

# New tools for predicting environmental concentrations in soil in regulatory context – potential implications for the soil organism risk assessment of Plant Protection Products

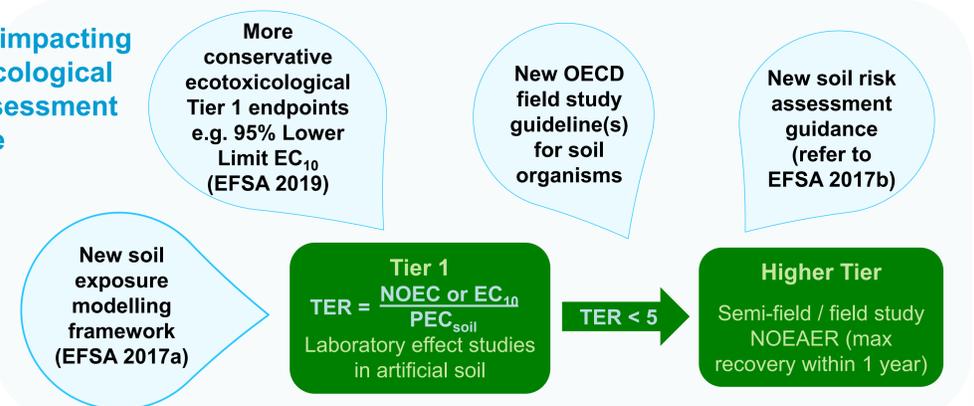
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## 1. Introduction

### 1.1 Background & Objective

- The EU risk assessment (RA) for soil organisms exposed to plant protection products (PPPs) is conducted as a two-tiered approach. At **Tier 1**, laboratory derived ecotoxicity endpoints are compared to predicted environmental concentrations in soil (PEC<sub>soil</sub>). If a potential risk is indicated, **higher tier** field studies are usually initiated to investigate whether effects on soil organism communities occur at relevant field application rates under natural field conditions.
- We present expected **impacts of the new soil modelling framework (EFSA, 2017) on the ecotoxicological Tier 1 RA for soil organisms**.
- We further discuss **other factors (see point 1.2) that will impact future soil RA, and the need for intermediate tier testing strategies** to address the additional uncertainty introduced by the new soil modelling framework.

### 1.2 Factors impacting the ecotoxicological soil risk assessment in the future



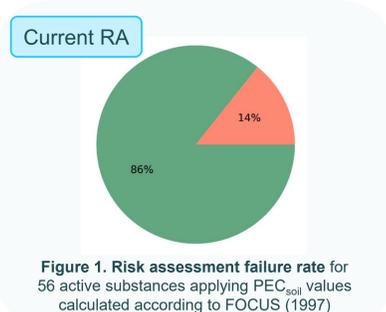
## 2. Materials and Methods

### 2.1 Modelling and risk assessment approach

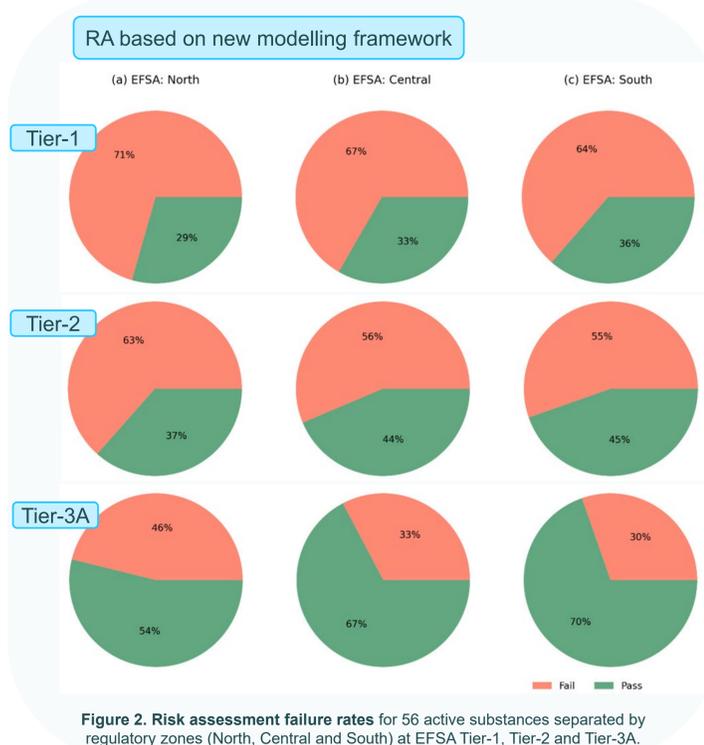
- EFSA Tier-1, Tier-2 and Tier-3A PEC<sub>soil</sub> values were calculated for 56 active substances and 65 metabolites for the three regulatory zones (North, Central and South), as outlined in more detail on the [poster by Multsch et al. \(session 3.08\)](#). PEC<sub>soil</sub> values based on current framework (FOCUS 1997) were calculated for comparison.
- For the ecotoxicological RA, each PEC value was divided by the regulatory acceptable concentration (RAC) for soil organisms (EU agreed Tier 1 NOEC or EC<sub>10</sub> values, divided by the trigger of 5) to calculate a failure rate (PEC/RAC ratio ≥ 1). For compounds with Log<sub>POW</sub> > 2, an endpoint correction factor of 2 was considered.

## 3. Results & Discussion

### 3.1 Failure rates per modelling Tier and regulatory Zone



- With PEC<sub>soil</sub> values based on the current framework (FOCUS 1997), **14% of the active substances** (Fig.1) and 8% of metabolites (not shown) fail in the soil RA.
- Using PEC<sub>soil</sub> values following the new framework of EFSA (2017a), the **failure rates for active substances are 67%, 58% and 36% using Tier-1, Tier-2 and Tier-3A PEC<sub>soil</sub> values, across all regulatory zones** (see Fig.2, per regulatory zone).
- With PEC<sub>soil</sub> values calculated according to EFSA (2017a), the failure rates for metabolites are 38%, 25% and 10% for Tier-1, Tier-2 and Tier-3A PEC<sub>soil</sub> values, across all regulatory zones (not shown).



### 3.2 Uncertainties resulting from new modelling

- Can the new Tier-1, Tier-2 and Tier-3A PEC<sub>soil</sub> values be compared to the current ecotoxicological Tier 1 endpoints?**
  - There is a huge mismatch between in soil scenarios used in exposure and effect assessment. Selection procedures of geographic locations for exposure assessment at Tier-3A result in **incompatible soil properties** (e.g., organic carbon content, bulk density) between e-fate and ecotoxicological data.
  - ⇒ This inconsistency hinders scientifically reasonable comparison, interpretation, and quantification of the risk. There is **no validated regulatory guidance** on how to use the new PEC<sub>soil</sub> values in a soil RA.
- Are the presented failure rates a worst-case assumption?**
  - In the current risk assessment NOEC or EC<sub>10</sub> (often regardless of biological relevance of results) are used, while EFSA (2019) even discusses the use the 95% Lower Limit EC<sub>10</sub> value if median EC<sub>10</sub> "offers scarce certainty on the actual level of protection".
  - ⇒ Applying over-conservative RACs would further increased failure rate.
- Can we address higher failure rates with increasing number of field studies to refine the soil RA?**
  - Unclear how e-fate soil properties will influence the discussion on representativeness of test field sites.
  - With the development of an OECD field study guideline for soil organisms, conclusions of available field data might be questioned.
  - ⇒ **Use of 'Inter-mediate Tier' testing help to filter substances with potential risks before the initiation of a full field study? --- Currently not accepted!**

## 4. Conclusions

The new EFSA soil exposure framework provides **tiered exposure** values. Further, much higher PEC<sub>soil</sub> values **significantly increase soil risk assessment failure rate**.

There is a huge mismatch between in soil scenarios used in exposure and effect assessment. Currently **no validated regulatory guidance** exists on how to use these exposure values in the RA for soil organisms.

Ecotoxicological **'Intermediate Tier' effect studies** or modelling approaches may be a potential option to overcome such discrepancies in the future but are currently not available / accepted.

A sufficiently long **transition period** will be required to ensure proper **alignment** between the new tiered modelling framework and a future tiered ecotoxicological RA for soil organisms.