A standardised approach to identify worst-case FOCUS surface water exposure profiles in aquatic pulsed exposure events

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The outcome of Tier 1 risk assessment for plant protection products frequently calls for the use of higher tier approaches to evidence an acceptable risk to aquatic organisms. In this context, laboratory pulsed exposure experiments can be used to test the effects of varying exposure concentrations on the mortality and/or immobilization of organisms. However, selecting the relevant exposure scenarios is highly challenging and often based on subjective expert judgments, only. Thus, we present here a standardized step-wise approach using the well-established TK/TD model GUTS (general unified theory of survival) developed by Jager *et al.* (2011) to determine the relevant exposure scenario from FOCUS models with the strongest impact on organisms. The approach aims to provide a scientifically sound and reproducible basis to select the appropriate worst-case exposure profile, which can be ultimately used in pulsed exposure experiments.

Stepwise Approach

Step 1

Step 2

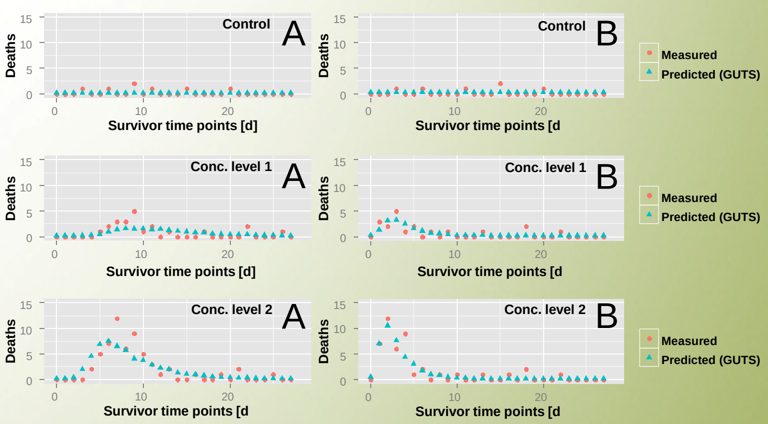


Figure 2: GUTS parametrization of aquatic laboratory tests, death individuals measured (red) vs. predicted (blue); left (A) late onset of effect; right (B) early onset of effect

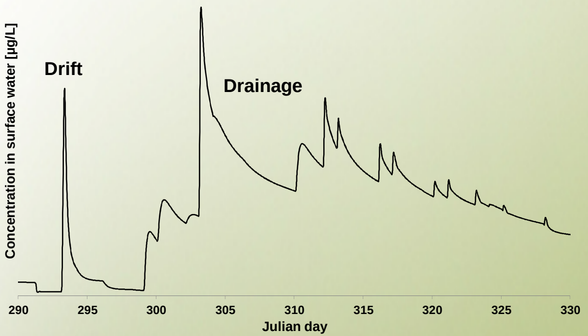


Figure 1: Calculation of predicted exposure patterns with FOCUS-SW models, e.g. drift and drainage inputs according to the FOCUS D2 (ditch) scenario.

Table 1: Estimated mortalities (%) compared to controls (calculated with a parameterised GUTS model and exposure profiles based on FOCUS SW models.

Crop / Application rate	GUTS	D1 ditch	D1 stream	D2 ditch	D2 stream	D3 ditch	D4 pond	D4 stream	D5 stream	D6 ditch
Winter OSR / 150 g/ha	A	-	-	+ 5.9	+ <0.1	0	0	0	0	0
	B	-	-	+26.5	+ 3.2	0	0	0	0	0
Leafy vegetables / 150 g/ha	A	-	-	-	-	0	0	0	-	+ <0.1
	B	-	-	-	-	0	0	0	-	+ 14.8
Pome fruits** / 1500 g/ha	A	-	-	-	-	+3.7	+ <0.1	0	0	-
	B	-	-	-	-	+38.4	+1.8	+ <0.1	+ <0.1	-
Winter cereals / 100 g/ha	A	+ 0.2	0	+ 64.9	+ 0.7	0	0	0	0	0
	B	+ 11.3	+ 10.5	+ 52.7	+ 9.8	0	0	0	0	0

For instance, a value of +52.7% signifies an increase in mortality in an exposed population compared to non-exposure conditions showing natural mortality only. PEC values were multiplied by 100 to consider an EU assessment factor for fish
** Main entry = Drift; Other crops = Drainage
A = Late onset of effect; B = Early onset of effect

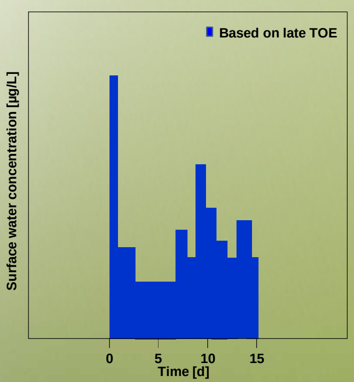
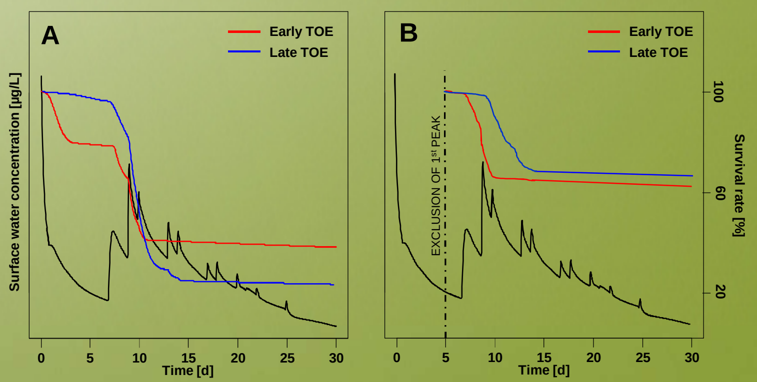


Figure 4: Proposed, schematic exposure profile for a pulse-exposure study to cover all intended uses provided in Table 1. TOE = Time of onset of effects.



Step 3

Figure 3: (A) Visualisation of modelled survival data based on worst-case FOCUS D2 ditch scenario (winter cereals). (B) Modelled survival without maximum peak in order to assess the dependence or independence of peaks on overall toxicity. TOE = Time of onset of effects.

Current strategies to select relevant exposure profiles often relied on the outcome of EPAT (Exposure Pattern Assessment Tool) evaluations. However, this approach failed to integrate crucial ecotoxicological information, which might have a significant impact on the selection of the worst-case scenario. Indeed, although mortality is partly determined by peak height and peak duration, *time of onset of effects* (TOE) and internal carry-over toxicity also strongly affects the response of test organism. Test species with a rapid toxic response (early TOE) may show an enhanced mortality even after a short, high drift pulse, whereas organisms with a late response (late TOE) potentially remain unaffected (e.g. D3 ditch, pome fruits). In contrast, the longer the duration of the peak, the more pronounced are the effects in organisms showing a late response (e.g. D2 ditch, winter cereals).

According to the EFSA Aquatic GD (2013), toxicological independence of peaks needs to be tested, before certain peaks (e.g. single drift peak) can be rejected from the test design. In case of the selected D2 ditch scenario (winter cereals), carry-over toxicity from the first peak clearly affects both, early and late TOEs (see Figure 3). Therefore, an independence of peaks could not be demonstrated and the first peak needs to be considered in the proposed pulsed-exposure experiment (Figure 4).

In conclusion, our developed step-wise approach is a valuable and reproducible tool to select ecotoxicologically relevant concentration profiles for pulsed-exposure studies. It is easy and simple to use and provides a comprehensible and scientifically sound way to demonstrate the worst-case exposure profile in higher tier aquatic risk assessments.

Reference: Jager T., et al. (2011) *Environmental Science and Technology,* 45: 2529-2540; EFSA Aquatic Guidance Document (2013) *EFSA Journal* 11(7):3290