

Stakeholder comments on EFSA draft GD on PECsoil

- Regulators -

(selected comments from UK, DE, DK)

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Introduction

Selected comments from regulators in UK, DK, DE:

- General considerations
- Practicality for regulatory work
- Technical aspects

General considerations

In comparison to the currently used approach for PECsoil calculation

- The new tiered approach is supported as more sophisticated and better scientific founded (DE)
- The new approach is more similar to PEC calculations in other environmental compartments (DE)
- More options are proposed for refinement in PEC calculation (DE)

General considerations

In comparison to the currently used approach for PECsoil calculation

- Evaluation is missing about the impact of the proposed methodology compared to the current approach (UK)
 - It is strongly recommended to perform an impact assessment (UK)
 - There is no explanation as to why the current methodology is insufficient to meet the protection goals
 - Implementing the new guidance may significantly increase the regulatory burden. The need to safeguard the competitiveness of Community agriculture should be considered prior to adopting this guidance (UK)
 - Has the proposed methodology been tested with any real data sets? (UK)

General considerations

In alignment with terrestrial risk assessment

- There is no evidence, that the modelling approach to calculate porewater contents and the approach to determine ecotox effects based on pore water concentrations sufficiently match together (DE)
- Has the proposed modelling approach to calculate the pore water content in soil be validated with experimental data? (DE)

General considerations

In alignment with terrestrial risk assessment

- The upper soil centimeter should be the relevant depth to calculate the realistic worst case PEC for soil organisms. This will define the true initial conditions soil organisms are exposed to in the field, since a.s. will always display the highest concentrations on the soil surface immediately after application (DE)
 - The average concentration over several decimeters of the soil profile (e.g. 20 cm for earthworms) does not allow to correctly assess the risk for soil organisms exposed to active substances
 - Active substance concentration is normally distributed as pronounced vertical stratification and not a ‘mean concentration’ in different depths
 - If the concentration in the upper soil profile is high enough to elicit effects, a relevant share of the soil organisms’ biocoenosis will be exposed to it – either because they live principally in the upper centimeters of the soil or because they move in the soil profile

General considerations

In alignment with terrestrial risk assessment

- As a refinement step (e.g. recovery, recolonisation of soil organisms after initial effects) numerical FOCUS models are considered suitable tools to identify different distribution pattern of active substances with diverging fate properties in the soil profile over relevant time frames (DE)
- The soil depth containing the largest proportion of active substance after a given time period should define per se the relevant soil depth to calculate the PEC (DE)

Practicality for regulatory work

Referring to the complexity of the new tiered procedure

- It could be suitable to see more examples calculated with the new methodology
- Trainee courses for PEC calculation and parameter selection could be helpful to avoid misunderstandings in future risk assessment
- There are still several open points how to apply the new approach, e.g. for cropping situations not covered by this guidance, e.g. for missing parameters for active substances and metabolites (formation fractions, “old” normalizations based on $Q_{10}=2.2$, ...)
- A proposed interim methodology for such situations should be included as part of the guidance document
- For efficiency reason, only PECs needed for the ecotox evaluation should be calculated and presented in the fate section

Technical aspects

which should be considered

- The implementation of wash-off factors may lead to inconsistency to PEC modeling for other compartments (groundwater, surface water) – this should be avoided (DE)
- Multiple application pattern with corresponding interception values and degradation between the application intervals should be implemented in PERSAM instead of cumulative application rates (DE)