Stakeholder comments on EFSA draft GD on PECsoil

- Consultancies and Academia -

Introduction

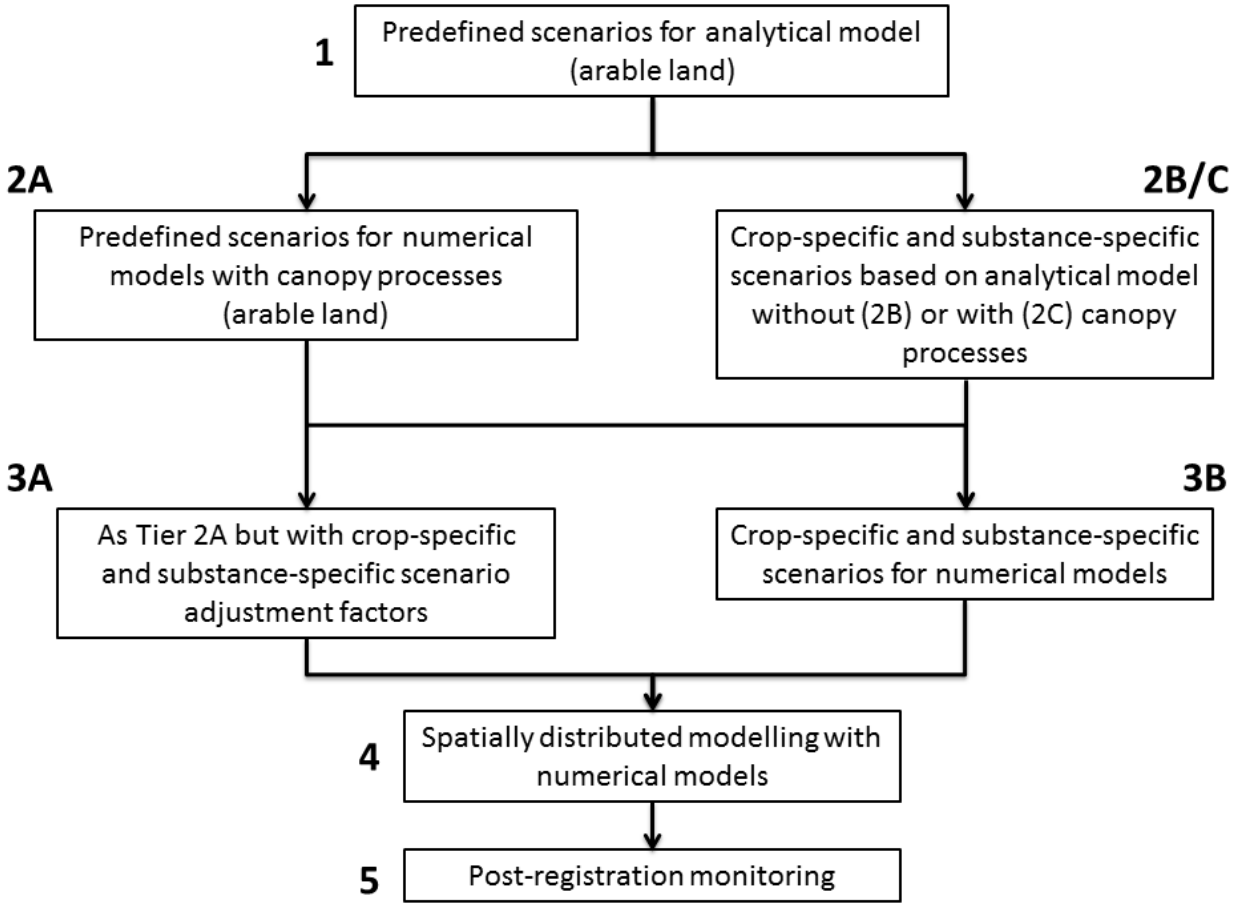
Selected comments from consultancies / academia:

- General considerations
- Tiered assessment scheme
- Pure PEC
- pH dependency of substance properties

General considerations

- **Guidance, simplifications, additonal work & development of PERSAM appreciated**
- **Complex procedure**
  - Time to understand differences between the various tiers and options
  - Time for undertaking and reporting exposure and risk assessment
- Need for a **shortened report** function (the results of a Tier 2B calculation with a parent and 2 metabolites resulted in a report around 40 pages long!).
- What is the **possibility of modifying the code of PERSAM**?
- There is no opportunity for selecting a **model other than PERSAM** at the lower tiers. A standard procedure for verification of alternative models would be helpful.

Tiered assessment scheme



Tiered assessment scheme

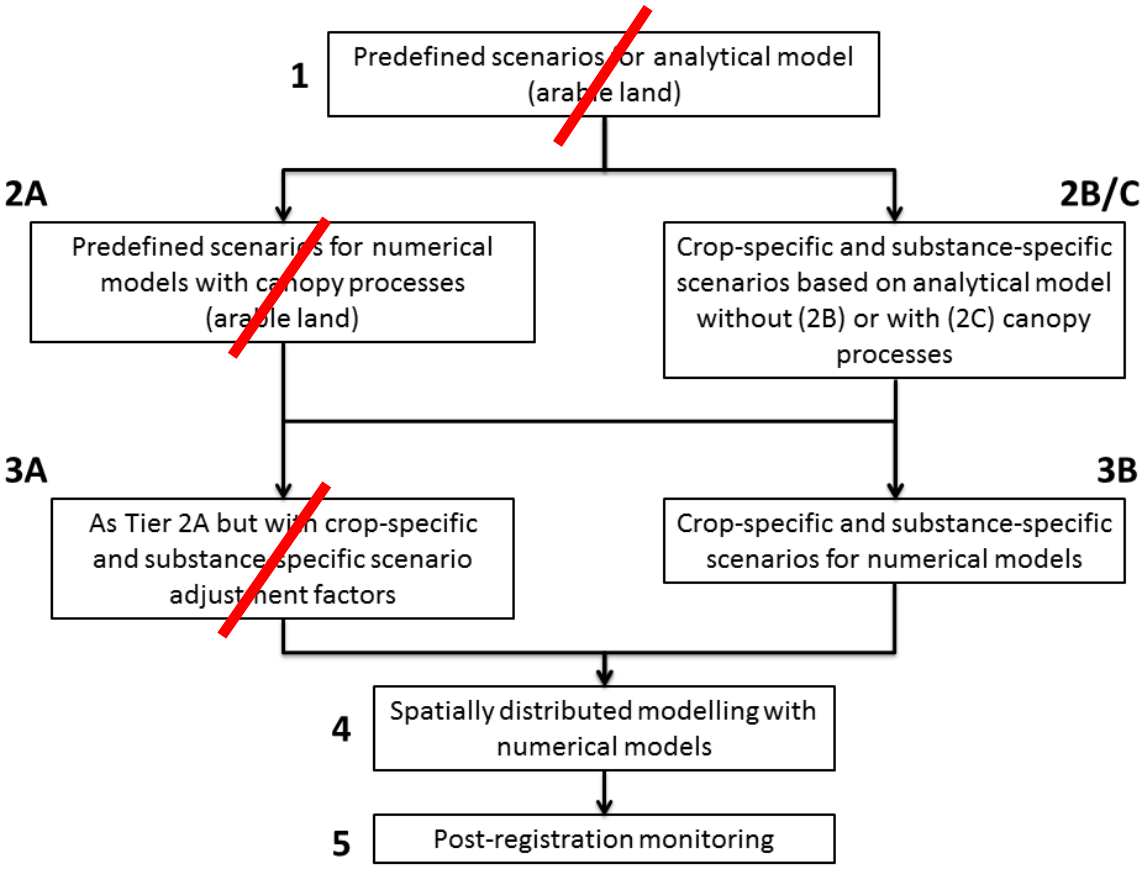
	1	2A	2B	2C	3A	3B
Analytical model	■		■	■		
Numerical model		■			■	■
Fixed scenarios	■	■			■	
Run all scenarios relevant for crop – generate frequency distribution and report 95th percentile PEC			■	■		
Crop and substance specific 95th percentile scenarios selected from 2B/C						■
Model adjustment factor	■		■	■		
Default scenario adjustment factor fs	■	■				
Crop and substance specific scenario adjustment factor = Tier 2B / (Tier 1 / fs)					■	
Canopy processes		■		■	■	■

Tiered assessment scheme

- The guidance allows to skip lower tiers and go straight to higher tiers – is the tiered system still working?
- Is Tier 1 suitable? When would you use it? Scenario and model adjustment factors to ensure Tier 1 is more conservative → level of protection re the 'pure' PEC is unknown.
- Is it possible to re-define Tier 1 completely choosing a different percentile of soil properties? (e.g. based on work in Appendix C, generate a more realistic Tier 1 with known level of protection)
- PEC Tier 2A always < Tier 1? PERSAM final review: similar results from both when PECsoil is < ~12 mg kg^{-1}.
- Is there unnecessary complexity in the tiered system? Inputs at Tier 2C are same as for Tier 2B. Why not include Tier 2C in Tier 2B?

Tiered assessment scheme

Suggestion to simplify by omitting Tiers 1, 2A and 3A



Tiered assessment scheme

	2B	2C	3B
Analytical model	■	■	
Numerical model			■

Fixed scenarios			
Run all scenarios relevant for crop – generate frequency distribution and report 95th percentile PEC	■	■	
Crop and substance specific 95th percentile scenarios selected from 2B/C			■

Model adjustment factor	■	■	
Default scenario adjustment factor fs			
Crop and substance specific scenario adjustment factor = Tier 2B / (Tier 1 / fs)			

Canopy processes		■	■

‘Pure’ PEC

Pure PEC = Actual PEC calculated with the analytical model (Tier 1, Tier 2B/C) without applying the adjustment factors

Comments:

- What is the reason behind discussing the 'pure' PEC?
- Is the 'pure' PEC of any use in a risk assessment?
- Could the 'pure' PEC be used as part of a justification for not using the adjustment factors?

pH dependency

- **The current recommendation by EFSA is to:**

  At Tier 1: Use worst case DT50 and Koc

  At tier 2A: Perform a conservativeness assessment

  At tier 2B/C: Use relationships between substance and soil properties

  At 3A and B: Use same inputs as at 2A

- **Comments:**

  Improve consistency between tiers and with groundwater and surface water assessment

  Conservatism should be within the soil scenarios and not the compound properties