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**CropLife Europe input for SCOPAFF meeting 20-21 March 2024**

- **General issues on regulatory processes**
- **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**
- **Amendments to Regulation (EU) No 547/2011**
- **Co-formulants and assessment of formulations – Ongoing actions**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 20-21 March 2024, CropLife Europe would like to provide input on several issues:

## A.03 - General issues on regulatory processes

Although not specifically mentioned on the March agenda and pending the minutes of the January SCoPAFF meeting, please note that in the Jan SCOPAFF, there was an agenda item to endorse this guidance:

*1. Renewal process (Regulation (EU) 2020/1740) - approach on access to old studies (to endorse)*

Can we kindly request a status update on this particular point?

## 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

The new 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 was published in August 2023 and is up for endorsement in the March SCoPAFF. Since the content of the Guidance is not expected to change before endorsement, CropLife Europe's (CLE) concerns remain that this Guidance will trigger many experimental studies with non-validated test systems and assessments for which notifiers, laboratories and regulators lack experience.

While CLE companies are preparing for the imminent entry into force of this Guidance, it is still not clear to date how it will be implemented. Key questions that call for pragmatic solutions are:

(1) When do new submissions have to fully comply with the Guidance?

(2) How will active substances currently under review be treated?

• Confirmatory data regarding water treatment have already been requested for some active substances. Uncertainty remains for the numerous active substances that do not have confirmatory

data requests on water treatment and are currently under evaluation. Will they also get confirmatory data requests with a two-year deadline? We strongly advocate for a staggered approach, as it would be virtually impossible to generate these data within two years for many substances simultaneously.

(3) Will the Guidance also apply to product authorizations when it has already been applied at active substance level before?

- An active substance may have passed at EU level without experimental data (due to low aquatic exposure), but experimental data may be needed to pass at zonal level for a specific formulated product (due to higher aquatic exposure); how can such new data on the active substance be made available in the authorization process?

The EU Commission indicated that guidance on the implementation concerning substances in different review stages would be provided in letters to applicants. With a nearing endorsement of the Guidance, applicants urgently need a transparent implementation schedule that takes the above aspects into consideration. A clear understanding of the applicability of the Guidance at EU, zonal and national level is key in this respect.

### A.13 - Amendments to Regulation (EU) No 547/2011

CropLife Europe would like to learn whether this topic concerns ongoing discussions on a draft Commission implementing regulation on labelling requirements for plant protection products and repealing the Commission implementing Regulation (EC) No 547/2011.

Since discussions on a draft proposal for a new regulation concerning labelling requirements have been ongoing since at least the October 2022 SCOPAFF, would it be feasible to make the latest draft version available for stakeholders, or to provide an indication for when a potential public consultation round would start.

Considering the expected significant impact on the downstream distribution chain when label changes would have to be implemented, we believe sufficient time should be allocated for commenting and subsequent implementation.

### A.15 (2) - Co-formulants and assessment of formulations – Ongoing actions

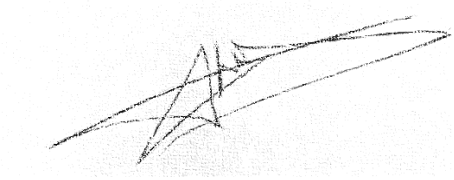
At the end of Jan 2024 CropLife Europe provided comments to the European Commission, Germany and France on the draft guidance document SANCO/12638/2011 XXX rev. 3 (Guidance Document on changes of the chemical composition of authorised PPP).

Given the potentially severe impact on the ability to manufacture products with a robust supply chain, we requested a further detailed review of the proposed guidance, with adequate opportunity for input from expert stakeholders, particularly in the areas of realistic physchem testing and efficiency gains utilizing existing legislation.

Our main concern was that given PPP formulations are manufactured for the common European market (not for individual member states), divergence in opinions on co-formulants would lead to fragmentation of the common market and single sourcing and supply chain risk.

Can we kindly request a status update on this particular point?

Yours sincerely



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