwater sediment: t½ > 120 d Soil: t½ >120 d	**PBT; B:** BCF > 2,000 in aquatic species	**PBT; T:** Chronic NOEC < 0.01 mg/L or is a carcinogen, mutagen, or toxic for reproduction, or other evidence of toxicity	**PBT; LTR:** None
PBT; vP: Water: t½ > 60 d Sediment: t½ > 180 d; Soil: t½ > 180 d	**PBT; vB:** BCF > 5,000		

Moermond et al 2011 Integr Environ Assess Manag 8

Issues with scoring systems – too simple a model

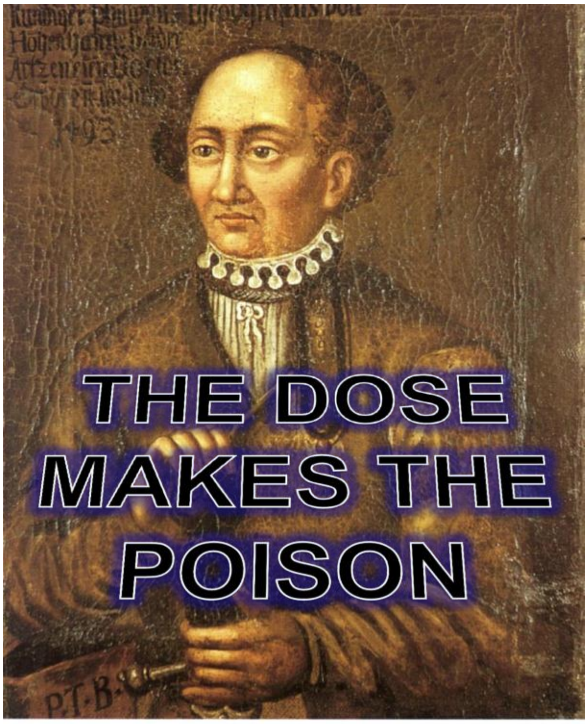
- Use of worst-case data
- Do not handle missing values, weighting or scaling appropriately
- Rank numbers have no meaning in the real world
- Best use is to allow prioritization of substances for more detailed assessment
- Incorrect use as a final step in risk assessment and management
- Problems with list-envy!

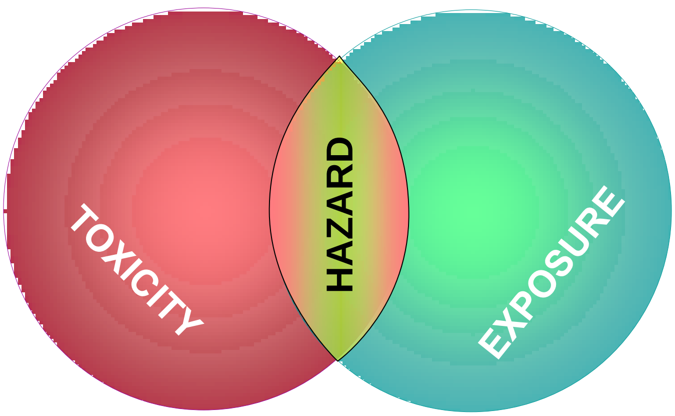


Criteria and objectives - protective, not predictive

Criteria setting

- Use most sensitive organism
- Apply an uncertainty factor (Human Health Approach)





QUOTIENTS

$$\text{HAZARD} \approx \frac{\text{EXPOSURE CONCENTRATION}}{\text{EFFECT CONCENTRATION}}$$

(Level of Concern or LOC)

Exceedence of LC50 or NOEC – quotient

$$\text{HAZARD} \approx \frac{\text{EXPOSURE CONCENTRATION}}{\text{EFFECT CONCENTRATION}}$$

(Level of Concern or LOC)

$$HQ = \frac{600}{200} = 3$$

Quotients

$$\text{Hazard} \approx \frac{\text{Exposure concentration}}{\text{Effect concentration}}$$

(Level of Concern or LOC)

$$\text{Margin Of Safety (MOS)} \approx \frac{\text{Effect concentration}}{\text{Exposure concentration}}$$

(Toxicity:Exposure Ratio or TER)

In the assessment, these are compared to a “safety” or uncertainty factor

Uncertainty factors

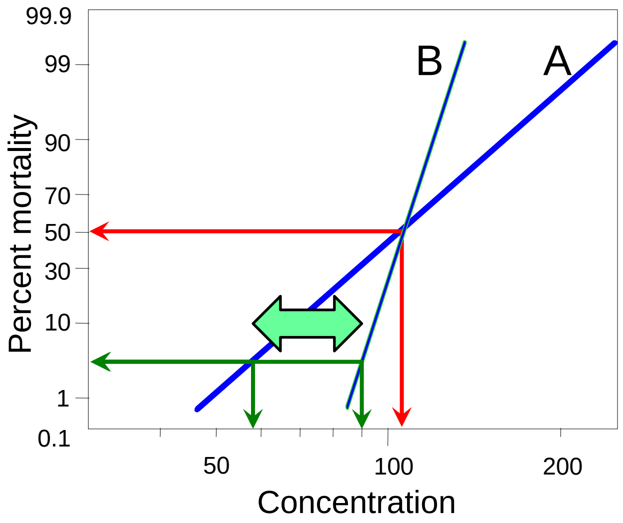
Data	Canada	OECD	OECD	US EPA	EU TGD
Quantitative structure activity relationships (QSAR)	1000	1000	1000	1000	1000
Acute data (one or two species)	1000	1000	1000	1000	
Acute data (3 taxa)	100	100	100-1000	100	1000
Chronic data (1 taxon)			50-100		100
Chronic data (2 taxa)			10-100		50
Chronic data (3 taxa)	10	10	10	10	10
Chronic probabilistic					1-5
Mesocosm data				1	Case by case

From, Solomon et al 2008 Extrapolation Practice for Ecotoxicological Effect Characterization of Chemicals.

Uncertainty in hazard quotients

- HQ assessments incorporate some form of uncertainly factor
  - Explicitly as part of the calculation itself, or
  - Criteria for acceptance of the HQ, and
  - Conservative values are used
- Common error
  - HQ itself is proportional to the “risk”
    - HQ is based on a point estimate of effect
    - Does not consider the relationship between the concentration and the effect

The LCx is a point-estimate

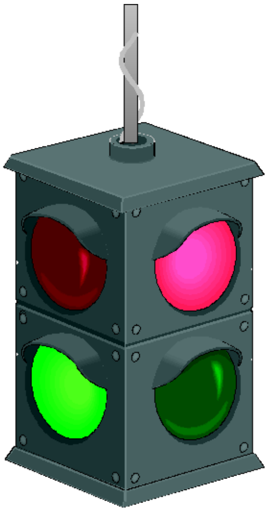


Problems with worst case

- May not be multiplicative or additive
- Inconsistent - it is always possible to conceive of a still worst case
- Do not consider the probability of occurrence
- Conservative assumptions based on premise of no societal or environmental costs resulting from regulation of false positives

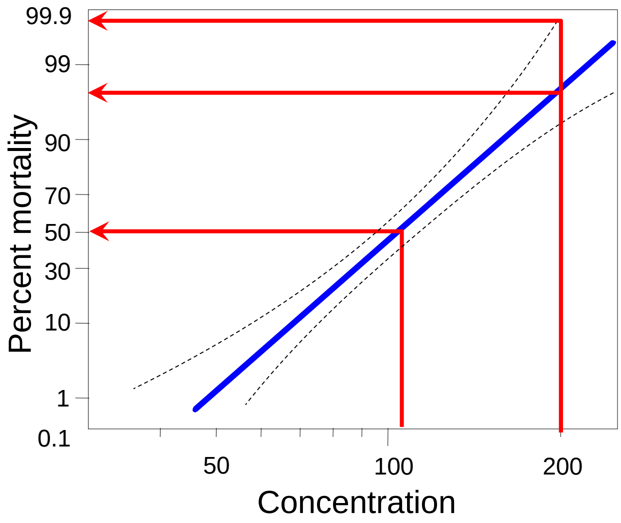
Quotient method

- The quotient approach is designed to be protective, not predictive.



"You can't say the government isn't trying."

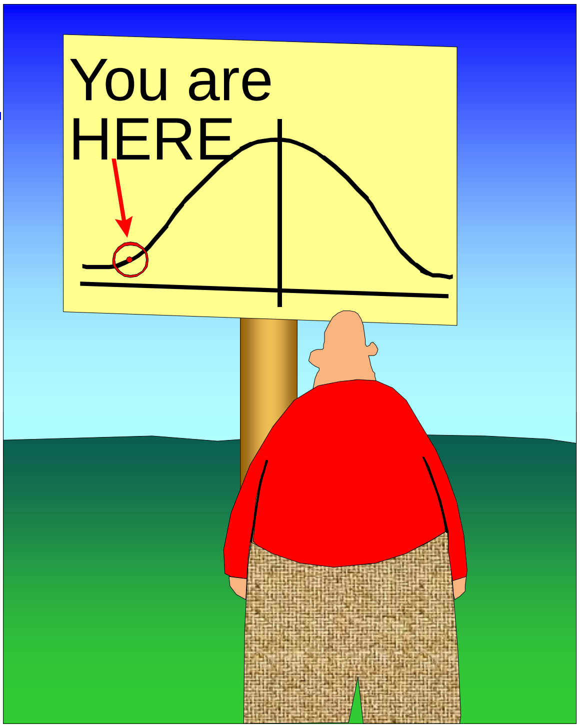
Proportion of the population of a test species

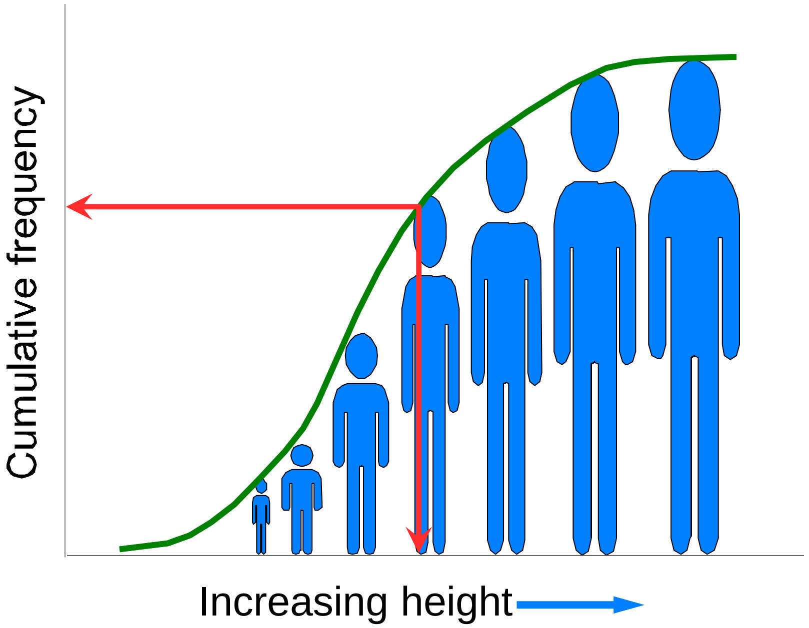


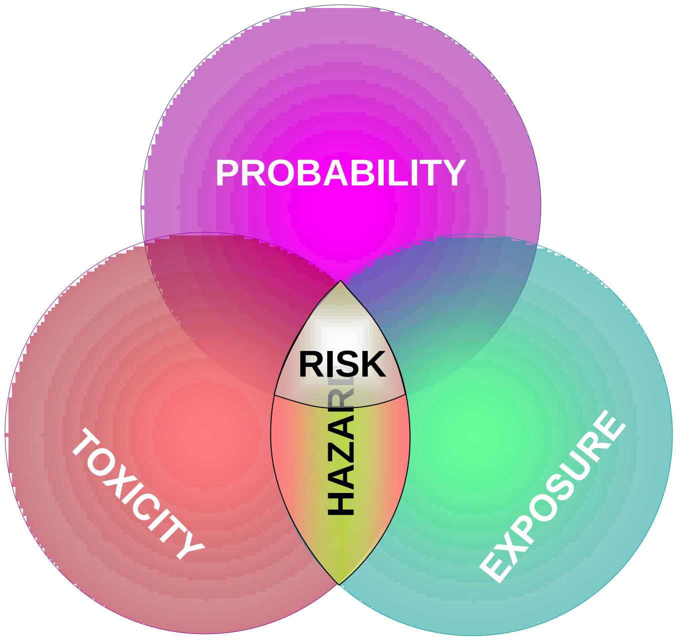
Probabilistic approach

CARL FRIEDRICH GAUß 30 April 1777 - 23 Feb 1855

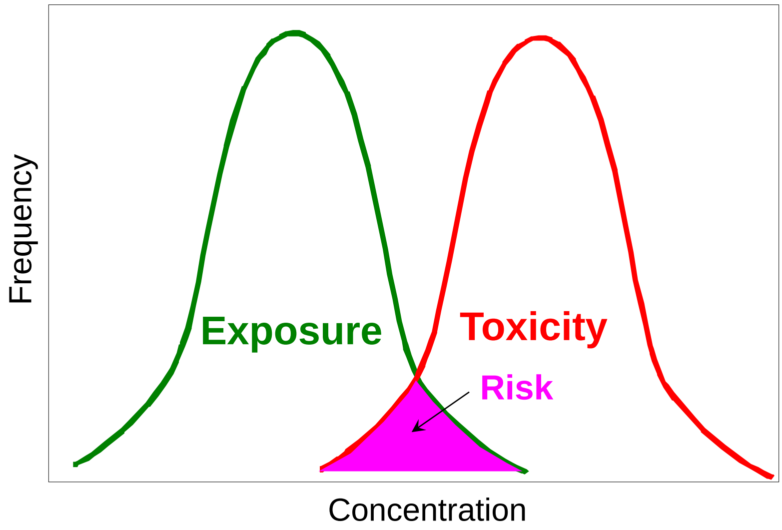
In all probability, ...



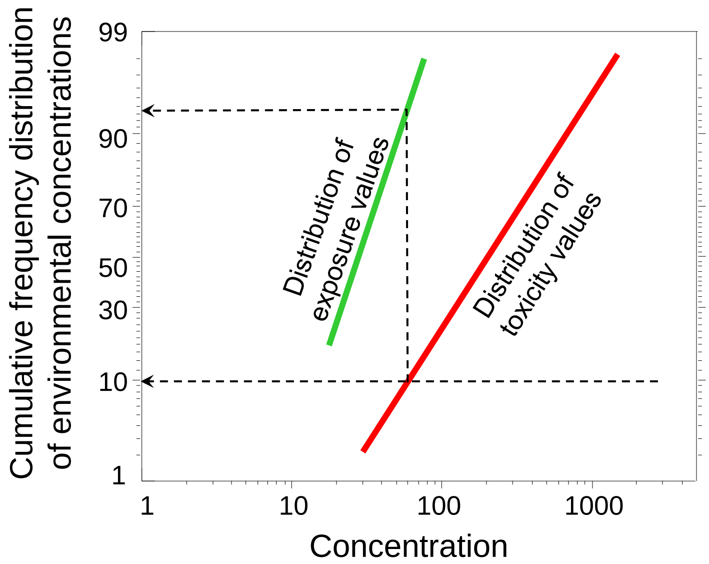




Probabilistic characterization of risk



Probability distributions



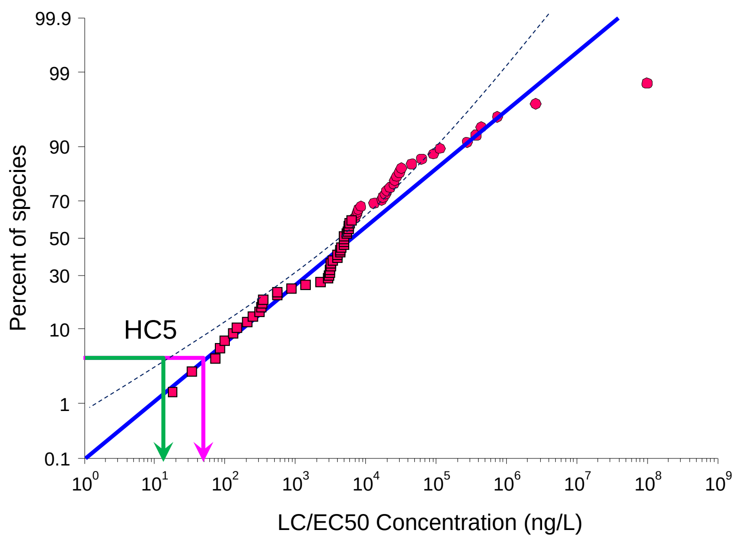
Uses of PRA

- Environmental guidelines and criteria
  - *A priori* decision on level of protection (inclusive)
    - 95% of species 95% of the time
    - Dutch HC5, US EPA's Final Acute Value, Final Chronic Value, Canada's new water quality guidelines.
- Risks in situations where exposures are known *a posteriori*
  - Predefined percentage of species to protect is not needed
  - Possible to exclude certain types of organisms
  - Risk can be expressed as a joint probability
  - Benefits can be considered in management

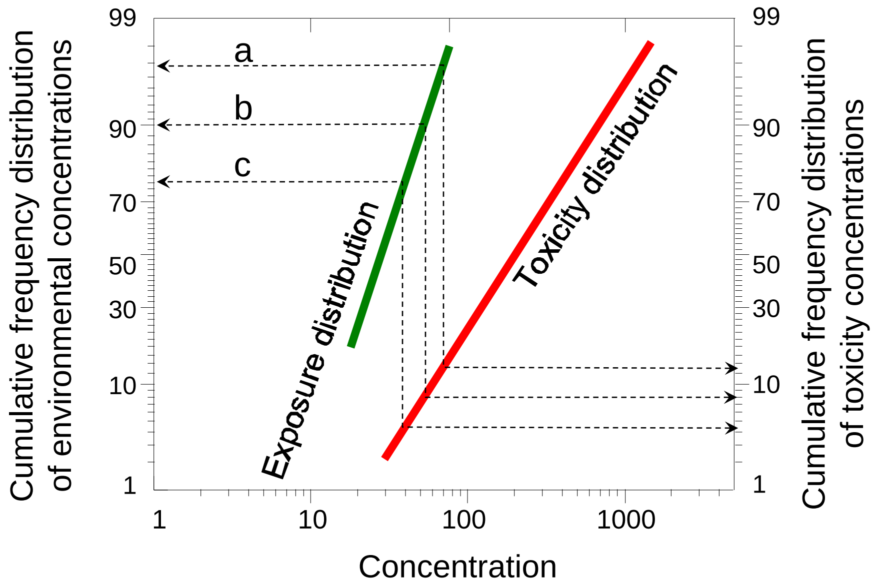
Criteria setting using probability

- Use a distribution of toxicity values (LC50 or NOEC)
- Take a lower centile of a distribution of toxicity values with or without an uncertainty factor (*a priori*)
  - USEPA Water Quality Criteria (WQC),
  - Great Lakes Initiative (GLI) approach,
  - EU HC5,
  - ANZEC,
  - Canadian Water Quality Guidelines.

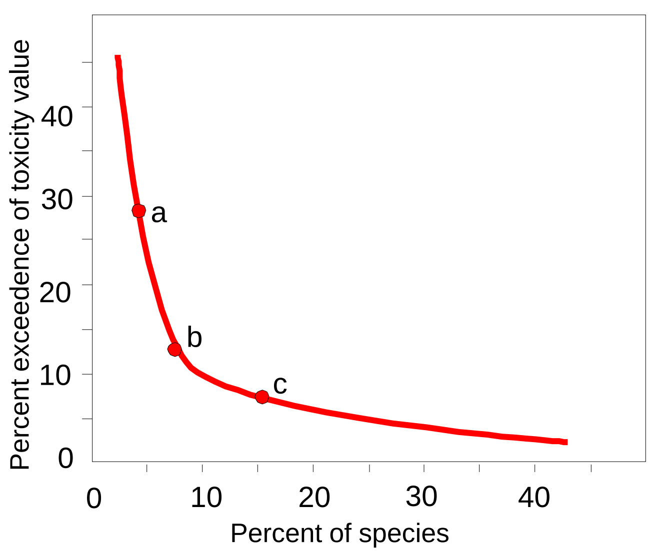
Cumulative distribution of toxicity values



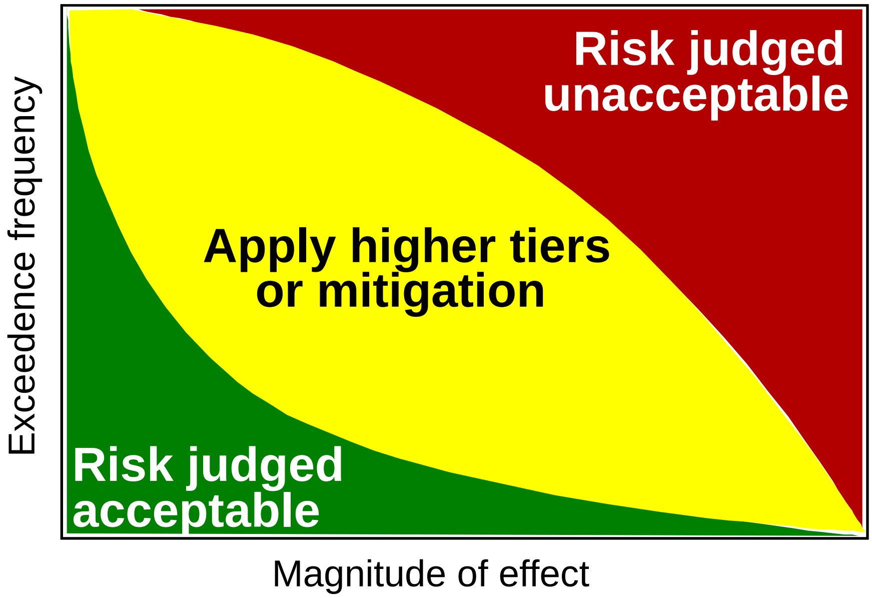
Exceedence profile



Joint probability curve

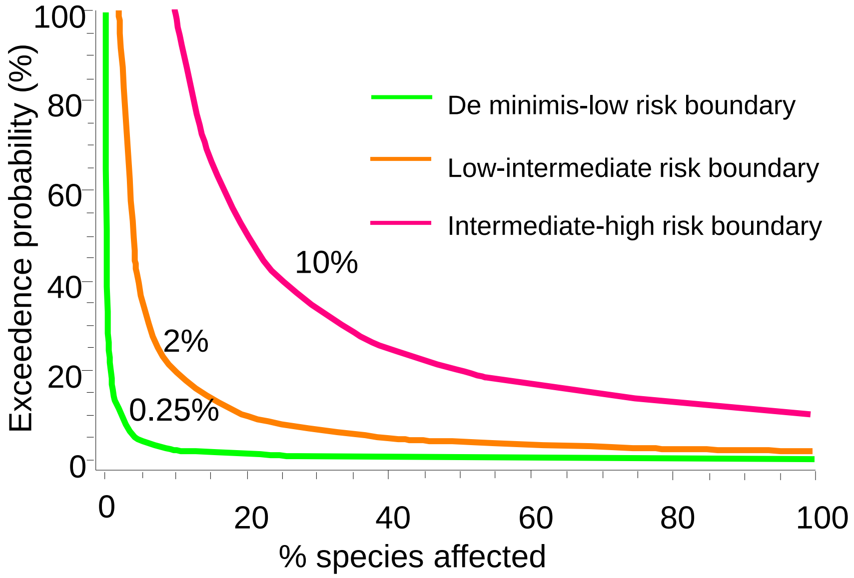


The JPC in decision making



From ECOFRAM 1999

Suggested criteria for risk



Moore et al 2010 Integr Environ Assess Manag 6:260

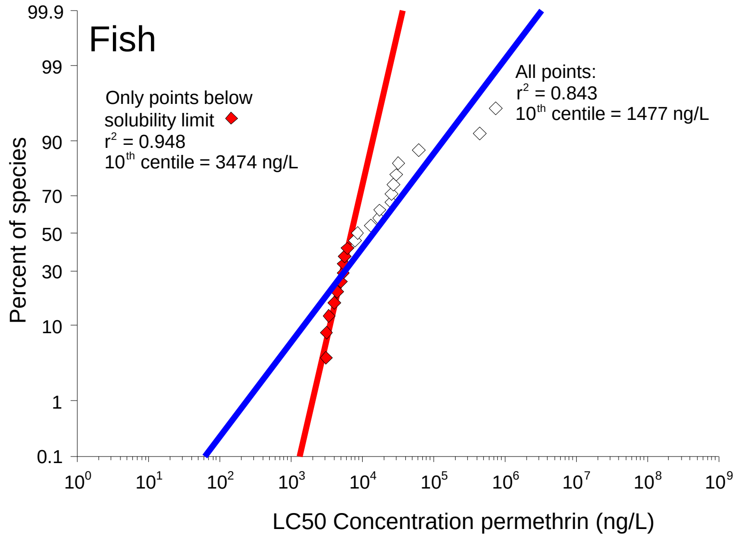
Frequency of effect

- In assessing ecotoxicological risks, the return frequency protected against should be consistent with the resiliency of vulnerable populations.
- Low return frequencies, for example, once in two or three years for fish.
- Higher return frequencies, days or weeks, for zooplankton.

Frequency of exposure and recovery

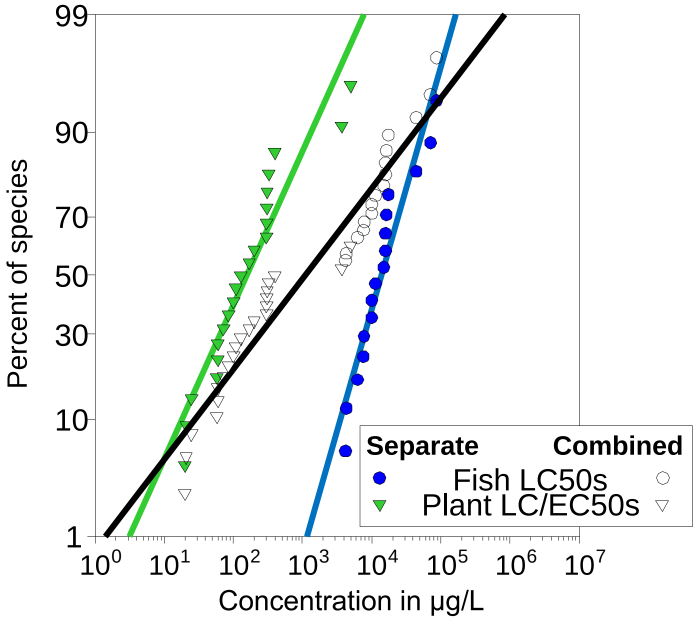
Mechanism	Examples where this applies	Examples where this does not apply
Short life cycle	Microalgae, bacteria, many arthropods and invertebrates, annual plants.	Most vertebrates, perennial plants, macroalgae
Many young produced	Most arthropods and invertebrates, some vertebrates (r-strategists), some plants	Most vertebrates (k-strategists), some plants
Protected stages and propagules	Arthropods from temperate regions, annual plants, some perennials	Almost all vertebrates, some perennial plants
Mobile stage that can cross habitat barriers (flying insects) to recolonize habitats	Most insects, most terrestrial vertebrates, many plants	Some arthropods, a few vertebrates, some plants

Solubility

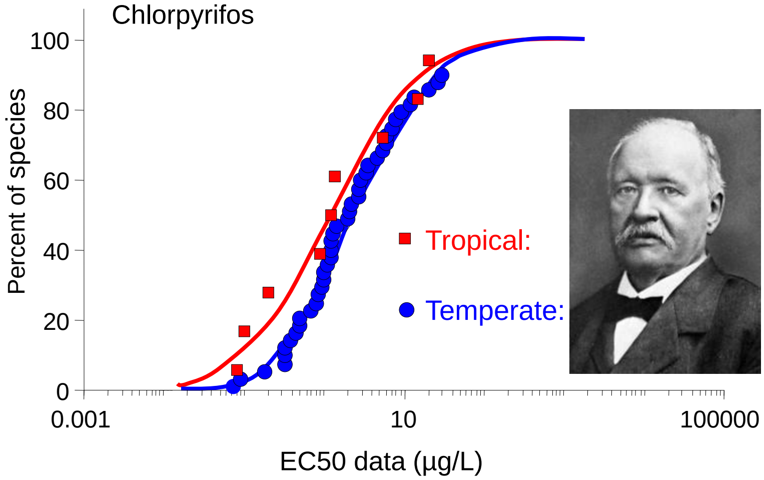


Solomon et al 2001 Environ Toxicol Chem 20:652

Mode of action



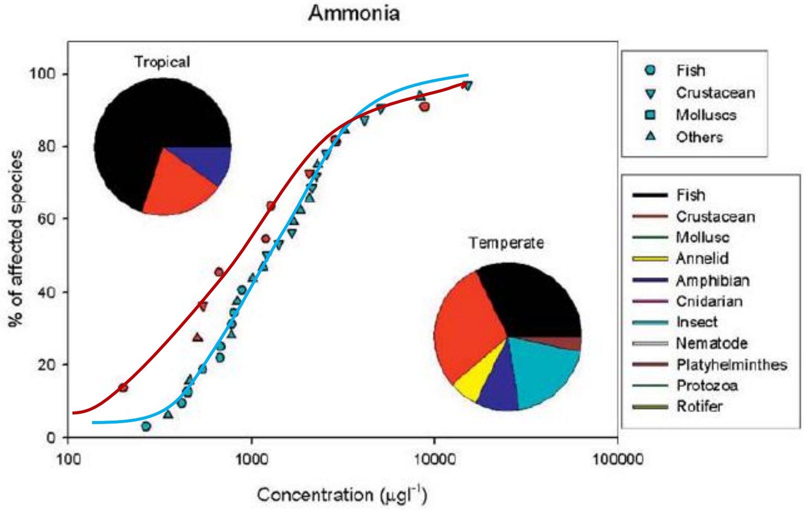
Different climatic regions



Toxicity sometimes increases with increasing temperature (Arrhenius equation) but does breakdown in the environment

Courtesy of Lorraine Maltby

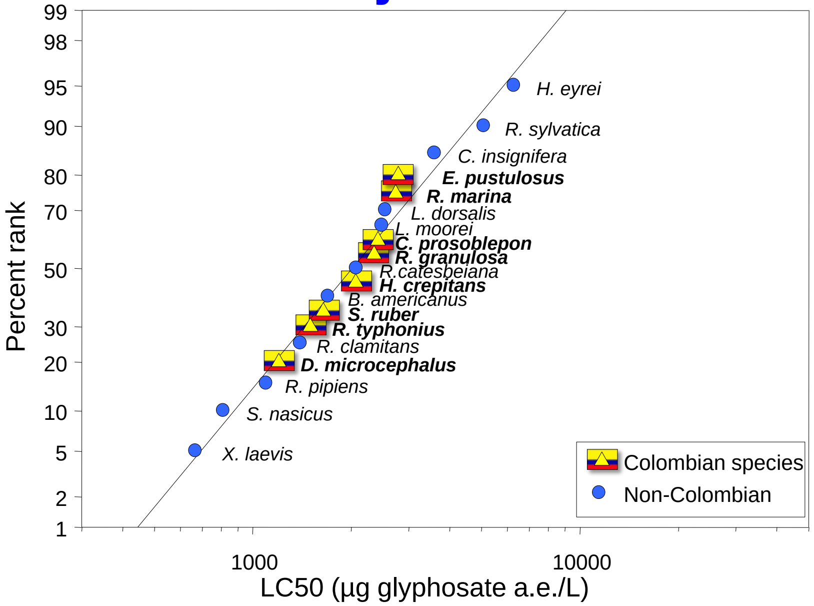
Difference between climatic regions



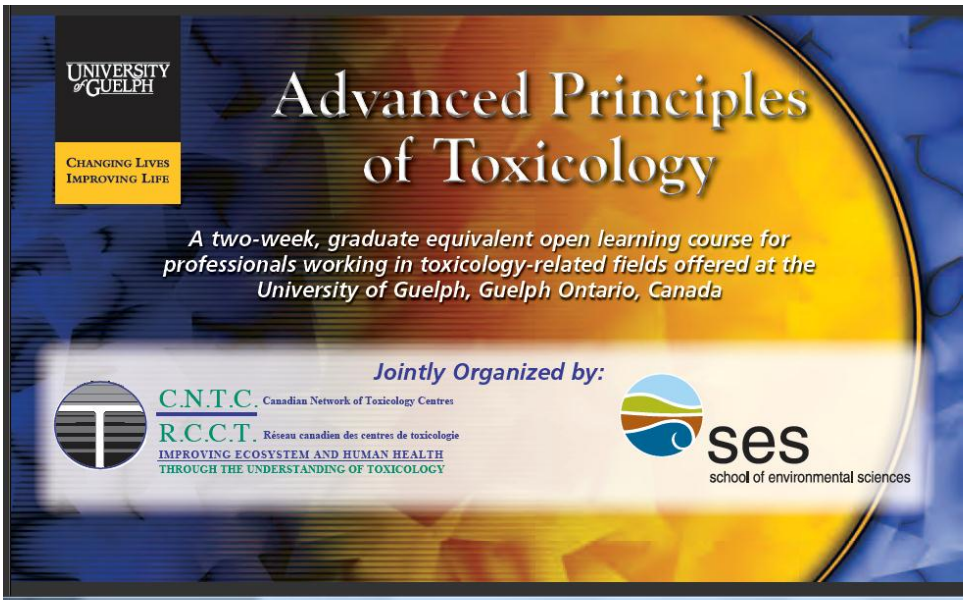
Differences driven by differences in types of species in the SSD

Kwok et al 2007 Integr Environ Assess Manag 3:49

Between jurisdictions



Bernal et al 2009 J Toxicol Environ Hlth A 72:961



April 29 to May 10, 2013 See
http://www.open.uoguelph.ca/offerings/offering.aspx?id=3982