Stakeholder comments on EFSA draft GD on PECsoil

- Industry -

Bernd Gottesbüren,

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The basis of the talk:

- ~100 general as well as detailed comments by ECPA companies (*being aware that the draft GD will likely be revised*)

- Selected key comments:

  -General considerations

  -Accumulation of adjustment factors

  -Proposal for simplified assessment scheme

  -Technical Aspects

  -Software tool issues

General considerations I.:

- **Lack of alignment with terrestrial risk assessment GD**
  - non-aligned timelines
  - missing protection goal
  - “double count” of safety factors Ecotox & PECsoil GD
- **Scientific credibility**
  - physically impossible soil concentrations due to multiplying PEC values with “adjustment factors” (2-6 x in lower tiers; see EFSA opinion 2012)
  - Update of spatial data sets → continuous update of scenario adj. factors
- **Premature, incomplete and complex GD**
  - permanent crop and no-till missing without interim recommendations;
  - incoherent assessment for products with diverse use pattern that require Tier 3B or higher calculations; → increased regulatory discussions !!
  - not „an easy to use GD“ (as given in the remit)

General considerations II.:

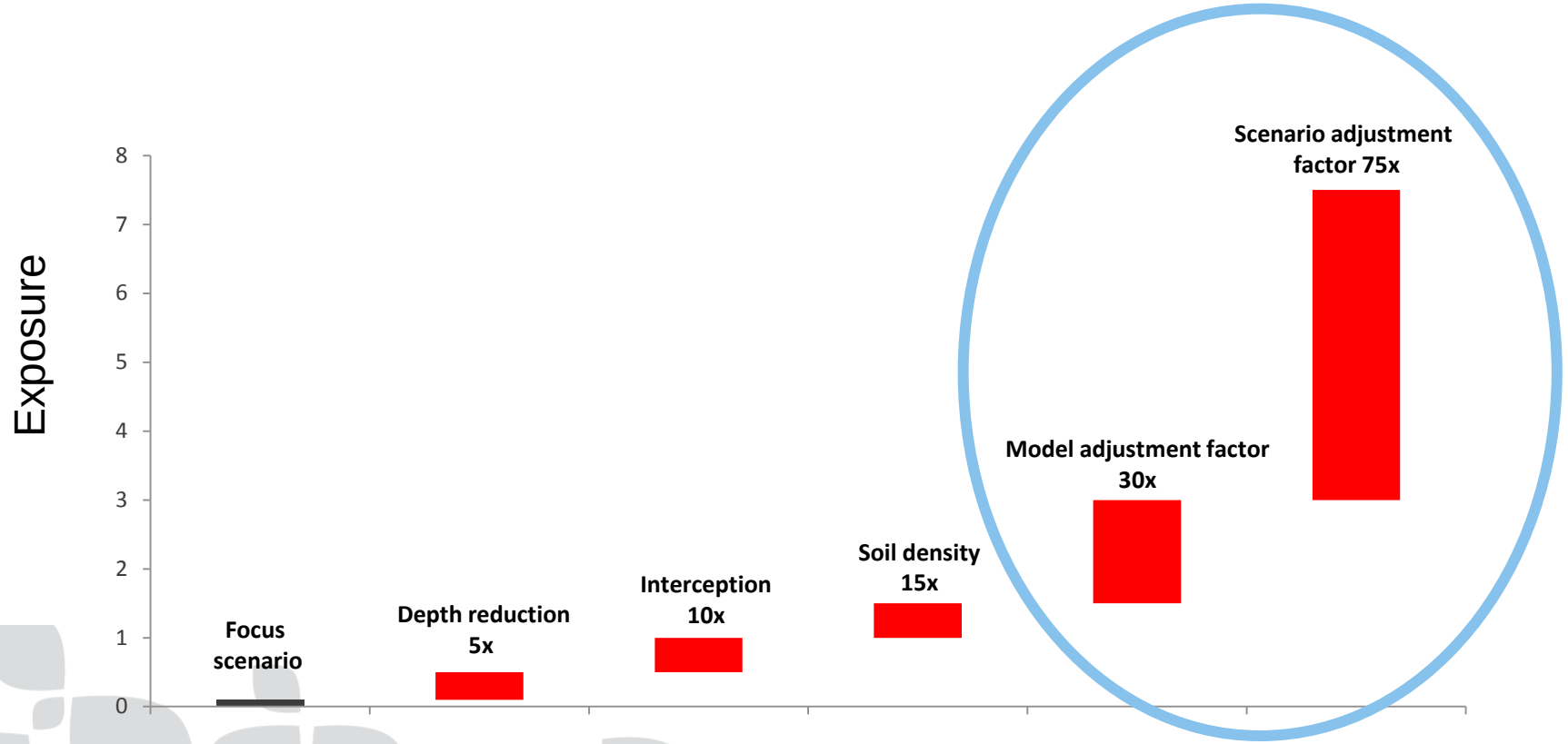
European Crop Protection

- **Impact assessment by ECPA**
  - Currently: 20 % cases require refined terrestrial risk assesment
  - In future: considering RAC in porewater 100 % cases fail at lower tier

- **Analytical model in the scheme leads to increased complexity**
  - does not simplify but complicates the assessment scheme
  - Introduces less useful steps for reporting (> 80 % ??) which inevitably will have to be used also for ecotox risk assessments without any added value

Accumulation of Adjustment Factors

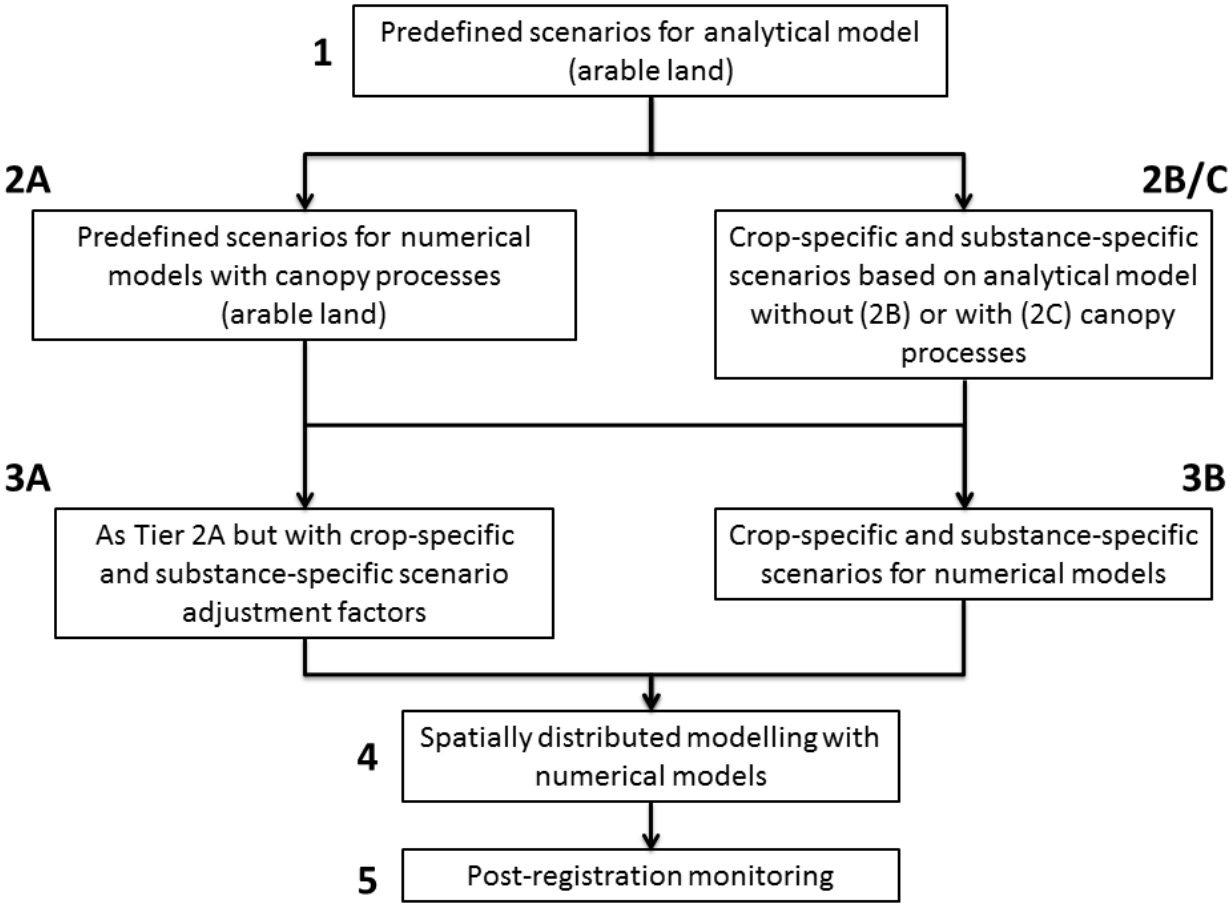
and additional elements of increased conservatism



+ Additional safety factor in ecotox guidance documents to cover uncertainties

Proposal for a refined assessment scheme to calculate soil exposure

- The 7 step scheme of the EFSA draft GD



Proposal for a refined assessment scheme to calculate soil exposure

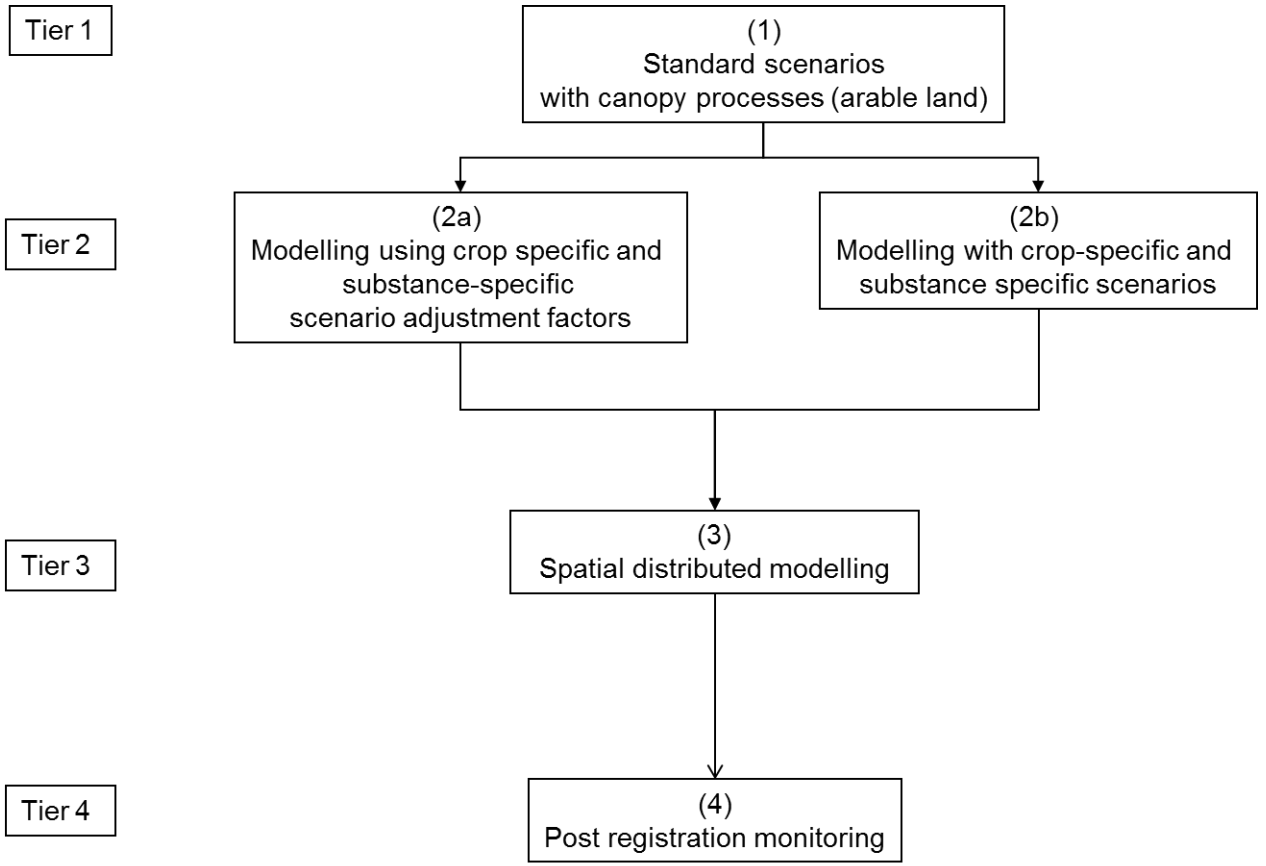
- **Drop the 2 steps of the analytical** model out of the scheme (reporting part)

- **Retain only the steps with the numerical model** (and the monitoring step)
  - "New" step 1 with standard scenarios and default scenario adjustment factor
  - In case soil specific behavior and/or only some specific crops are considered
    → Scenario identification/parameterisation outside the assessment report (FOCUSgw)

- **PERSAM may be used outside the modelling routines**
  like e.g. METAPEARL / GeoPearl or the INDEX approach for FOCUSgw to identify specific scenario adjustment factors.

- **Ideally the "new" tier 2 a is dropped at a later stage** of the guidance development, once more standardised approaches for parameterisation of tier scenarios are agreed upon. (*see presentation of S. Beulke*)

Proposal for a refined assessment scheme to calculate soil exposure



* Mitigation possible at all tiers

- numerical model in PEC reports;
- analytical model to define scenarios and adjustment factors

Software tool issues

- **PERSAM**
  - Use and storage of geographic data not transparent
  - Verification of the code is not transparent and partly missing
  - Calculations unnecessarily simplified: multiple applications not included
  - Bugs in the code identified
  - Lon runtime, unnecessarily long reports
  - No alternative
  - Version control and future development not assured
- **PEARL, PELMO**
  - Well established codes in regulatory context (version control exists)
  - Alternatives exist
  - Watch-out: avoid too many different distributions in parallel

Conclusions

- The draft GD is premature and is not yet fit for purpose
- The draft guidance is overly conservative
- The PERSAM tool does not fulfill needs for regulatory practice

→ Link to the terrestric risk assesment GD to be made

→ A simplified assessment scheme to be implemented

→ Assessment shall rely on well established numerical models