

Risk assessment for amphibia in the EU – how much additional animal testing is adequate?

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INTRODUCTION

The EFSA Opinion Paper on the risk of pesticides to reptiles and amphibians [1] aims to answer – among many other points – how much additional testing is necessary for a protective risk assessment (RA) for amphibians and reptiles. On behalf of EFSA, endpoints (largely LC50 endpoints) of amphibia and of fish were gathered and compiled in a supporting publication [2] as Appendix K, comparing their sensitivity.

These data proved to be very heterogeneous, in particular regarding the test substance (a.s. or formulation) there was often no close match. The data also included datapairs with astounding differences in sensitivity, differing by several orders of magnitude, in both directions. This led to EFSA's conclusion that fish endpoints were not a good predictor for amphibian endpoints – in contrast to other reviews, e.g. Weltje et al. 2013 [3].

Therefore, EFSA proposed an additional assessment factor of 100 for cases where amphibia were not tested separately, but where fish endpoint served as surrogates in the amphibian RA.

We expected that the database could be improved if data pairs were defined strictly by formulation; and that such an improved - i.e. more stringent - database was likely to include fewer cases with huge differences in sensitivity between fish and aquatic amphibia stages.

● Targets:

1. Improve database
2. Verify or falsify cases with huge differences in sensitivity
3. Reassess if regular testing of aquatic amphibians is needed
4. Reassess any assessment factor to bridge between fish and amphibian toxicity

Results: If RQ >1, amphib more sensitive

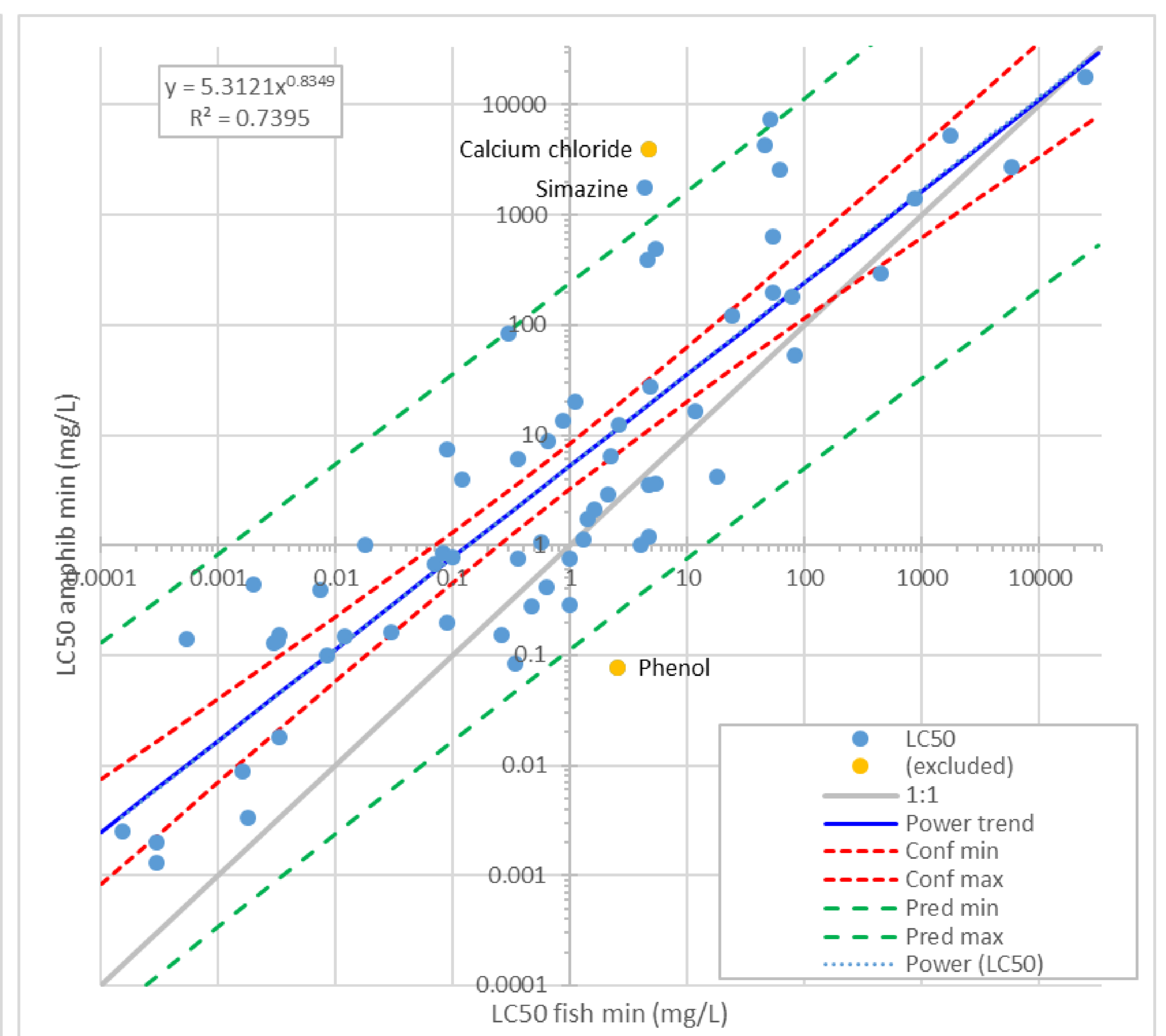
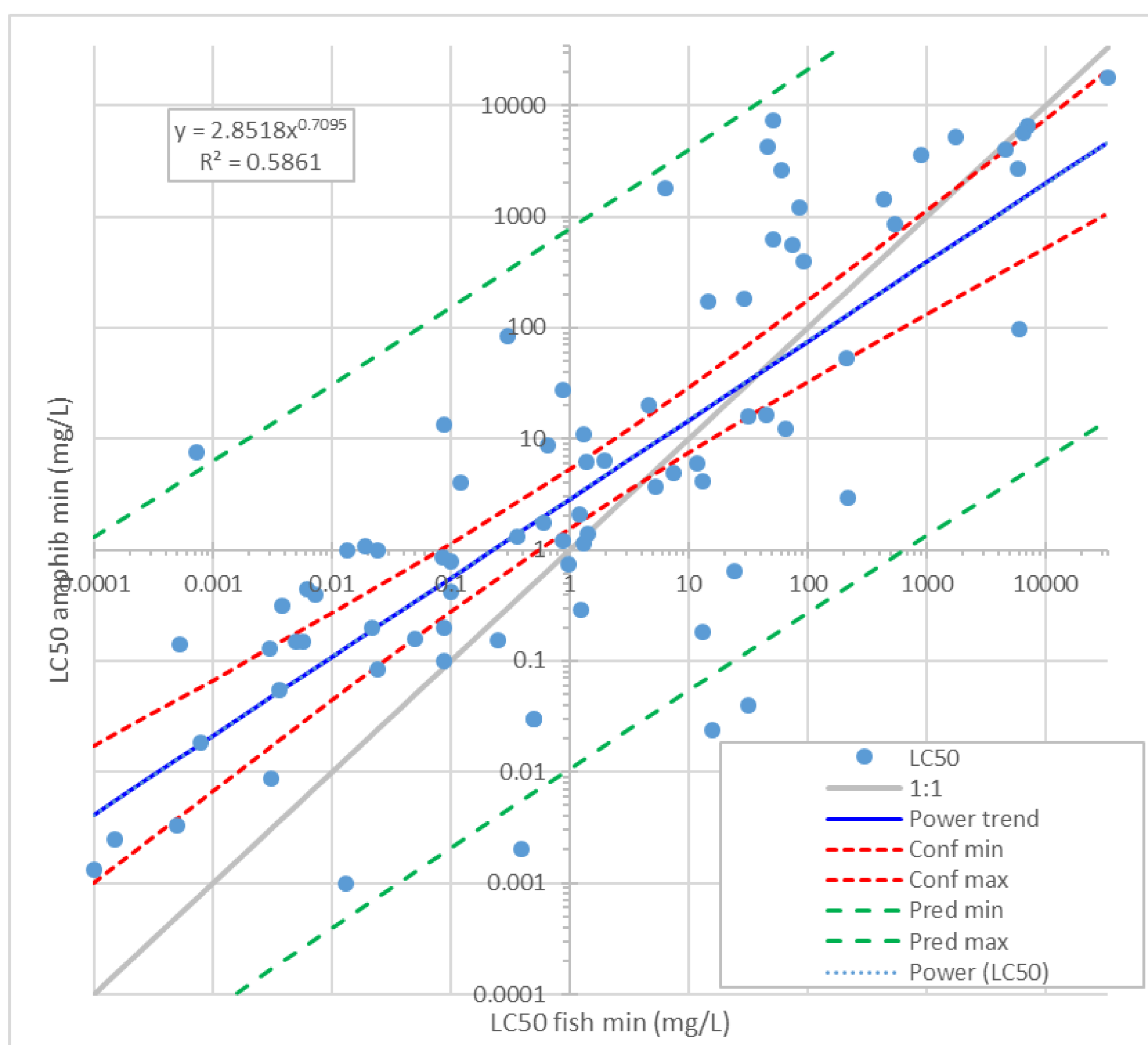
	Original	Reviewed
RQ Median	0.29	0.19
RQ 95%ile	75.3	3.9
RQ <0.33	54%	56%
RQ ≥0.33 and ≤3	27%	36%
RQ >3	19%	8%
RQ >10	14%	1% (Phenol)

Method: consolidate data

Based on the reference-ID included in the supplement, the sources of the amphibian datasets were retrieved, and endpoints listed there were compared with the entries appearing in Appendix K.

Next, potential matching fish endpoints were retrieved with the exact test material (formulation) that was used in the amphibia test: data from dossiers, DARs, RARs, SDS, which proved to be a reliable and easily accessible source for virtually all formulations, so that matching LC50 endpoints of fish could be included. If any data were generated later than 2012, even a specific cold-water fish, normally *O. mykiss* (rainbow trout) had to be tested, which is regarded to be a consistently sensitive species.

In case of multiple datasets, for now the lowermost value was included in the revised database, although an evaluation based on geometric means would also be possible. Furthermore, existing entries were checked, focussing on the unit, on potential misconceptions and other errors.



Original data: as listed in EFSA opinion paper, Appendix K

Revised data: Amphibia f. Appendix K & matching formulation fish endpoints

● RESULTS & CONCLUSIONS

Appendix K of the supporting publication [2] did not follow the principle of comparing like with like i.e. data from similar formulations, identical units, and it includes multiple mistakes. It is therefore not yet suitable as a basis for a decision about any additional AF to bridge between fish endpoints and amphibian endpoints; the former being used as surrogate for the latter in the RA. The database should be revised and expanded prior to any inclusion in a final guidance document on amphibians and reptiles. Based on the revised data with matching endpoints, acute fish toxicity is a good predictor for acute amphibian toxicity. Hence there is no need for extensive testing of aquatic amphibian stages. Any additional assessment factor to bridge between fish and amphibian acute endpoints may be small – or even entirely dispensable, same as in case of warm-water fish.



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[1] EFSA 2018 Scientific Opinion on the state of the science on pesticide risk assessment for amphibians and reptiles. EFSA Journal 16(2): 5125 doi: 10.2903/j.efsa.2018.5125

[2] EFSA Supporting Publication - Ortiz-Santaliestra ME, Maia JP, Egea-Serrano A, Brühl CA, Lopes I. 2017. Biological relevance of the magnitude of effects (considering mortality, sub-lethal and reproductive effects) observed in

studies with amphibians and reptiles in view of population level impacts on amphibians and reptiles. EFSA supporting publication 2017:EN-1251. 151 pp. doi:10.2903/sp.efsa.2017.EN-1251; therein Appendix K.

[3] Weltje et al. 2013-Comparative acute and chronic sensitivity of fish and amphibians- a critical review of data. Env Tox Chem 32(5) 984–994