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CropLife Europe input for SCOPAFF meeting 22-23 March 2023

- **Renewal process under 2020/1740**
- **EFSA Guidance on the use of the benchmark dose approach in risk assessment**
- **EFSA Guidance Risk assessment for Birds and Mammals**
- **EFSA soil exposure modelling framework and the underlying spatial data**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 22-23 March 2023, CropLife Europe would like to provide input on several issues:

A.03 – Point 2 - Renewal process under 2020/1740

The point was already listed in the January SCoPAFF agenda and considering the minutes of this meeting are not available yet, we would invite the Commission to provide clarification to applicants especially regarding access to old studies, as well as when could a consultation of stakeholders take place.

A.07 – Point 7 - EFSA Guidance on the use of the benchmark dose approach in risk assessment

CropLife Europe agrees on the value of benchmark dose (BMD) level analysis. However, this approach is complex involving a need to understand Bayesian statistical methods to conduct or review analyses. The associated tools should not simply be used as a black box. Also, the BMD approach is also vulnerable to significant subjectivity differences between different experts. **Therefore, we believe several points need further development before the approach is introduced into the EU evaluation framework**, for example there are still significant problems with the tool which need to be fixed.

In addition, the view of the group of academics who have developed the guidance and its corresponding tool is clear that not all datasets are suitable for or benefit from BMD analysis. **We then see a risk in its premature use for endpoint derivation – as illustrated by the recent inclusion in the revised EFSA Birds and Mammals guidance document.**

Current OECD guideline studies are not designed to support BMD analysis, therefore there is a very real and frequent risk for standard data sets of generating very low limits of confidence. This in turn will distort the real endpoints by orders of magnitude from the true values and result in adding substantial invisible and inappropriately high conservativeness to the risk assessment which will lead to potential increased vertebrate testing and animal welfare concerns. Conducting BMD analysis on unsuitable datasets from OECD guideline studies would result in assessors requiring expert knowledge and a deep dive into the data to distinguish what the scientifically true endpoint

value and appropriate safety factor is and would complicate the decision making and communication process for most risk managers and of course the public.

CropLife Europe calls for an open and transparent discussion between EFSA, Commission, Member States, and Industry experts on how BMD-modelling could be introduced in the EU pesticide regulatory framework in a meaningful way.

A.07 – Point 8 - EFSA Guidance Risk assessment for Birds and Mammals

CropLife Europe supports a high level of protection for birds and mammals. However, we do not understand the unrealistic increase of complexity and conservativeness in this new version of the guidance document. This is not justified or supported by a demonstrated lack of protection for birds and mammals resulting from current evaluations, related protection levels agreed by risk managers, nor by any available monitoring data on wild bird or mammal poisoning incidents.

This new version dramatically increases the complexity and number of assessment scenarios. It has not only consequences on the pass and fail rate of the risk assessment for currently registered pesticides and biopesticides, but moreover on the workload for regulatory authority risk assessors and risk managers in the evaluation process. **In its current state the document will lead to a lack of timely available resources needed for applicants and Contract Research Organisations (CROs) to conduct the required studies and assessments, and for the evaluating authorities (particularly from smaller member states) to navigate their way through the uncertainty, complexity and newly raised procedural concerns. This will result in a clear impact on delivery of both registrant submissions and authority evaluations of dossiers, ultimately reducing innovation and delivery of new solutions to European farmers.**

The benchmark dose (BMD) level analysis based on Bayesian statistical methods needs an open and transparent discussion between stakeholders before its final implementation in the EFSA Birds and Mammals guidance document.

The increased failure rate in lower tiers means more substances will require higher tier options. However, when it comes to field studies the document fails to provide meaningful guidance on how to conduct them in practice, the expectations remain controversial, and how to evaluate them for use in the risk assessment. A sufficient minimum time of 30 months is needed before the new expectations for field studies can be met. The calculator provided with the document, while helpful in certain situations, still needs many improvements to facilitate evaluation processes. CropLife Europe is ready to support the software development effort as it was developed without sufficiently considering assessors' and applicants' practical needs. Its transparency should also be increased with the release of its source code as well as a traceability of updates to any version in the future.

Considering the above points, CropLife Europe recommends to the Commission and Member States to launch a concerted technical review by end users and develop an implementation roadmap for this document focused on:

- **BMD analysis implementation,**
- **Clarification on how to perform higher tier studies that meet new expectations and provides sufficient time (minimum 30 months) to generate them,**
- **Calculator full transparency and fit for purpose.**

We remain prepared to contribute transparently to such exercise including by providing specific data.

A.07 – Point 9 - EFSA soil exposure modelling framework and the underlying spatial data

We would like to raise an issue with the PERSAM modelling software. It is used to calculate predicted environmental concentrations in soil at Tier-1 and Tier-2 integrates European scale environmental and agronomic data from the so-called "EFSA spatial datasets v1.1"[1]. If a spatial

[1] https://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool

map is not available for a specific crop, such crop specific land use scenarios can be provided by the user as stated in the soil exposure guidance document (EFSA Journal 2017;15(10):4982):

"When a crop is not specified in Tables 6 and 7, the notifier should use the crop in PERSAM with the highest scenario adjustment factor (see Tables C.1–C.4 for their values) unless it can be justified that the crop under consideration should be assigned a different crop. Only if a well-documented crop map is available, it is acceptable to use Tier-2 or Tier-3A to calculate the 95th spatial percentile of the PEC using this crop map. 'Well documented' implies that the methodology for deriving this crop map should be described preferably by referring to a scientific background report and/or paper. The methodology should be reproducible and be based on generally accepted procedures. Further considerations on data quality are given in EFSA's scientific Opinion on Good Modelling Practice (EFSA PPR Panel, 2014)."

However, the implementation of the land use and crop maps in PERSAM is unclear and cannot be reproduced based on the technical implementation. This includes scaling of input resolution, masking of crop cover and classification of land use pixels. Further significant inconsistency between different crop types might be found due to different release dates. **We call for increased transparency on the entire dataset in this regulatory tool to allow for reproducibility of the approach.**

Yours sincerely

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