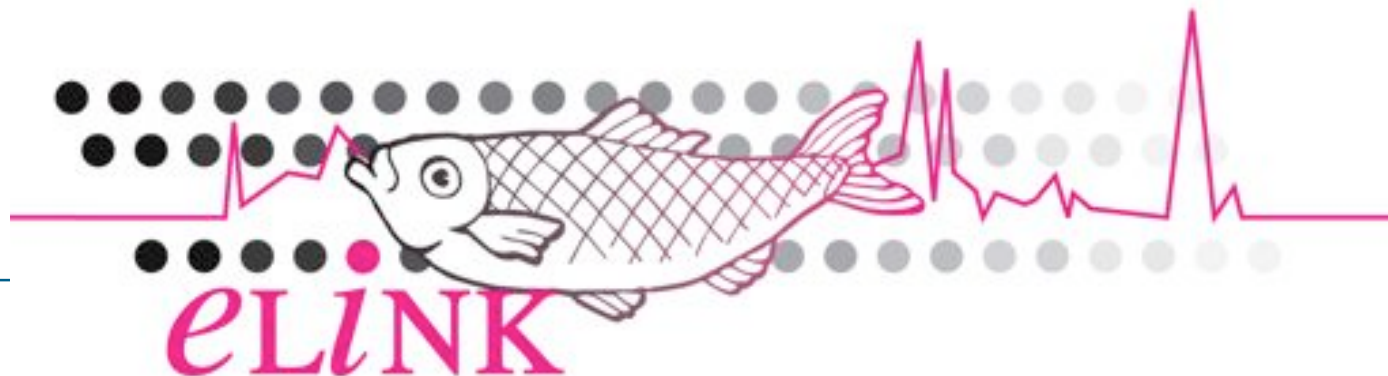


Linking aquatic exposure and effects in the registration procedure of plant protection products (ELINK)

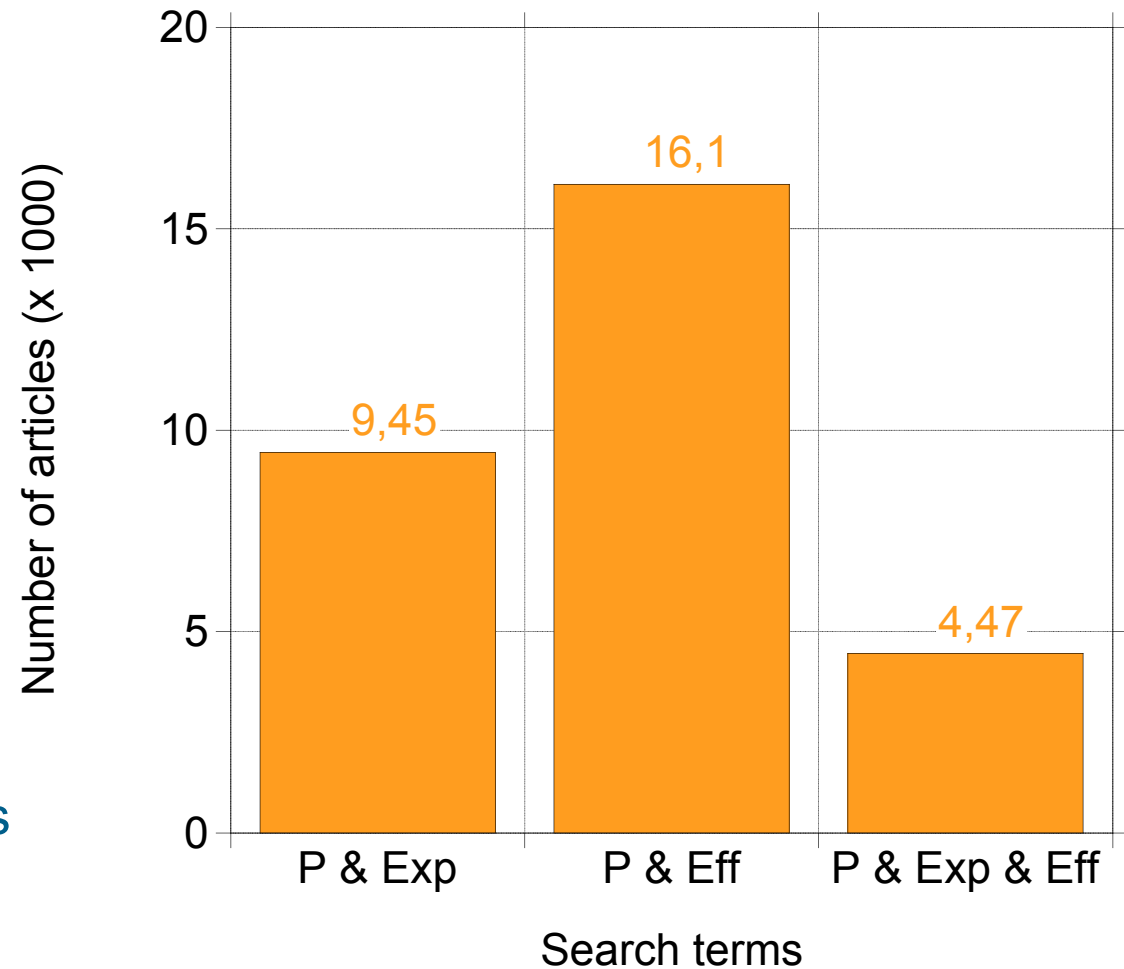
Ralf Schulz (Univ. Koblenz-Landau), R.Schulz@uni-landau.de

Theo Brock (Alterra), Anne Alix (AFSSA), Colin Brown (Univ. of York), Ettore Capri (Univ. Piacenza), Bernhard Gottesbueren (BASF), Fred Heimbach (RIFCON), Chris Lythgo (EFSA-PRAPER) & Martin Streloke (BVL)

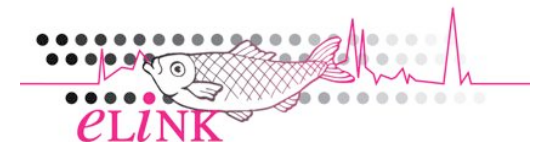


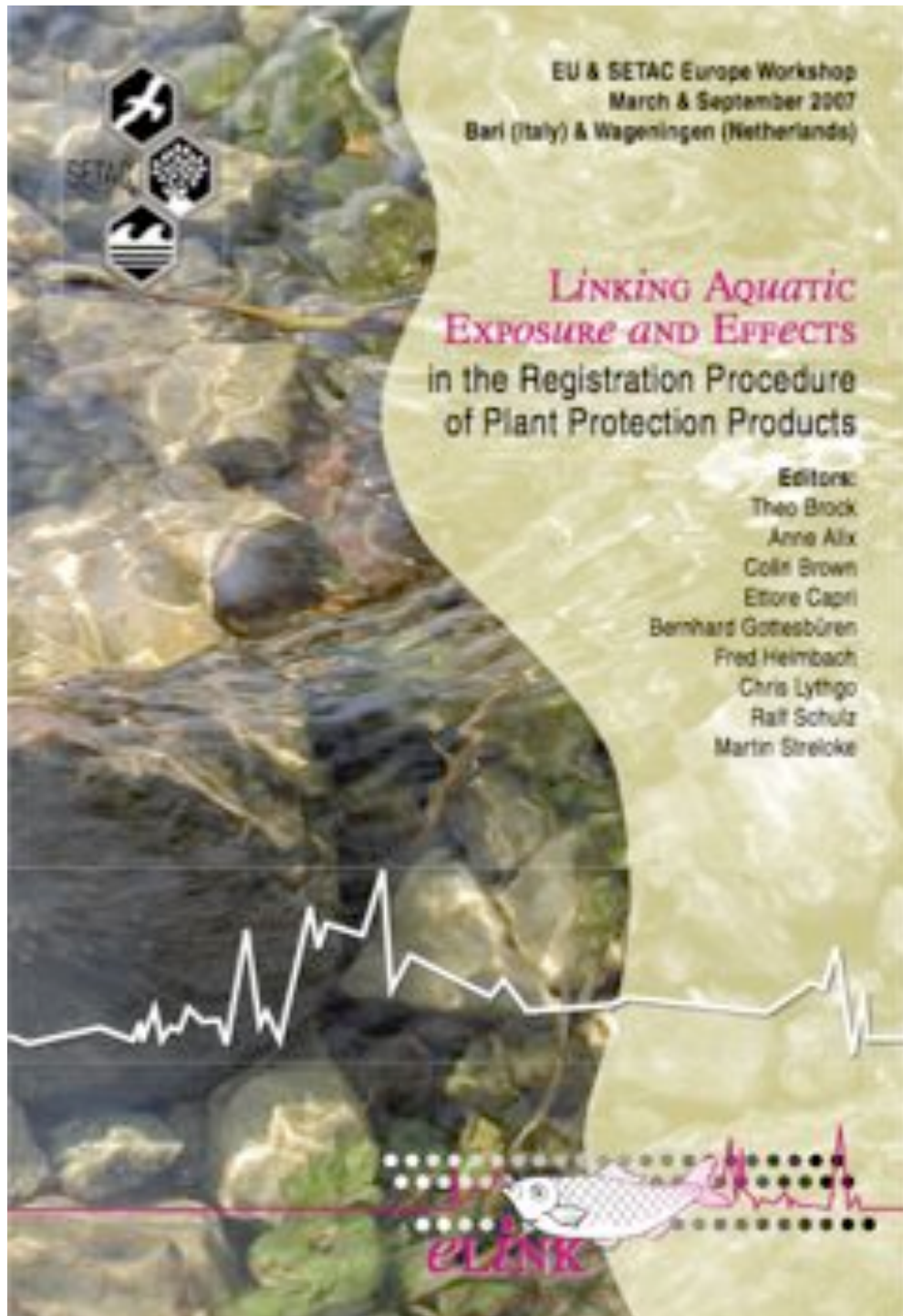
Problem formulation: Linking exposure and effects

- 1 Combined exposure and effect consideration is rare
- 2 Exposure experts do more frequently include effects
- 3 Effect experts publish more
- 4 **Don't take these simple figures too serious!**



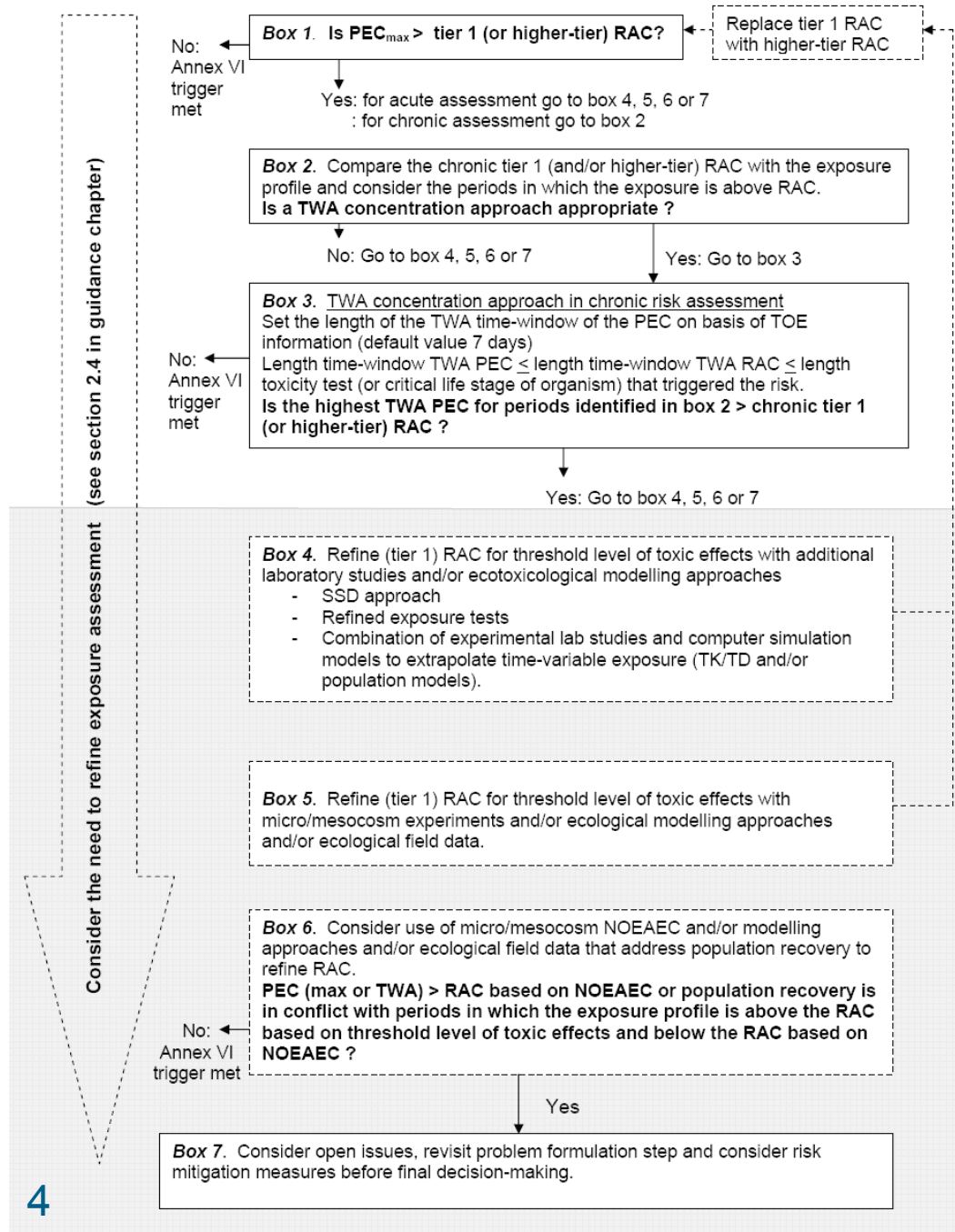
ISI WoS, 1960 - 2009





- Aims ELINK initiative
 - Bring together specialists in aquatic exposure and effect assessment of plant protection products
 - Improve guidance on linking exposure and effects in the risk assessment under Directive 91/414/EEC

Problem formulation: check validity of exposure; define critical eco(toxico)logical issues



- Two workshops in 2007
- ELINK decision scheme for acute and chronic risk assessments
- Guidance chapter to support this decision scheme
- 6 work groups
- 9 recommendations



ELINK Work groups

WG 1 Communication and education

Information exchange and confidence building!

WG 2 Characterizing the exposure profile

Which level of complexity is appropriate?

WG 3 Key parameters for risk assessment

Measures of exposure concns (TWA) and independency of events?

WG 4 Interaction between fate and effect experts

How to improve interactions throughout the assessment process?

WG 5 Extrapolation tools

Toxicokinetic/toxicodynamic as well population/metapopulation models!

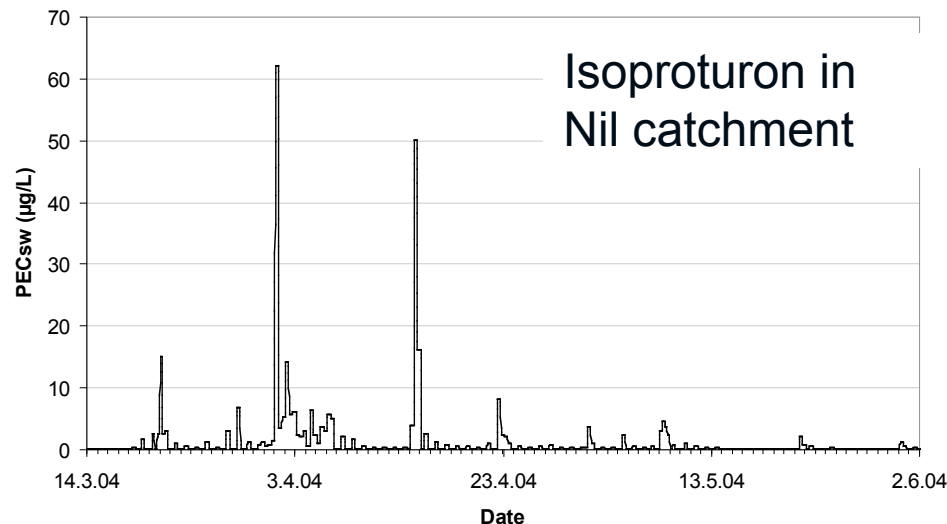
WG 6 Characteristics of water bodies

5 Protection goals and ecological scenarios for FOCUS surface waters!

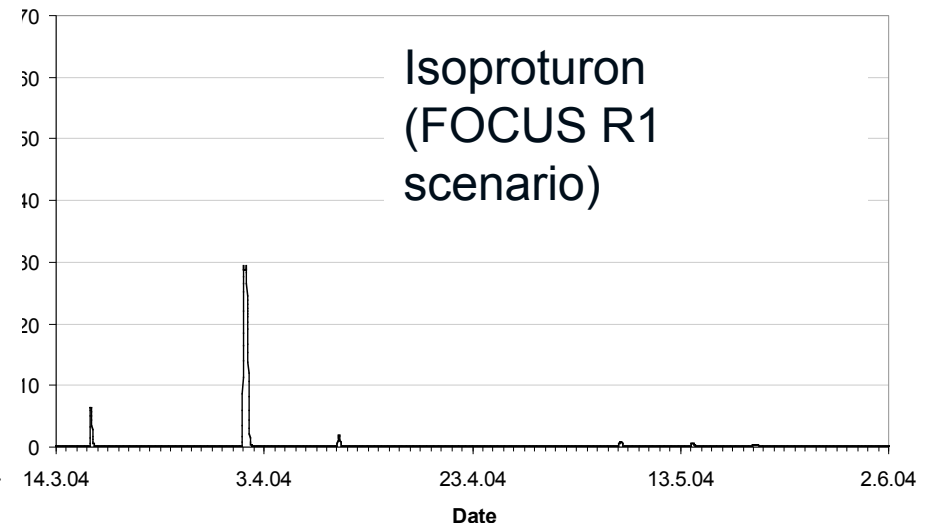
Recommendation 1: Implications of simulated time-variable exposure profiles need to be considered in the aquatic risk assessment process.

Further experimental and monitoring work required to underpin validity of exposure profiles.

Chemical field monitoring data

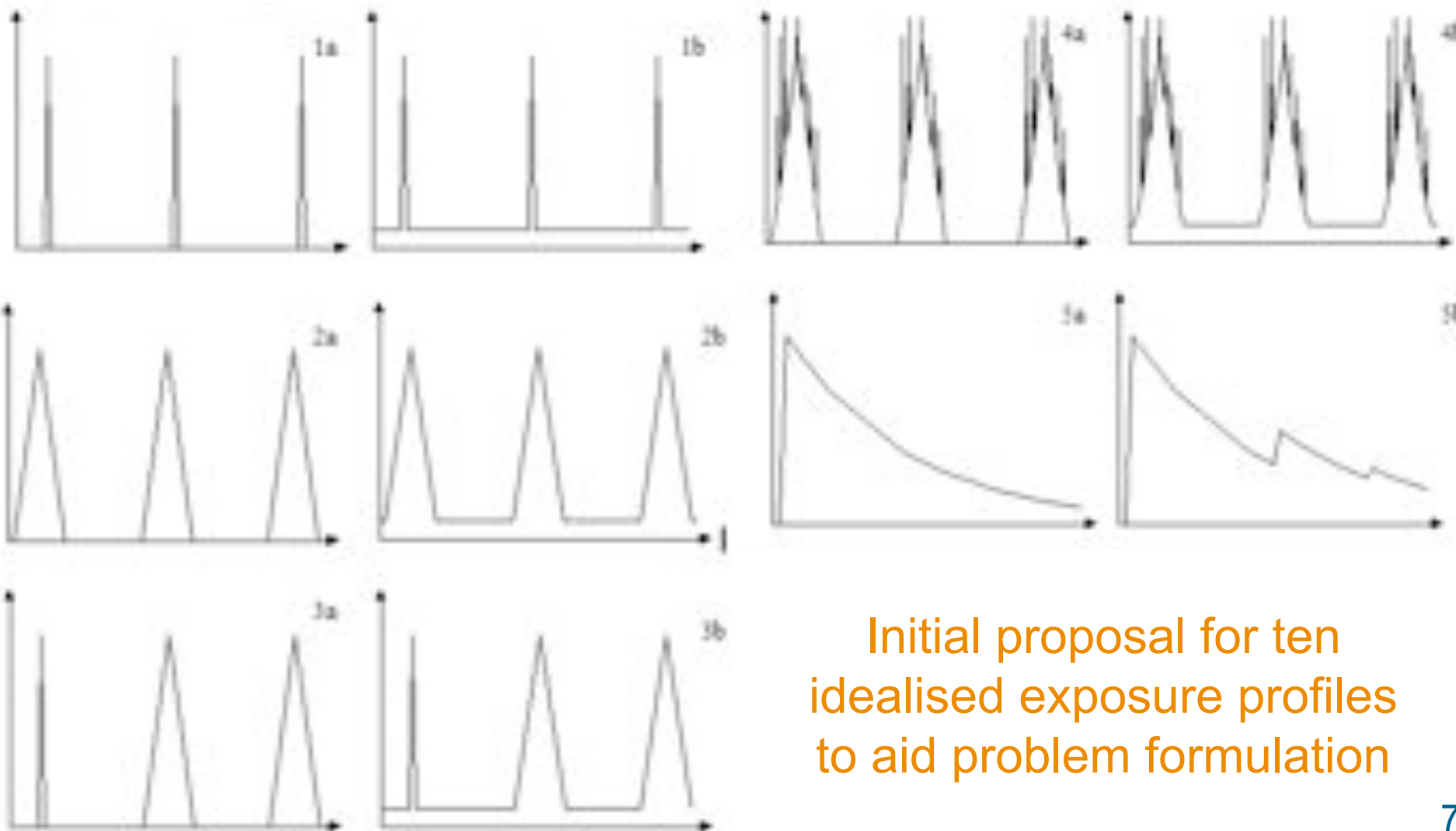


FOCUS SWS calculations



Time-variable exposure concentrations are the rule rather than the exception in edge-of-field water bodies

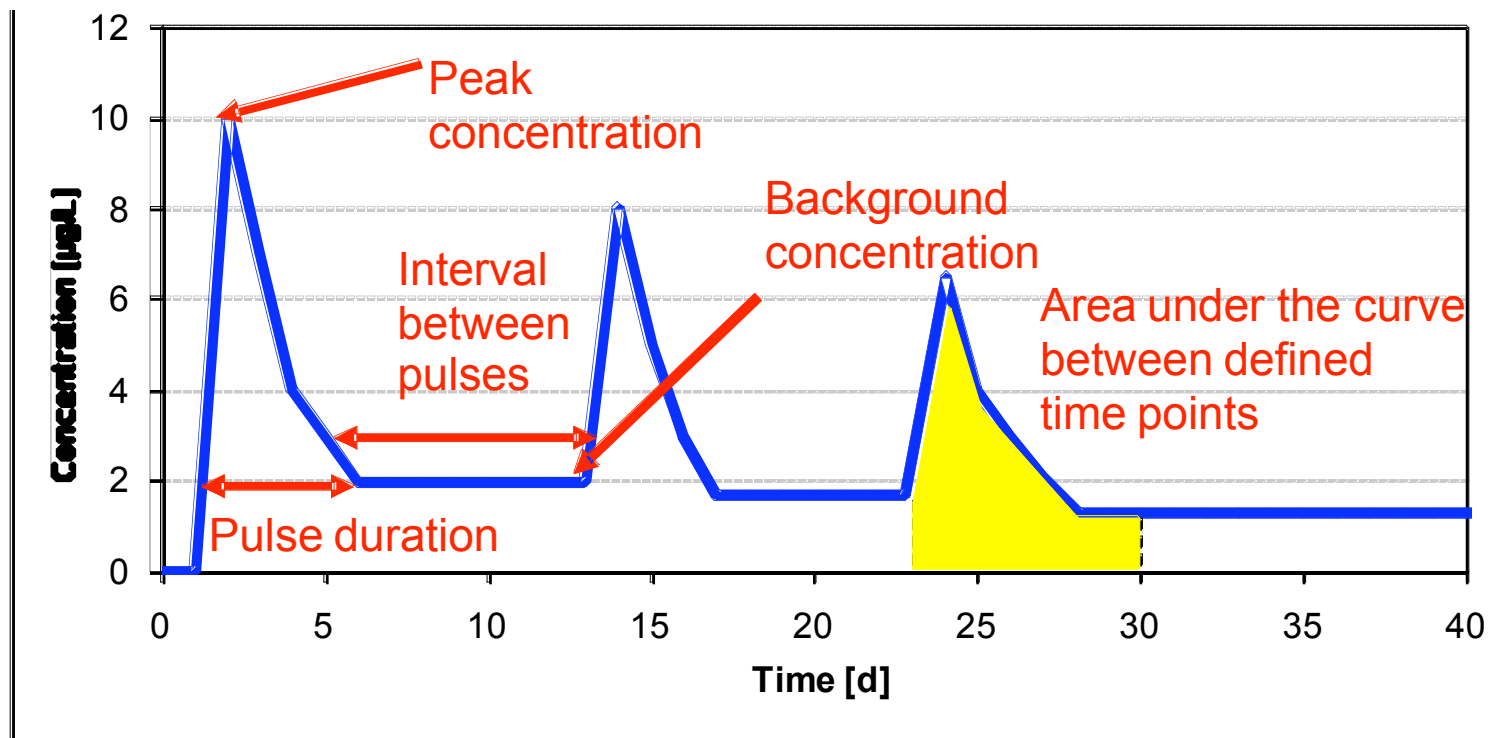
Recommendation 2: Support problem formulation with generalised exposure profiles for edge-of-field surface waters and pesticides differing in properties and use patterns



Initial proposal for ten idealised exposure profiles to aid problem formulation

Recommendation 2 contd: Determine key parameters from the exposure profile to provide information for exposure profiles that have to be simulated in ecotoxicological effects studies.

ECPA and RIFCON have developed a tool called EPAT

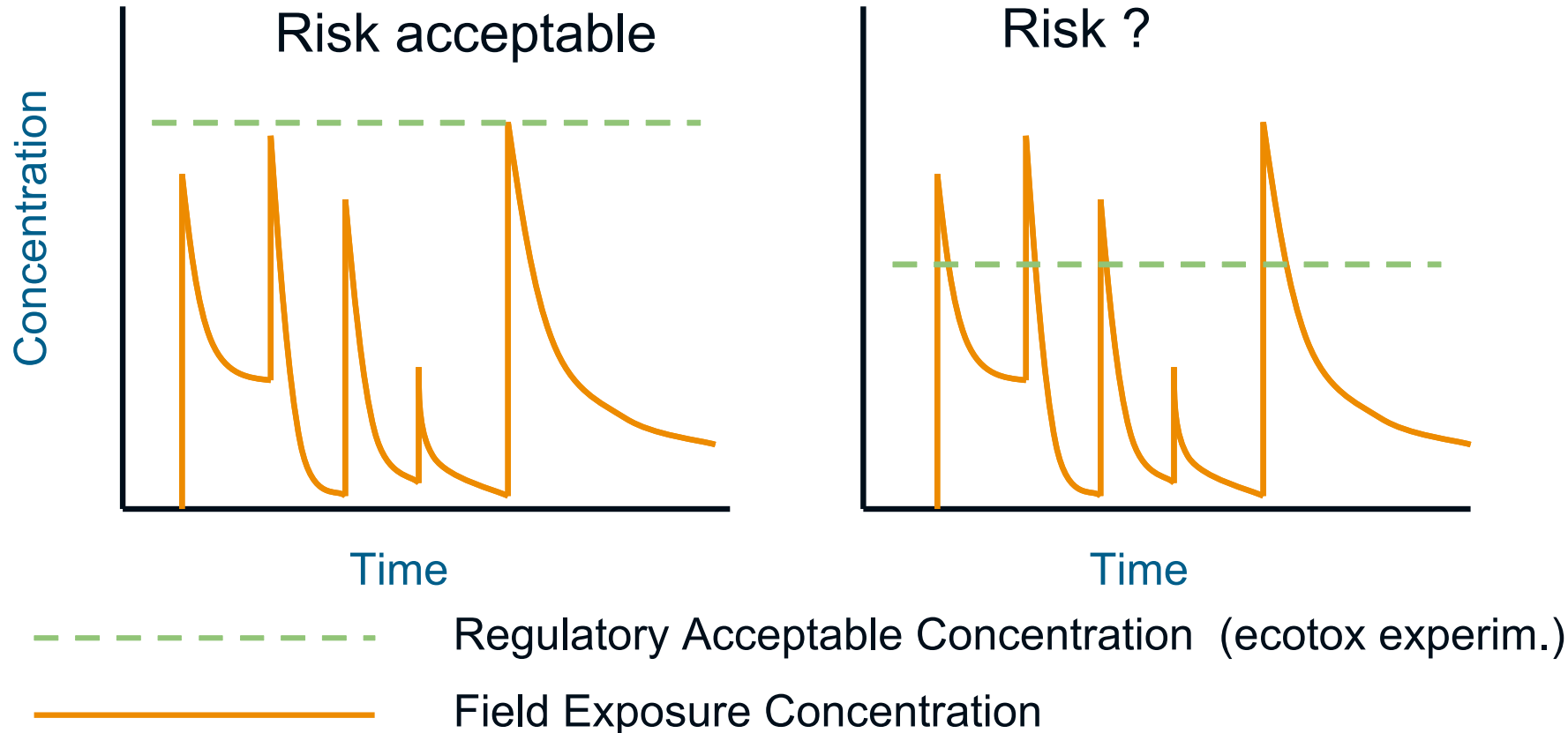


Toxicological independence of pulses:

Pulsed exposure toxicity tests or TK/TD models

Ecological independence: If peak interval > recovery time

Exposure in ecotox experiments and field

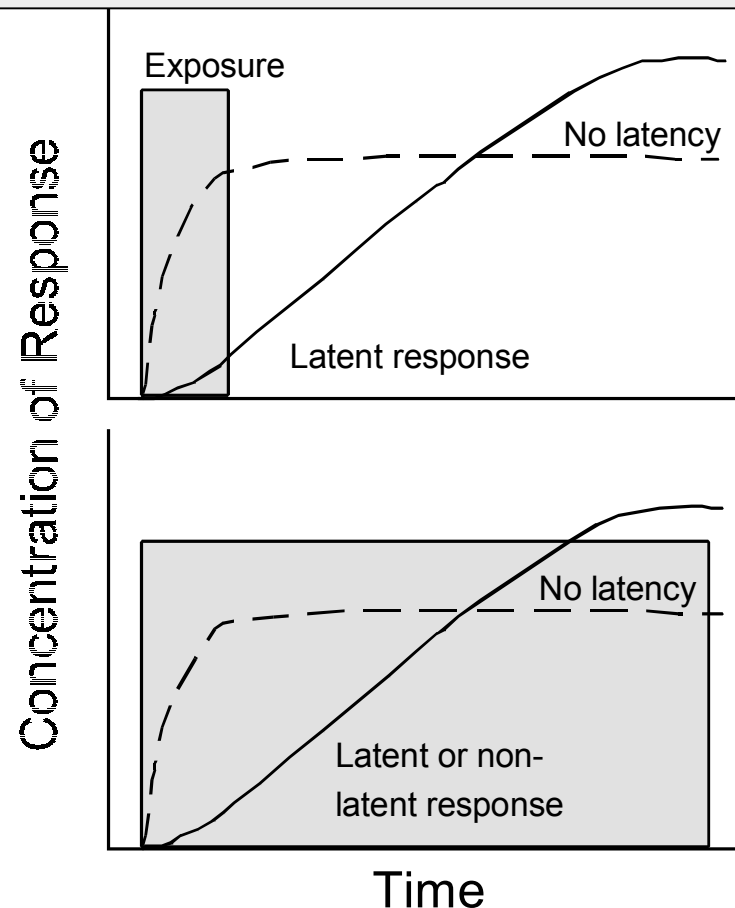


RAC = Regulatory Acceptable Concentration (based on relevant endpoint in ecotox test and application of UF or extrapolation technique). In the risk assessment the RAC should be $>$ PEC.

Should peak or TWA conc. be used in the chronic risk assessment?

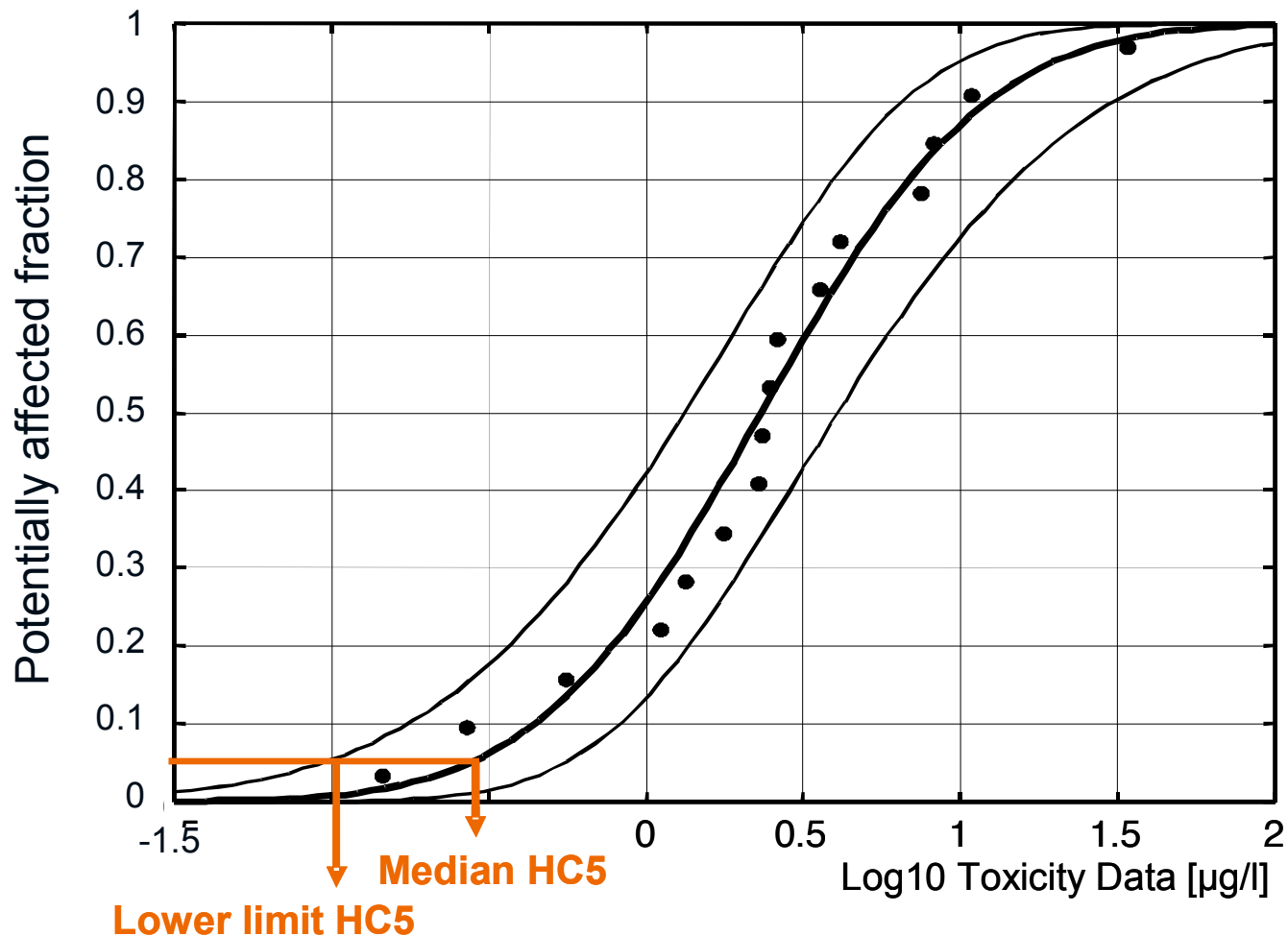
Recommendation 3: Ecotoxicology must determine if the TWA concentration approach is appropriate to use in chronic risk assessment, and which time window it should be based on.

- TWA approach is **not** appropriate
 - In risk assessments based on toxicity data of algae and effect studies where the exposure is not maintained and/or loss of the substance is fast
 - When effect endpoint in the chronic test is based on a developmental process during a specific life-cycle stage
 - When there is evidence of an endocrine disruption effect (unless...)
 - When the (acute EC50/chronic NOEC) ratio is < 10
 - If latency of effects has been demonstrated (or might be expected)

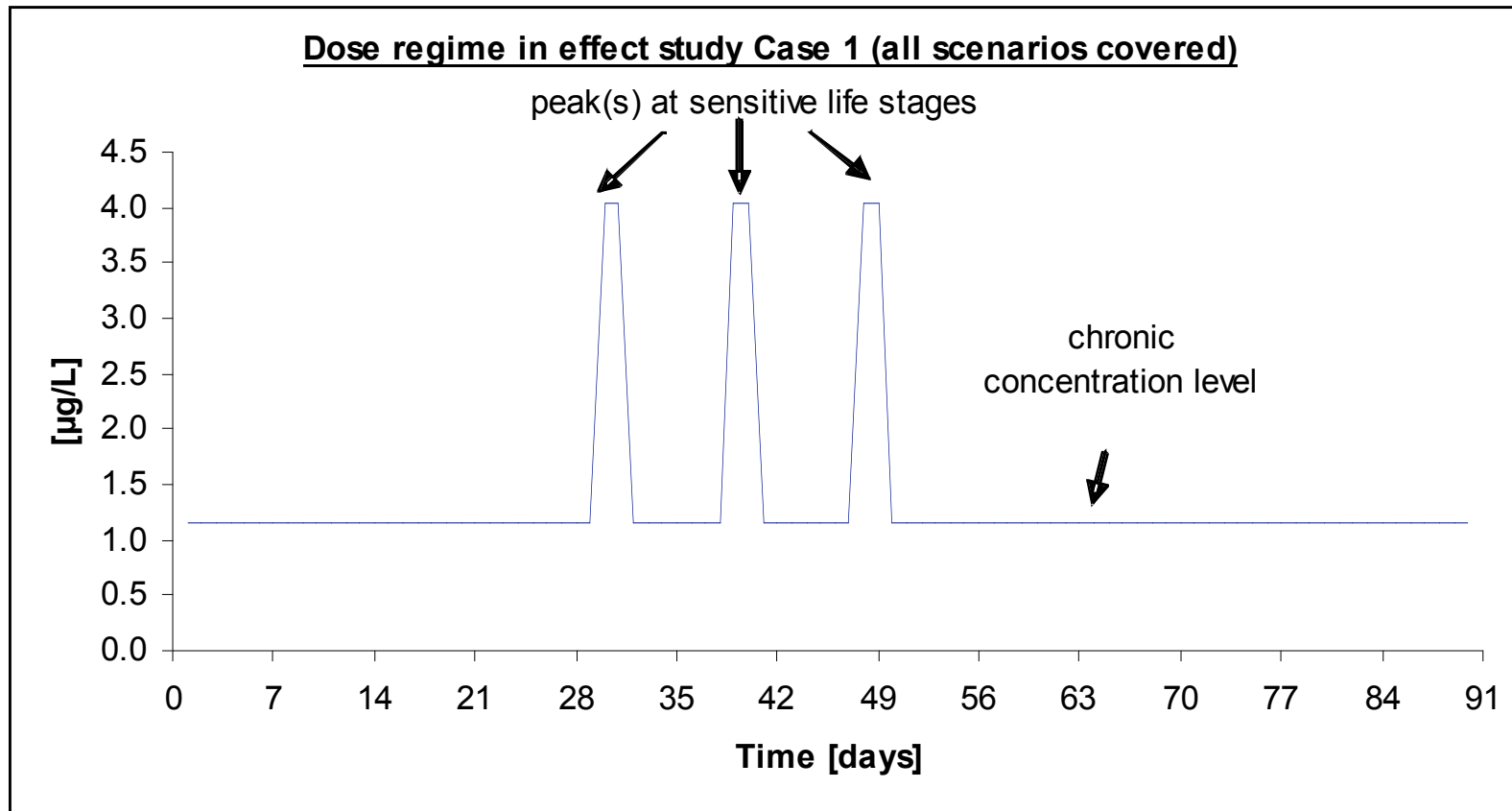


Recommendation 3 contd: If the TWA approach is deemed appropriate it is proposed to use a 7-d TWA PEC as default for fish and invertebrates (and possibly also macrophytes)

Recommendation 4: Lower limit or median HC5 values calculated from (acute data) SSDs for relevant taxonomic group may be used to derive RACs

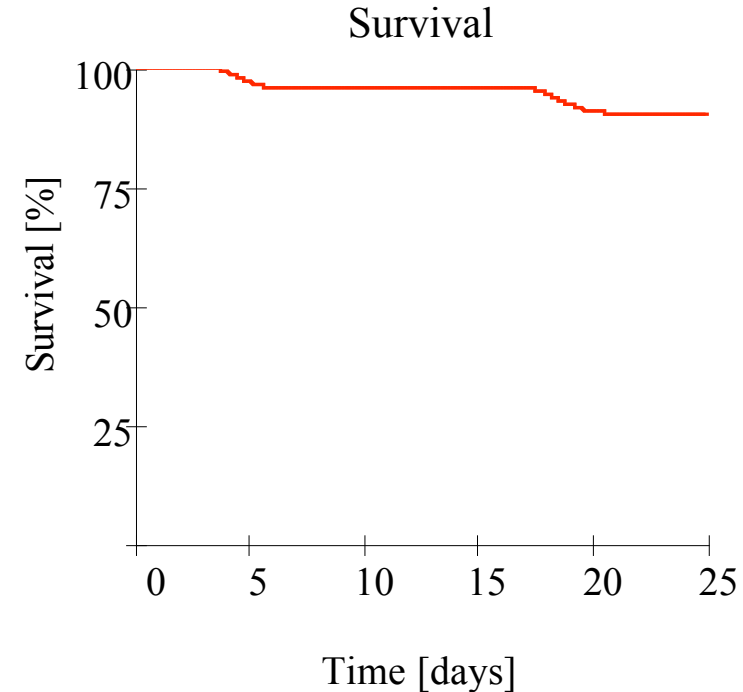
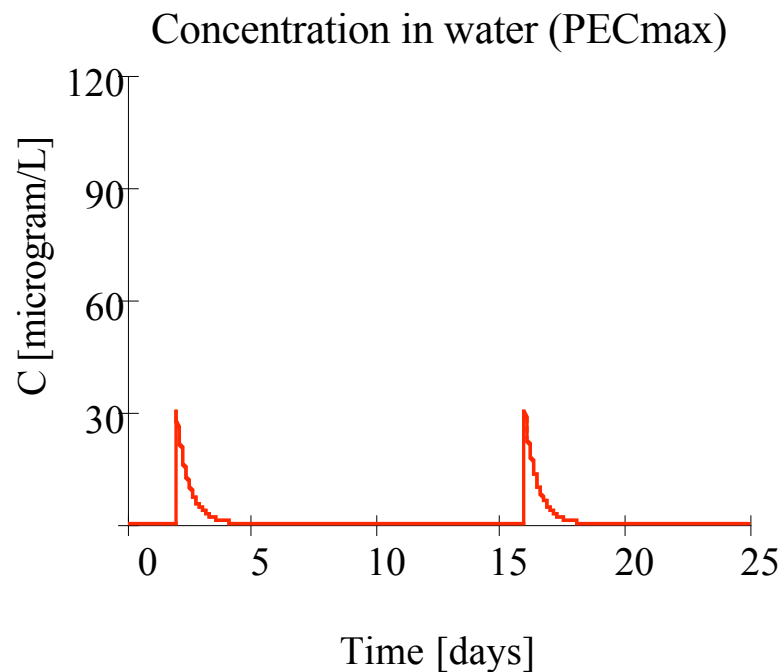


Recommendation 5: Ecotoxicological studies with refined exposure may be a higher-tier option. Exposure conditions guided by species properties and generalised exposure profile.

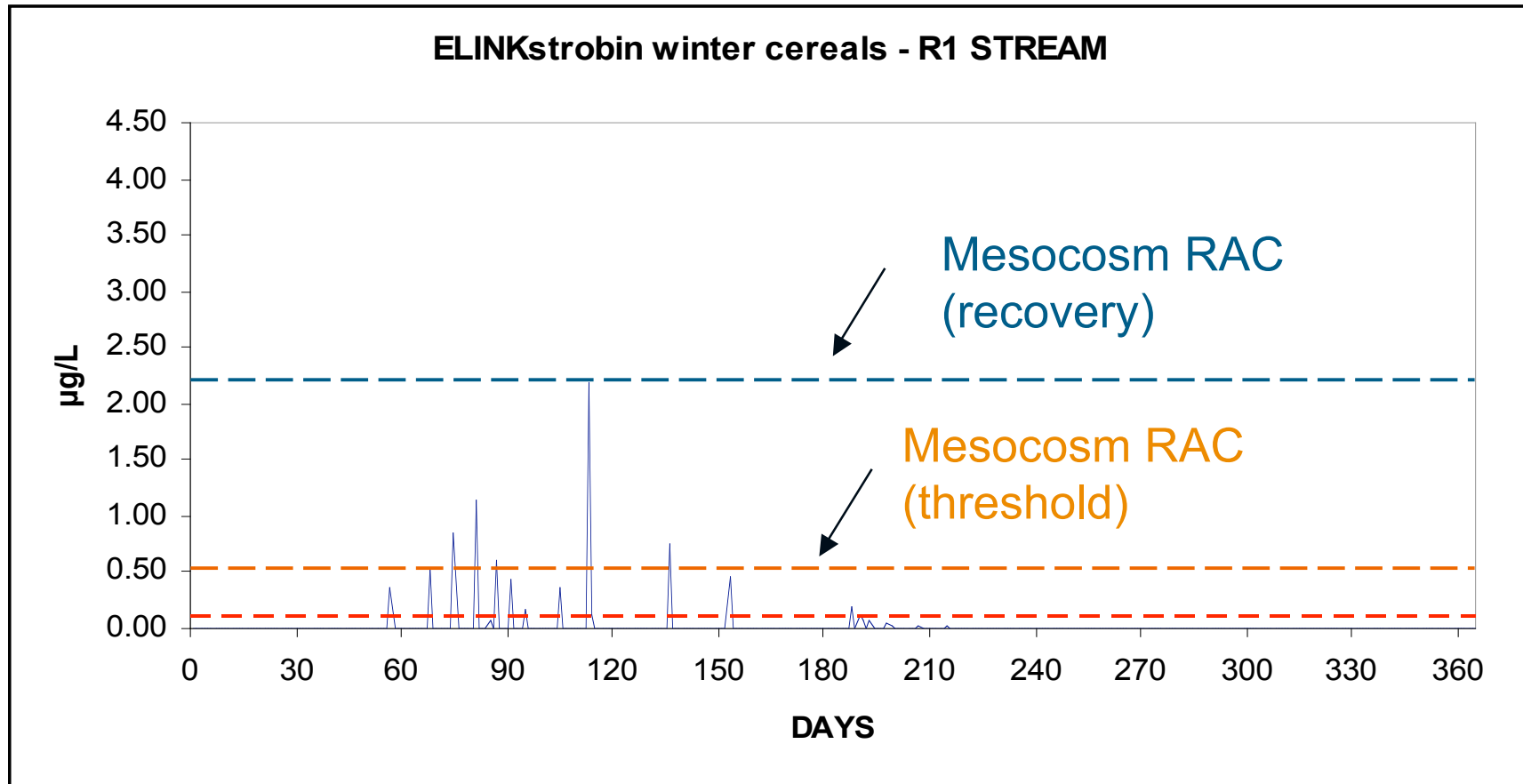


Recommendation 6: Toxicokinetic/toxicodynamic models are promising tools to assess effects from time-variable exposure regimes of pesticides (primarily a research activity to date).

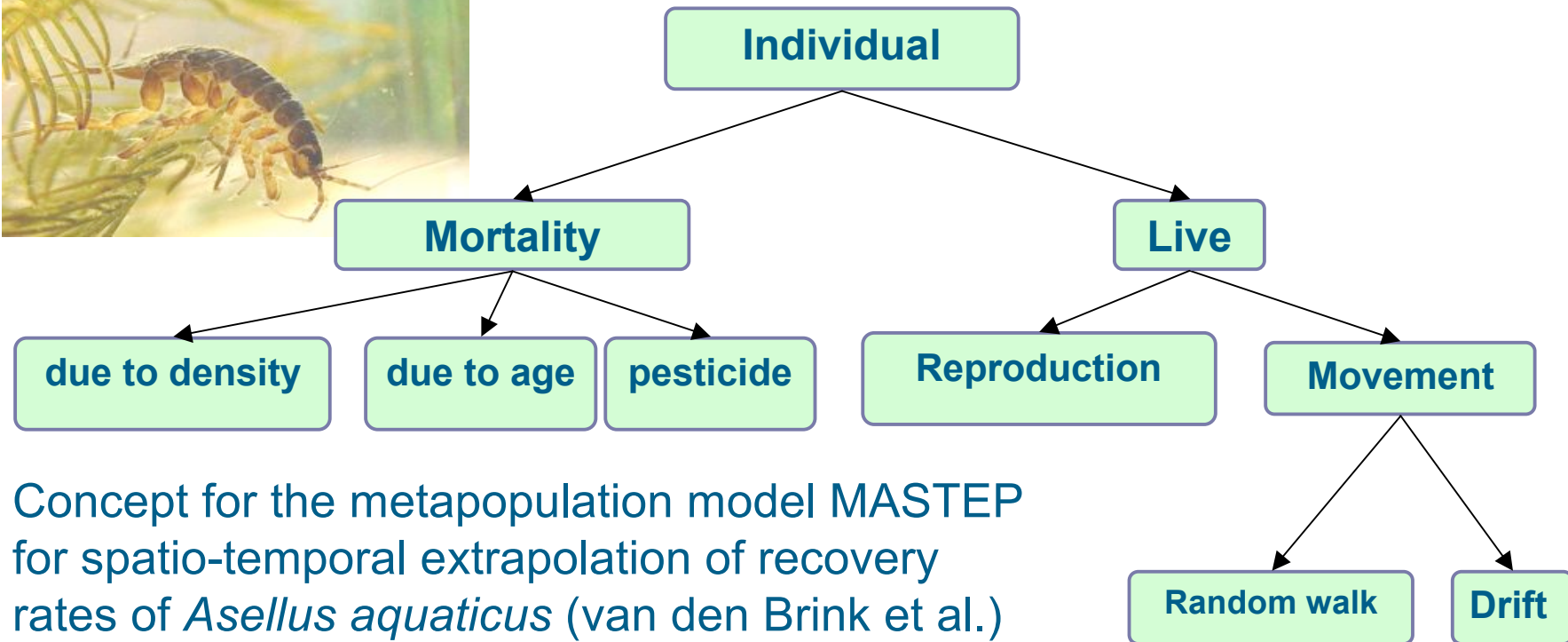
- Direct link between exposure and effects for individual organisms
- Toxicokinetics: concentration in organism as $f(\text{conc}^n \text{ in water})$
- Toxicodynamics: time-course of damage and repair
- Approach to assess toxicological independence of peaks



Recommendation 7: Micro/mesocosm experiments may be used to derive RAC's for threshold level of toxic effects and for population recovery.



Recommendation 8: Ecological modelling is generally considered as a helpful and a promising tool in pesticide risk assessment. Guidance and quality control is needed.

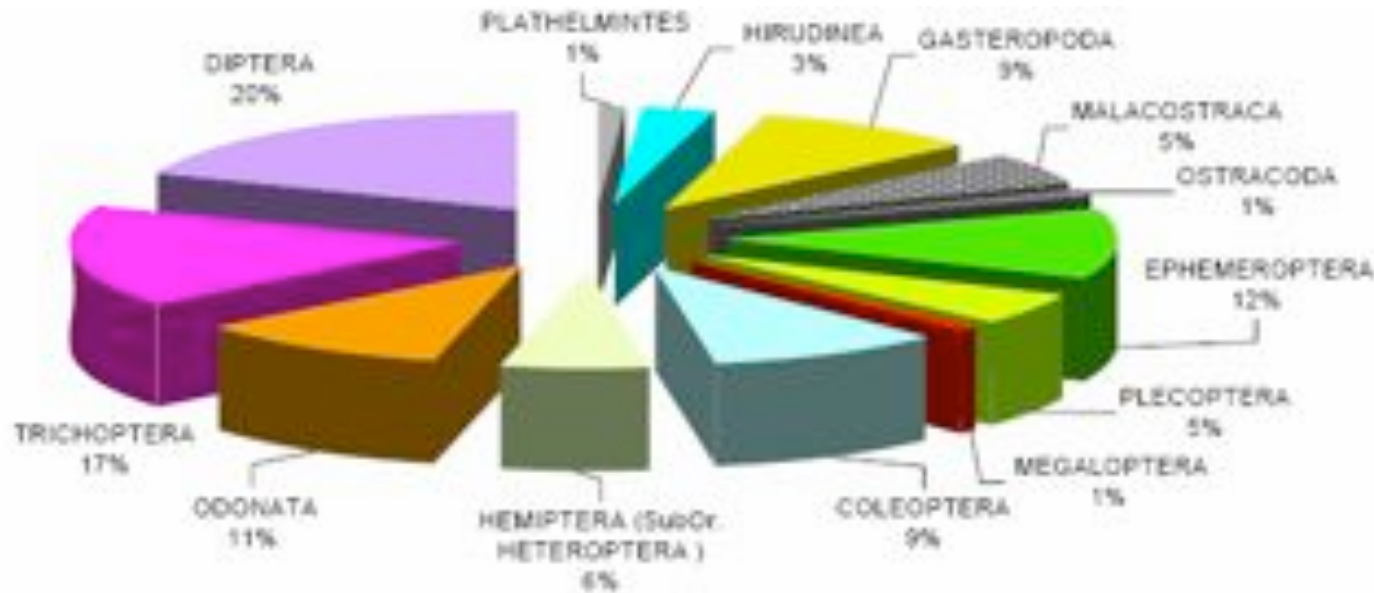


Concept for the metapopulation model MASTEP for spatio-temporal extrapolation of recovery rates of *Asellus aquaticus* (van den Brink et al.)

A FOCUS-type process is required for ecological modelling

FP7 project “CREAM” is targeting development in this area

Recommendation 9: Develop a “handbook of ecological scenarios” to which fate and effect experts can refer in performing and evaluating refined exposure, effect and risk assessments.



	Median (10 – 90 th percentile)
Water depth (m)	0.6 (0.3 – 1.0)
Width of ditch (m)	5 (2 – 10)
Electronic conductivity (mS/m)	40 (20 – 130)
pH	7.9 (7.3 – 8.5)
Depth organic debris layer (cm)	5 (1 – 35)

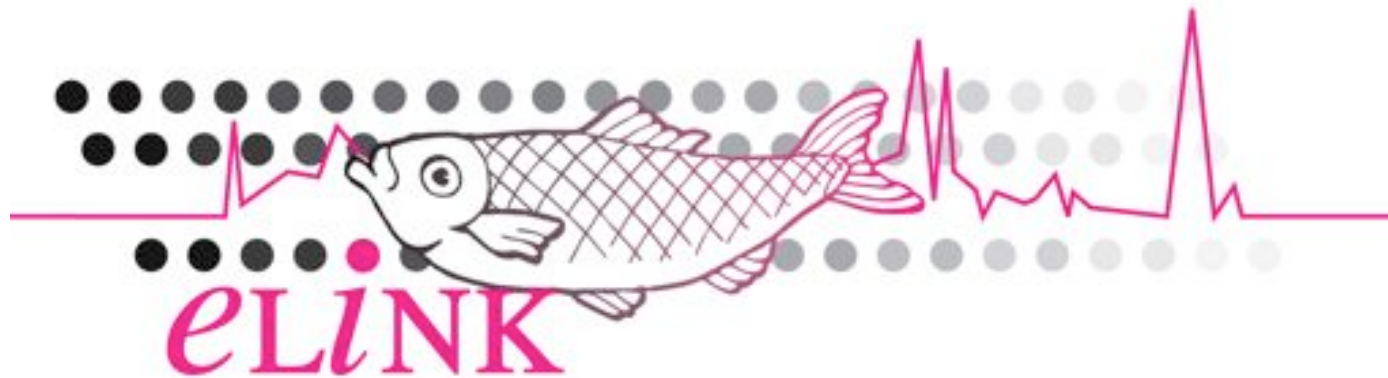
Conclusion: Output ELINK

- SETAC guidance report published
 - Decision tree for how to link fate and effects in the aquatic risk assessment procedure
 - Guidance chapter around decision scheme
 - Reports of different working groups



Brock TCM, Alix A, Brown CD, Capri E, Gottesbueren BFF, Heimbach F, Lythgo CM, Schulz R, Streloke M (Editors) (2009). Linking Aquatic Exposure and Effects in the Risk Assessment of Plant Protection Products. SETAC Press & CRS Press, Tayler & Francis Group, Boca Raton, London, New York

<http://www.elink-info.org>



Thank you for your attention!