ECOLOGICAL RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS

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ECOLOGICAL RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS

Course outline

Day 1: Overview of PPP ERA in the EU + New PPP Regulation + Defining SPGs

Day 2: ERA for aquatic compartment

Day 3: ERA for Birds and Mammals

Day 4: ERA for Non target plants + ERA for In-soil organisms

Day 5:ERA for Bees + ERA for Non-target arthropods

REFRESHING SOME KEY CONCEPTS ON ECOTOXICOLOGY AND ECOLOGICAL RISK ASSESSMENT

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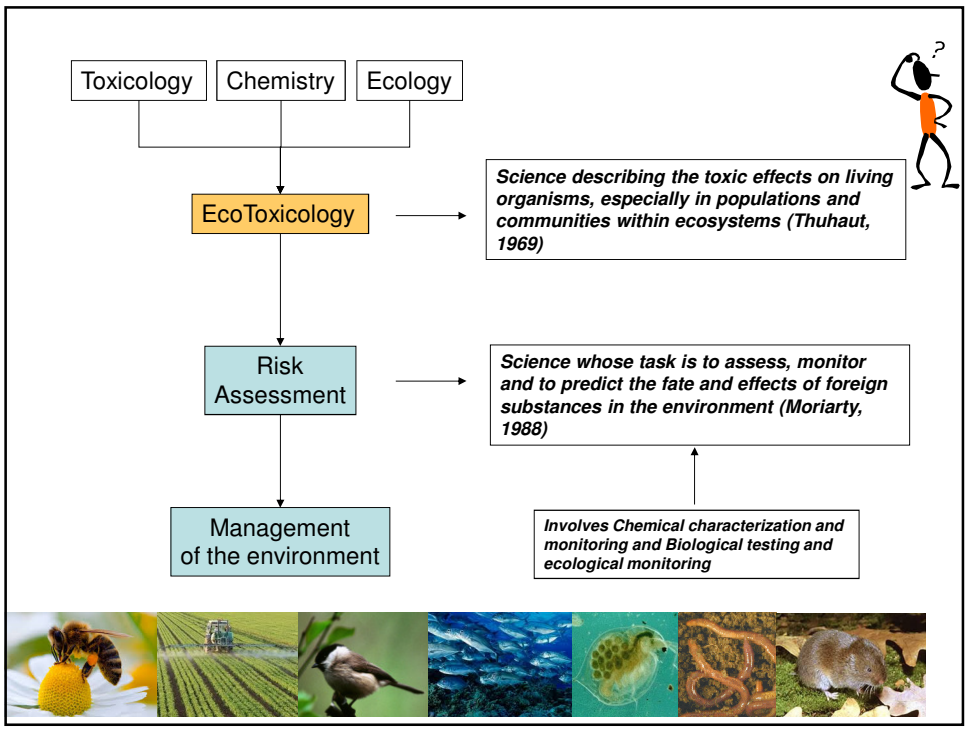
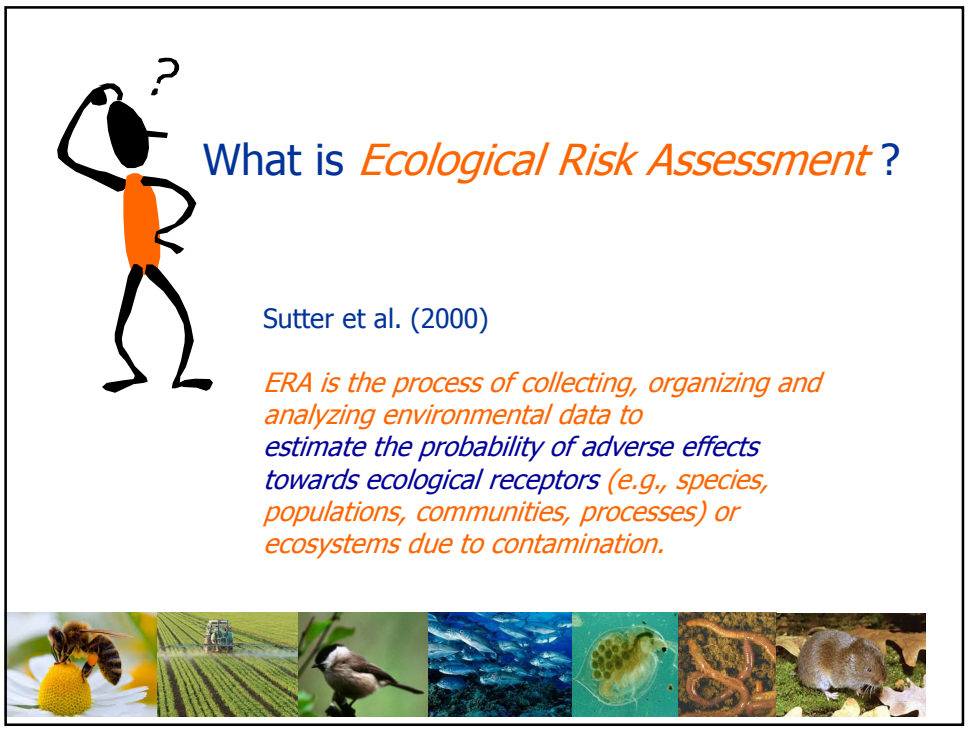
"All substances are poisons. There is none which is not a poison. The right dose differentiates the poison from a remedy"

Paracelcius (1493-1541)





What is *Ecological Risk Assessment* ?

Sutter et al. (2000)

ERA is the process of collecting, organizing and analyzing environmental data to estimate the probability of adverse effects towards ecological receptors (e.g., species, populations, communities, processes) or ecosystems due to contamination.

Ecological Risk Assessment - ERA

Prospective ERA

- Assessing potential future effects;
- Used to evaluate the effects of chemical substances (e.g., pesticides, veterinary pharmaceuticals) or complex matrices (e.g. sludge application)
- 'Substance testing'

Retrospective ERA

- Assessing previous or ongoing effects;
- Used to assess risks of contaminated sites
- 'Direct toxicity assessment'

Ecological Risk Assessment - ERA

Prospective ERA

- Assessing potential future effects;
- Used to evaluate the effects of chemical substances (e.g., pesticides, veterinary pharmaceuticals) or complex matrices (e.g. sludge application)
- 'Substance testing'

Basic scheme of a risk asessment...

Close dialogue between Risk Assessors and Risk Managers

Problem formulation (general and specific PGs)

Defining assessment scenarios (effects & exposure) Defining acceptability criteria

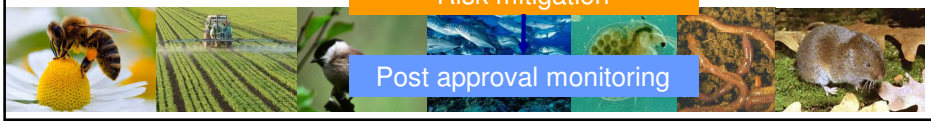
EXPOSURE assessment

EFFECTS assessment

Risk characterization

Risk mitigation

Post approval monitoring



Basic scheme of a risk asessment...

Define the SPGs (what, where and when)
Will the substance occur in the environment and where, and wich receptors will it affect

Problem formulation (general and specific PGs)

Defining assessment scenarios (effects & exposure) Defining acceptability criteria

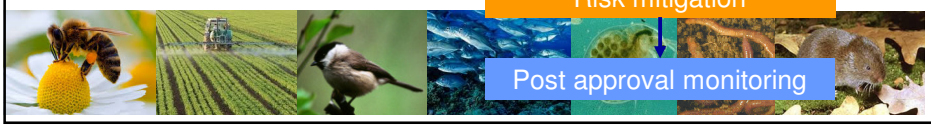
EXPOSURE assessment

EFFECTS assessment

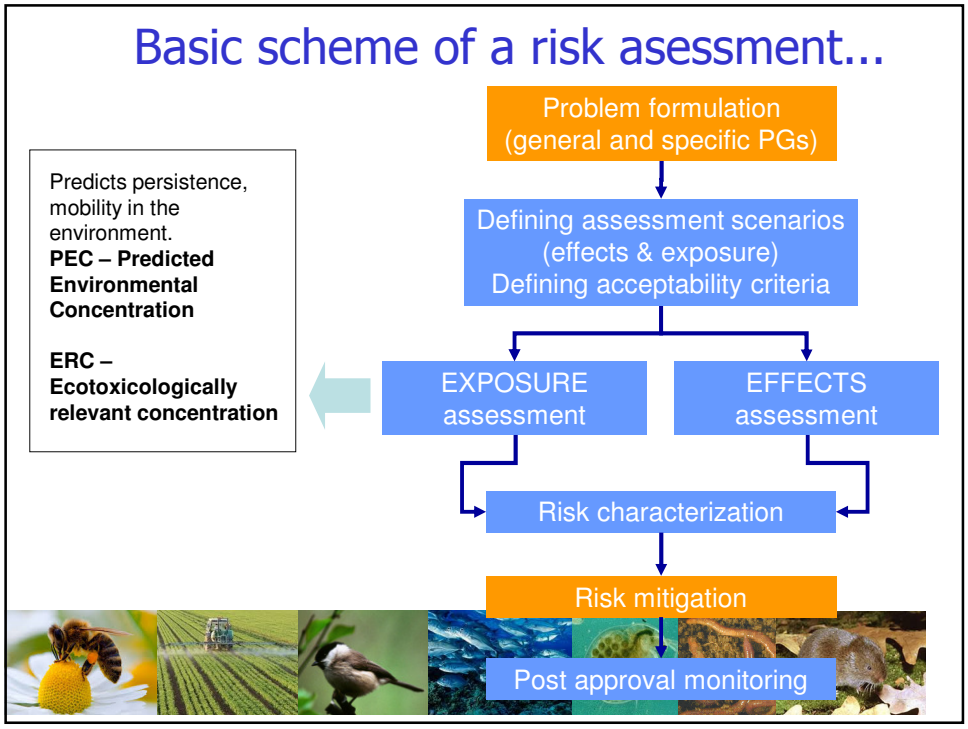
Risk characterization

Risk mitigation

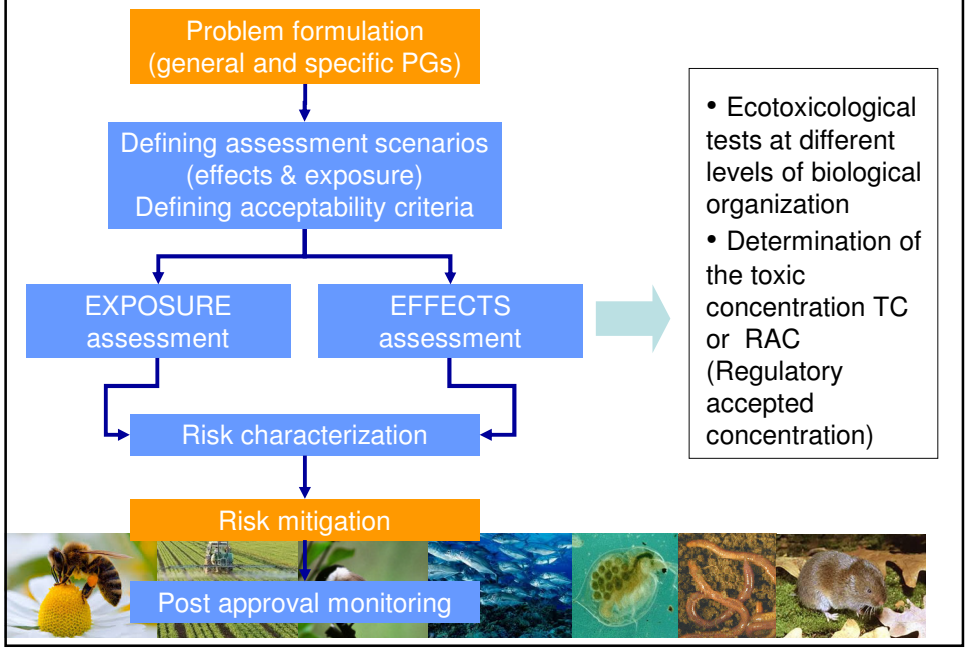
Post approval monitoring



Basic scheme of a risk asessment...



Basic scheme of a risk asessment...



Basic scheme of a risk asessment...

Problem formulation
(general and specific PGs)

Defining assessment scenarios
(effects & exposure)
Defining acceptability criteria

EXPOSURE
assessment

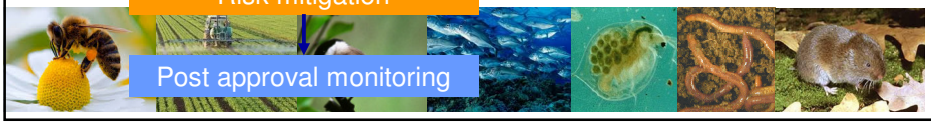
EFFECTS
assessment

Risk characterization

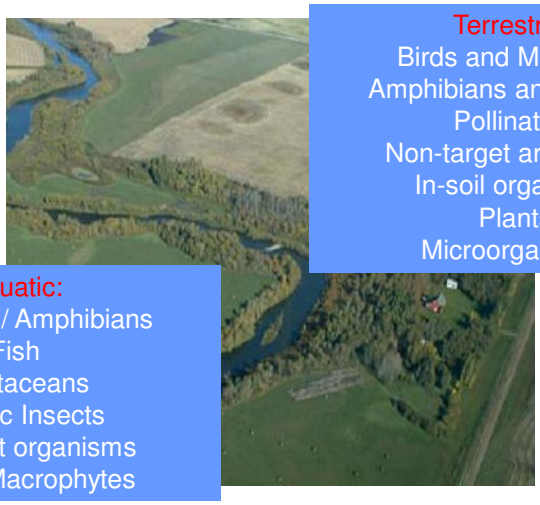
Risk mitigation

Post approval monitoring

Prospective ERA
Risk ratios:
- **PEC/TC**
- **TER**
- **Assessment factors**



Which organism groups are assessed…



Terrestrial:
Birds and Mammals
Amphibians and Reptiles
Pollinators
Non-target arthropods
In-soil organisms
Plants
Microorganisms

Aquatic:
Waterfowl / Amphibians
Fish
Crustaceans
Aquatic Insects
Sediment organisms
Algae / Macrophytes

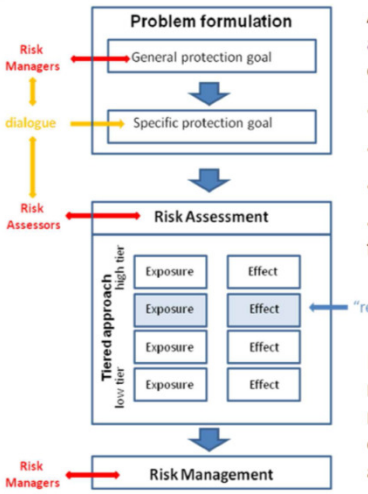
How are they assessed…?

- **TER-approach** (Toxicity-Exposure Ratio)
  - Ratio between effect threshold and environmental concentrations
  - Effect threshold estimated from effects observed in biological test systems (ecotoxicological tests + birds and mammals – mammals also used in human RA)
  - Environmental concentrations are calculated with models based on a standard set of input variables

How are they assessed…?

- Assessment endpoints in the Directive:
  - no unacceptable effects on the environment, real environmental concentration must be safely below the effect threshold
- Strategy
  - use of very conservative input parameters (test system design, percentiles)
  - Reduction of uncertainities for the parameters 'derived effect threshold' and 'predicted environmental concentration' (higher tier tests, complex models)
  - Tiered approach (Tier I and Higher Tiers)

SPGs and tiered Risk Assessment Schemes



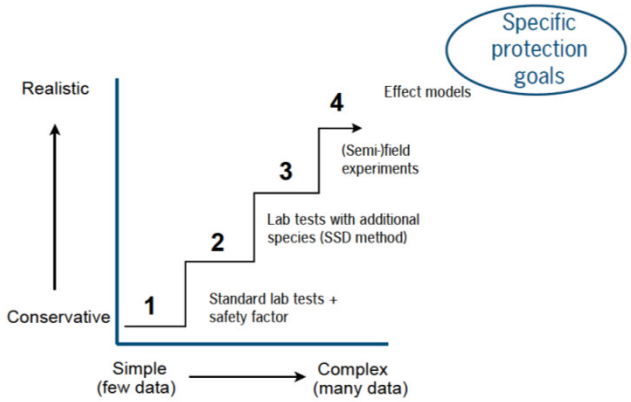
After SPGs are clear, **tiered risk assessment schemes** can be developed that are:

- Appropriately protective
- Internally consistent
- Cost-effective
- More accurate and precise when going from lower to higher tiers

For each SPG a **reference tier** needs to be identified based on the most practical and sophisticated experimental/modeling risk assessment method.

Nienstedt et al, (2012) STOTEN, 415:31-38

SPGs and tiered Risk Assessment Schemes



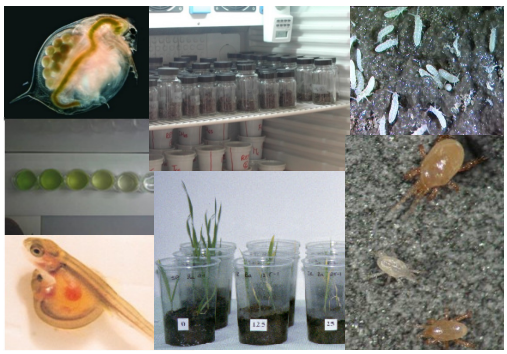
For all tiers the same specific protection goal is applicable but the different tiers achieve a different level of precaution

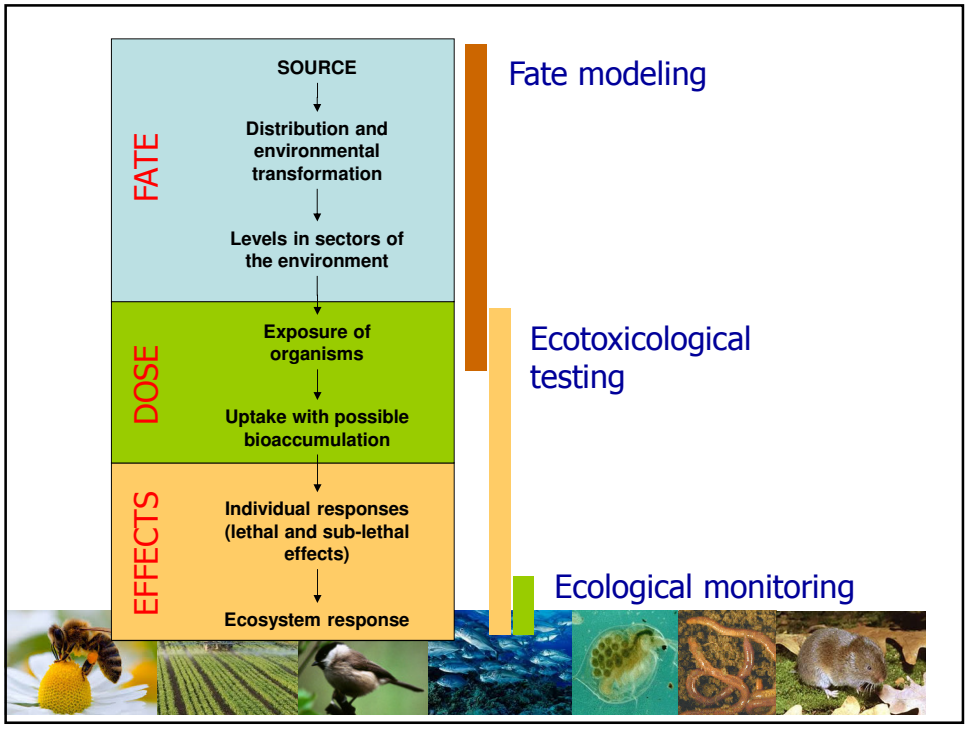
Nienstedt et al, (2012) STOTEN, 415:31-38

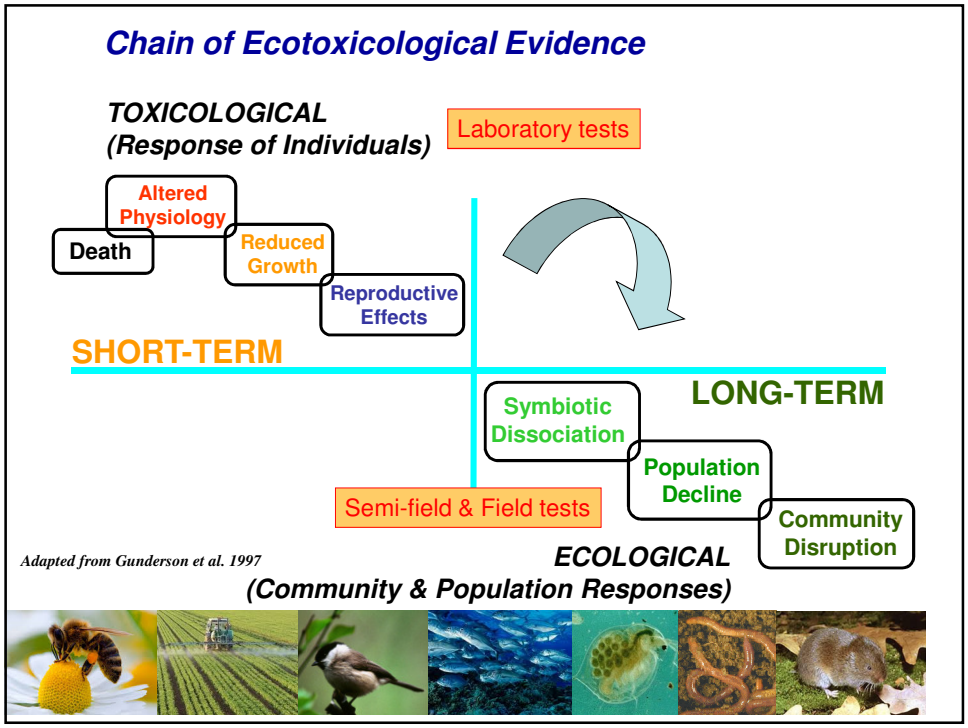
How are they assessed…?

- Tiered approach (Tier I and Higher Tiers)
  - input at Tier I conservative / realistic worst case
    - screening of the data for problematic areas possible
  - if Tier I with standard data sets is not passed
    - Higher Tier defined for each organisms group/ scenario (Refinement)
  - if Higher Tier not passed
    - no authorization

ECOTOXICOLOGICAL TESTING: GENERAL CONCEPTS




FATE
SOURCE
Distribution and environmental transformation
Levels in sectors of the environment
DOSE
Exposure of organisms
Uptake with possible bioaccumulation
EFFECTS
Individual responses (lethal and sub-lethal effects)
Ecosystem response
Fate modeling
Ecotoxicological testing
Ecological monitoring


Chain of Ecotoxicological Evidence
TOXICOLOGICAL
(Response of Individuals)
Laboratory tests
Altered Physiology
Death
Reduced Growth
Reproductive Effects
SHORT-TERM
LONG-TERM
Symbiotic Dissociation
Population Decline
Community Disruption
Semi-field & Field tests
Adapted from Gunderson et al. 1997
ECOLOGICAL
(Community & Population Responses)

DOSE is the KEY

Control

Increasing concentration of the contaminant

ANOVA

NOEC - No Observed Effect Concentration

% response

50

20

LOEC - Lowest Observed Effect Concentration

ANOVA

EC_{20}

EC_{50}/LC_{50}

Regression methods

Concentration (mg/l)

Parameters used to express the toxicity of a chemical (or contaminated matrix) and used in risk assessment

NOEC (CENO) – *No-observed-effect-concentration*. It is the highest tested concentration whose effect is not statistically different from the control treatment

LOEC (CEO) – *Lowest observed effect concentration*. It is the lowest tested concentration that originated na effect that is statistically different from the control treatment

EC50 – *median effective concentration*. It is the concentration of the substance in the medium (water, soil, etc) that causes a specific toxic effect to 50% of the test organisms. Other ECx values can be derived and the importante is to derive relevant ECx values according to the organism group we are calculating the risk to.

SPECIES SENSITIVITY DISTRIBUTIONS

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Species Sensitivity Distributions (SSDs)

Derivation of safety values for the protection of the habitat function

- Pre-conditions
- Extrapolation methods

Pre-condition: data sources

Test Protocols:

Only data from tests performed according to international standard protocols or well documented results from mesocosm/field experiments

End species:

Tests with microbes, plants and invertebrates
Microbial functions are treated like species

Data set (all from chronic soil tests):

NOEC / EC10 values ➔ precautionary values
EC_{50}-values ➔ trigger values

Extrapolation methods I

Extrapolation methods include safety or assessment factors to overcome uncertainties

(van Leeuwen *et al.* 1996)

- from effects on organisms to effects on populations
- from one species to many other species
- from lethal to chronic effects
- from direct to indirect effects
- from one ecosystem to another
- in time and space
- synergistic / antagonistic effects when complex contamination is given

Extrapolation: FAME I

US-EPA (1984), European Community (1996)

- The lowest available (no)effect concentration is divided by a safety factor between 1 and 1000
- Can be applied even if the data set is meager
- Problematic for the 'static' relationship between L(E)C50-concentrations and NOECs

This approach is very formal. Its outcome mainly depends on the lowest effect value, meaning that it is very inefficient and also easily biased.

Extrapolation: FAME II

Data set	Safety factor
Few data a./o. organisms: the lowest L(E)C50- concentration *divided by*	**1000**
Sufficient number of data / taxonomic groups: the lowest L(E)C50- concentration *divided by*	**100**
Sound NOEC data set: the lowest NOEC *divided by*	**10**
Model ecosystem or field investigation: data *divided by*	**x***

* decided from case to case

Extrapolation: FAME III

Relationship between L(E)C50-concentrations and NOECs ➔ highly variable

TABLE I

Comparison of lethal and sublethal effects of cadmium on five different species of soil invertebrates. LC_{50} = median lethal concentration. NOEC = no observed effect concentration for reproduction. SSI = sublethal sensitivity index = LC_{50}/NOEC.

Species	*LC_{50} (µg/g)*	*NOEC (µg/g)*	*SSI*	*Source*
Lumbricus rubellus	575	10	57.5	MA (1982)
Eisenia fetida	1843	25	73.7	MALECKI *et al.* (1982)
Orchesella cincta	180	56.2	3.2	VAN STRAALEN *et al.* (1989)
Folsomia candida	854	148	5.8	CROMMENTUIJN *et al.* (1993)
Platynothrus peltifer	817	2.9	282	VAN STRAALEN *et al.* (1989)

Extrapolation: DIBAEX I

The extrapolation method is based on the **species sensitivity distribution (SSD).**

Van Straalen & Dennemann (1989), Wagner & Løkke (1991), Aldenberg & Slob (1993), Aldenberg & Jaworska (2000)

Basic assumption:

Test data (EC_{10} or EC_{50} or NOECs) for every tested species and for all species in the community are independent variables that follow a continuous symmetric log-normal distribution

Extrapolation: DIBAEX II

Determination of the HC_5 (Hazard Concentration 5%):

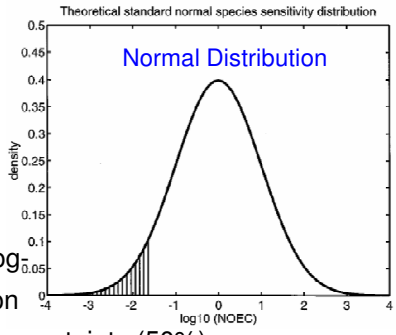
$$\log(HC_p) = \bar{x} - k_s \cdot s$$

with:

$\bar{x}$ = mean value

s = standard deviation of the log-transformed EC_{50} values

k_s = tolerance factor for the log-, depending on the protection level (95%) and statistical uncertainty (50%)



In case there are several effect data available for one species, the geometrical mean / median will be used for the calculation.

Extrapolation: DIBAEX III

- Cannot be applied if the data set is meager
- The extrapolated values are not dependent from one data set (the lowest)
- If applied with NOECs as data basis, the concentration calculated may be lower or similar to the background concentration (not for PPPs)

The soil ecosystem is considered to be protected when 95% of the species have an ECx higher than the trigger value (HC5).

But: do have all species the same importance?

Extrapolation: DIBAEX IV

Principles of SSD derivation:

► Origin of toxicity data: EC_{50} values

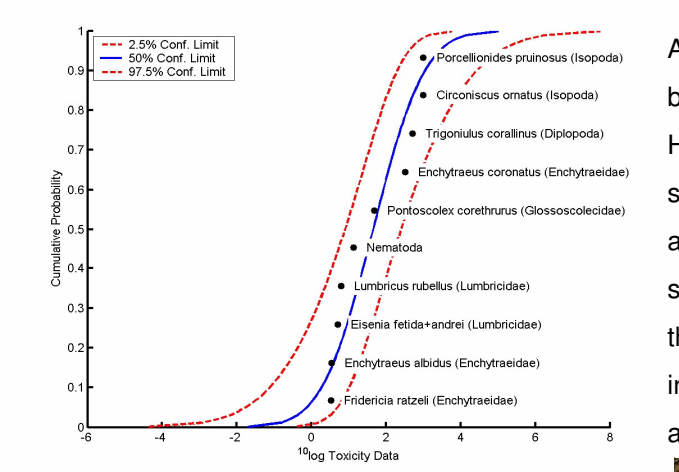
► If possible, differentiation according to pH or texture

► Extremely important ➔ Check of result plausibility with

- Soil background concentrations (not for PPPs)
- Trigger values for other compartments
- Effect data from the field
- International soil values
- Expert judgment

Extrapolation: DIBAEX V

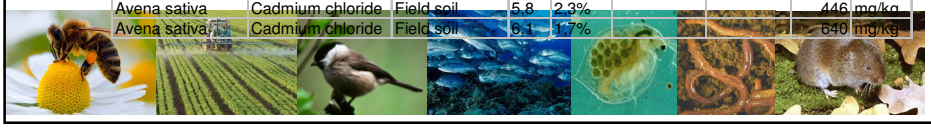
Graphical presentation of SSD results:



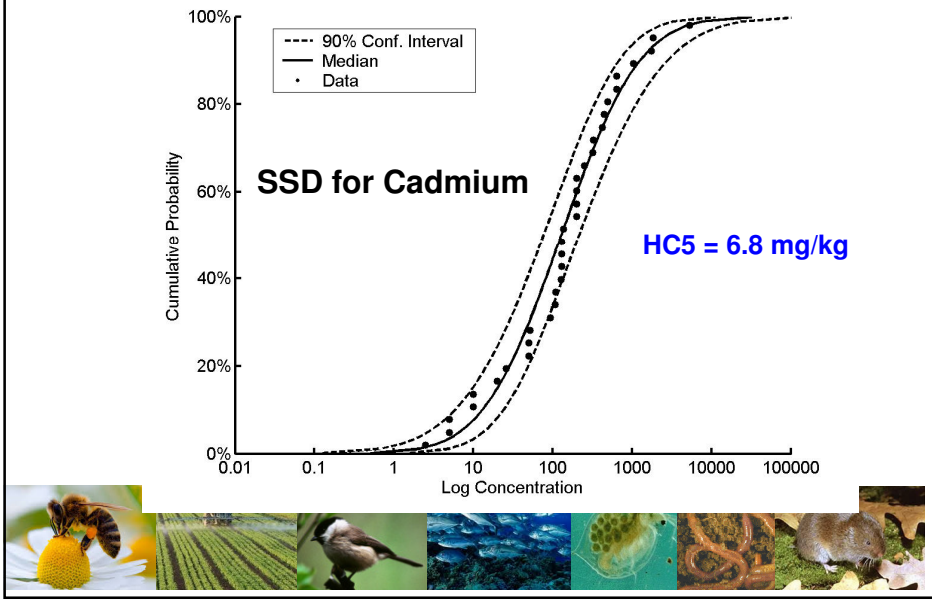
At the bottom: Highly sensitive annelid species, at the top insensitive arthropods.

Example: Cadmium test data (part)

ORGANISM	SUBSTANCE	SOIL	pH	OC	DURATION	UNIT	EC50	UNIT
N-mineralisation	Cadmium chloride	Field soil	6,0	1,2	28	days	50	mg/kg
N-mineralisation	CdSO4		6,4	1,20%	48	hours	2	mg/kg
Phosphatase	Cadmium chloride	Field soil	7,4	2,4%	6	weeks	5485	mg/kg
Phosphatase	Cadmium chloride	Field soil	7,4	2,4%	18	months	230	mg/kg
Phosphatase	Cadmium chloride	Field soil	6,8	3,2%	18	months	5305	mg/kg
Phosphatase	Cadmium chloride	Field soil	6,8	3,2%	6	weeks	9779	mg/kg
Phosphatase	Cadmium chloride	Field soil	7,7	1,6%	6	weeks	840	mg/kg
Phosphatase	Cadmium chloride	Field soil	7,7	1,6%	18	months	330	mg/kg
Phosphatase	Cadmium chloride	Field soil	5,1	5,7%	18	months	9869	mg/kg
Potential ammoniu	Cadmium chloride	Field soil	5,5	1%			149	mg/kg
Potential ammoniu	Cadmium chloride	Field soil	5,4	3,3%			472	mg/kg
Potential ammoniu	Cadmium chloride	Field soil	6,1	1,7%			328	mg/kg
Protease activity	Cadmium chloride	Field soil	6,0	1,2			200	mg/kg
proteolytische Akti	Cadmium chloride	Field soil		?	30	days	4,97	mg/kg
SIR	Cadmium chloride	Field soil	5,5	1%			538	mg/kg
SIR	Cadmium chloride	Field soil	6,1	1,7%			640	mg/kg
SIR	Cadmium chloride	Field soil	5,4	3,3%			640	mg/kg
Urease activity	Cadmium chloride	Field soil	7,7	1,6	5	hours	120	mg/kg
Urease activity	Cadmium chloride	Field soil	5,1	5,7	5	hours	30	mg/kg
Urease activity	Cadmium chloride	Field soil	6,8	3,2	5	hours	520	mg/kg
Urease activity	Cadmium chloride	Field soil	4,3	12,8	5	hours	490	mg/kg
Urease activity	Cadmium chloride	Field soil	7,4	2,4	5	hours	520	mg/kg
Allium cepa	Cadmiumsulfat Hep	Field soil	8,3	0,28			200	mg/kg
Avena sativa	Cadmium chloride	Field soil	5,8	2,3%			446	mg/kg
Avena sativa	Cadmium chloride	Field soil	6,1	1,7%			640	mg/kg



Example: Cadmium



Example: Cadmium

	FAME – Method		DIBAEX - Method	
Data basis	**Factor**	**Cd (mg/kg)**	**Protection-level**	**Cd (mg/kg)**
EC50	10	**0.2**	95%	**6.8**

Plausibility check

- **FAME method produces too low values**
- Background concentrations: up to 2 mg/kg soil
- calculated value + expert knowledge

  ➔ Trigger value = 7.0 mg cadmium/kg soil

Proposed test battery for the derivation of SSDs

In accordance with recommendations for the use of SSDs in other areas of ecotoxicology, the following criteria are proposed:

- As a minimum, 8 effect values from species out of at least 6 different groups, representing different exposure pathways, taxonomy, physiology etc., should be used.
- All tests have to be performed according to standardized guidelines and with different soils.
- Plausibility data, such as results from field test, should be provided.

Summary

- ► An European metal database is available which can easily be used for further derivations of SSD/HC5 values.
- ► Using the SSD methodology, robust soil values could be calculated. In addition, it is internationally accepted
- ► For PPPs and other compounds more data is needed.
- ► In the next step, a test strategy should be agreed-on, including considering the implementation of the bioavailability of the individual substances.