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CropLife Europe letter on geodata used in the EFSA PERSAM tool to predict environmental concentration of plant protection product residues in soil

Dear Dr. de Seze,

We are reinitiating our contact with you regarding the EFSA PERSAM software tool for predicting environmental concentrations of plant protection products (PPPs) in soil.

Following your advice (in a letter dated 07/06/2023) we have engaged in correspondence with JRC regarding various technical aspects of the spatial geodata layers underlying the PERSAM software. The intention of this correspondence with JRC was to obtain a reproducible set of steps to enable the generation of the same data layers utilized in the EFSA Spatial Dataset v1.1 [1]. Starting from the same set of inputs referenced in the technical documentation [2,3] any user should be able to follow these defined steps and arrive at the same output. Without this defined, robust and reproducible GIS data handling description, the resulting geodata layers which underly PERSAM [4], are not sufficiently transparent for regulatory purposes.

A clear procedure allowing the replication of data layers within the EFSA Spatial Dataset [1] is in accordance with the commitment of EU institutions to guarantee and promote findable, accessible, interoperable and reusable (FAIR) data within their portals. Furthermore, input data used in a methodology, like papers and publications, need to be fully referenced and in the public domain to allow open and unequivocal access to all users.

As stated in the user manual [5] and confirmed in your letter dated 17/02/2023, the intention of EFSA is to allow PERSAM end-users to utilize updated and detailed land use maps within PERSAM. For this reason, every thematic layer used in a PERSAM assessment needs to be generated consistently with the other layers already in the dataset, using the same set of steps which can be reproduced by everyone (the public, NGOs, EFSA, Member State competent authorities, industry).

The response from JRC, dated 09/10/2023, agreed that the steps to reproduce the GIS data layers should be published and that without this the geodata layers are not sufficiently transparent for regulatory purposes:

"We do agree with your statement "Starting from the same set of inputs referenced in the technical documentation any user should be able to follow these defined steps and arrive at the same output. Without this defined, robust and reproducible GIS data handling description, the resulting geodata layers which underly PERSAM are not sufficiently transparent for regulatory purposes.""

The response went on to detail that:

"The data that come with PERSAM were produced in a collaborative effort between EFSA and JRC. One person at JRC committed himself to produce the necessary data layers along with documentation. At the time of release, these data were accepted by all involved parties. The person at JRC retired and was not replaced. [...] Although we

CropLife Europe aisbl | 9 Rue Guimard | 1040 Brussels | Belgium | BE 0447 618 871 Register of Legal Persons Francophone Section of the Business Court of Brussels | croplifeeurope@croplifeeurope.eu | www.croplifeeurope.au Tel: +32 2 663 15 50 | Fax: +32 2 663 15 60 fully agree with your statement above, at this moment we don't have the resources (and specific expertise) to dive deeper into your specific questions and look for answers."

In summary, JRC is currently not able to advise how the spatial geodata layers were created. End users are, therefore, unable to appropriately analyze them, nor create updated crop maps in a fully compatible manner, thus creating a lack of transparency in the proposed soil risk assessment.

JRC appear to agree and make some recommendations regarding how to resolve this unsatisfactory situation:

"Ideally, the current data layers should be scrutinized by a board of experts (including experts from your organization) and though a strict and well-documented methodology (as you propose) be updated. These updated data should then be presented to EFSA for inclusion in PERSAM.

An alternative: The data should be redeveloped in collaboration and agreement with EFSA and some other players suggested by EFSA. In practice, this means a new project funded by EFSA which can dedicate resources towards the re-engineering of the processes/data that you mentioned.

EUSO/ESDAC remains available for independent and 'official' hosting of such data."

Separately, CropLife Europe (CLE) has engaged in communication with competent authorities in fourteen selected Member States to advise them of the statements from JRC regarding the unsuitability of the current geodata layers in PERSAM. In this correspondence a country-bycountry impact analysis was also presented, demonstrating the significant impact of the selected organic matter map used in PERSAM when compared with a more up-to-date soil organic matter map for their country. We would be happy to provide these impact assessments to EFSA should you request them.

CLE agrees with JRC that the data layers underlying PERSAM "are not sufficiently transparent for regulatory purposes" and should be scrutinized by a board of experts (including those from industry). We would ask EFSA to consider resolving this situation in partnership with JRC and CLE by collaborating to publish a clear set of steps by which the PERSAM GIS data layers can be precisely reproduced from the source data.

Ultimately, it is envisaged that the use of GIS data in risk assessments will increase and will be updated/superseded more frequently. Thus, it is in the interests of regulatory authorities, industry and the public that the use and processing of this data is well coordinated and transparent via a peer review or version control process as suggested by JRC. CLE is willing to engage co-operatively to achieve this and will support any EFSA initiatives in this direction, to ensure the incoming soil risk assessment in the EU is fit for purpose.

Yours sincerely,

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cc. Manuela Tiramani (EFSA) Mark Egsmose (EFSA) Karin Nienstedt (DG SANTE)

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

References:

 Official "EFSA spatial datasets v1.1", made available with PERSAM code at https://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool
Roland Hiederer, 2012. EFSA Spatial Data Version 1.1 Data Properties and Processing. JRC Technical Reports. Report EUR 25546 EN

[3] Ciro Gardi, Panos Panagos, Roland Hiederer, Luca Montanarella, Fabio Micale, 2011. Report on the activities realized within the Service Level Agreement between JRC and EFSA as a support of the FATE and ECOREGION Working Groups of EFSA PPR (SLA/EFSA-JRC/2008/01). JRC Technical Reports. Report EUR 24744EN

[4] EFSA, 2017. 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 2017;15(10):4982, 115 pp. <u>https://doi.org/10.2903/j.efsa.2017.4982</u>

[5] Lieve Decorte, Ingeborg Joris, Stijn Van Looy, Jan Bronders, 2022. User manual PERSAM 3.0.8 -Update of PERSAM software models for predicting environmental concentrations in soil in permanent crops and annual crops. Doi:10.2903/sp.efsa.2019.EN-1756