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PERSAM PECsoil calculation and pesticides risk assessment: support or burden for regulators?

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Introduction

A new approach for the exposure assessment of soil organisms to Plant Protection Products (PPPs) has been developed in the new EFSA Guidance Document [A]. The recommended procedure consists of five tiers with different levels of complexity. Tier 1 is very conservative, while the higher Tiers even if closer to realistic conditions are quite complex and time-consuming, since the entire calculation process is quite slow and long-lasting. The new software tool PERSAM (Persistence in Soil Analytical Model) should be used to predict pesticide concentration in soil (PEC_{soil}) in lower tiers (Tier 1, Tier 2b and Tier 2c), which are very similar. The usefulness of three separate steps of evaluation within the same analitycal model is questionable. In addition, PERSAM does not consider the degradation of the active substance occurring between the applications. This fact can be considered an extreme worst-case approach, especially for the less persistent pesticides.

Objectives

This work addresses the use of PERSAM in the context of the standard evaluation procedure that regulators have to deal with in their registration activity of both active substance and PPPs. In particular, attention has been focused on how often a higher tier is required for risk assessment and how often Tier 1 allows to identify pesticides of acceptable risk for soil non-target organisms. A subset of PPPs authorized at National level has been considered. PEC_{soil} for the selected active substances have been calculated either with PERSAM or with the equations used in the last 20 years; PEC_{soil} has then been compared with the Regulatory Acceptable Concentration (RAC). The percentage of active substances showing an unacceptable risk for each Tier has been calculated, and comparison between the current assessment and the new one is presented together with some considerations on the efficacy, reliability and usefulness of all the PERSAM tiers. Since an EFSA opinion on which ecotoxicological averaging depth should be used for soil organisms risk assessment is not yet available, an assessment of the impact of the depth on PEC_{soil} calculation has been performed. The influence of degradation between the applications in PEC_{soil} results has also been evaluated.

Materials and methods

Data selection

- Dataset: 60 active substances have been selected. Substances with the highest number of toxicity data on soil arthropods and earthworms were selected from the PPDB database [B].
- Up to 5 GAP and labels of PPPs registered in Italy have been taken from the PESTIDOC web database [C] and evaluated to derive the worst-case application rates to be used in PEC_{soil} calculation. Application on perennial crops and incorporations above 20 cm have not been considered, since PERSAM software does not yet consider these uses.
- EFSA Conclusions and Draft Assessment Reports of the active substances have been examined to derive DT_{50} and Koc values to be used in PEC_{soil} calculation and ecotoxicological data to calculate RAC.

Calculations

PEC calculations:

- PEC_{soil} values have been calculated with PERSAM v. 1.0.2 (Tier 1, Tier 2b and Tier 2c) for the Southern zone following the recommendations of the EFSA Guidance [A].
- In case of multiple applications, a further calculation was performed with a modified approach which considers degradation between the applications.

$A_i = NA_i \times fs_i + Zp_i$

A_i: total actual application rate of app. no. *i* (g/ha)
NA_i: nominal application rate no. *i* in the sequence of applications (g/ha)
fs_i: fraction of application *i* reaching the soil (-)
Zp_i: residues remaining from previous applications considered for application no *i* (g/ha)

$Zp_i = A_{i-1} \times exp(-ln(2)/DT_{50} \times t_i)$

Zp_i: residues *i* remaining from previous applications *i-1* (g/ha)
A_{i-1}: total actual application rate of app. no. *i-1* (g/ha)
DT_{50}: half life of the substance at scenario temperature (d)
t_i: time since the last application for application no *i* (d)

PERSAM parameters:
zEco = Ecotoxicological averaging depth (1, 2.5, 5, 20 cm)
tAvg = Time period (0, 7, 14, 21, 28, 56 d)

- FOCUS PEC_{soil} values have been calculated with a Microsoft Excel spreadsheet using the Tier 1 assumptions of the current guidance [D].

RAC calculations:

- Regulatory Acceptable Concentrations for the active substances have been calculated dividing by 10 the acute toxicity endpoints (LC_{50}) and dividing by 5 the chronic toxicity endpoints ($NOEC/EC_{10}$).
- When a substance has a LogKow higher than 2, the NOEC and the LC_{50} values for both earthworms and soil arthropods were further divided by 2 (SANCO 10329/2002).

RAC/PEC ratio calculations:

- RAC values were divided by all the calculated PEC_{soil}. An acceptable risk is obtained when the ratio RAC/PEC is equal 1 or higher.

Data reporting

Database creation and use:

- A comprehensive database was created with Microsoft Excel. All data were recorded in this tool.
- The database was used to calculate the No of a.s. with at least one acceptable risk depending on the considered parameters (Tier, zEco, tAvg, ecotoxicological data).
- A separate database was developed for the calculation performed with the modified approach. Comparison between the two approaches was made considering just PPPs with multiple applications.

Results

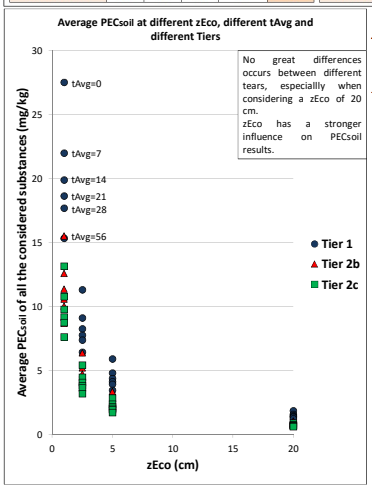
Percentage of active substances with an unacceptable risk

	PERSAM, Tavg=0, zEco=1			Current assessment	No of a.s. considered
	Tier 1	Tier 2b	Tier 2c		
Chronic r.a. soil arth.	79%	68%	68%	21%	19
Chronic r.a. earth.	98%	98%	98%	32%	60
Acute r.a. earth.	35%	20%	18%	0%	60

	PERSAM, Tavg=56, zEco=1			Current assessment	No of a.s. considered
	Tier 1	Tier 2b	Tier 2c		
Chronic r.a. soil arth.	68%	63%	63%	21%	19
Chronic r.a. earth.	87%	85%	83%	32%	60
Acute r.a. earth.	23%	13%	12%	0%	60

	PERSAM, Tavg=0, zEco=5			Current assessment	No of a.s. considered
	Tier 1	Tier 2b	Tier 2c		
Chronic r.a. soil arth.	58%	32%	32%	21%	19
Chronic r.a. earth.	88%	83%	82%	32%	60
Acute r.a. earth.	12%	7%	3%	0%	60

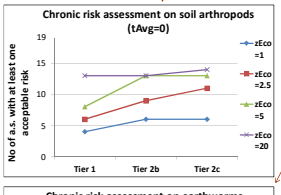
	PERSAM, Tavg=56, zEco=20			Current assessment	No of a.s. considered
	Tier 1	Tier 2b	Tier 2c		
Chronic r.a. soil arth.	32%	26%	26%	21%	19
Chronic r.a. earth.	40%	30%	28%	32%	60
Acute r.a. earth.	0%	0%	0%	0%	60

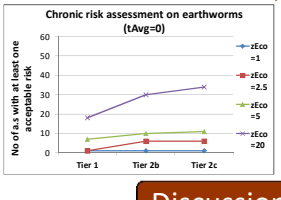


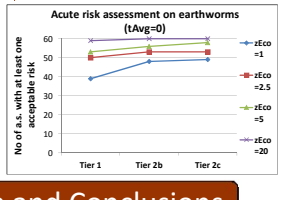
Tier efficacy and differences

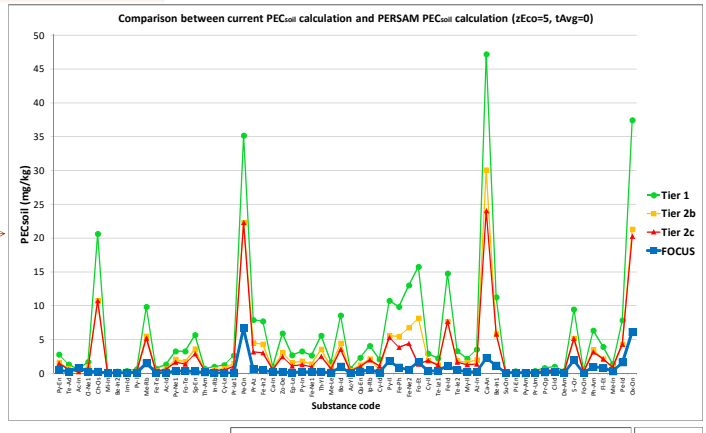
PERSAM calculations versus FOCUS calculations

Effect of the mixing depth on PEC_{soil} calculation









Evaluation of the modified approach

Percentage of active substances with an unacceptable risk

	PERSAM, Tavg=0, zEco=1						
	Tier 1		Tier 2b		Tier 2c		
Approach	Modified	Not modified	Modified	Not modified	Modified	Not modified	No of a.s. considered
Chronic r.a. soil arth.	70%	80%	60%	60%	60%	60%	10
Chronic r.a. earth.	97%	97%	94%	97%	94%	97%	36
Acute r.a. earth.	19%	31%	14%	17%	14%	14%	36

	PERSAM, Tavg=56, zEco=1						
	Tier 1		Tier 2b		Tier 2c		
Approach	Modified	Not modified	Modified	Not modified	Modified	Not modified	No of a.s. considered
Chronic r.a. soil arth.	60%	70%	60%	60%	60%	60%	10
Chronic r.a. earth.	86%	89%	81%	86%	81%	83%	36
Acute r.a. earth.	14%	19%	6%	11%	6%	8%	36

NOTE:
In order to mantain a uniform approach, chronic risk assessment was performed even when it was not mandatory according to the guidelines

Discussion and Conclusions

- Results obtained show no great differences between the **different Tiers**, especially between Tier 2b and Tier 2c. **MAJOR QUESTION**: is it worthwhile keeping all these three separate steps or would it be better to select just one of these, in order to have a less time-consuming but reliable risk assessment?
- PEC_{soil} calculated by **PERSAM** (with a zEco of up to 5 cm) are significantly higher than the ones calculated with the **FOCUS** approach. The No of products showing an unacceptable risk is higher too, especially for the chronic risk assessment for earthworms. **MAJOR QUESTION**: is such a worst-case approach justified by a real concern or, to keep a too severe conservative approach, unrealistic concentrations are taken into account?
- The choice of the **zEco** to be used for the risk assessment has a big impact on both the PEC_{soil} calculation and the results of the risk assessment. Selecting a zEco value of 1 cm leads to a disastrous situation for the chronic r.a. of earthworms (just 1 a.s. has an acceptable risk over 60 considered). PEC_{soil} calculated considering a zEco value of 20 cm are very similar to PECsoil calculated with the current approach. **MAJOR QUESTION** as above.
- The **modified approach** gave results quite identical to the original one. The influence of the adjustment factors included in the model is probably too strong to be offset by the proposed approach. **MAJOR QUESTION**: if quick degradation between application does not modify the final outcome of the risk assessment with respect to single total application, isn't the approach too conservative and unrealistic?

References

A – *EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil* (EFSA Journal 2015;13(4):4093).
B – Lewis, K.A., Tzilivakis, J., Warner, D. and Green, A. (2016). An international database for pesticide risk assessments and management. Human and Ecological Risk Assessment: An International Journal. http://dx.doi.org/10.1080/10807039.2015.1133242
C – PESTIDOC - http://www.icps.it/pestidoc/
D – FOCUS, 1997. Soil persistence models and EU registration. Report of the FOCUS modelling Workgroup. EC Document SANCO/9188/VI/97.