New tools for predicting environmental concentrations in soil in regulatory context - an impact assessment

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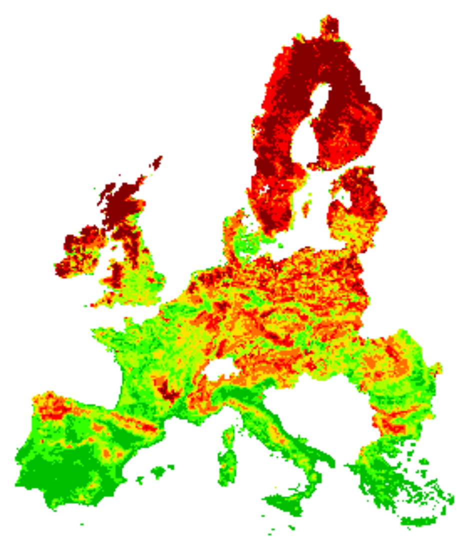
1. Introduction

In 2017, EFSA published a **new guidance in which a tiered approach with in total four different tiers in the exposure assessment of pesticides in soil** was introduced (EFSA, 2017). Tier-1 and Tier-2 procedures can be calculated with the new software tool PERSAM (VITO, 2019). Tier-2 results include the necessary inputs for subsequent Tier-3A calculations which can be performed with the FOCUS models PEARL and PELMO. Tier-4 addresses post-registration monitoring.

We present an **impact assessment of these future requirements** for calculations of predicted environmental concentrations in soil (PEC_{soil}) (Multsch & Guevara Montemayor, 2022) and the associated ecotoxicological risk assessment for soil organisms (RA).

EFSA Tier-1:
Plot scale (three sites)
Analytical model

EFSA Tier-2
Pan-European scale (1km grid)
Analytical model



EFSA Tier-3A
Plot scale (95[th] spatial percentile of Tier-2)
Numerical model (PELMO/PEARL)

2. Materials and Methods

2.1 PEC and risk assessment

- Tier-1 and Tier-2 PEC_{soil} (at 5cm soil depth) values were calculated using **PERSAM** (Persistence in Soil Analytical Model, v3.0.6).
- Tier-3A PEC_{soil} (at 5cm soil depth) calculations were conducted using **FOCUS PELMO** (v6.6.1soil).
- PEC_{soil} was divided by the regulatory acceptable concentration to calculate a **failure rate** (**PEC/RAC ratio ≥ 1**).

2.2 Compounds and GAPs

- **56 parent substances** (plus up to two metabolites) assigned to nine categories based on their K_{OC} and DT_{50} in soil covering a wide range of efate parameters (Tab 1).
- Typical GAPs for real-world application patterns for the associated products.
- **Spray applications** in annual crops (cabbage, maize, oilseed rape, potatoes, soybean, strawberries, sugar beets, tomatoes and winter cereals).
- **Air blast applications** on permanent crops grown in rows (apples, vines and olives)
- Majority of simulations for oilseed rape and cereals.

Tab 1. Compound categories (parent substances).

		DT_{50} [days]		
		0 - 50 N=33	51 - 100 N=12	> 100 N=11
K_{OC} [mL g^{-1}]	0 - 300 N=24	I N=16	II N=7	III N=1
	301 - 1000 N=11	IV N = 6	V N=2	VI N=3
	> 1000 N=21	VII N=11	VIII N=3	IX N=7

3. Exposure Assessment

- **New $PEC_{soil,EFSA}$ values are substantially higher at all Tiers** (Fig 1.): up to ×200 for Tier-1, ×80 for Tier-2 and ×34 for Tier-3 in comparison to the current assessment ($PEC_{soil,FOCUS}$; FOCUS, 1997).
- The main driver of higher PEC values is the **soil bulk density** besides other factors such as crop interception and wash-off.
- This is clearly shown via a geostatistical evaluation (Fig 2.): **Soil bulk density values in the scenarios are far below the median of European agricultural areas.**
- **Tier-3A geographic locations do not represent relevant conditions for intended uses** as selected by spatial 95[th] percentile at Tier-2 in particular for Northern scenarios.

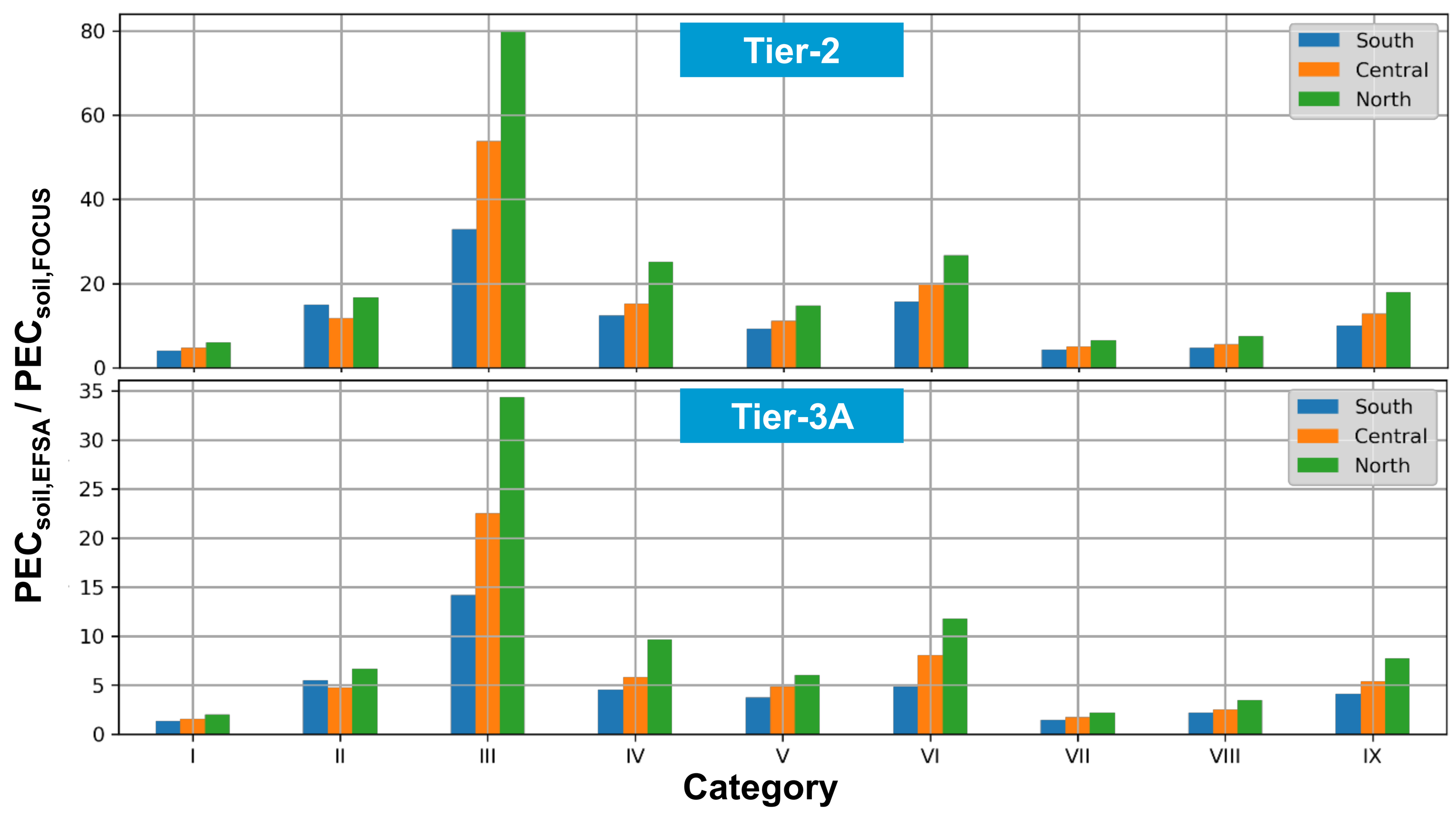


Fig 1. Median $PEC_{soil,EFSA}$ / $PEC_{soil,FOCUS}$ ratios of active substances separated by substance categories.

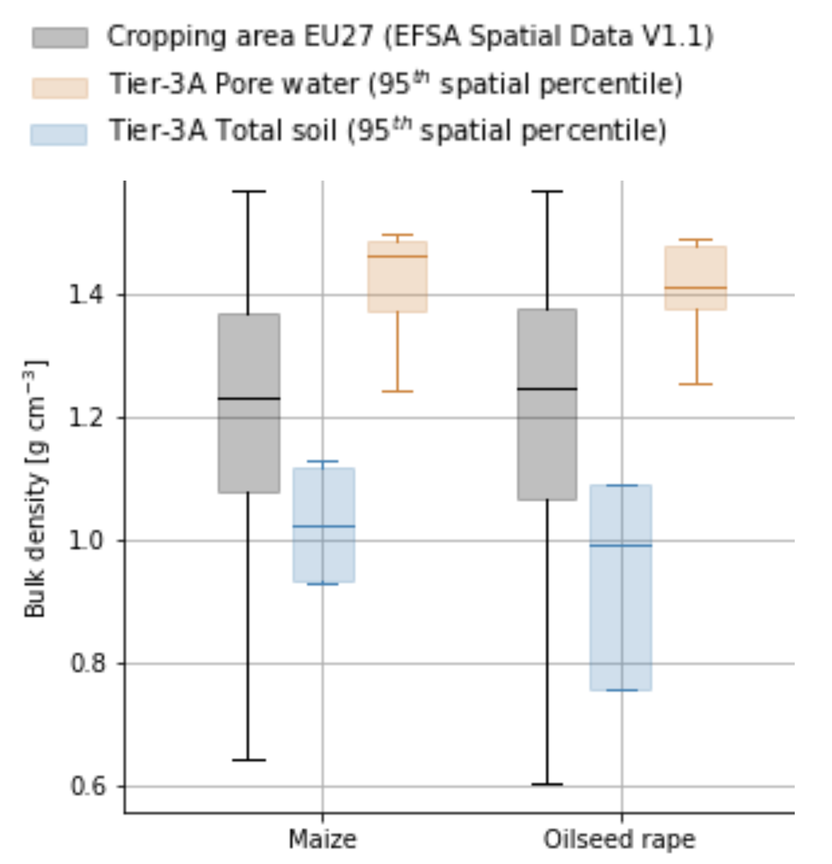


Fig 2. Variability of bulk density at Tier-3A in comparison to European cropping areas (EFSA Spatial Data v1.1).

4. Risk assessment

- Risk assessments show a substantial change in overall pass/fail ratios with **a significantly higher rate of failure** (Fig 3).
- In future **roughly five times more higher tier ecotox risk assessments will be triggered** than currently, including the need for field studies.

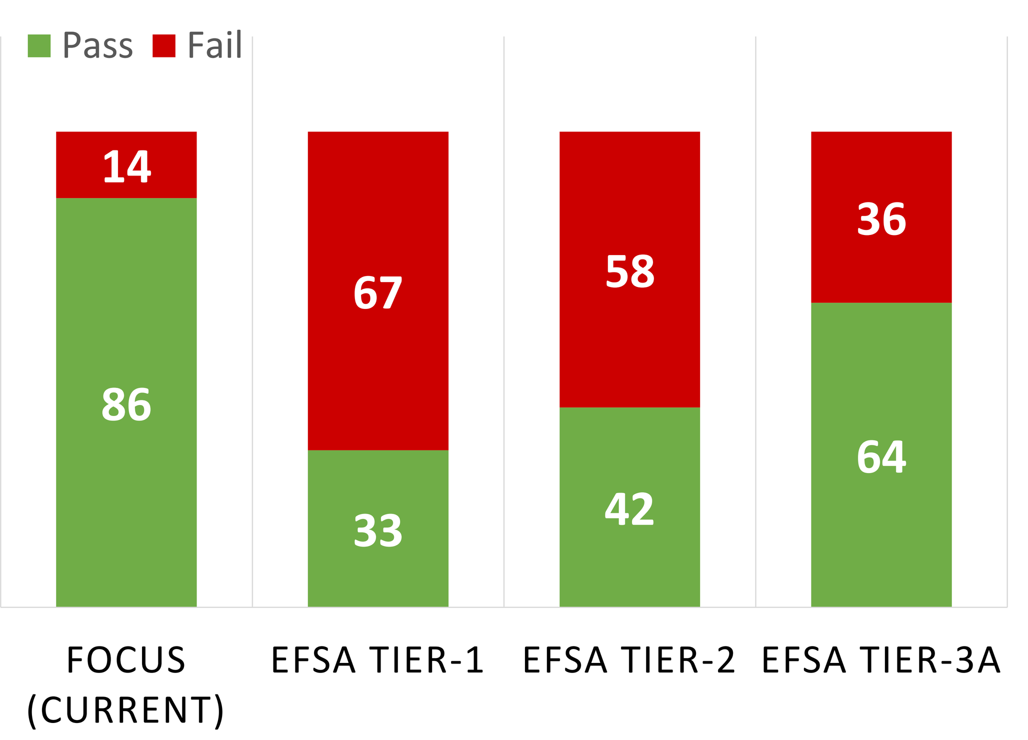


Fig 3. Comparison of pass/fail rates [%] (parent substances).

5. Conclusions

- The **workflow with the new models appeared to be inefficient** leading to increased workload for evaluators and applicants. Thus, some usability features are necessary before implementation, including reporting, a substance database and automation.
- **PEC_{soil} scenario selection procedures generally result in agronomically atypical (and frequently extreme) soil characteristics.** This widens inconsistency between exposure and effects assessments; experimental procedures and soil selection for derivation of ecotoxicological endpoints are then less aligned with exposure assessments. This increased inconsistency then extends uncertainty and hinders risk assessments. **This is particularly significant when considering higher tier study designs.**
- Please visit the **⇒ poster by Schimera et al. (session 4.10 – Soil Ecotoxicology & Biodiversity) ⇐** for a detailed discussion of potential implications for the soil organism risk assessment of Plant Protection Products.

References

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