Current issues in the aquatic risk assessment for pesticides: HARAP, CLASSIC and ELINK revisited

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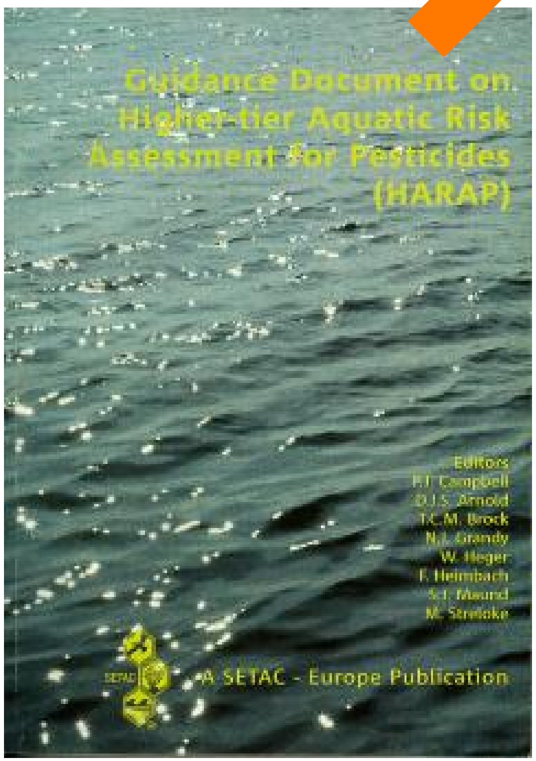
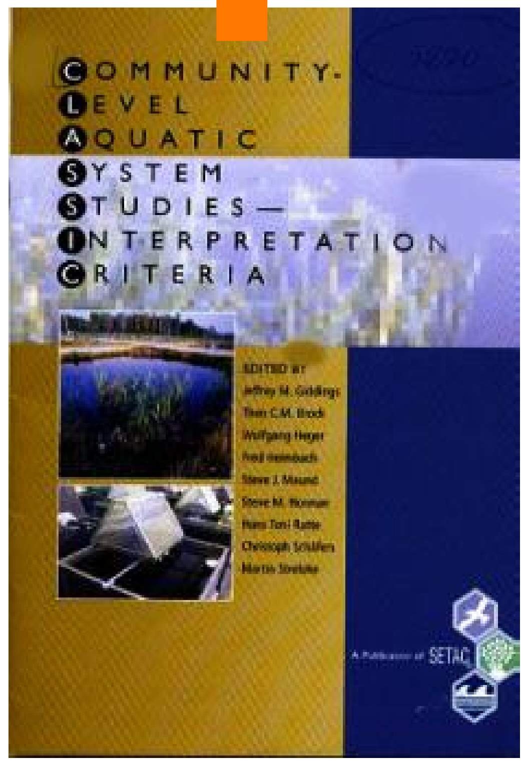
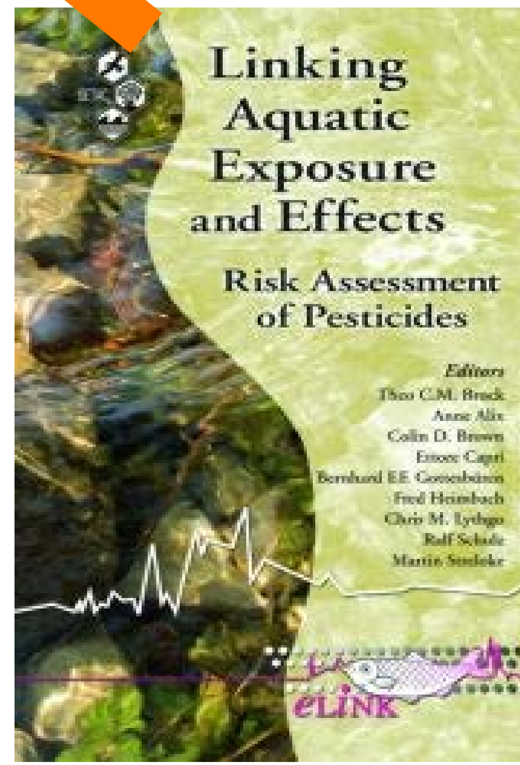
Aquatic Guidance Document (EFSA PPR, 2013)



HARAP Workshop 1998 (SETAC, 1999) Recommendations for higher-tier effects assessment



CLASSIC Workshop 1999 (SETAC, 2002) Further guidance on interpreting micro/mesocosm studies



ELINK Workshop 2008 (SETAC, 2009) Recommendations for linking exposure and effect estimates

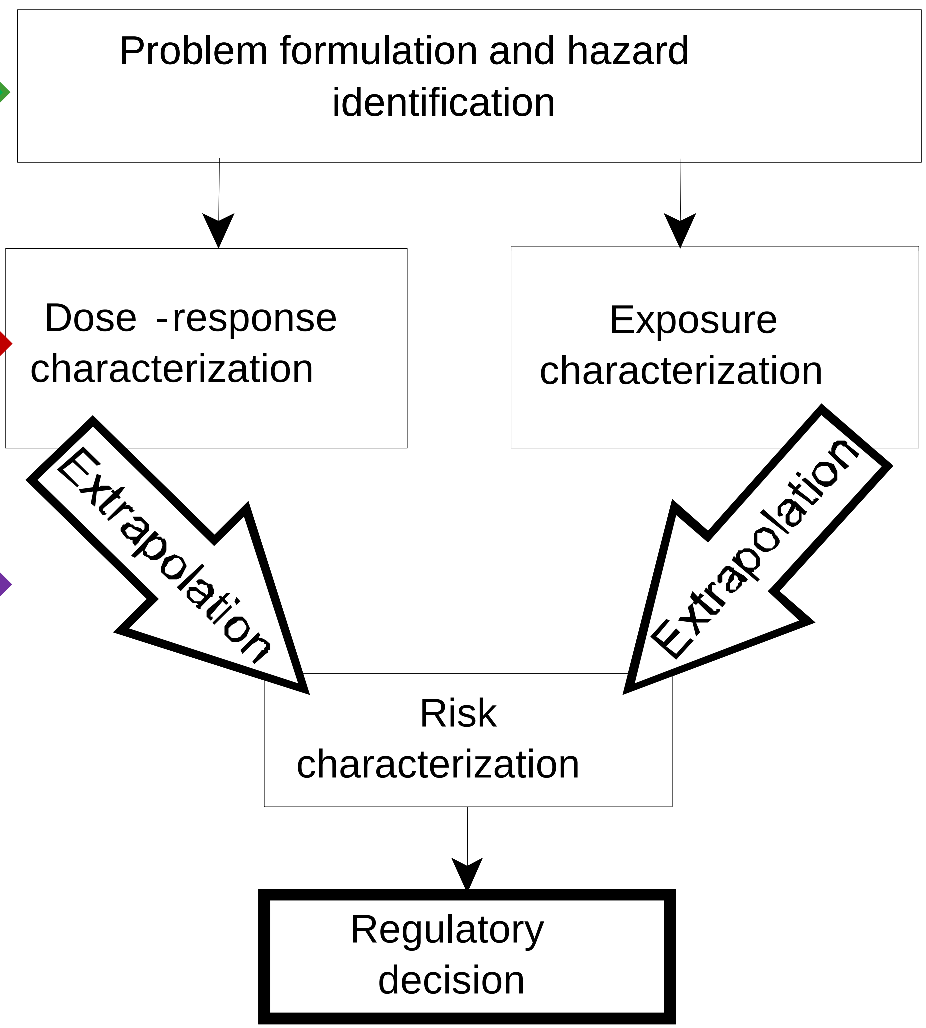
Issues discussed in this presentation

Specific protection goals
- Ecological Threshold Option
- Ecological Recovery Option

Consistency tiered approach
- Protectiveness lower tiers
- Validity criteria higher tiers

Extrapolation tools
- Ecological and environmental scenarios
- Effect models

RISK ASSESSMENT



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Specific Protection goals in AGD (EFSA PPR, 2013)

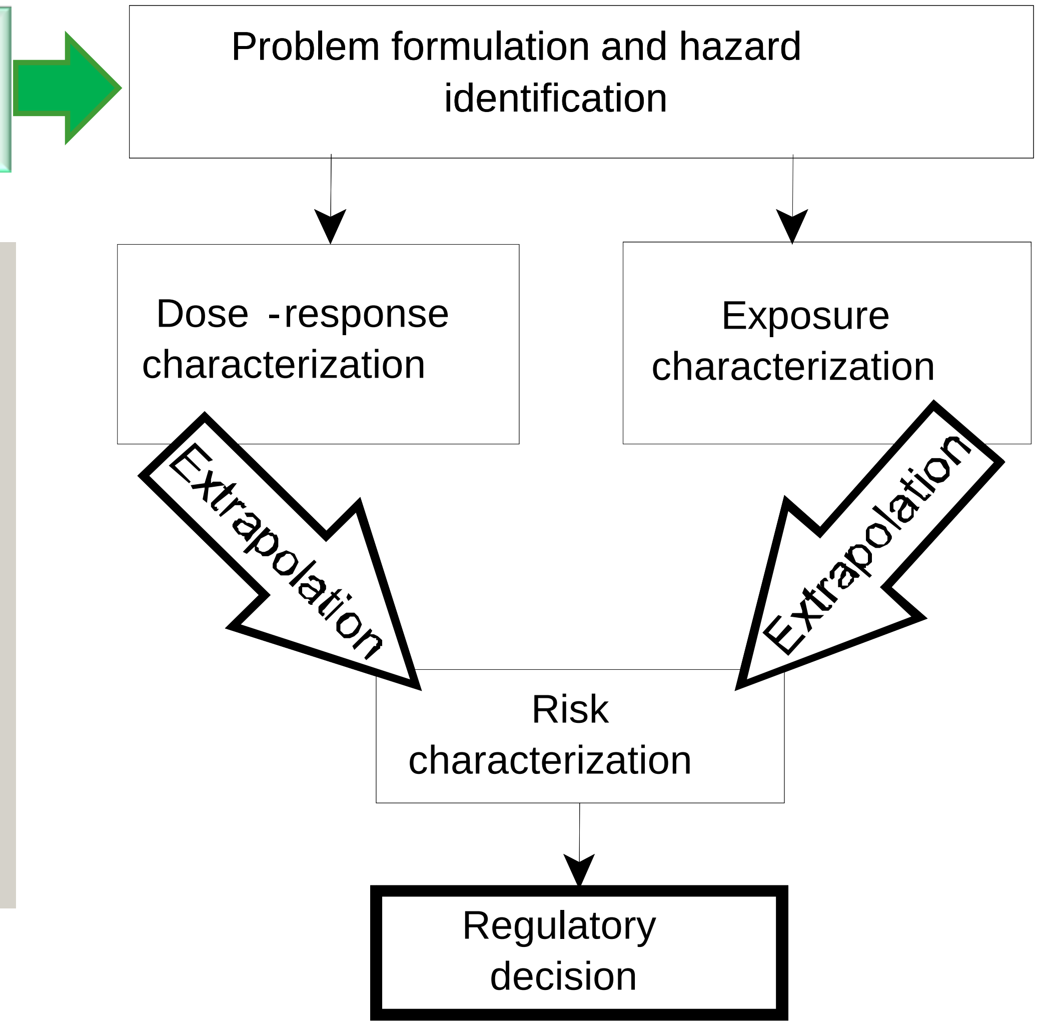
Specific protection goals
- Ecological Threshold Option
- Ecological Recovery Option

Before drafting the AGD, EU risk managers were offered several SPG options.

They selected both the ETO and ERO options

In the AGD, decisions schemes are described that address both options

RISK ASSESSMENT



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Specific protection goals for water organisms

Ecological threshold option (ETO)

Organism group	Ecological entity	Attribute	Magnitude	Time
Algae	population	abundance/ biomass	negligible effect	not applicable
Aquatic plants	population	survival/growth abundance/ biomass		
Aquatic invertebrates	population	abundance/ biomass		
Vertebrates	individual	survival		
	population	abundance/ biomass		
Aquatic microbes	functional group	Processes (e.g. litter break down)	RA is not developed since Tier-1 data requirements are not defined	

EFSA PPR, 2013

Specific protection goals for water organisms

Ecological recovery option (ERO)

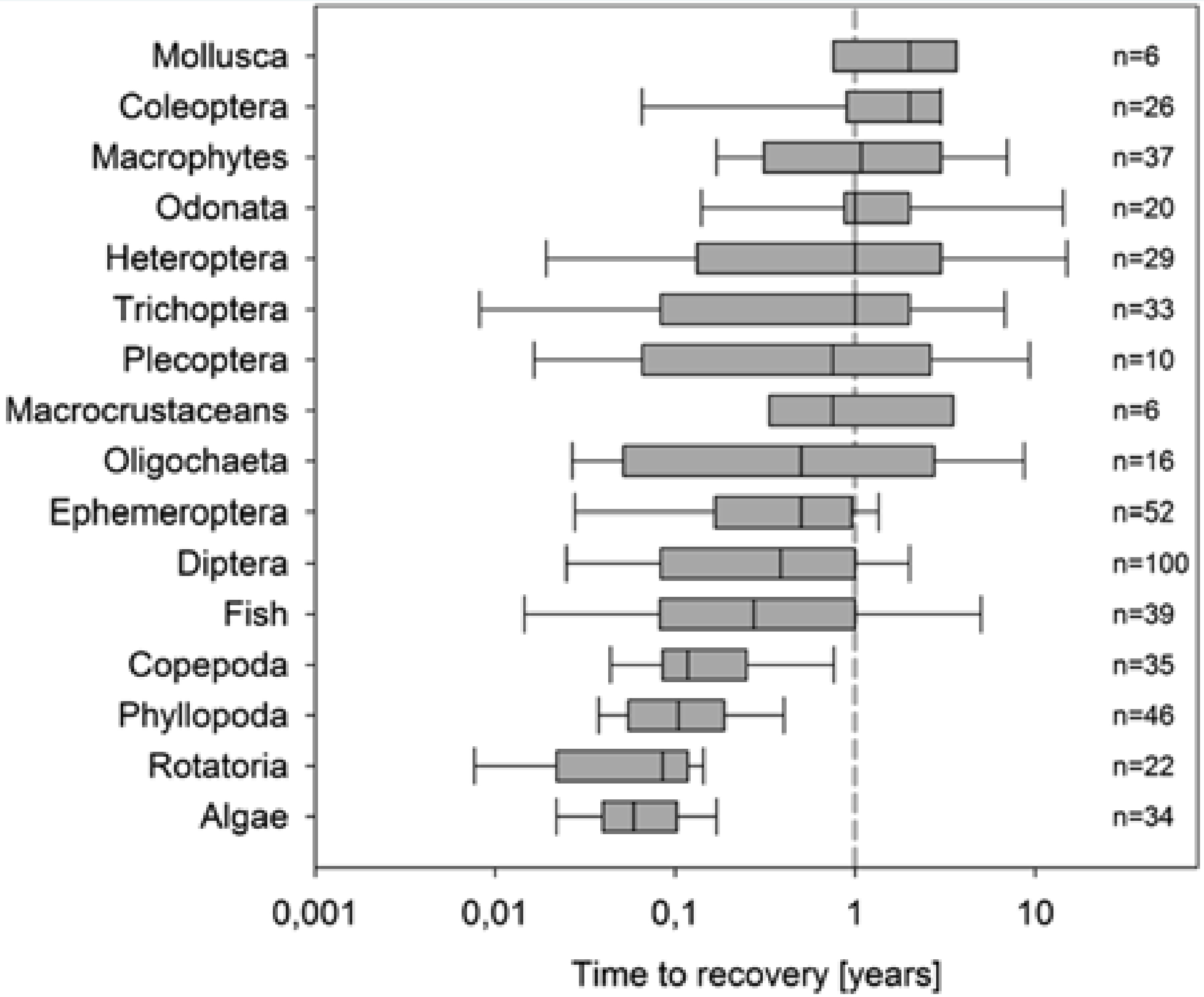
Organism group	Ecological entity	Attribute	Duration and magnitude of effect on sensitive and vulnerable populations
Algae	Population	Abundance/ Biomass	Total effect period < 8 weeks (also for repeated applications) Usually not possible for vulnerable populations with long life cycles and low dispersal abilities Not leading to ecologically important indirect effects
Aquatic plants	Population	Survival/growth abundance/ Biomass	
Aquatic invertebrates	Population	abundance/ biomass	
Vertebrates	No recovery option		

EFSA PPR, 2013

Ecological Recovery Option (ERO)

- ERO may be addressed by micro-/mesocosm experiments and effect models for vulnerable taxa at risk
- Reluctance of regulatory authorities to accept an ERO-RAC derived from a micro-/mesocosm experiment
    - Representativeness of test system for vulnerable species
    - Possible risks due to simultaneous or repeated use of different PPPs
- Reluctance of regulatory authorities to accept population models in absence of EFSA guidance
    - Lack of experience and expertise in interpreting results of population-level models at MS level

Reported recovery times (years) for different groups of aquatic organisms independent of stressor



Gergs et al. 2016. Reviews Environ Contam Toxicol 236, 259-294

Boxes represent quartiles and whiskers symbolize 95 % confidence intervals. *n* = number of recovery endpoints

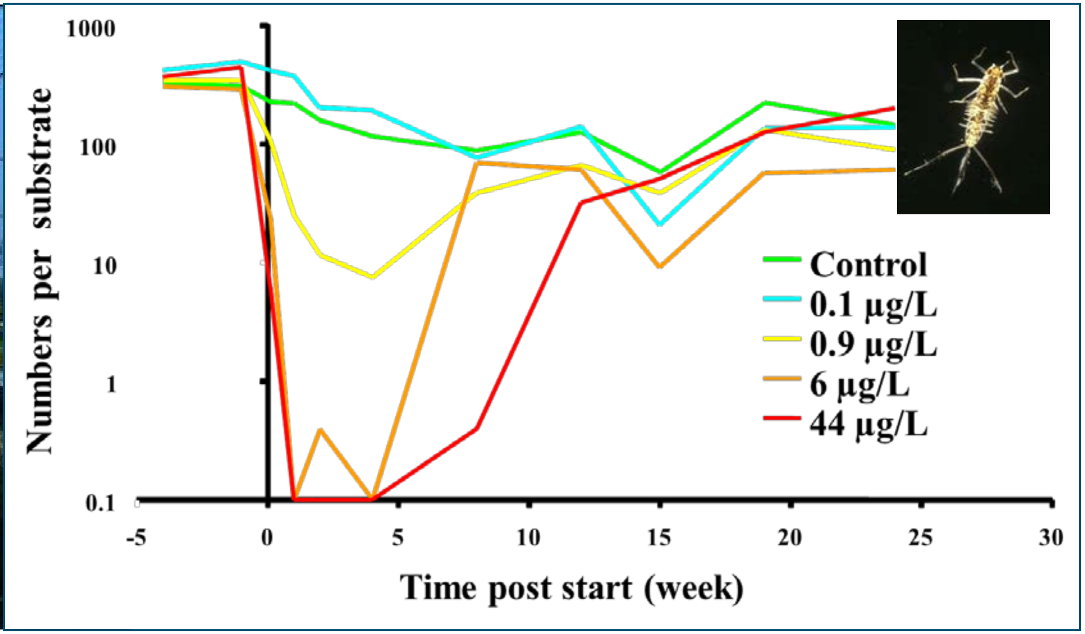
Recovery times differ between taxonomic groups and variability within taxonomic groups and between habitats high

Species traits affecting recovery

- Life-history traits determining internal recovery:
  - Voltinism (number of generations per year)
  - Reproduction rate
  - Resistant life stages
  - Development time
- Additional traits determining external recovery:
  - Dispersal ability (active or passive)
- Other important traits
  - Habitat choice and chance to become exposed
  - Susceptibility to indirect effects
  - Genetic diversity / population fitness (particularly important for small populations of endangered species)

EFSA SC, 2016. Recovery in ERA at EFA

Evaluation of micro-/mesocosm tests (EFSA PPR, 2013)



- ETO and ERO Option: Possibility to demonstrate treatment-related effects for a sufficient number of **potentially sensitive populations** (at least 8)
- ERO Option: The observation period is long enough to demonstrate effects and recovery for representative **vulnerable taxa**

Vulnerable populations in micro-/mesocosms

Criteria

- Chance to become exposed to the pesticide(s)
  - Habitat preference (*e.g. an epi-benthic arthropod and exposure to an insecticide that accumulates at the water-sediment interface*)
- Intrinsic sensitivity
  - Specific toxic mode-of-action
- Recovery potential
  - Species traits (*e.g. uni-/semi-voltine)*
  - Properties of test system/habitat (*e.g. isolated; no refuges*)

Motivate that either the potentially sensitive species with a poor recovery potential are not impacted or that the conditions for recovery were not 'best case' in the test systems used. Alternatively, use effect models for extrapolation.

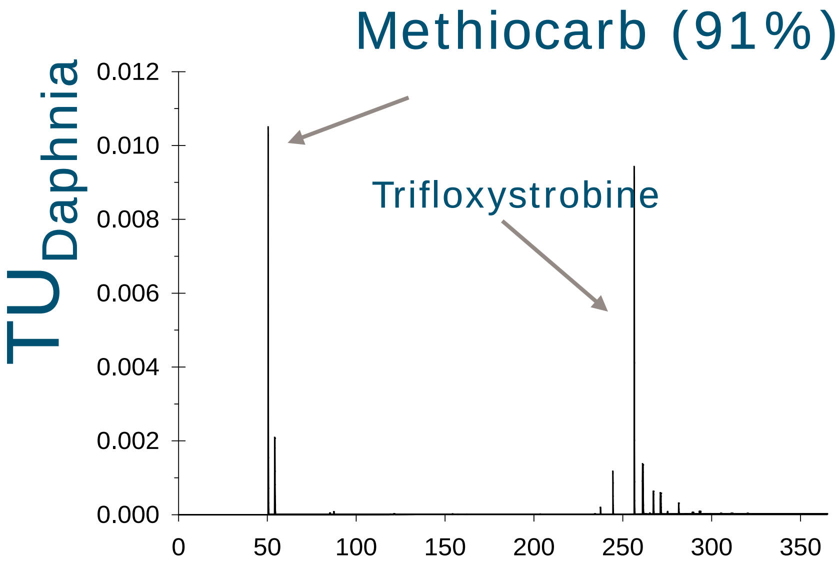
Ecological recovery and intensive PPP use

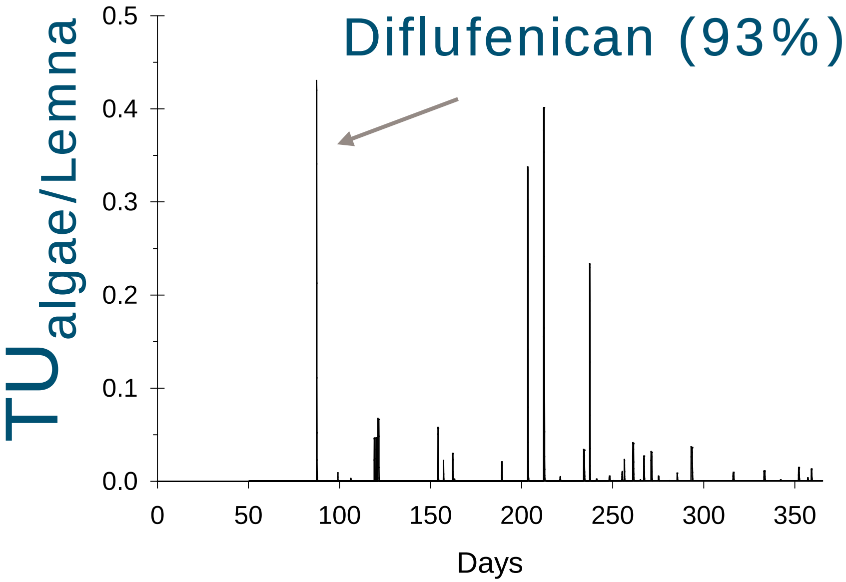
- EFSA PPR (2013) states: "…*it is more uncertain if the ERO option can be achieved when assessing risks for individual PPPs for their use in crop protection programmes characterised by intensive PPP use*."

Insight in potential impact of cumulative PPP-stress due to normal agricultural practise is required to address this concern

- Crop-oriented approach
- Landscape-oriented approach

Crop approach in ERA for pesticides



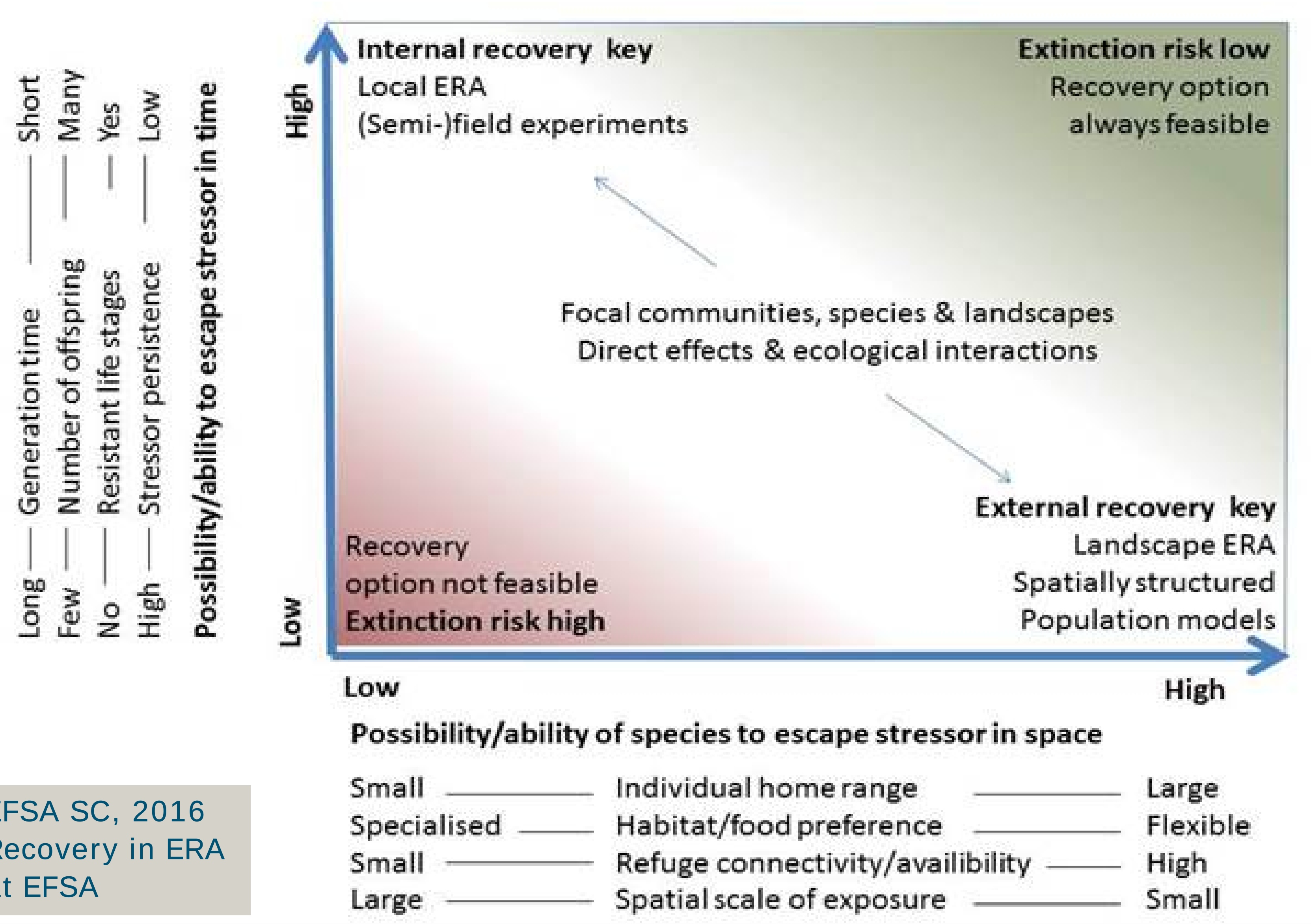


Experimental and modelling studies simulating the crop approach for edge-of-field surface water reveal:

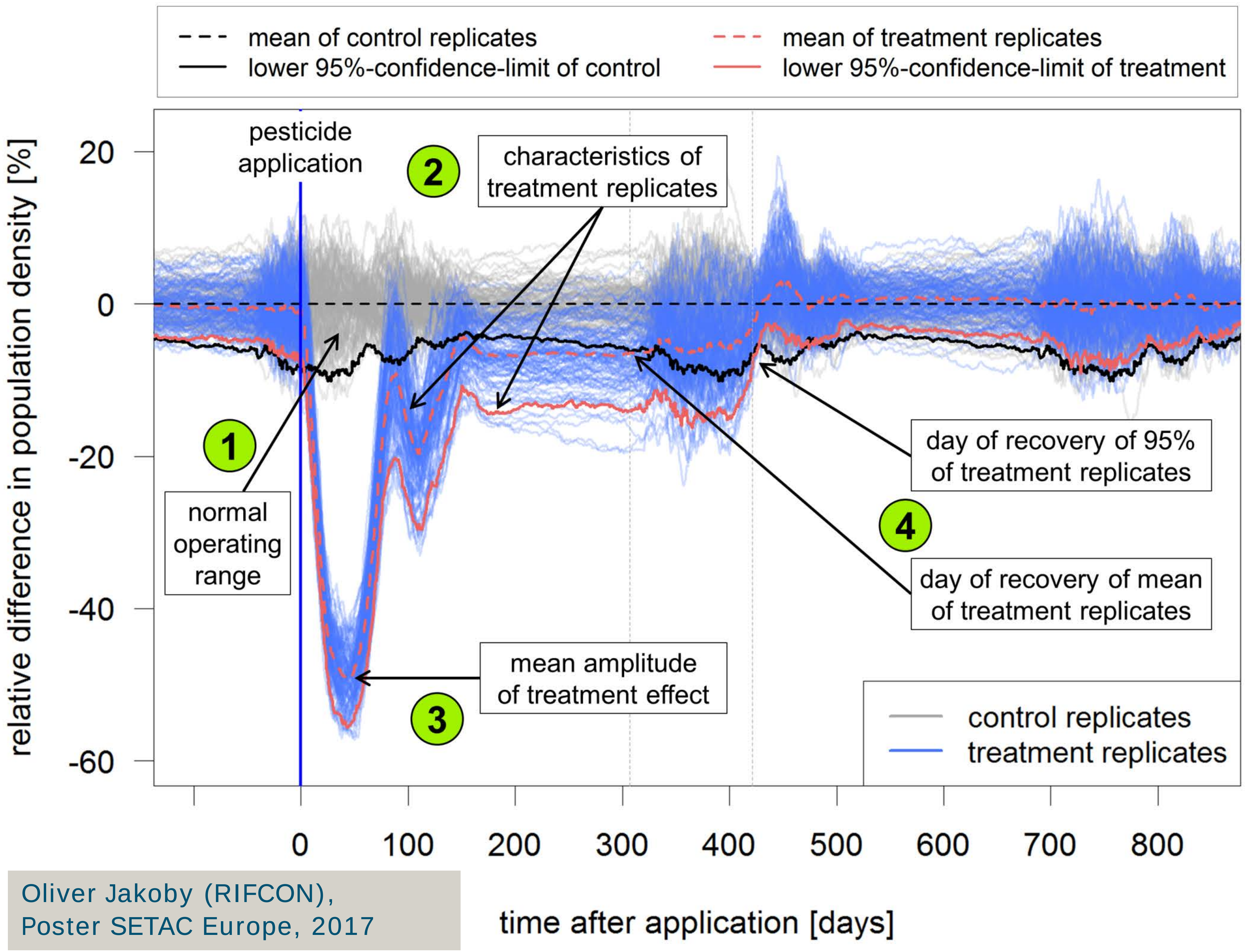
- Individual pulse exposures are generally dominated by single substances
- Different pulses may concern different substances
- Major effects observed usually are caused by one or a few pesticides

Van Wijngaarden et al. (2004) ET&C 23:1479-1498
Arts et al (2006) IEAM 2:105-125
Auber et al. (2011) Ecotoxicology 20:2042-2055
Focks et al. (2014a) ET&C 33:1489-1498

ERO option requires a systems approach since many factors affect ecological recovery of non-target taxa



EFSA SC, 2016
Recovery in ERA
at EFSA

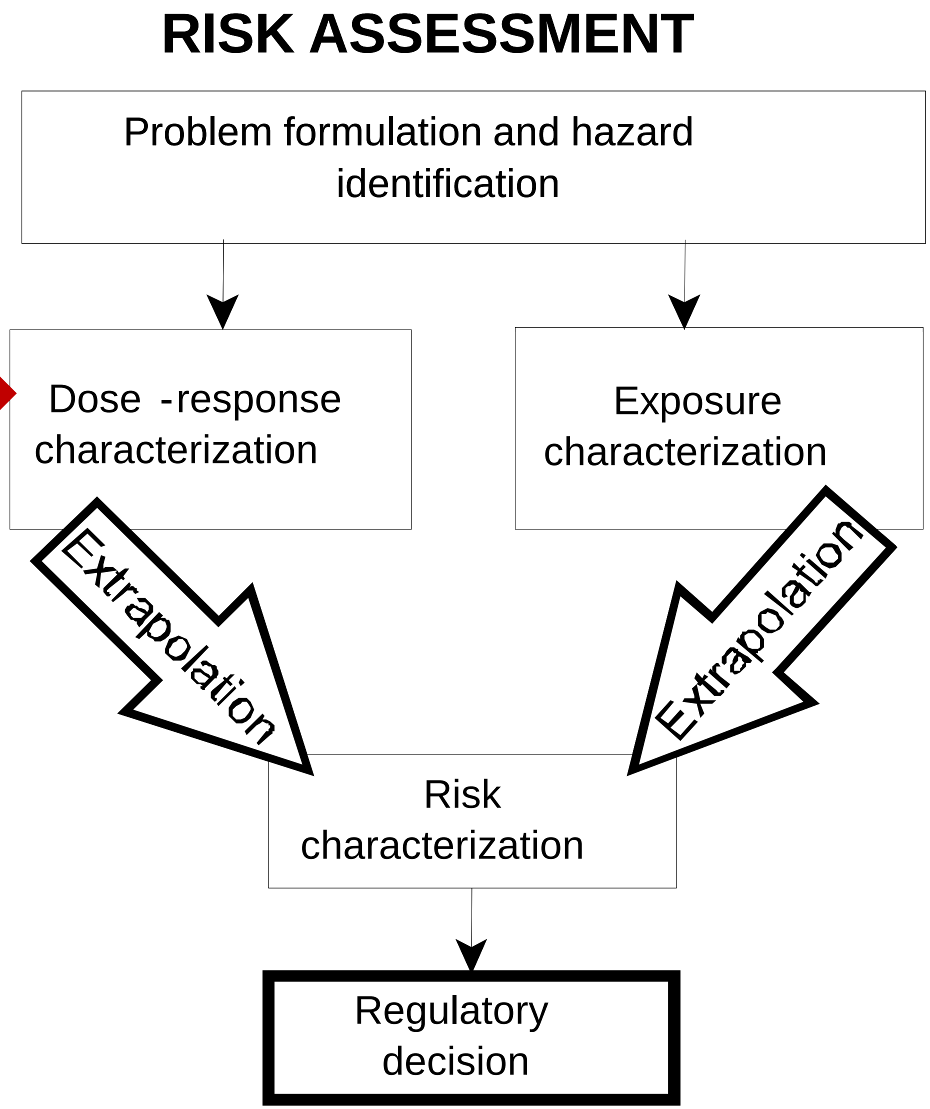


Oliver Jakoby (RIFCON),
Poster SETAC Europe, 2017

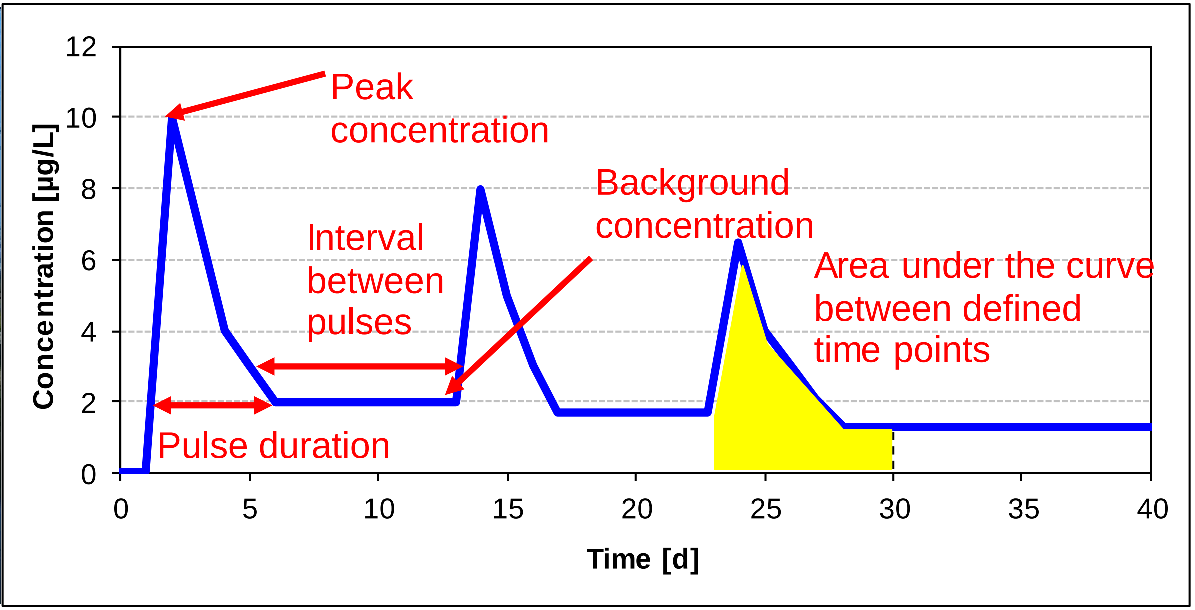
Consistency of tiered approach

Consistency tiered approach
- Protectiveness lower tiers
- Validity criteria higher tiers

According to EFSA (2010) the protectiveness of lower tiers should be verified by results of the (surrogate) reference tier (e.g. semi-field tests)



Validity criteria micro-/mesocosm tests (EFSA 2013)



The **exposure** in the test system is **relatively worst case** to that predicted for edge-of-field surface water (pulse height and duration, number of pulses, interval between pulses)

Information on the statistical power of test

- Appropriate **Minimum Detectable Difference** (MDD) values for at least 8 taxa of the potentially sensitive taxonomic groups

Minimum Detectable Difference (MDD)

- The MDD defines the mean amount of difference between a treatment and the control that must exist to detect a statistically significant effect
- The lower the MDD, the less severe treatment-related declines in population abundance between controls and treatments need to be, to calculate a NOEC/LOEC

$$MDD = (\bar{x}_0 - \bar{x})^* = t_{1-\alpha,df,k} \sqrt{\frac{s_0^2}{n_0} + \frac{s^2}{n}}$$

$$MDD = (\bar{x}_0 - \bar{x})^* = t_{1-\alpha,df,k}\, s \sqrt{\frac{1}{n_0} + \frac{1}{n}}$$

$(\bar{x}_0 - \bar{x})^*$ = corresponding difference between control and treatment mean

$t_{1-\alpha}$ = quantile of the t-distribution

df = degrees of freedom

k = number of comparisons

s^2 = residual variance one-way ANOVA

n_1, n = sample sizes

MDD classes are given in EFSA AGD (but further guidance not given)

MDD Class	MDD%	Comment
0	>100%	No effects can be determined statistically
I	90-100%	Only large effects can be determined statistically
II	70-90 %	Large to medium effects can be determined statistically
III	50-70 %	Medium effects can be determined statistically
IV	< 50%	Small effects can be determined statistically

Proposal how to use MDD information in the evaluation of micro-/mesocosm tests for te derivation of ETO-RAC and ERO-RAC values is given by Brock et al. (2015. Environ Sci Pollut Res 22:1160-1174)

How to report MDDs

Minimum Detectable Difference (MDD) should be reported in concert with NOEC/LOEC values

Geometric mean abundance of *Daphnia galeata*

day	Controls	2 µg/L	6 µg/L	18 µg/L	54 µg/L	162 µg/L	Williams	% MDD_{abu}
-5	94.3	93.3	88.8	139.3	86.2	108.5	- NOEC>=162 µg/L (incr.)	40.9
3	121.1	131.2	97.2	158.7	87.9	16.0	* NOEC=54 µg/L (decr.)	42.6
9	114.0	107.4	32.9	49.2	26.4	1.1	* NOEC=18 µg/L (decr.)	70.5
23	98.1	142.1	143.6	147.9	36.4	2.6	* NOEC=18 µg/L (decr.)	44.4
37	50.2	44.0	49.7	49.2	42.7	10.0	* NOEC=54 µg/L (decr.)	68.4
51	35.0	50.2	28.3	45.4	43.2	16.6	- NOEC>=162 µg/L (decr.)	57.6
65	35.0	87.9	29.2	32.9	108.5	18.6	- NOEC>=162 µg/L (decr.)	67.2
79	54.9	122.3	39.1	66.4	218.5	45.8	- NOEC>=162 µg/L (decr.)	82.9

The MDD_{abu} needs to be below 100% to allow a statistical evaluation on treatment-related declines in abundance, and subsequent recovery.

The lower the MDD the larger is the power of the test.

How to report MDDs

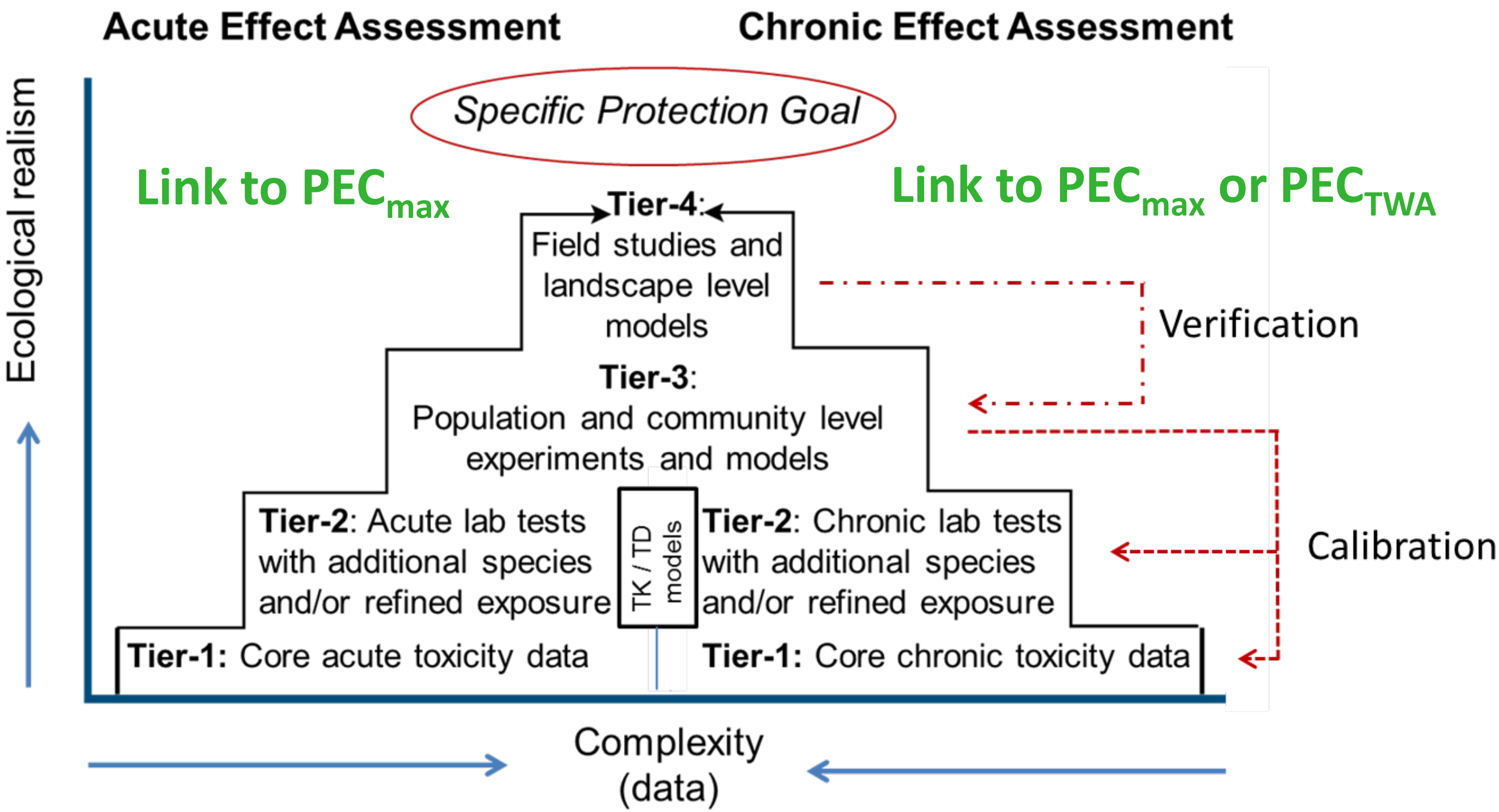
Geometric mean abundance of *Stylaria lacustris*

day	Controls	2 µg/L	6 µg/L	18 µg/L	54 µg/L	162 µg/L	Williams	% MDD_{abu}
-5	7.9	5.0	13.8	15.3	6.1	6.2	- NOEC>=162 µg/L (incr.)	94.0
9	2.5	2.6	2.1	2.0	1.6	1.4	- NOEC>=162 µg/L (decr.)	107.1
23	5.3	4.5	5.3	6.0	3.8	2.4	* NOEC>=18 µg/L (decr.)	71.9
37	2.1	3.1	3.2	4.2	2.3	2.0	- NOEC>=162 µg/L (decr.)	104.9
51	0.5	1.0	1.5	2.2	0.5	0.0	- NOEC>=162 µg/L (decr.)	173.2
65	1.7	0.4	1.7	1.0	6.0	0.0	- NOEC>=162 µg/L (decr.)	114.8
79	0.8	1.0	1.5	0.4	5.2	1.4	- NOEC>=162 µg/L (incr.)	144.2

If the MDD is consistently larger than 100% then

- the statistical power is too low to demonstrate treatment-related declines
- it will be difficult to draw firm conclusions on recovery if on isolated samplings a NOEC can be calculated

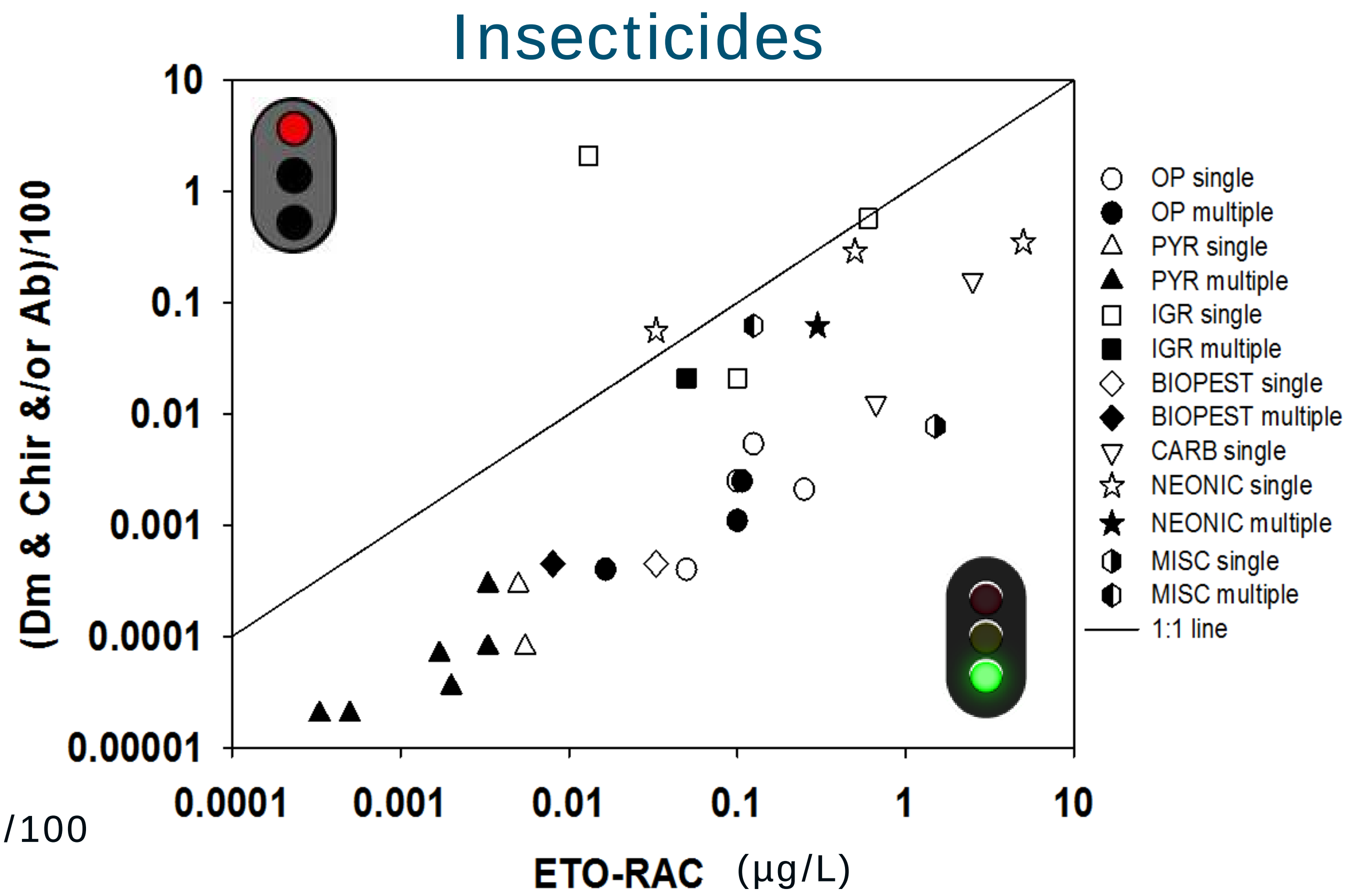
Tiered risk assessment schemes



Micro-/mesocosm tests can be used to evaluate the protectiveness of lower tiers

(EFSA PPR, 2013)

Calibration/verification acute Tier-1



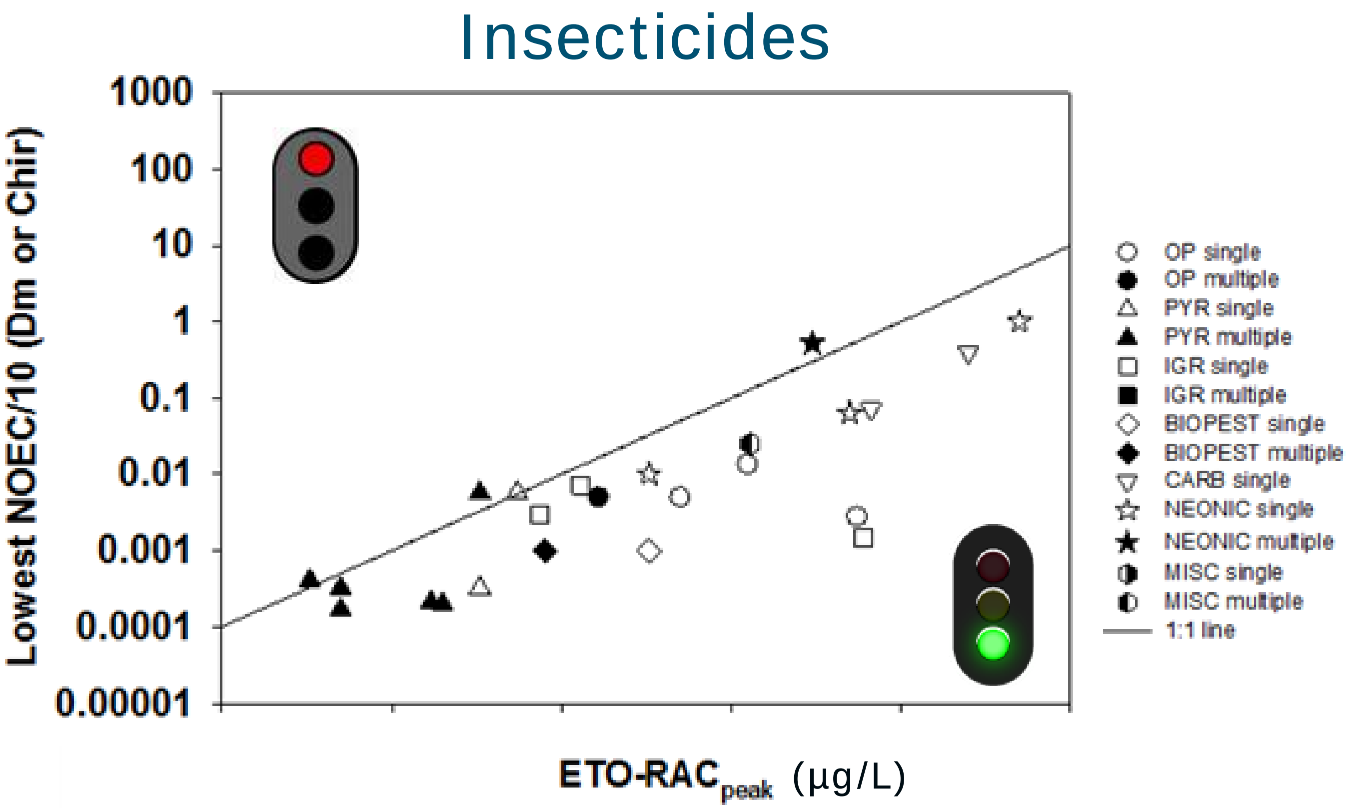
RAC = lowest 48-h EC50/100

In 28 out of 30 insecticide cases the acute tier-1 RAC is protective

Particularly the IGR fenoxicarb is exception (wide range in Effect class 2 concentrations in mesocosms) and to a lesser extent the neonicotinoid thiacloprid (less than a factor of 2)

Van Wijngaarden, Maltby & Brock (2015)
Pest management science 71 (8), 1059-1067

Calibration/verification chronic Tier-1



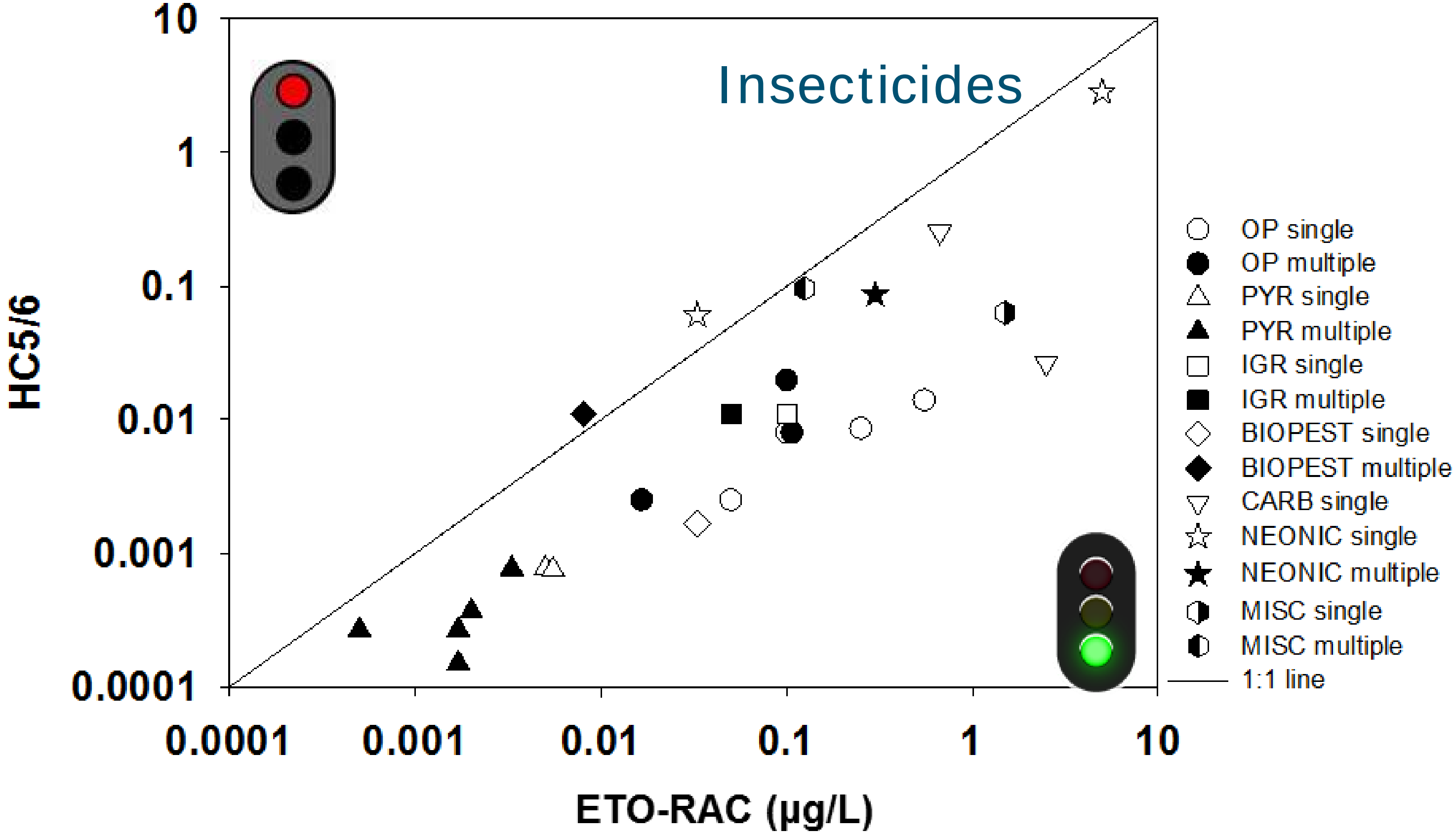
RAC = lowest 21d/28d NOEC/10

In 21 out of 24 insecticide cases the chronic tier-1 RAC is protective

Brock et al. (2016) IEAM 12:747-758

SSD-RAC calibration with micro-/mesocosm RACs (ecological threshold option)

Assessment on basis of SSDs for arthropods (acute HC5/6)

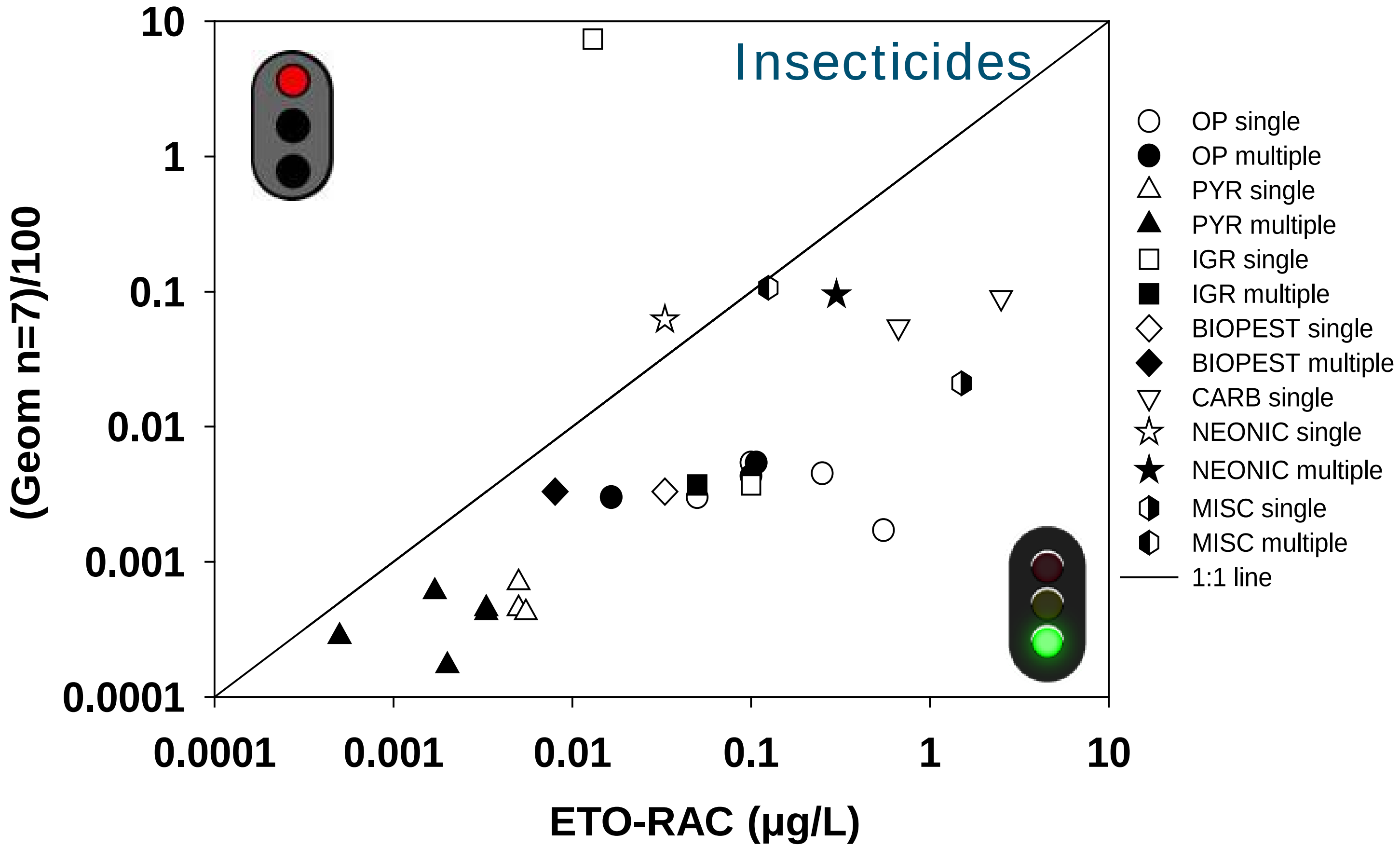


In 25 out of the 27 insecticide cases the SSD approach is protective, but two borderline cases within a factor of 2 (thiacloprid and abamectin)

Van Wijngaarden, Maltby & Brock (2015) Pest management science 71 (8), 1059-1067

Geom-RAC calibration with micro-/mesocosm RACs (ecological threshold option)

Lowest acute Geomean/100 value for insects and crustaceans



In 28 out of the 30 insecticide cases the Geomean approach (AF of 100) is protective (IGR fenoxicarb is clear exception; thiacloprid within a factor of 2)

Van Wijngaarden, Maltby & Brock (2015)

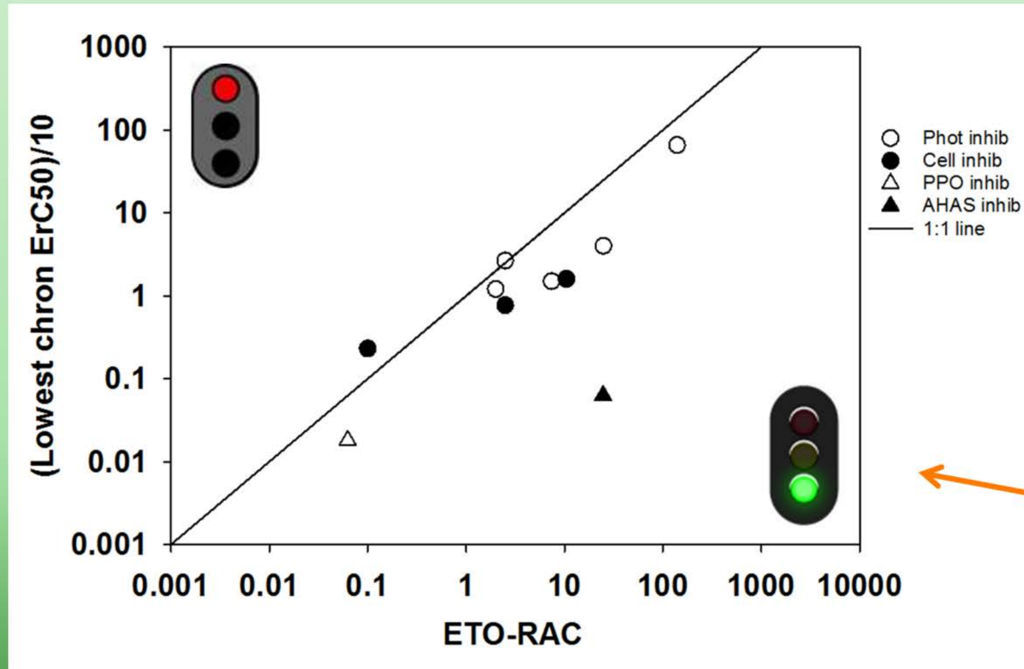
Pest management science 71 (8), 1059-1067

Geom-RAC calibration with micro-/mesocosm RACs (ecological threshold option)

- Geom-RACs could only be calibrated for acute toxicity data and insecticides
- The EFSA Guidance document recommends to use toxicity data of the same taxonomic group and of a similar endpoint and similar test duration (e.g. 48h-mortality or 96h-immobility) in the Geomean approach
- The requirement to use similar endpoints and test durations may hamper the use of the Geomean approach in chronic effect assessments
- Currently, EU Member States do not use the Geomean approach in chronic risk assessments (a weight of evidence approach is advocated)

Consistency of tiered approach

Protectiveness chronic Tier-1 effect assessment for individual herbicides and water organisms



Arts & Van Wijngaarden (2015) *Poster SETAC Europe Annual Meeting, Nantes*
Arts & Van Wijngaarden (submitted)

Herbicides

Several MSs debate the use of ErC50 values in herbicide effect assessment

Few data points only

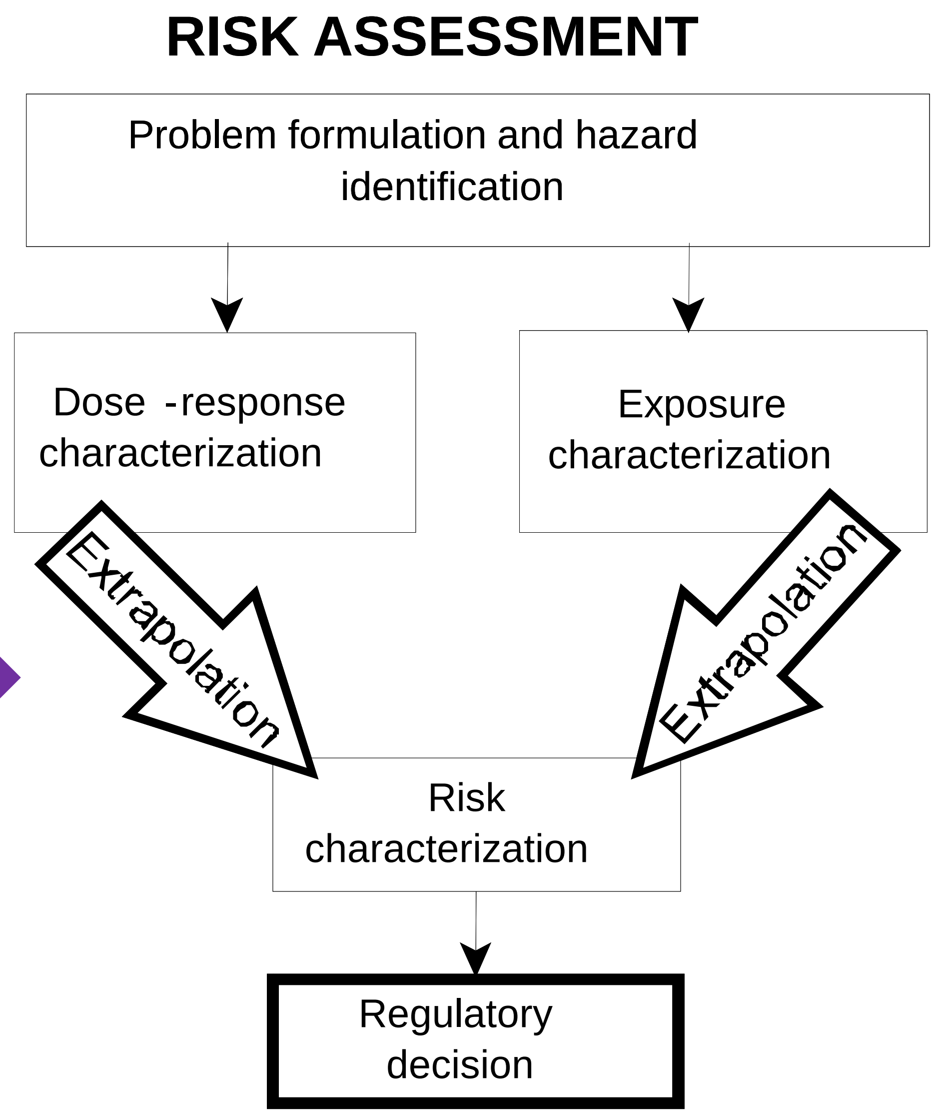
More efforts needed to verify the consistency of the tiered approach for aquatic ERA of herbicides and fungicides, and sediment ERA for pesticides in general

Extrapolation tools

Currently exposure assessment mainly depends on modelling approaches while the effect assessment is based on experiments

Several developments to promote modelling approaches in effect assessment

Extrapolation tools
- Ecological and environmental scenarios
- Effect models



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Experimentation and modelling

	Model ecosystems	Population / Ecosystems models
Pros	■ Design easier to understand & communicate ■ Represents a 'real' system ■ Guidance available	■ Controlled by the modeller ■ No population and spatial/temporal limitations ■ Easier to extrapolate
Cons	■ Not all focal populations present ■ Spatial/temporal scale limited ■ Extrapolate problems	■ Black box problem ■ Validation issues ■ Guidance not yet available

Promising modelling approaches

- TK-TD models as tools to assess the effects of time-variable exposures
  - GUTS approach for acute risk
  - DEBTOX approach for chronic risks (*validation issues*)
  - EFSA scientific opinion under development
- Population and community-level models for spatial-temporal extrapolation of experimental studies
  - Recovery option
  - Integrated exposure and effect assessment
  - Requires appropriate scenarios

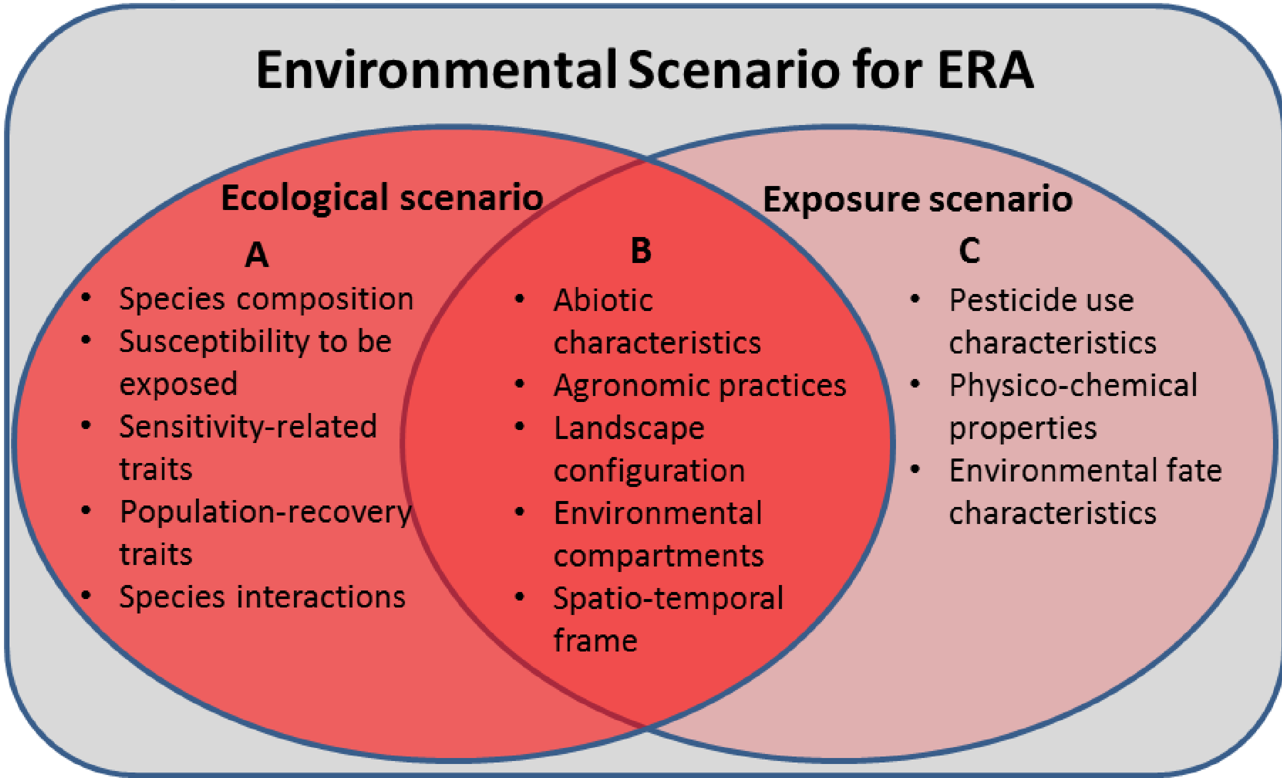
Population and community-level assessments require environmental scenarios to which both fate and effect experts can refer (EFSA PPR, 2014)

Integration of exposure and ecological scenario in an environmental scenario

- Environmental scenarios: combination of biotic and abiotic parameters that are required to provide a realistic worst-case representation of the exposure, effects and recovery in the ecological entities (focal species) that are evaluated

- FOCUS exposure scenarios available, but ecological scenarios are urgently needed

Rico et al., 2015 IEAM 12, 510–521



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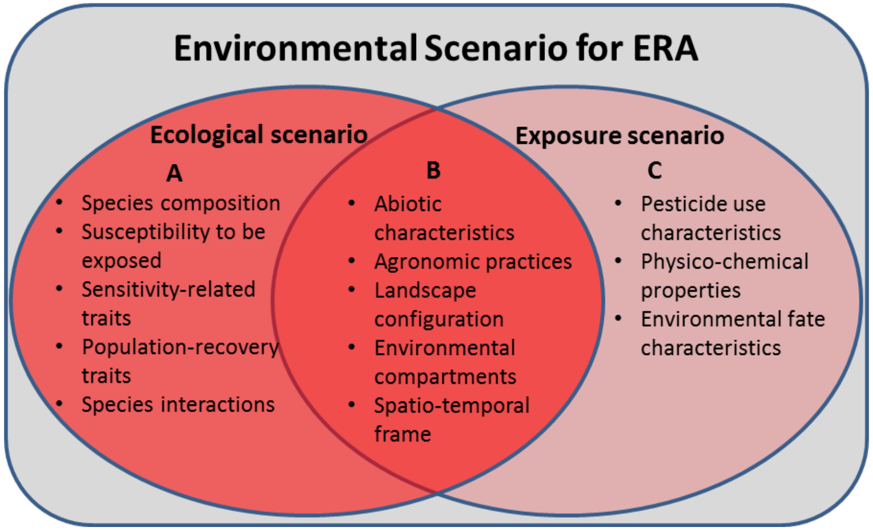
Population and community-level modelling

- Selection of focal species and ecological scenarios should be developed in a standardized way for the main landscape units and climatic regions in EU
- The implementation of ecological scenarios may require a refinement of exposure scenarios (*e.g. allowing spatially explicit exposure assessments*)



- Environmental scenarios will contribute to an increase in 'ecological realism' of ERA
- But new expert knowledge required
- EFSA PPR will probably start with a scientific opinion on population and community-level modelling in 2018 - 2020

Thank you for your attention
Questions ?

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