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CropLife Europe input for SCOPAFF meeting 12-13 October 2023

- **Transparency on Section A documents on the agenda**
- **Planned ECHA guidance document on Endocrine Disruptor identification**
- **EFSA scientific Guidance Documents**
- **Co-formulants and assessment of formulations**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 12-13 October 2023, CropLife Europe would like to provide input on several issues:

Transparency on Section A documents listed for endorsement

CropLife Europe is calling the European Commission to ensure transparency of the final version of documents listed on the agenda for endorsement by the Committee. This is the case for instance this time for the documents under point A.03 on the access to old studies, or under A.07 with some notes and technical guidelines. We call on DG SANTE to make use of the comitology register to upload the versions which will be discussed so all stakeholders are informed in a timely manner and still may comment before final endorsement.

ECHA draft guidance document on Endocrine Disruptors in the context of the CLP regulation

CropLife Europe would like to draw the attention of DG SANTE and members of the SCoPAFF on the ongoing ECHA work to prepare a guidance document on the identification of Endocrine Disruptors. This new document is needed following the Delegated Regulation 2023/707 amending CLP Regulation (EC) No 1272/2008 and introducing this new hazard class. The guidance development process is ongoing with comments being submitted through the ECHA Partner Expert Group (PEG).

The draft version available so far, shows a clear missing opportunity to apply the methodology from the existing EFSA-ECHA guidance document developed in 2018 for the identification of endocrine disruptors in the context of Biocides and PPPs regulations. While already raised to ECHA EDEG after the first commenting phase in May 2023, we are highly concerned that substances for which more data are available, which is typically the case for PPP substances, will be penalised by this document. The document makes very conservative assumptions, like considering that any effect is related to an endocrine mode of action or applies a very unbalanced weight of evidence approach. The draft is also rejecting the inherent complexity linked to the ED assessment and testing tiered approach taken for PPPs and aims at designing simplistic solutions. In its current form, the ECHA guidance document would create loads of false positive results and risk to create inconsistent regulatory decisions across the different framework dealing with ED identification.

In the spirit of the 'One Substance, One Assessment' Concept and cooperation between regulators, we call on Commission, EFSA and Member States involved in PPP ED assessment to engage with ECHA and highlight the specificities and experience gathered over the last 5 years on ED identification for PPPs.

CropLife Europe is recognizing the challenging exercise to provide a guidance that needs to cover both data rich and data poor substances, however clear distinction between the two needs to be made in this case. CropLife Europe will continue to provide technical comments to ECHA as well as detailed case studies showing how the approach used for data rich substances works at providing science-based conclusions. We also invite to use these case studies to validate the accuracy of the approach proposed by the draft guidance in ED identification.

A.07 – Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water

CropLife Europe (CLE) wishes to draw the attention of the Commission and Member States to the need for significant revisions of the proposed Guidance Document on the impact of water treatment processes before endorsement for regulatory use.

CropLife Europe is concerned that the proposed document in its current form will create regulatory uncertainty by triggering extensive experimental work, even for substances that are unlikely to be of concern based on a realistic exposure assessment. We estimate that more than 750 substances (active ingredients and metabolites) would require such assessment and more than 500 experimental work. We believe this non-discrimination is a result of an unrealistic exposure assessment and the guidance should be corrected to provide a calibrated approach focusing efforts on substances realistically at risk of reaching raw drinking water. In addition, the document suggests experiment test procedures which lack all basic requirements of tests procedures for regulatory purposes such as proper description, validation and (ring-)testing for consistency of results.

CropLife Europe suggests revisions should be made to the document on the exposure assessment and the proposed test procedures before any endorsement for regulatory use. In addition, flexibility in the implementation timeline will be required due to the substantial amount of experimental work that will anyway be triggered by an updated document. A CropLife Europe detailed position document is available in the annex to this letter.

A.07 – EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)

CropLife Europe supports a high level of protection for bees and pollinators and welcomes the development of a new version which includes positive elements, especially regarding honeybees.

Nevertheless, we strongly recommend caution with regards to a full and immediate implementation of the document as there is a drastic increase in complexity at all tiers which will lead to a substantial increase in workload and level of expertise needed by Risk Assessors and applicants, and consequently is likely to lead to diverging interpretations and outcomes of the risk assessment. In addition, the document has raised the level of conservatism, which will still lead to an increased failure rate even for substances of no toxicity and does not provide workable higher tier study options to refine the assessments.

Therefore, Croplife Europe recommends that a common understanding and agreement is needed between Regulatory Authorities and Applicants as to exactly which of all the potential requested studies within the revised Guidance are practically possible to be conducted at this time. This can then be used to design a phased implementation of the Guidance which will enable applicants to comply.

CropLife Europe also recommends that before implementation, substantial training, and guidance on how to use the Guidance Document is provided to end users and Risk Managers, including provision of illustrated case studies, supporting calculator tools, and correction of existing errors.

A position document is available in the annex to this letter.

A.14 – Clarity on co-formulant data information requests

Taking note of the 23 May 2023 and 21-22 June 2023 co-formulant-focused workshops, of which the summary refers to "*a proposal for follow-up actions with the aim of mapping an action plan*", CropLife Europe would like to request clarity on which information or data will be requested for co-formulants in plant protection products. Associations representing applicants did not take part in

the workshop discussions and no EU decision on changed co-formulant templates seems to be available, yet we would like to report on recent MS divergences already following these workshops, namely in requesting additional co-formulant data in representative formulations as part of the EU active substance registration process.

We call upon all stakeholders involved (COM, EFSA, MSs) for a consolidated and timely communicated approach, with respect to the one-substance one-assessment concept (including if similar information would also need to be provided for co-formulants at product level).

We think it is worth reflecting on what the added value brought by the collection of this additional information would be, considering all hazardous substances are already listed on the Safety Data Sheet of the co-formulants. While we are mindful that applicants are responsible to demonstrate that the requirements of Article 4 (active substances) and Article 29 (products) of Regulation 1107/2009 are satisfied, they generally need to rely on EU or global suppliers in case specific, additional information is requested (like data on tox and ecotox properties of individual co-formulants). In addition, the information requested may often be confidential, adding an extra layer of complexity.

These uncoordinated requests are creating supply chain communication issues and there will be cases where the information will not be provided (e.g., case of a global supplier not caring for an EU PPP use of its chemical). **In these situations, we believe sufficient flexibility should be allowed in the process, as composition adaptations could be numerous and with a big impact on the workload at company and MS level**. We would also highlight that these requests are impacting all types of products, conventional as well as biopesticides.

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/

In Annex to this letter:

- *Annex 1 - CropLife Europe position on the proposed EFSA guidance document on Water Treatment*
- *Annex 2 - CropLife Europe position on the proposed new version of the EFSA guidance document on the risk assessment of plant protection products on bees*