Introduction to terminology, tiered approach, specific protection goals and linking exposure to effects

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Terminology

- ***Prospective Risk Assessment***
  - Evaluation of the probability of adverse effects of plant protection product (PPP) exposure before the marketing, release, or use of the product

    → Focus of Regulation (EC) No 1107/2009 and Aquatic Guidance Document

    → Evaluation of agricultural use of one active substance or one formulated product at a time
- ***Retrospective Risk Assessment***
  - Evaluation of the impact from existing and/or past releases of pesticides to the environment on basis of chemical and biological monitoring (e.g. Water Framework Directive)

Prospective aquatic risk assessment of PPPs

- ***Exposure assessment***
  - Calculation of time-dependent concentrations in the compartment water (and sediment)
  - Predicted Environmental Concentrations (PECs) by means of FOCUS surface water scenarios and models and on basis of good agricultural practice
- ***Effect Assessment (focus of AGD)***
  - Analysis of possible effects of predicted exposure on aquatic organisms (individuals, populations, communities)
  - Regulatory Acceptable Concentrations (RACs) by means of controlled ecotoxicity tests in lab and semi-field and models

Terminology

Acute (= short-term) effect assessment

- Assessment of the RAC for adverse effects of PPP exposure to (non-target) organisms occurring within a short period of exposure

Acute (= short-term) risk assessment

- Comparing the RAC of the acute effect assessment scheme with the appropriate PEC (usually peak concentration)

Terminology

Chronic (= long-term) effect assessment

- Assessment of the RAC for adverse effects of PPP exposure to (non-target) that develop slowly and/or have a long-lasting course, and that are caused by short-term exposure (latency) or long-term exposure

Chronic (= long-term) risk assessment

- Comparing the RAC of the chronic effect assessment scheme with the appropriate PEC (may be peak or time-weighted average (TWA) concentration)

Terminology

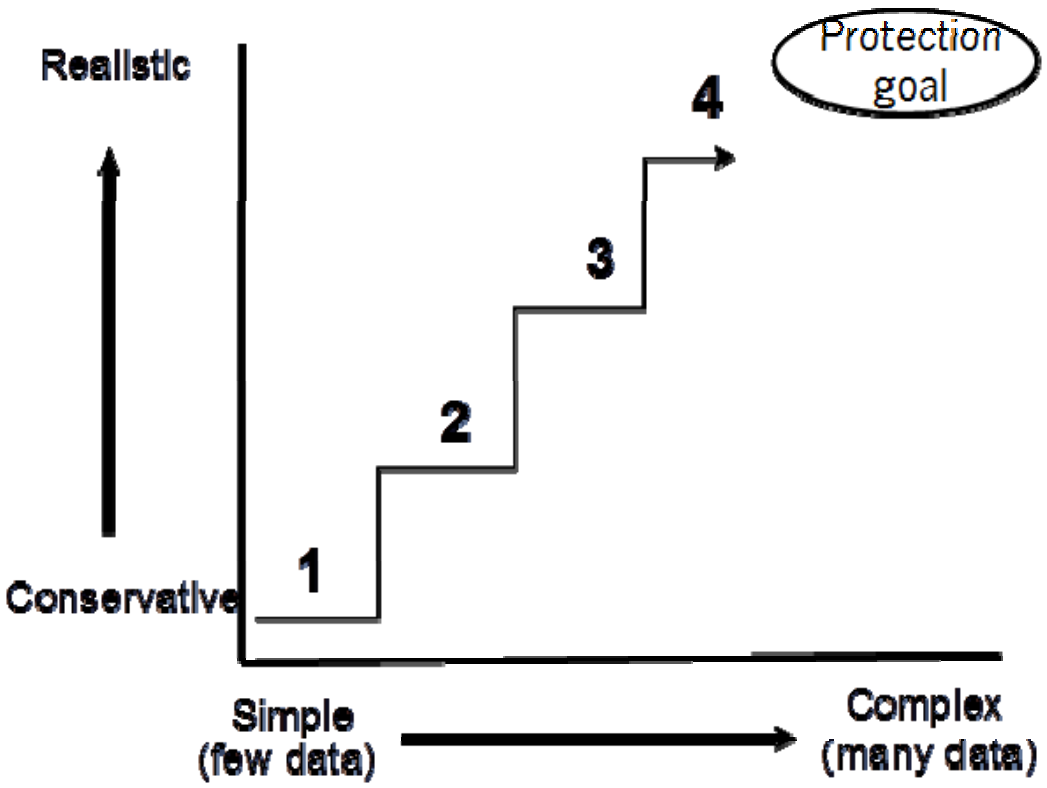
$RAC_{sw;ac}$ or $RAC_{sw;ch}$

= Regulatory Acceptable Concentration for surface water (sw) within context of acute (ac) or chronic (ch) effect assessment scheme

$PEC_{sw;max}$ or $PEC_{sw;twa}$

= Maximum (max) or time-weighted average (twa) Predicted Environmental Concentration for surface water (sw)

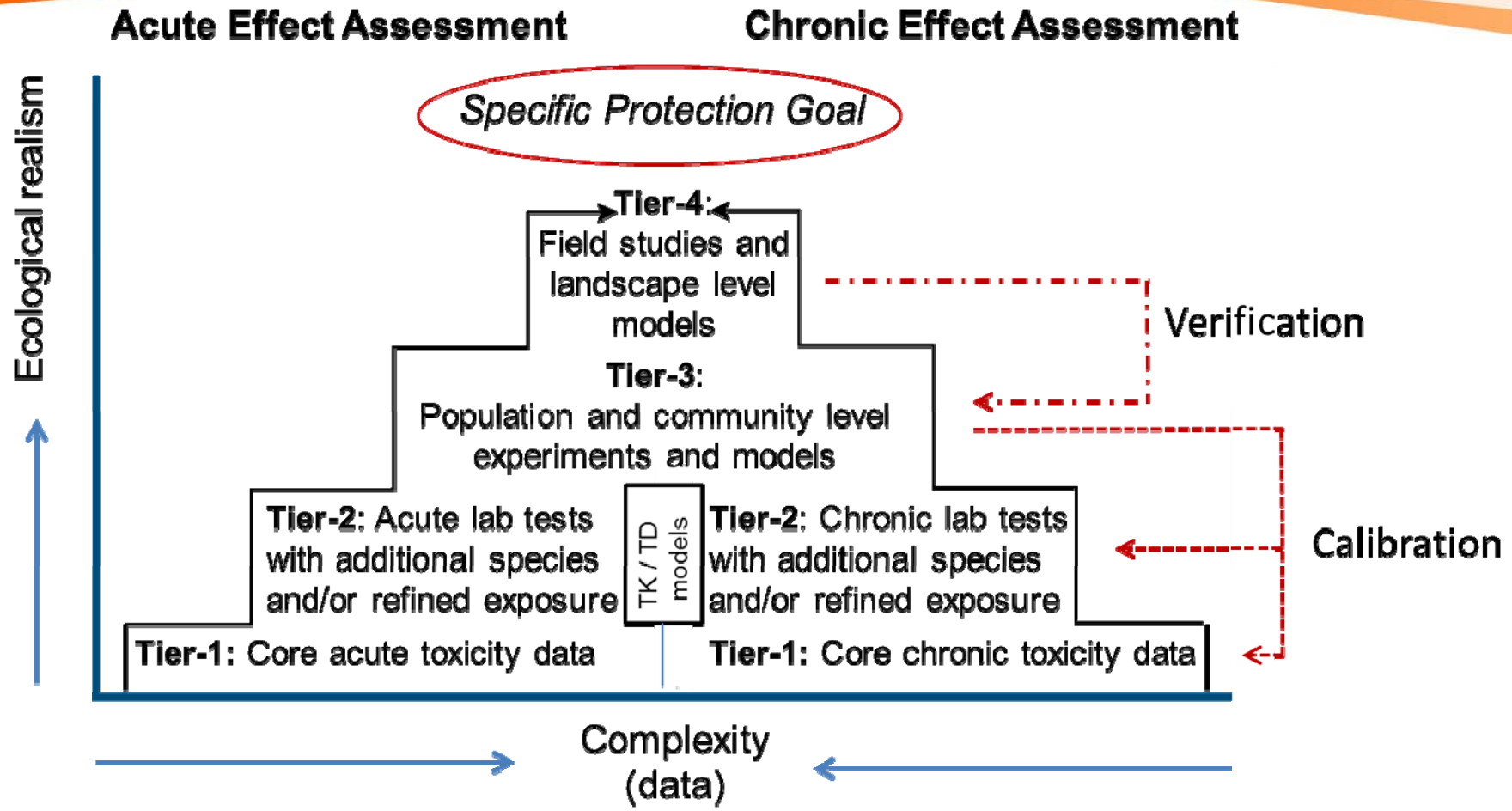
Outline tiered approach



- All tiers within a decision scheme aim to assess the same protection goal
- Lower tiers are more conservative
- Higher tiers aim at being more realistic
- Lower tiers require less effort than higher tiers
- Experimental higher tiers can be used to calibrate lower tiers

Separate schemes for acute and chronic effect assessment

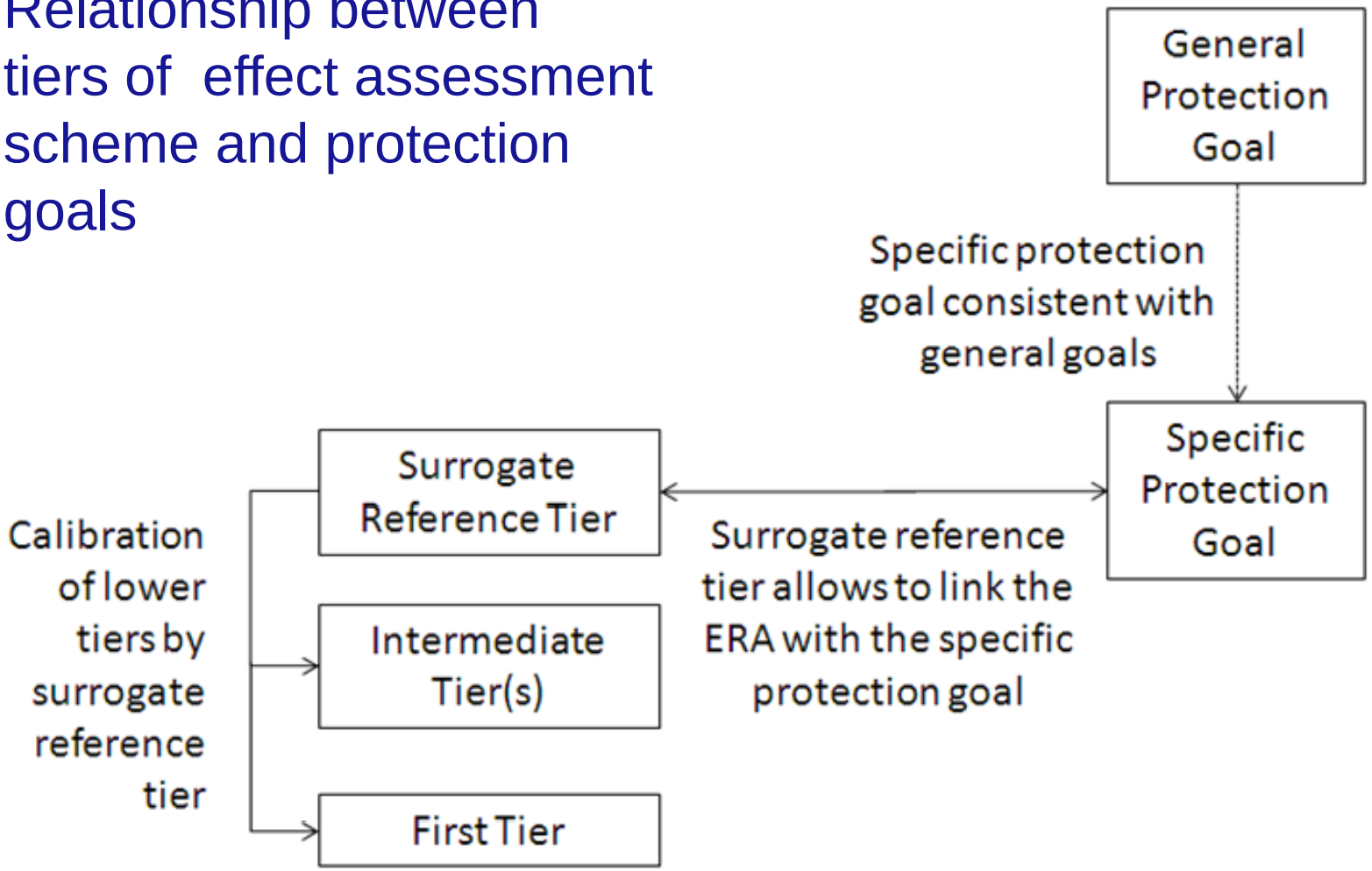
Outline tiered approach



Focus of aquatic guidance document on experimental approaches. Micro-/mesocosm studies (Tier 3) may be considered as surrogate reference tiers to calibrate lower tiers

Protection goals

Relationship between tiers of effect assessment scheme and protection goals



Procedure used by PPR Panel

List of **Ecosystem Services (ES)**

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Identify **ES affected by PPPs**

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Identify **key drivers** for these ES

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Specific protection goals: identify "**assessment dimensions**" for each key driver/ES combination

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Focus on **"vulnerable" representatives**

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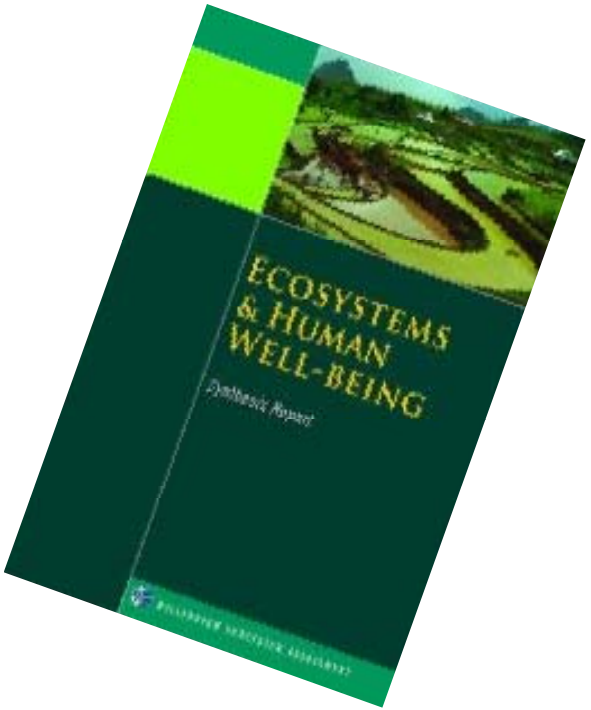
develop protective ERA schemes (testing endpoints, species, etc.)



Dimensions to define SPGs

Procedure to develop Specific Protection Goals (SPGs) for edge-of-field surface waters

Key drivers: microbes, algae, vascular plants, invertebrates, vertebrates

Ecol. entity: **individual – (meta)population – functional group – ecosystem**

Attribute: **behaviour – survival/growth – abund./biomass – process – biodiversity**

Magnitude: **negligible effect – small effect – medium effect – large effect**

Duration: **days – weeks – months – seasons – > 1 year**

Spatial scale: in crop – edge of field – nearby off-crop – watershed/landscape

Degree of certainty: high

Fixed in AGD

SPGs: Two options

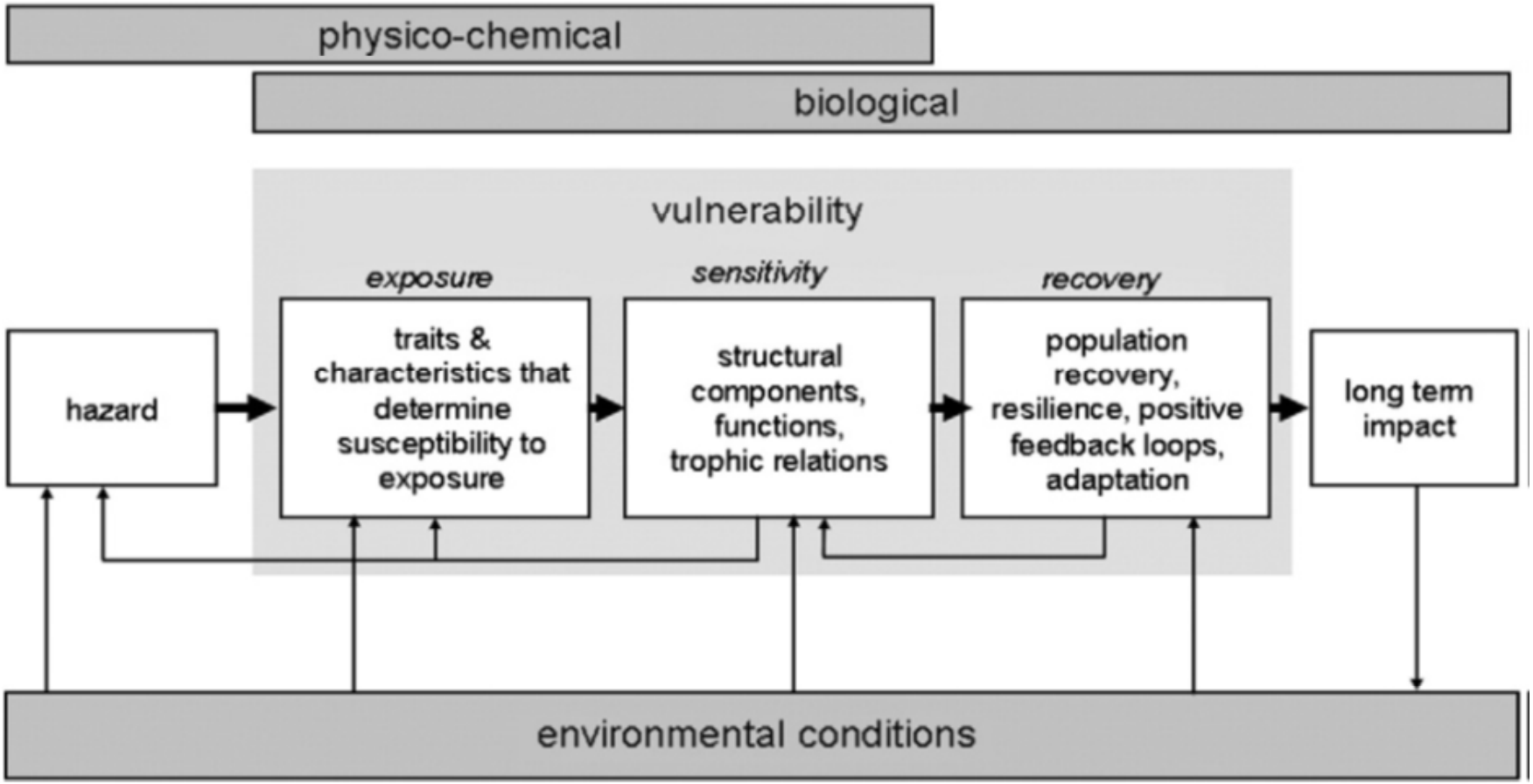
Ecological Threshold Option (ETO)

- Accepting only negligible effects on populations of aquatic non-target organisms in edge-of-field
- Propagation of effects to the community, ecosystem and landscape will be less likely
- All tiers can address ETO

Ecological Recovery Option (ERO)

- Accepting some population level effects if ecological recovery takes place within an acceptable time
- Focus on vulnerable populations of aquatic organisms
- Reasonable option only if recovery is not hampered by multi-stress of pesticides
- ERO may be addressed by mesocosm experiments and effect models

ERO and vulnerability



General framework for ecological vulnerability assessment (after De Lange et al. 2010)

Specific Protection Goals

Ecological threshold option

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 will not be developed since Tier-1 data requirements are not defined	

Specific Protection Goals

Ecological recovery option

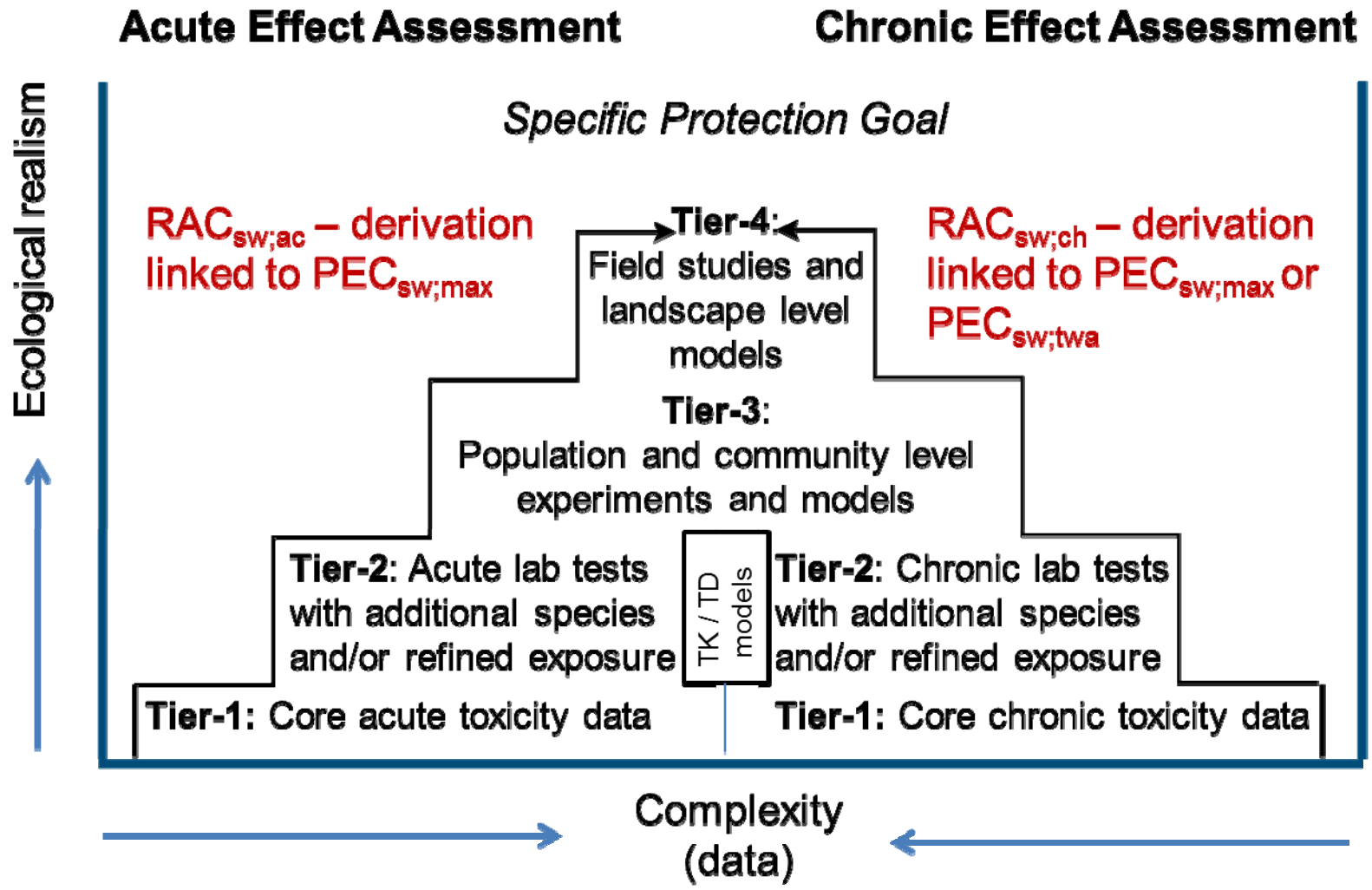
Organism group	Ecological entity	Attribute	Duration and magnitude of effect on sensitive and vulnerable populations
Algae	population	Abundance/ Biomass	Total effect period < 8 weeks (also for repeated applications) Usually not possible for vulnerable populations with long life cycles and low dispersal abilities Not leading to ecologically important indirect effects
Aquatic plants	population	Survival/growth abundance/ Biomass	
Aquatic invertebrates	population	abundance/ biomass	
Vertebrates	No recovery option		
Aquatic microbes	functional group	processes	RA will not be developed since Tier-1 data requirements are not defined

Linking exposure to effects

Ecotoxicologically relevant concentration (ERC)

- ERC is the exposure concentration that gives an appropriate correlation to ecotoxicological effects
- For a realistic to worst-case risk assessment the ‘C’ in the PEC estimate should not be in conflict with the ‘C’ in the RAC estimate
- In the AGD the freely dissolved chemical averaged over the water column (of ponds, ditches and streams) is chosen as the most relevant ERC

Linking exposure to effects



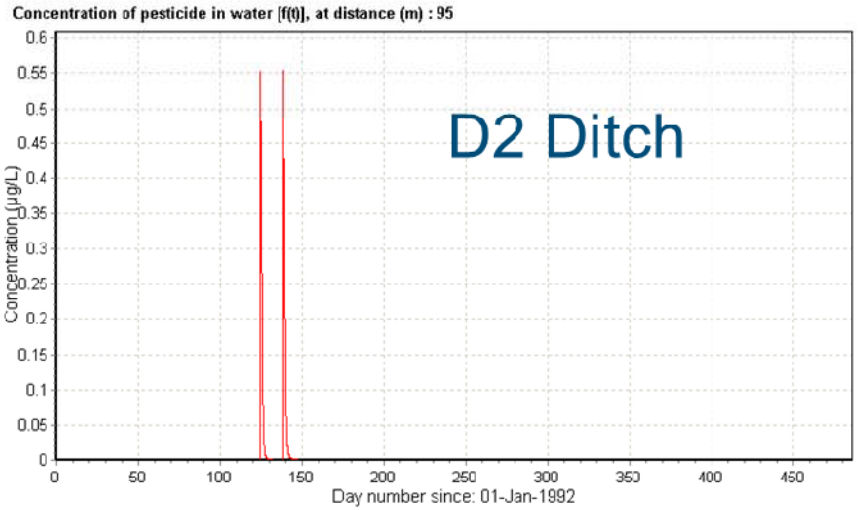
$PEC_{sw;max}$ and $PEC_{sw;twa}$ in chronic risk assessment

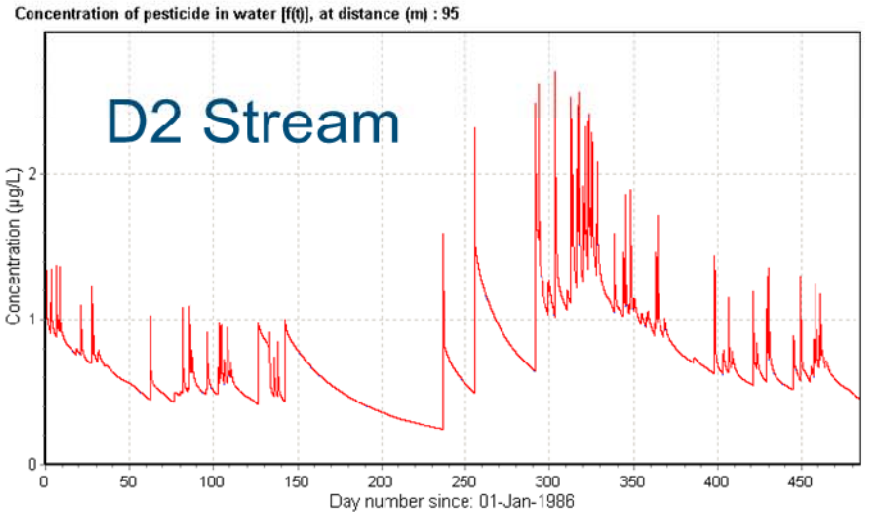
In chronic risk assessments in first instance the $PEC_{sw;max}$ is used, and under certain conditions the $PEC_{sw;twa}$ (default 7 day time window) (Decision scheme section 4.5.2)

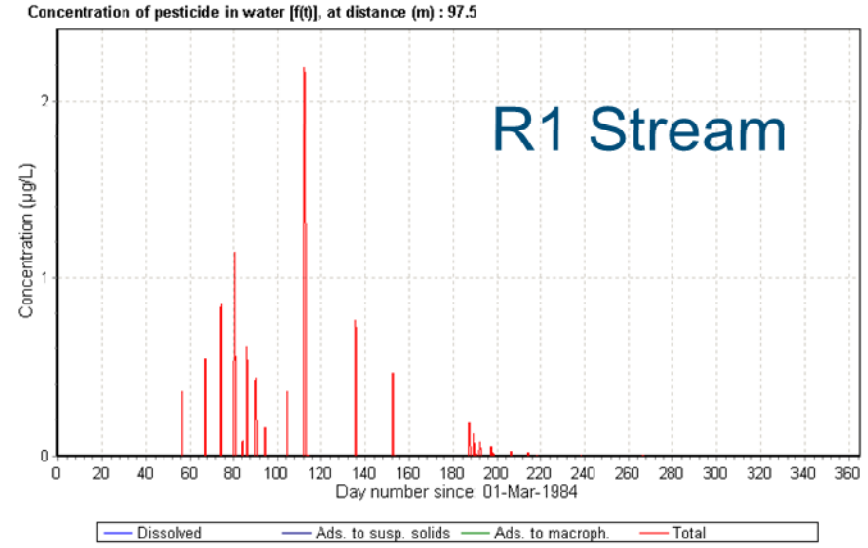
Use of $PEC_{sw;twa}$ may not be appropriate

- When linked to RACs based on effect studies where the loss of the substance is fast and toxicity is expressed in terms of initial concentration
- When effect endpoint in the chronic test is based on a developmental process during a specific life-cycle stage
- When the (acute L(E)C50/chronic NOEC) ratio is < 10
- If latency of effects has been demonstrated (or might be expected)

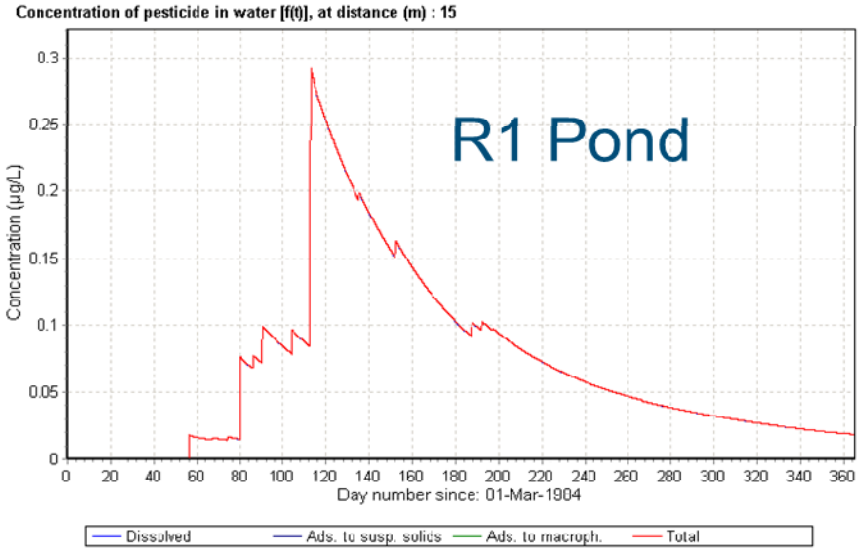
FOCUSsw exposure profiles (examples)





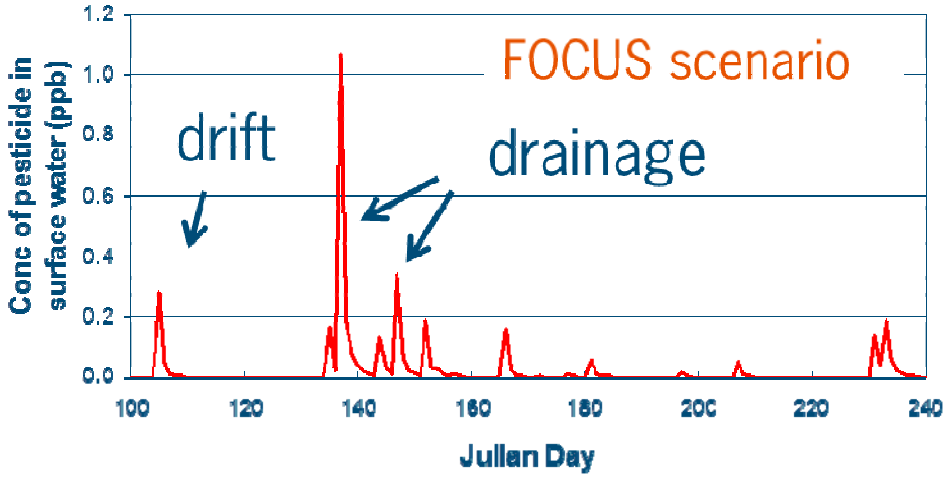


Project : Elinkstrobin_WC
RunID : 00128s_pa
Substance : ELINK "Strobilurin"
Location : R1 (Meteo station Weiherbach)
Water body : Stream
Crop : Cereals, winter



Project : Elinkstrobin_WC
RunID : C0128p_pa
Substance : ELINK "Strobilurin"
Location : R1 (Meteo station: Weiherbach)
Water body : Pond
Crop : Cereals, winter

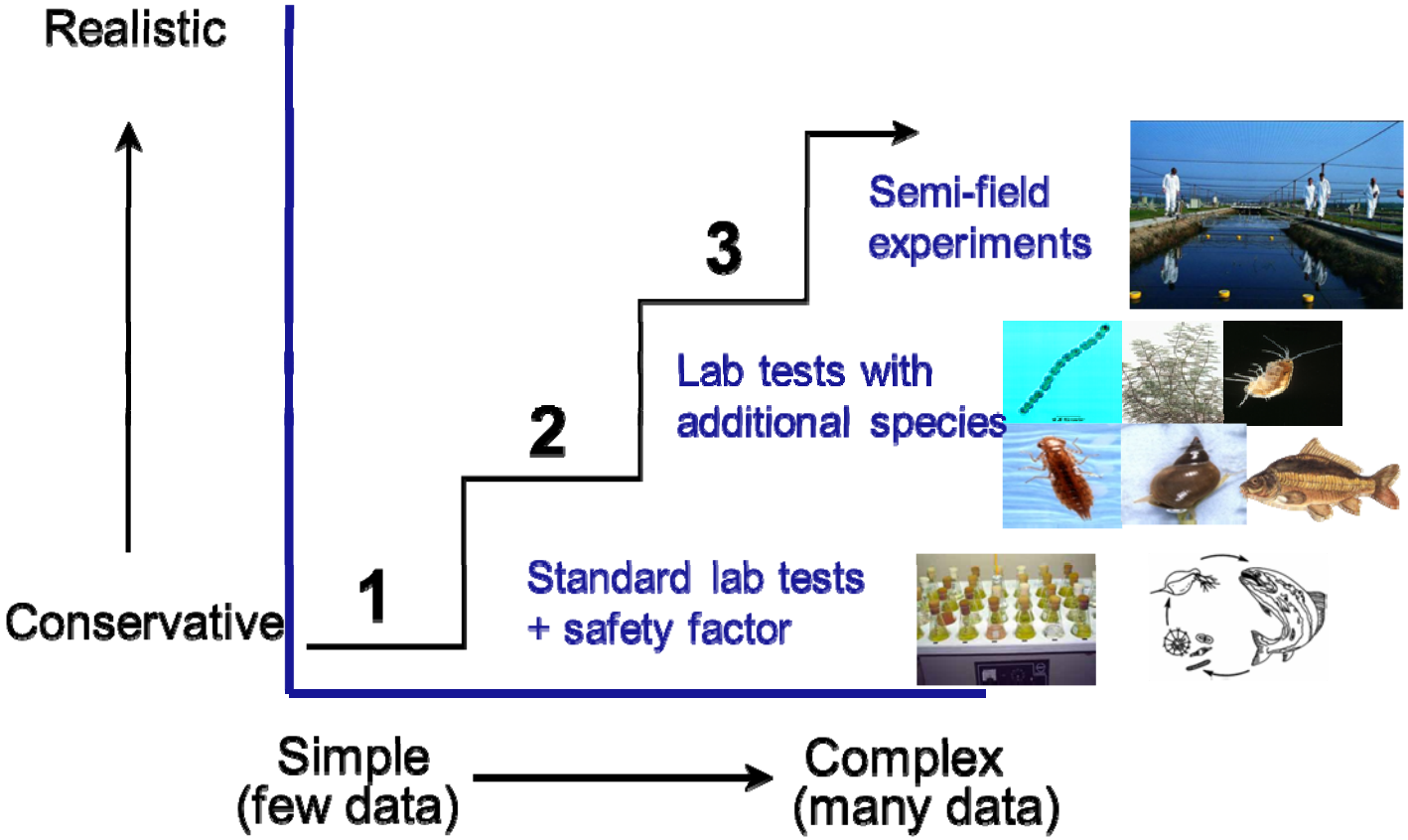
Time-varying exposure regimes



- In edge-of-field surface waters time-variable exposure regimes are the rule rather than the exception
- Dynamics in predicted exposure concentrations considerably vary per exposure scenario and type of freshwater ecosystem (streams, drainage ditches, ponds)
- Implications of time-variable exposure profiles in relation to ecotoxicity (higher tier option)

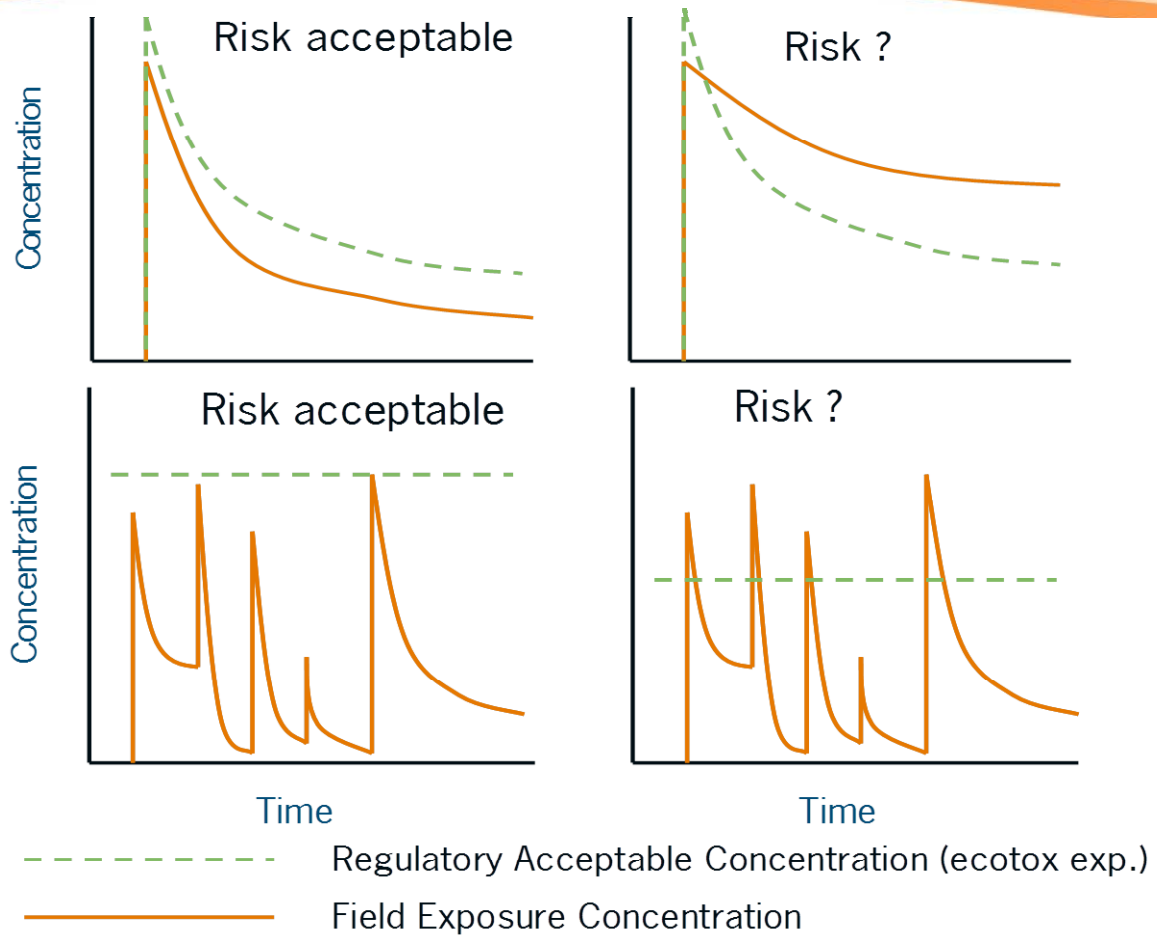
Exposure in ecotoxicity studies

Exposure patterns in different tiers



In higher tier tests the exposure regime selected should be realistic to worst case relative to the predicted field exposure regime

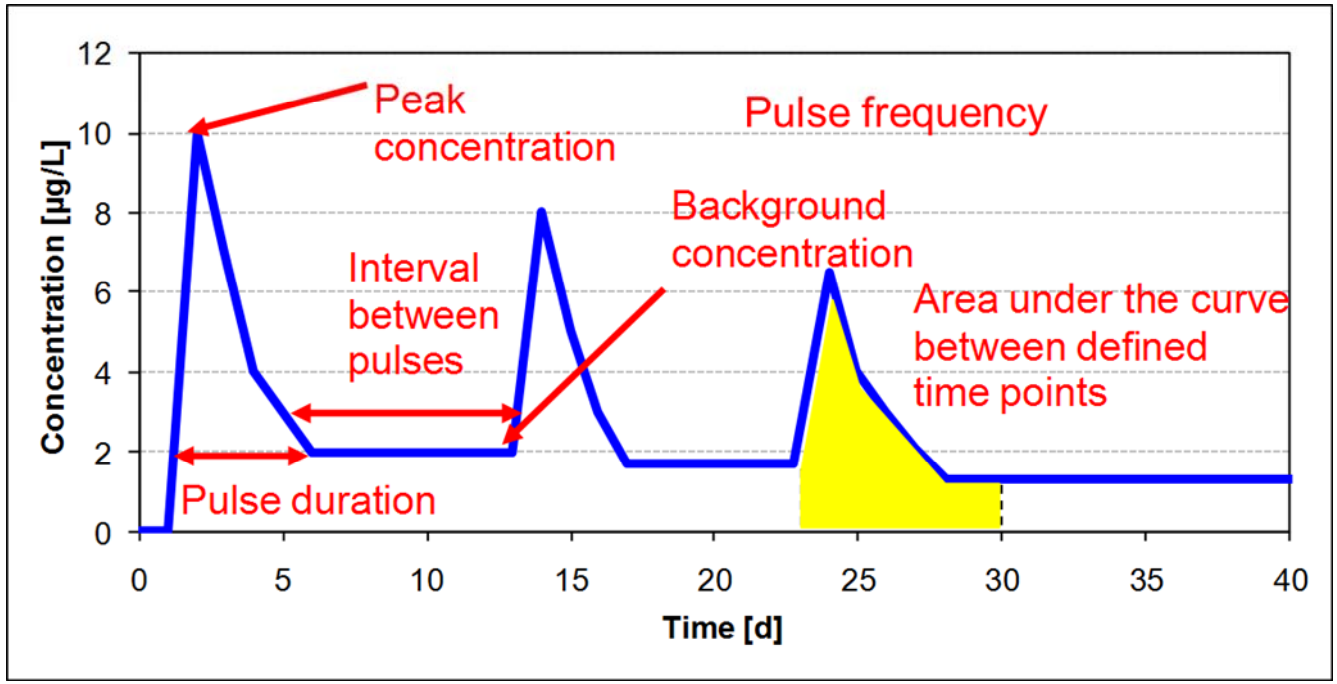
Linking PECs and RACs



Particularly if the TWA approach cannot be applied in the risk assessment, refined ecotoxicological exposure studies may be a higher-tier option.

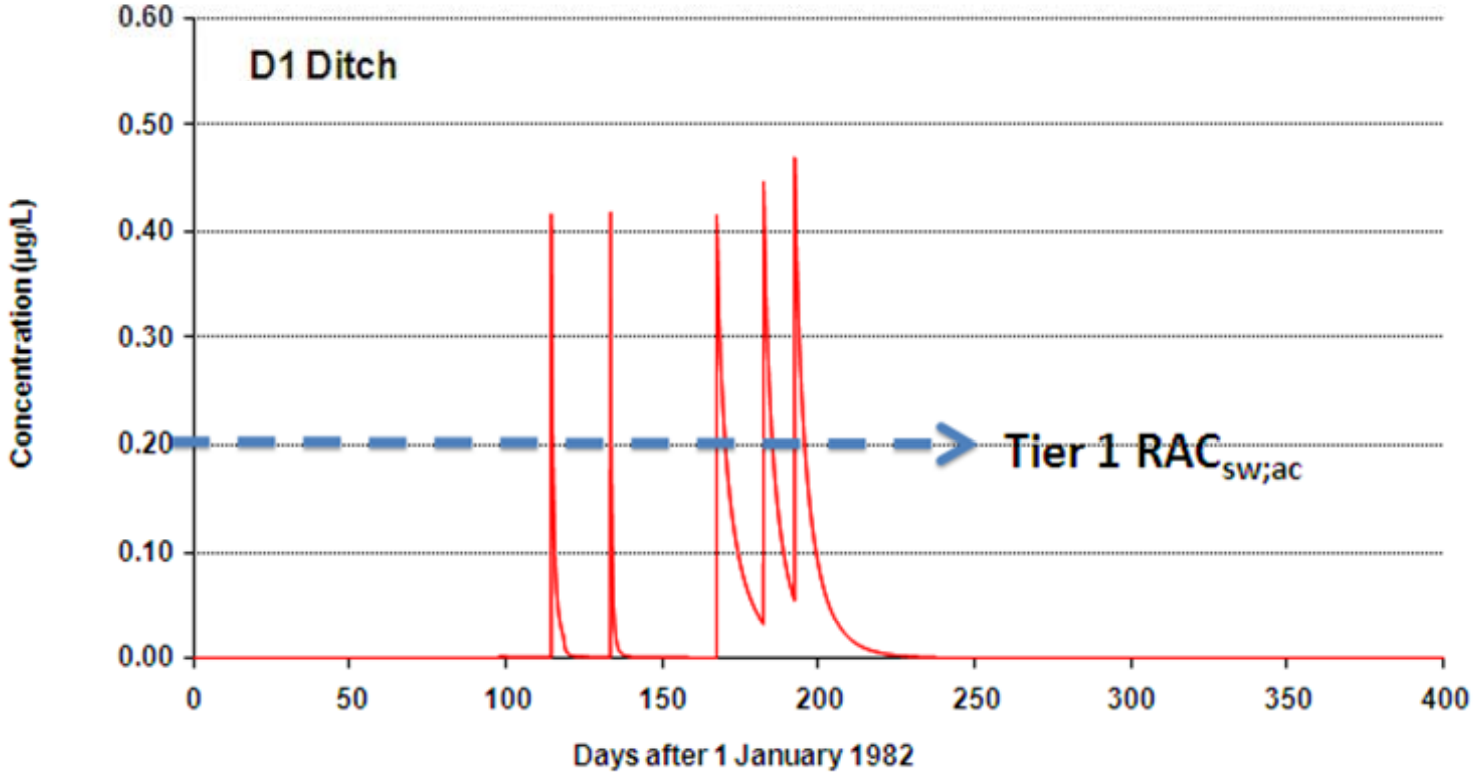
Selecting the appropriate exposure regime in higher-tier tests

- Refined exposure laboratory tests (Tier 2C)
- Model ecosystem approach (Tier 3)



Determine key parameters from the FOCUS exposure profile to inform exposure profiles that have to be simulated in ecotoxicological effects studies.

Selecting the appropriate exposure regime in higher-tier tests



Are pulses above the Tier 1 threshold level toxicologically and/or ecologically independent?

European Food Safety Authority

Thank you !