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CropLife Europe input for SCOPAFF meeting 8-9 December 2022

- IUCLID
- PPAMS
- EFSA PECsoil guidance document

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 8-9 December 2022, CropLife Europe would like to provide input on several issues:

General issues on regulatory processes – IUCLID (A.03)

CropLife would like to point that the recent release of IUCLID (October release) has left applicants facing severe technical issues hampering their ability to compile dossiers to meet legal deadline obligations. The overall continuous operability of IUCLID cannot be ensured, with datasets that cannot be opened and dossier creation failures. In addition, the updater necessary for migration to the new version was significantly delayed, in essence providing a release that existing data could not be migrated to.

CropLife Europe would welcome the next IUCLID update to focus on functionality, usability, scalability, and robustness improvements as a priority. We are also calling, and ready to provide support, for thorough testing of IUCLID updates prior to release when it comes to PPP Active Substance dossiers.

General issues on regulatory processes - PPPAMS (A.04)

We noticed a Commission presentation on PPPAMS and its successor system – the E Submission Food Chain platform (ESFC) was uploaded on Circabc the Commission on the 26th of September, linking it to a 20th of September meeting with Member States. For the moment the ESFC User Guide puts crop protection products out of scope, but it seems clear the Commission intends to revitalize PPPAMS ambitions, moving crop protection products to this system which is already in place for the (lighter) dossiers in other food-related sectors. Although we certainly agree and encourage the fact that the Commission is checking with Member States on their preferred options for this system, CropLife Europe **calls for a transparent and consultative process, including industry stakeholders, before making a decision.** The presentation clearly expresses the Commission's preferred option (*full implementation, meaning applications and authorisations*), yet **we would nevertheless urge the Commission to check the possible impact this could have on applicants, especially on SME's.** We think a reasonable transition time is necessary when the ESFC system is being introduced for crop protection products. This concern is all the more pertinent since it is stated that the PPPAMS current platform is already to be discontinued by the end of 2022.

EFSA guidance document for predicting environmental concentrations and transformation in soil (A.07)

Earlier this year, CropLife Europe shared its impact assessment of this proposed new exposure modelling framework¹. **Since the finalisation of this document (2017) new scientific and technical supporting data are available, especially more reliable EU wide spatial data set on organic matter contained in soils.** We believe these new elements need to be considered at technical level to produce a robust and up to date document for regulatory use. Please find in annex of this letter a one pager describing them and how their consideration can lead to an updated and more robust guidance document.

CropLife Europe offers to provide a transparent impact and feasibility analysis of the new soil organic matter map with better data to revisit the soil scenarios in the document and derive new ones.

Yours sincerely



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cc. Almut Bitterhof
Karin Nienstedt
Manuela Tiramani

This letter will be published on the CropLife Europe website and will be available at:
<https://croplifeeurope.eu/resources-library/>

¹ CropLife Letter to the Commission and Standing Committee members dated 25 March 2022

Annex - CropLife Europe position on the proposed new EFSA soil exposure modelling framework and the underlying spatial data

In a previous impact assessment by CropLife Europe (POS/22/LO/35109), predicted environmental concentrations in soil (PECsoil) were calculated using the current approach (FOCUS 1997) and the new approach proposed by EFSA to evaluate 56 active ingredients and metabolites.

- The failure rate of the lower tier risk assessment for soil organism increased from 10% (current FOCUS approach) to 67%, 58% and 36% at Tier-1, Tier-2 and Tier-3A (EFSA) respectively. The higher failure rates originate from higher PECsoil values arising in the new scheme driven primarily **by atypical pedoclimatic scenarios, representing agronomically unrealistic soil conditions - particularly with respect to organic carbon/matter content and bulk density.**
- Bulk density, which has a particularly large impact** on PECsoil was derived using the organic carbon content (OC) information in the ESDB (European Soil Data Base Version 2.0; published in 2006) to generate a European scale OM and BD map (EFSA spatial data, 2012). At the time EFSA concluded that it was best to use the current EFSA OM map until a better alternative is available (EFSA 2017), recognising that a distinction between arable land and grassland soils should be made in future, which is not addressed in the 2012 dataset.
- Meanwhile a more reliable EU wide spatial data set on organic matter is available (SoilGrids Organic Matter map) that could provide an alternative basis for assessment. De Sousa et al. (2022) demonstrated that the OM content in soils with arable land use is over-estimated in the EFSA dataset,** especially for Northern Europe and, consequently, this underestimates scenario bulk density and overestimates PECsoil. Soil OM content depends also on land use which was neglected in the EFSA OM map from 2012 but is considered by De Sousa et al. (2022) resulting in a more reliable organic matter dataset.
- The OM content of the EFSA and the SoilGrids data set for the crops wheat and potatoes are shown below. Most important are the 95th spatial percentiles on which the soil scenarios are based. **The biggest differences can be seen in the Northern Zone and also the Central Zone.**

Zone	Name	Crop	Spatial weighted percentile [%] (values > 5% marked red)				
			q5	q25	q50	q75	q95
North	EFSA ¹	Wheat	2.4	4.5	9.3	10.8	29.3
		Potatoes	4.0	7.7	10.8	19.4	90.5
	SoilGrids ²	Wheat	2.5	3.2	4.0	5.1	7.1
		Potatoes	2.7	3.4	4.3	5.6	9.2
Central	EFSA ¹	Wheat	1.8	3.0	5.2	8.2	14.2
		Potatoes	1.9	3.4	6.5	9.9	20.8
	SoilGrids ²	Wheat	1.7	2.1	2.5	3.0	4.8
		Potatoes	1.7	2.1	2.4	2.9	4.5
South	EFSA ¹	Wheat	1.1	1.7	2.5	4.6	7.6
		Potatoes	1.1	1.7	2.6	4.8	8.1
	SoilGrids ²	Wheat	1.3	1.9	2.3	2.9	4.4
		Potatoes	1.7	2.1	2.4	2.9	5.1

¹ Hiederer, R. (2012): *EFSA Spatial Data Version 1.1 Data Properties and Processing*. Publications Office of the European Union EUR 25546, ISBN 978-92-79-27004-8, doi:10.2788/54453.

² De Sousa et al. (2022): *A soil organic matter map for arable land in the EU*. Report No. 3126. Wageningen Environmental Research. ISSN 1566-7197. CC BY 4.0 license (<https://creativecommons.org/licenses/by/4.0/>). Data version 0.2 (19-February-2019)

- Furthermore, it is currently not possible to test the effect of the new soil organic matter map on PECsoil using the PERSAM model. The essential conversion framework to integrate spatial soil datasets into a format employed by the **PERSAM software is not publicly available**. This is considered as a clear breach of the transparency regulation and EFSA rules on good modelling practice (EFSA, 2014).

Recommendations

- In recognition of the current availability of an improved soil OM map that directly addresses deficiencies in the current framework employed it is now recommended that EFSA update the software package considering the new and realistic spatial data, which would, in turn, provide more realistic and reliable PECsoil estimates.
- Further, to support implementation CLE now offers to conduct an impact and feasibility analysis based upon the new soil OM map to assist in the revision of soil scenarios to ensure a greater degree of reliability. To support these efforts CLE offers the possibility to undertake these efforts via a joint project to revisit the derivation of soil scenarios taking into account this improved dataset.