LET/24/KH/37857
16 May 2024

Eric Thévenard
European Commission
DG Sante - Unit E.4 - Pesticides and Biocides
1049 Brussels
Eric.Thevenard@ec.europa.eu

Kevin Heylen
Senior Regulatory Affairs Manager
+32 (0)2 663 15 56
kevin.heylen@croplifeeurope.eu

CropLife Europe input for SCOPAFF meeting 22-23 May 2024

- **EFSA Guidance Risk assessment for Birds and Mammals**
- **Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment**
- **Co-formulants and assessment of formulations – Ongoing actions**
- **Amending Commission Regulation (EU) No 547/2011 as regards labelling requirements for plant protection products**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 22-23 May 2024, CropLife Europe would like to provide input on several issues:

A.07 (1) – EFSA Guidance Risk assessment for Birds and Mammals

Taking into consideration that the revised version of the EFSA Guidance Document on Risk Assessment for Birds and Mammals is indicated in the SCoPAFF agenda for endorsement, CropLife Europe would like to highlight that the implementation of this Guidance would require significantly more resources and expertise on the part of both applicants and assessors to write and assess a regulatory dossier, as well as lead to unharmonized registration decisions since clear guidance and processes for hazard and higher tier risk assessments are lacking.

Therefore, **CropLife Europe recommends to SCoPAFF members not to endorse this Guidance before these shortcomings are addressed.** Our recommendation in that regard would be to launch a concerted technical review by end-users, as well as to develop an implementation roadmap for the revised Guidance focusing on hazard identification (BMD, fTWA) and classification on how to perform higher tier studies that meet the new expectations. Meeting the updated Guidance expectations would require an estimated extension of implementation timelines by 30 months. CropLife Europe detailed comments on the revised EFSA Guidance on Risk Assessment for Birds and Mammals can be found in the attached position paper – see **Annex 1**.

As stated in the recently published final report of the Dec 2023 ZAPID workshop, when discussing the complexity of assessment methodologies, a clear desire by all stakeholders was to introduce a feasibility check both during the development of guidance documents as well as before finalisation to ensure that the guidance document produced is fit for purpose. This is an opportunity to take this proposed action into account.

A.07 (5) - Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment

CropLife Europe would like to learn more about the proposed amendment to this guidance document, as the Commission previously indicated the provisions for granting an emergency authorisation would be looked at in light of the court ruling in the case C-162/21.

Since discussions on this draft amendment have been ongoing since at least mid-2023 in SCOPAFF, in order to achieve a uniform interpretation amongst Member States, would it be feasible to make the latest draft version available for all stakeholders, or to provide an indication for when a potential public consultation round would start?

A.14 - Co-formulants and assessment of formulations – Ongoing actions

In preparation of a draft guidance document on the **Assessment of PPPs and co-formulants** CropLife Europe learned that a *"Workshop on guidance document and database for the assessment of PPP including co-formulants (with the participation of MS authorities, EFSA, ECHA and Commission) – 20 June 2024"* is being scheduled.

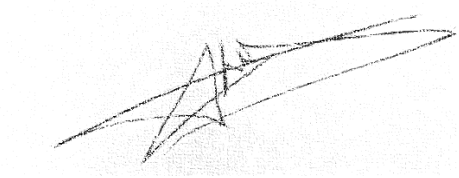
Would there be a possibility to open up the workshop towards external stakeholders (f.e. CropLife Europe to nominate a "hearing expert"), as was the case in previous instances?

C.01 - Amending Commission Regulation (EU) No 547/2011 as regards labelling requirements for plant protection products

As the draft regulation is on the SCoPAFF agenda already as a C-point for discussion, CropLife Europe would like to reiterate our concern that 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 clear timeframe on when the stakeholder feedback would take place is needed.

In addition, possibilities for interaction with regulatory authorities (Commission and Member States) would need to be explored before an endorsement of this amendment would take place, to ensure a predictable smooth (re)-labelling process and to align on key (new) labelling provisions, particularly for a digital label.

Yours sincerely



Kevin Heylen
Senior Manager Regulatory Affairs

cc. Karin Nienstedt
Almut Bitterhof
Manuela Tiramani

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

Annex 1 - CropLife Europe Position on the Revised EFSA Birds and Mammals Guidance Document