

# Experiences in deriving and implementing Specific Protection Goal options in the EFSA PPR Aquatic Guidance Document

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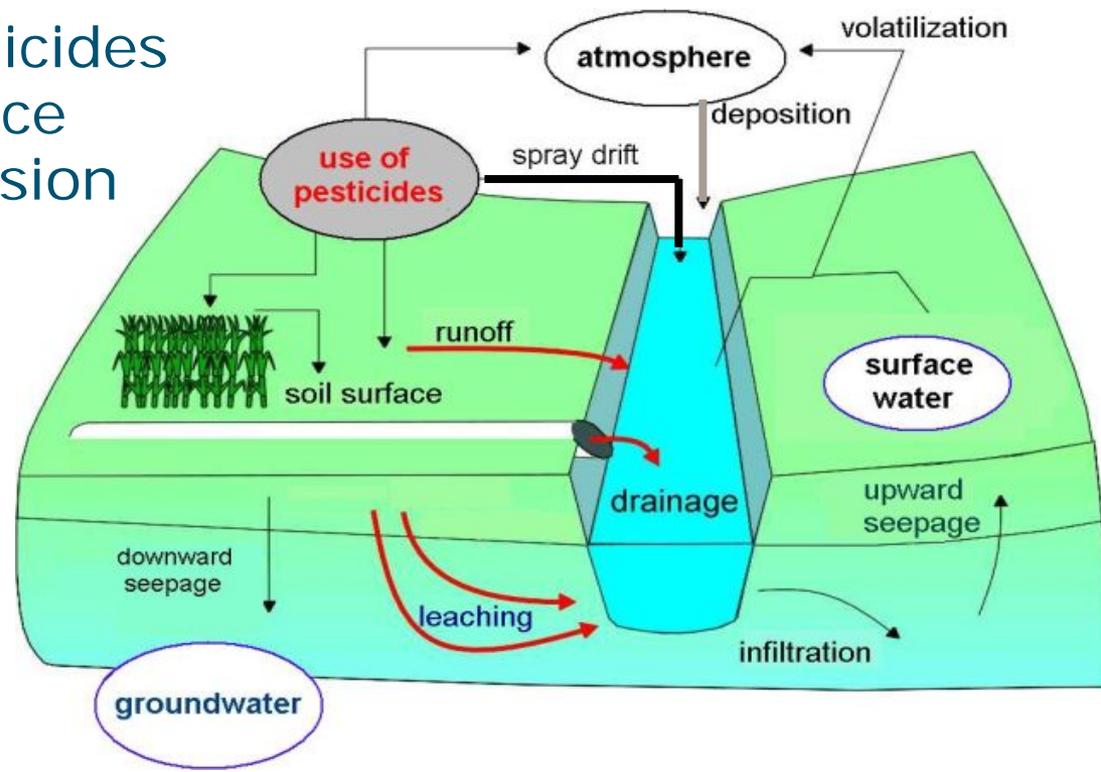
EFSA PPR Panel Member since 2009



# Problem formulation

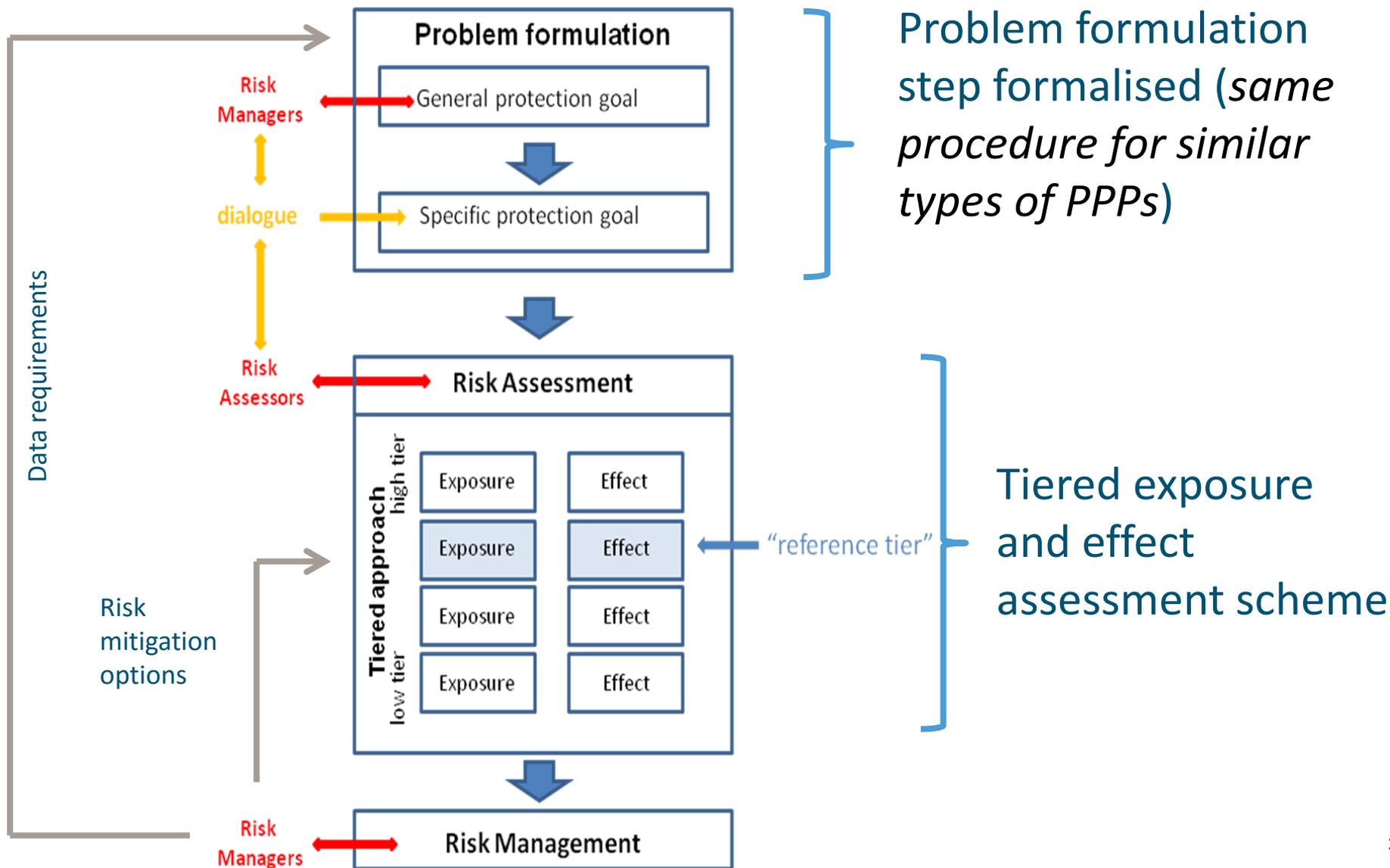
## Importance of aquatic ecosystems in ERA for pesticides

- Surface waters play a crucial role in
  - *Water regulation of agricultural fields and terrestrial ecosystems (watersheds)*
  - *Provision of habitats for aquatic and semi-aquatic organisms (biodiversity)*
- Agricultural use of pesticides may contaminate surface waters by several emission routes
- Protection of water organism is required in EU legislation





# Generalised prospective ERA scheme for pesticides



# Steps in SPG derivation

List of **Ecosystem Services (ES)**  
(Millennium Ecosystem Assessment)

Identify surface waters and **ES affected by agricultural use of pesticides**

Identify **key drivers (=SPUs)** for these ES  
(i.e. representative taxa or functional groups)

Development of **specific protection goals**:  
identify "**assessment dimensions**" for the  
main key drivers / ES combination

Focus on **representative species/functional groups**

Develop protective RA schemes (testing  
endpoints, tiered test approach, etc.)

**SPG opinion**, EFSA Journal  
2010;8(10):1821

*Risk manager  
consultation  
(Brussels) on SPG  
opinion in May 2010*

*Risk manager  
consultation on  
aquatic SPG options  
in 2012*

*Risk manager  
consultation  
(Brussels) on aquatic  
ERA decision schemes  
in 2013*

**Aquatic Guidance Document**  
EFSA Journal 2013;8(10):1821

**Sediment opinion**, EFSA  
Journal 2015;13(7):4176

# Example: Identification of important key drivers

Ecosystem service	Organisms in edge-of-field sw	General protection goal	Desired protection goal
Food (Provisioning ES)	Fish, crayfish	No unacceptable lethal andsublethal effect.	No to small effects on biomass and abundance
Water purification (Regulating ES)	Microbes, algae, aquatic vascular plants	No unacceptable lethal andsublethal effects.	No to temporary impacts on functional groups
Aesthetic (Cultural ES)	Aquatic vertebrates, invertebrates, algae, aquatic vascular plants	No unacceptable lethal andsublethal effects.	No decline in abundance and biodiversity
Nutrient cycling (Supporting ES)	Algae, aquatic vascular plants, microbes, benthic invertebrates	No unacceptable lethal andsublethal effects.	No to temporary impacts on functional groups
Etc.			

The organisms potentially affected and that perform important ecosystem services can be grouped in main service providing units

# Proposed main aquatic key driver groups

## ■ Aquatic microbes

- Bacteria, archaeans, fungi, protozoans
- Currently not an obligatory data requirement

## ■ Aquatic algae

- Green algae, diatoms, blue-greens
- Green alga data requirement (+ 2<sup>nd</sup> species for herbicides)

## ■ Aquatic vascular plants

- Mono- and dicotyledons; floating and rooting macrophytes
- Data requirement for herbicidal substances (e.g. *Lemna*)

## ■ Aquatic invertebrates

- Crustaceans, insects, worms, molluscs, rotifers
- *Daphnia* data requirement (+ 2<sup>nd</sup> arthropod for insecticides)

## ■ Aquatic vertebrates

- Fish, amphibians
- Rainbow trout data requirement

Two SPG options were proposed for each SPU group



***Ecological threshold option***

***Ecological recovery option***



### Ecological entity:

individual - (meta)population - functional group - community - ecosystem - habitat

### Attribute:

behaviour - survival - growth/repro - abundance/biomass - process - species diversity

### Magnitude:

negligible effect - small effect - medium effect - large effect

### Temporal scale:

<days - days - weeks - months - seasons - years - decades

### Spatial scale:

field - edge-of-field - farm - watershed/landscape - region - continent

# Dialogue risk assessors and risk managers

- **RA role:** Present (a limited number of) SPG options, including the option in line with the old practise
- **RA role:** Explain the scientific background and ecological consequences of each SPG option
- **RM decision:** Develop decision schemes for both the Ecological Threshold Option (ETO) and the Ecological Recovery Option (ETO) in the Aquatic Guidance Document
- **RM decision:** Focus on edge-of-field surface waters but conflicts with WFD objectives should be avoided
- **RM decision:** Specific Tier-1 data for aquatic microbes not necessary



# SPGs for water organisms in edge-of-field surface water

## Ecological threshold option (ETO)

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

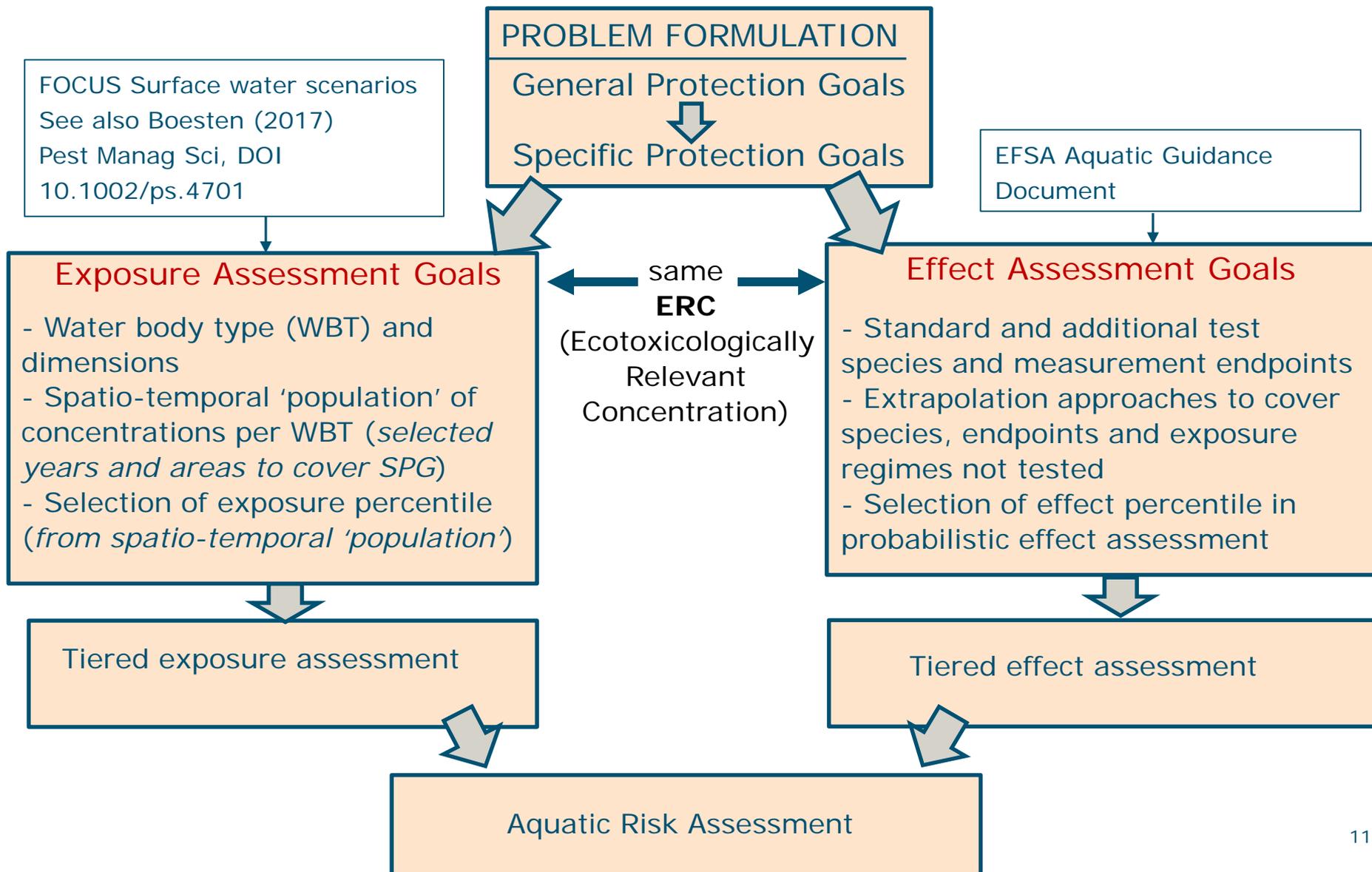
# SPGs for water organisms in edge-of-field surface water

## Ecological recovery option (ERO)

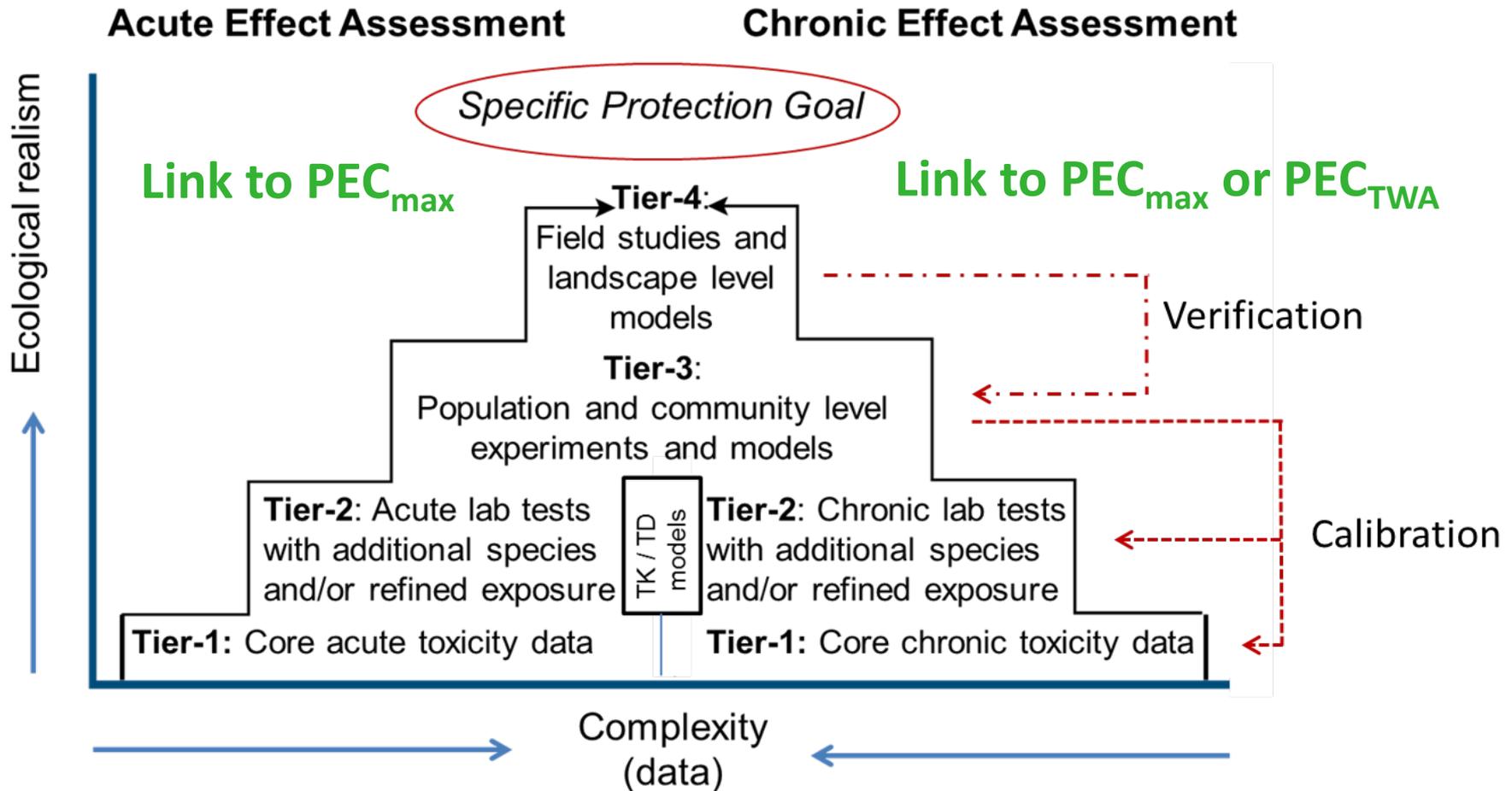
Organism group	Ecological entity	Attribute	Duration and magnitude of effect on sensitive and vulnerable populations
<b>Algae</b>	Population	Abundance/ biomass	Total effect period < 8 weeks (also for repeated applications)
<b>Aquatic plants</b>	Population	Growth/ abundance/ biomass	Focus on vulnerable populations ( <i>e.g. long life cycles and low dispersal abilities</i> )
<b>Aquatic invertebrates</b>	Population	abundance/ biomass	Not leading to ecologically important indirect effects
<b>Vertebrates</b>	No recovery option		

# Exposure and Effect Assessment Goals

(some aspects also need dialogue between risk managers and risk assessors)



# Tiered effect assessment schemes



For all tiers the same SPG is applicable but higher tiers address them with a higher degree of realism and complexity

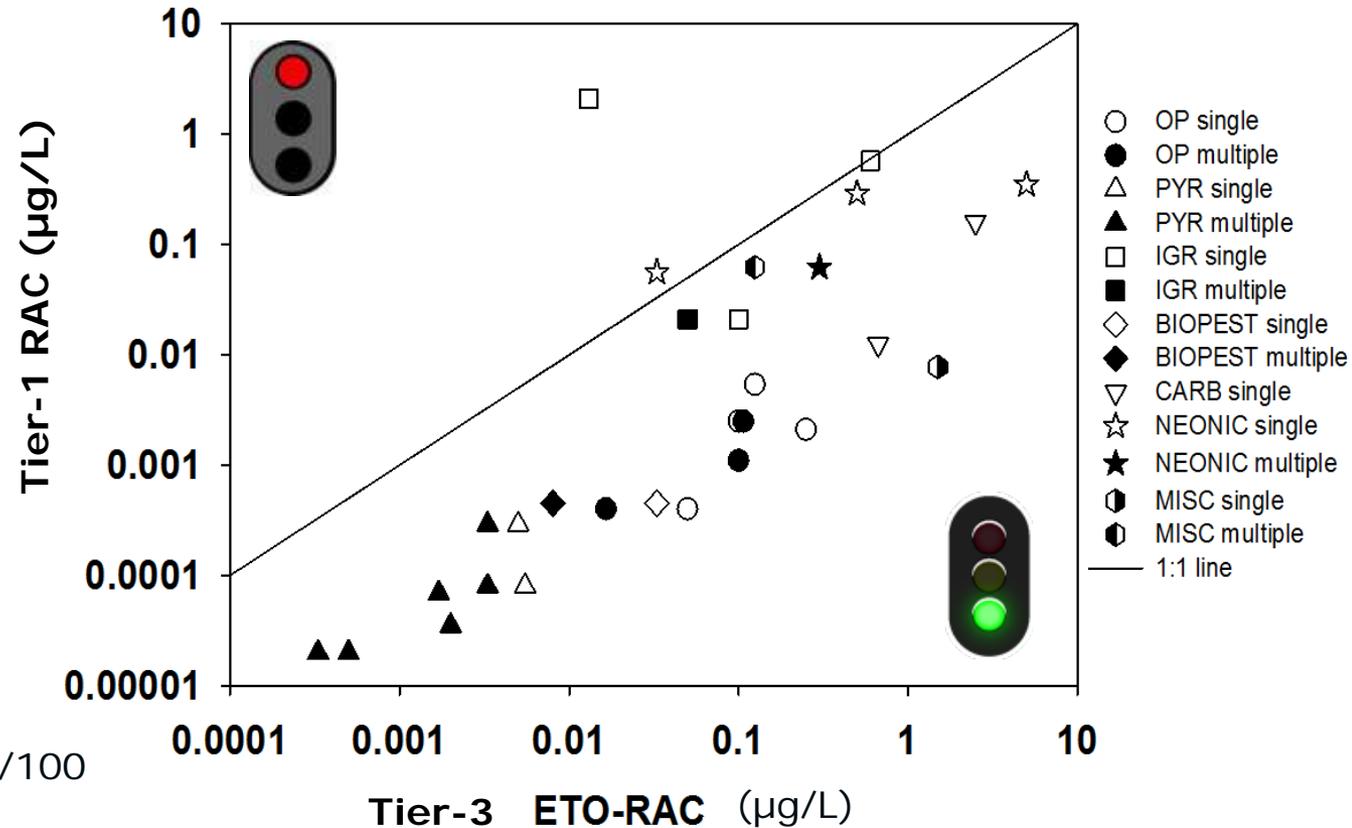
Tier-3 studies can be used as (surrogate) **reference tier** since they are able to address population-level effects (link to SPGs)

# Tier-1 RAC calibration with micro-/mesocosms



RAC = lowest 48-h EC50/100

## Insecticides



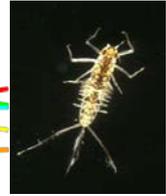
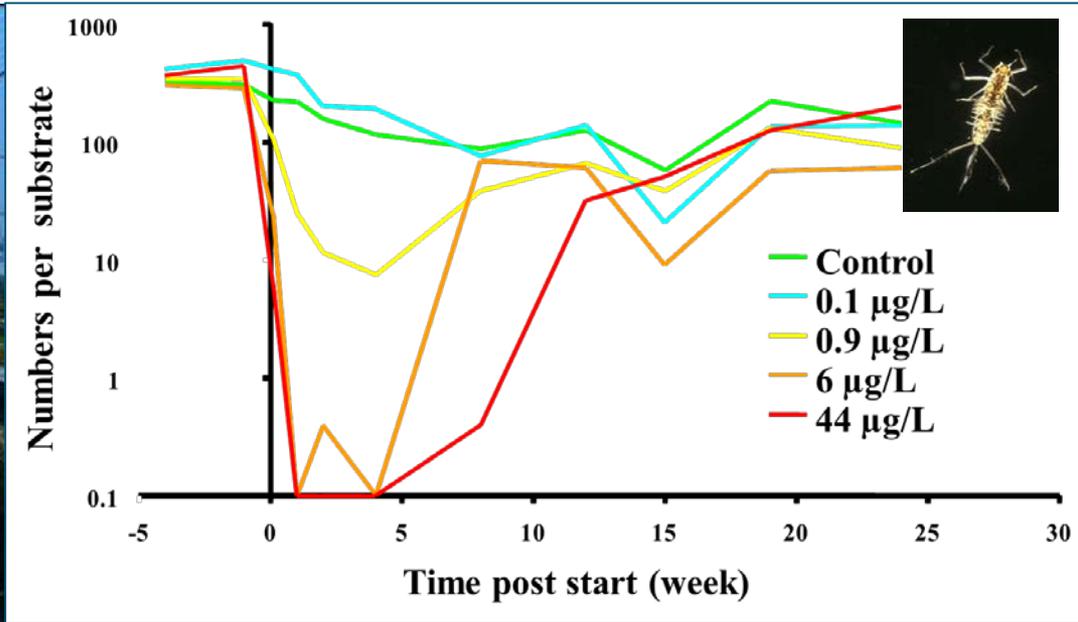
Van Wijngaarden, Maltby & Brock (2015)

Pest management science 71 (8), 1059-1067

Tier-1 RAC is overall more conservative than the Tier-3 RAC (reference tier).

This is in line with the concept of the tiered approach

# SPGs and reference tiers (mesocosms; models)



- **ETO and ERO Option:** Requires the possibility to demonstrate treatment-related effects for a sufficient number of **potentially sensitive populations**
- **ERO Option:** The observation period is long enough to demonstrate effects and recovery for representative **vulnerable taxa**
- By focussing on sensitive and vulnerable species it is assumed that the protection of aquatic biodiversity is addressed

# Vulnerable populations (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. duration of life cycle*)
  - Properties of test system/habitat (*e.g. isolated; no refuges*)
- Susceptibility to indirect effects (*e.g. insensitive epiphytic organisms may decline due to herbicide effects on aquatic vascular plants*)

Conditions for recovery should not be 'best case' in Tier-3 tests (see also EFSA Journal 2016;14(2):4313)

# Dialogue with risk managers (SCoFCAH)

- Risk managers requested information on the possible consequences of the new guidance for the active ingredients on the market (***information required for cost-benefit analysis***)
- Overall agreement with the new Aquatic Guidance Document (*adoption and decision to come into force in 2015*)
- Concerns were expressed related to e.g.:
  - *The time-weighted average PEC in chronic ERA*
  - *The Geometric mean approach in chronic effect assessment*
  - *The use of the ErC50 endpoint in effects assessment for algae and macrophytes*



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# Experiences with MS regulatory authorities

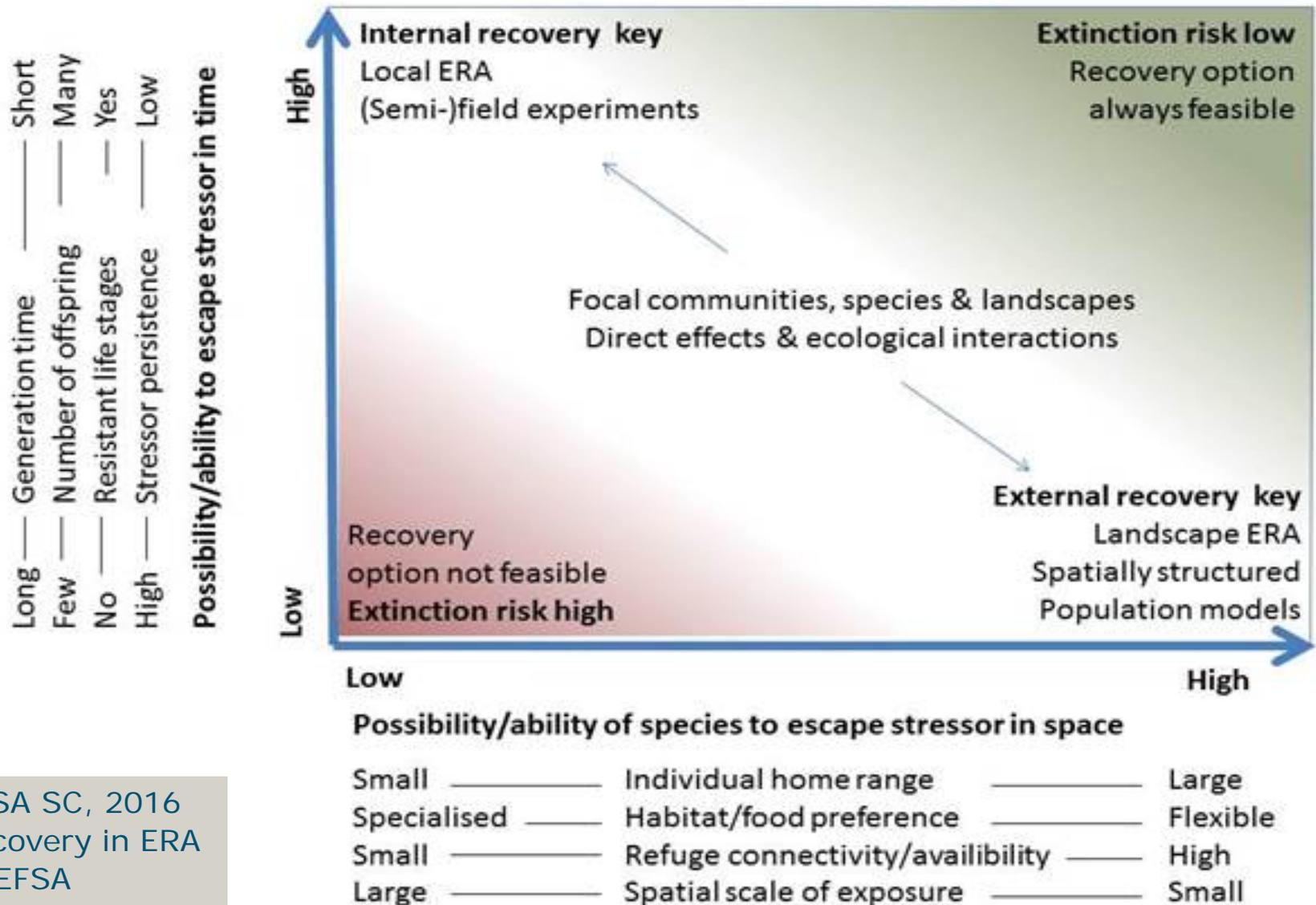
## Ecological Threshold Option (ETO)

- Overall acceptance
- Covers better multi-stress effects

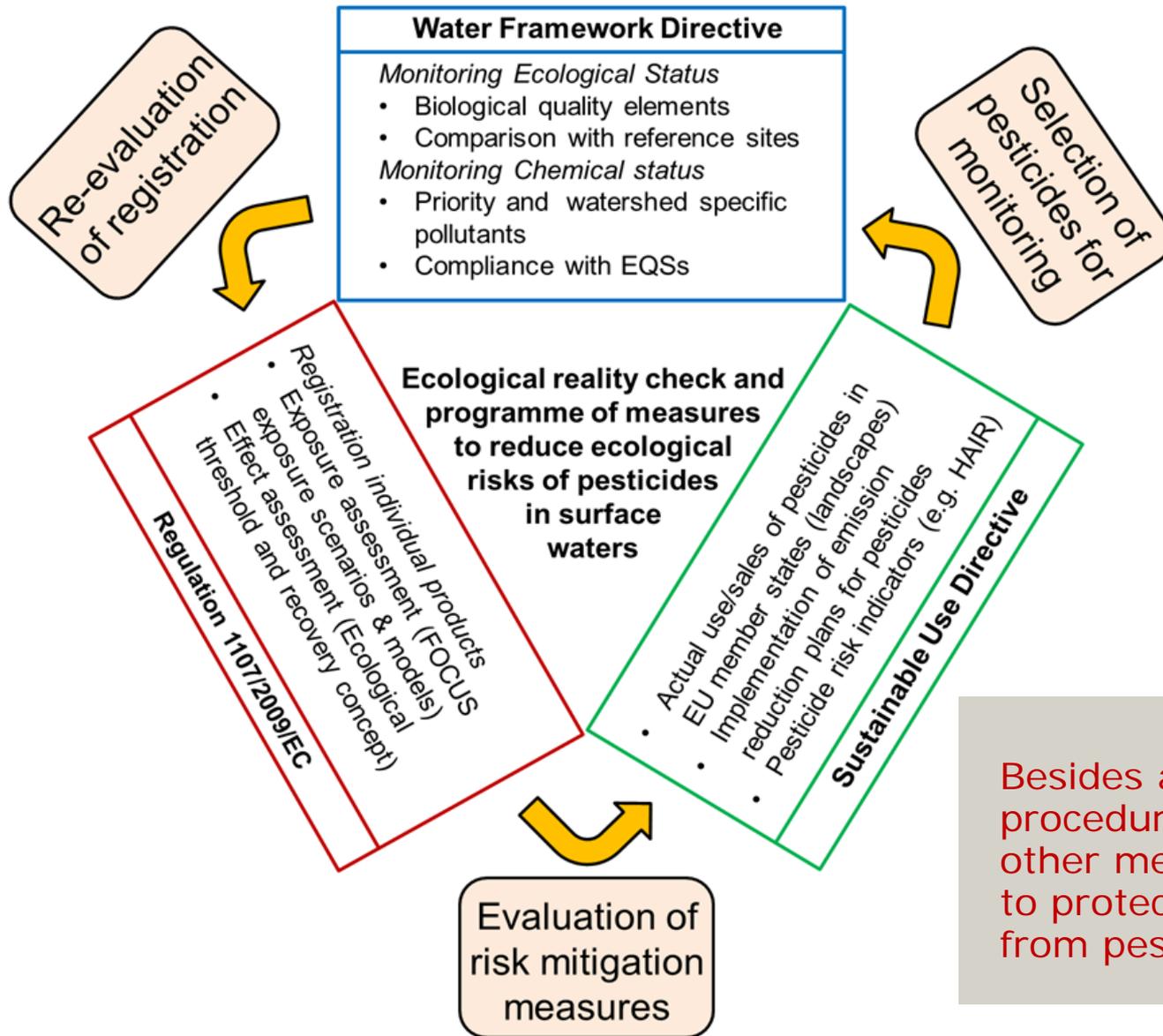
## Ecological Recovery Option (ERO)

- 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

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



## Ecosystem / watershed oriented assessment



## Pesticide oriented assessment

Besides a proper registration procedure for pesticides also other measures are required to protect aquatic biodiversity from pesticide-stress

# Thank you for your attention

## Questions ?



# ERO option and population-level modelling

For surface waters of the main landscape units and climatic regions in EU:

- Select **vulnerable focal aquatic species**
- **Develop ecological and environmental scenarios** (*refinement of existing exposure scenarios may be required allowing spatially explicit assessments*)
- Develop **population models** for these species.

Further reading: EFSA SC, 2016  
Recovery in ERA at EFSA. EFSA Journal  
2016; 14(2):4313

Rico et al., 2015 IEAM 12, 510–521

