

4/5 June 2019

Effects endpoints used to complete the risk characterisation

EFSA info session

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Trusted science for safe food

USED FIRST TIER INDICATOR SPECIES TESTS

- OECD 222 Earthworm reproduction test
 - Test substance mixing aimed to homogenously mix in standardised medium (artificial soil)
 - Analysis necessary including for metabolite levels if separate metabolite dosed tests not done
 - EC 10 EC 50 and NOEC determined
- Earthworm field studies can be used at higher tier
 - Test substance (and when needed to complete risk characterisation metabolites) analysis important in new studies
 - For 'legacy' studies where is only study g/ha exposure information, conservative risk characterisation possible following section 2.9 of PEC soil guidance



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USED FIRST TIER INDICATOR SPECIES TESTS

- OECD 232 Collembola reproduction test
 - Test substance mixing aimed to homogenously mix in standardised medium (artificial soil) or natural soil
 - Analysis necessary including for metabolite levels if separate metabolite dosed tests not done
 - EC 10 EC 50 and NOEC determined
- Option for soil model ecosystems at higher tier
 - Limited guidance / few examples



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USED FIRST TIER INDICATOR SPECIES TESTS

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- OECD 226 Predatory mite test
 - Test substance mixing aimed to homogenously mix in standardised medium (artificial soil)
 - Analysis necessary including for metabolite levels if separate metabolite dosed tests not done
 - EC 10 EC 50 and NOEC determined
 - Option for soil model ecosystems at higher tier
 - Limited guidance / few examples

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Concentration outputs to facilitate assessment of residues in following crops (to support human dietary exposure assessment)

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METRICS FOR USE REGARDING RESIDUES IN FOLLOWING CROPS

■ **Total soil PEC mixed over top 20cm**

- PERSAM (Tier 1&2) PEARL and PELMO (Tier 3A) provide this PEC
- 20cm is relevant as soil is cultivated and mixed over at least this depth before following crops are planted
- A 'fade away' PEC at different times after a simulated last application is provided by the tools
- Accommodates variable harvest intervals of the treated crop + variable plant back intervals of following crops

■ **PEC has use confirming OECD 502 and 504 rotational crop experiments had representative enough study designs**

- Can be used in context of proportionality scaling in following crop MRL assessments
- Can be used in assessing the risk management option of plant back intervals





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