



# Re-calibration of the earthworm tier 1 risk assessment of plant protection products – an update

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## Introduction

For plant protection products (PPP) in Europe the earthworm tier 1 risk assessment is conducted by dividing the chronic endpoints (NOEC or EC<sub>10</sub>) from laboratory effect studies of the sensitive indicator species *Eisenia fetida/andrei* with the predicted environmental concentration in soil (PECsoil). A potential risk to earthworms is indicated as soon as the resulting toxicity-exposure ratio (TER) is below the critical trigger value of 5 (Commission Regulation 546/2011, uniform principles). Within the current European risk assessment scheme the trigger value of 5 is considered conservative for extrapolating the risk from a tier 1 risk assessment to the risk under realistic field situations if PECsoil are calculated for a soil depth of 0-5 cm (Commission Regulation 546/2011, uniform principles). Due the recently published guidance on exposure estimation in soil (EFSA 2017) PECsoil values are expected to significantly increase. EFSA propose to calculate PECsoil over depths of

0-1 cm, 0-2.5 cm, 0-5 cm, and 0-20 cm. Christl et al. (2016) demonstrated with a representative dataset that the critical TER trigger of 5 combined with a PECsoil for 0-5 cm soil layer provides a sufficiently conservative tier 1 earthworm risk assessment. However, in the recently published EFSA Scientific Opinion (Ockleford et al., 2017) new Specific Protection Goals (SPG) for soil risk assessment are proposed, which includes shorter acceptable recovery times in higher tier studies (i.e. 6 months instead of 12 months). Following PRAPer 133 decision (EFSA, 2015) the earthworm tier 1 conservatism further increases due to logP correction of lab endpoints by factor of 2 even for laboratory studies with artificial soil containing 5% peat. The available data set in Christl et al. (2016) is evaluated with regard to these changings and proposals by EFSA.

## Materials and Methods

A dataset of 54 data pairs was compiled by ECPA member companies where an earthworm laboratory reproduction test and a field study with the same test substance were available allowing a direct comparison of the relevant endpoints. The dataset covered a range of substance of different indications (Insecticides (9 substances), Fungicides (11), & Herbicides (13)), modes of actions, environmental conditions, and substance properties (see Table 1). Laboratory endpoints were derived from earthworm reproduction tests conducted according to OECD 222, 2004 or ISO 11268-2, 1998 guidelines. In the presented figures a no-observed ecologically adverse effect rate (NOEAER) was defined as the effect level where no effects on earthworm populations > 30% were observed six months after application as proposed by EFSA (2017) as a SPG (maximum tolerable time until recovery). In most field studies the 6 months-NOEAER was the highest application rate tested and the real 6 months-NOEAER could potentially be higher.

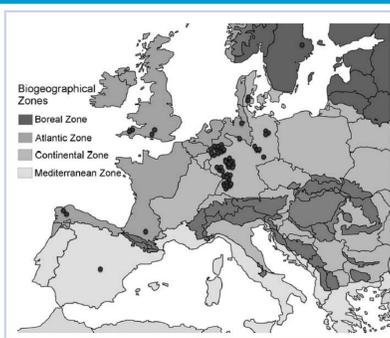


Figure 1: Distribution of the earthworm field studies in different biogeographical zones in Europe

Table 1: Information on substance and field site properties of the case studies considered in this dataset

	Substance properties		Field site properties			
	KOC [ml/g]	DT <sub>50</sub> [days]	C <sub>org</sub> content in soil [%]	Soil pH	Soil bulk density [g/ml]	Crops/land use (with number of field studies)
Mean	1954	93.0	3.78	6.01	1.26	Grassland 22
Median	486	50.6	1.79	6.28	1.33	bare soil 5
5%- percentile	52	4.2	0.93	4.89	1.03	cereals 10
95%-percentile	9782	295.7	5.43	7.51	1.45	maize 15
						Orchard 1
						Clover-Grass mix 1
						Total 54

The outcome of the tier 1 calibration was reevaluated with regard to the new procedure regarding logP correction of lab endpoints; i.e. correction by factor of 2 as well for cases where 5% peat in artificial soil is used in the lab test.

## Results

### Sprayed laboratory studies (Figure 2):

- The tier 1 regulatory acceptable rates (RAR) are consistently lower than the field 6-m-NOEAER (recovery after 6 months; Figure 2).
- The AF of 5 is conservative based on 21 comparisons
- All 6-m-NOEAER represent the highest application rates tested there were no LOEAERs in this subset of data, indicating that real toxicity might be lower

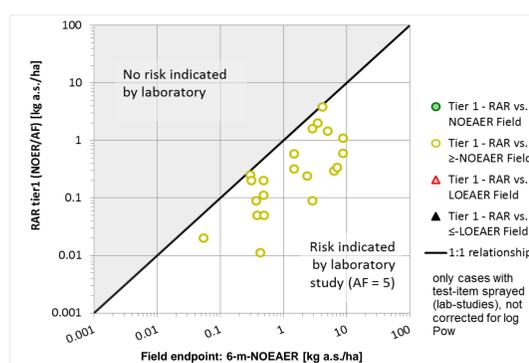


Figure 2: The tier 1 regulatory acceptable rates (tier 1 RAR=NOER from laboratory earthworm reproduction tests (only studies where substances were sprayed) divided by the tier 1 assessment factor (AF) of 5) is plotted with the no-observed ecologically adverse effect rates (NOEAER, recovery after 6 months) in the earthworm field studies (n=21). The diagonal bold line (1:1 relationship) represents the case where the tier 1 RAR corresponds to the field NOEAER. Laboratory NOER were corrected for high logP only if NOER were derived from studies using 10% peat in artificial soil.

### Mixed-in laboratory studies (Figure 3):

- The field 6-m-NOEAEC were higher than the tier 1 RAC in the majority of the cases, if a tier 1 AF of 5 and a regulatory relevant soil layer of 0-5 cm were considered
- In most of the cases a potential risk was indicated in the tier 1 risk assessment at a concentration where earthworms were not ecologically adversely impacted in the field 6 months after application.
- Six case studies showed a higher RAC compared to the field NOEAEC, in case logP correction is considered only for NOECs from lab studies with 10% peat. In five out of these six potentially critical case studies no ecologically adverse effects on earthworms were observed at the highest application rate in the field (≥6-m-NOEAEL). Only one out of the six potentially critical cases revealed a critical “real” 6-m-NOEAEC in the field study. At the corresponding field 6-m-LOEAEC of this study (at the same RAC level on the opposite side of the 1:1 relationship) the tier 1 risk assessment did however indicate a potential risk at the field 6-m-LOEAEC). Thus, even in this most critical case study the field study confirmed the prediction of this tier 1 risk assessment.
- Considering a logP correction as well for NOECs from studies with 5% peat reduces the tier 1 RAC for all these potentially critical cases by factor 2 providing a larger margin of safety.

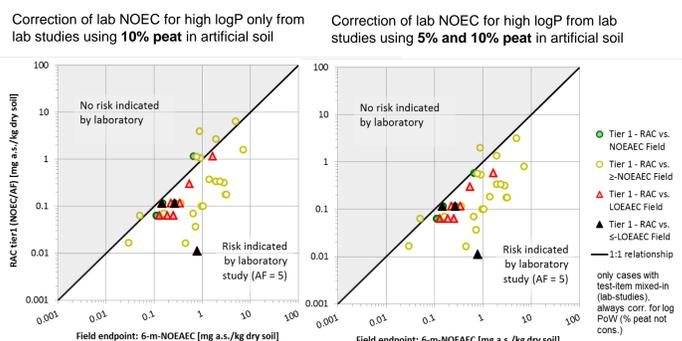


Figure 3: The tier 1 regulatory acceptable concentrations (tier 1 RAC=NOEC from laboratory earthworm reproduction tests (only studies where substances were mixed into soil) divided by the tier 1 assessment factor (AF) of 5) is plotted with the no-observed ecologically adverse effect concentrations (NOEAEC) in the earthworm field studies (n=33) considering a maximum recovery time of 6 months as proposed by Ockleford et al. (2017). Concentrations are based on total concentrations of the test substances in the field soil. The diagonal bold line (1:1 relationship) represents where the tier 1 RAC corresponds to the field endpoint. Field LOEAECs are plotted at the level of the corresponding RAC, so are always to the right of the matching NOEAEC. The ≥NOEAEC is defined as the concentration where no ecologically adverse effects were seen at the highest concentration tested and the ≤LOEAEC as the concentration where ecologically adverse effects were observed at the lowest concentration tested in the field study. Left: Correction of lab NOEC for high logP only from lab studies using 10% peat in artificial soil; Right: Correction of lab NOEC for high logP from lab studies using 5% and 10% peat in artificial soil

## Discussion

- The comparison of the NOER from laboratory studies where a PPP was sprayed with the 6-m-NOEAER from the field studies showed that an AF of 5 would be appropriate for the risk assessment.
- Comparing the NOEC obtained from the earthworm reproduction tests, where the test substances are mixed into soil, with the 6-m-NOEAEC obtained from field studies, demonstrates that the tier 1 risk assessment would be protective with an AF of 5 and a regulatory relevant soil layer of 0-5 cm used even if the maximum acceptable recovery time would be reduced from 12 to 6 months.
- Where adverse effects were identified in a field study after 6 months, a risk to earthworms had been indicated in the tier 1 risk assessment as well. Hence, there is no example where an actual risk would have been underestimated in the tier 1 risk assessment if calibrated to 0-5 cm soil depth and a trigger value of 5 for the laboratory NOEC.

## Conclusions

This evaluation demonstrates that the tier 1 earthworm risk assessment is appropriately conservative if a tier 1 assessment factor (AF, trigger value) of 5 on the laboratory NOEC and a regulatory relevant soil layer for PEC<sub>soil</sub> modeling of 0-5 cm are considered, even if the maximum acceptable recovery time in field studies would be reduced from 12 to 6 months. Including the logP correction factor as well for NOECs from lab studies using 5% peat would increase the margin of safety in the calibration, however, this is considered not necessary. This evaluation shows that correcting endpoints only for 10% peat studies already provides a conservative tier 1 risk assessment.

## References

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