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CropLife Europe input for SCOPAFF meeting 10-11 July 2024

- **EFSA Guidance Risk Assessment for Birds and Mammals**
- **Memorandum accompanying the compendium of conditions of use to reduce**
- **exposure and risk from plant protection products**
- **Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment**
- **EFSA Bee Guidance Document plus amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013**
- **CLE legal opinion on Court cases C308/22, C309-310/22**
- **Revision of Reg. (EU) 547/2011 - labelling requirements for PPPs**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 10-11 July 2024, CropLife Europe (CLE) would like to provide input on several items:

A.07 (01) EFSA Guidance Risk assessment for Birds and Mammals (for endorsement)

CLE is concerned that implementing this Guidance will require significantly more resources and expertise for both applicants and accessors. This could also lead to unharmonised registration decisions due to the lack of clear guidance and processes for hazard and higher tier risk assessments.

Therefore, CLE recommends to SCoPAFF members not to address the aforementioned areas of improvement before endorsing this Guidance.

To address this, a concerted technical review by end-users could be launched. In addition, the development of 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. CLE's detailed comments on the revised EFSA Guidance on Risk Assessment for Birds and Mammals can be found in the attached position paper (Annex 1).

There is an opportunity to action the clear desire by all stakeholders when discussing the complexity of assessment methodologies, at the December ZAPID workshop, to introduce a feasibility check both during the development of guidance documents and before finalisation. This step will ensure that the guidance document produced is fit-for-purpose.

A.07 (2) – Memorandum accompanying the compendium of conditions of use to reduce exposure and risk from plant protection products

CLE recognises the value of the compendium in the overall context of farmers' toolbox depletion. To support the Commission's ambition and activities, CLE would like to learn more about the scope and nature of the memorandum and the concrete commitments, including how to streamline the use and adoption of the practices.

A.07 (3) - Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment

CLE is looking forward to the latest draft and public consultation of this Guidance. To ensure the sector can provide a detailed submission, advanced notice of the date (and possible extension to accommodate the summer period) would allow all the stakeholders to feed input. CLE would also like to better understand the practical cases of "controlled" conditions of use, which, along with the time limits, concur to form the backdrop for emergency use authorisation. Another aspect to note is the concept of "applicant" and the practical venues of cooperation with the input providers to maximise the information available and favour an optimal use of the plant protection products.

A.07 (6) EFSA Guidance Document on the risk assessment of plant protection products on Bees and Amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013.
and
A.13 Amendments to Regulations (EU) No 546/2011, (EU) No 283/2013 and (EU) No 284/2013.

CLE would like to highlight several critical challenges related to the revised version of the EFSA Bee Guidance as well as amendments to Regulation (EU) No 546/2011 and Regulations (EU) No 283/2013 and (EU) No 284/2013 setting out the data requirements for active substances. CLE's detailed comments on the revised EFSA Guidance on Risk Assessment for Bees can be found in the attached position paper (Annex 2).

A summary of the concerns is here outlined:
- Lack of accepted workable intermediate Tier options;
- Lack of effective considerations for low-risk plant protection products that pose minimal risk to bees within the Guidance;
- Lack of robust risk assessment options and a specific protection goal (SPG) for wild (non-Apis) bees, as well as;
- The draft Bee Risk Calculator tool which is resource-intensive to use, requiring extensive data entries and data evaluations, and which needs to be road-tested with real case studies by Member States and then reviewed to ensure its fitness for purpose.

CLE strongly recommends that the above-mentioned concerns are duly addressed ahead of any endorsement of the revised Bee Guidance Document at SCoPAFF.

A collaborative approach with relevant stakeholders that considers both the scientific evidence, and practical implications, is crucial to ensure an effective risk assessment framework for both protecting bees and promoting sustainable crop protection.

A.17 Court cases, requests for internal review, Ombudsman cases.

On 20th June, CLE published on its website its legal interpretation of the recent Court Case judgements C-308/22, C-309/22- C-310/22, underlining the relevance of legal certainty and importance of the harmonized product assessment system based on the division of work and mutual trust between Member States (please find it enclosed as Annex III). CLE considers that there are very limited situations where a cMS may depart from the assessment of a zRMS, and that MS are not obliged to conduct a de novo active substance ED assessment at the national level. To ensure regulatory certainty, Member States should demonstrate thorough consideration of all available reliable scientific and technical data during their assessment. Duly taking into account the specifics of the cases referred to the ECJ, these judgments must be interpreted as contributing to the importance of the system of division of work and mutual trust between Member States.

Furthermore, CLE would like to inquire about how to maintain cohesive, scientifically sound EU requirements for other MS to depart from the zRMS risk assessment. It would be relevant to adopt harmonised risk assessment criteria regarding the very definition of "most reliable/recent scientific and technical knowledge", as per the ECJ rulings. In that sense, CLE wonders if, in the absence of more specific interpretation/guidance, the recently discussed "EFSA guidance on the Application of systematic review methodology to food and feed safety assessments to support decision-making" and the "EFSA guidance on open literature review in the context of the Regulation (EC) No 1107/2009" (SCoPAFF point A.07 (12) as per 22 - 23 May 2024 Agenda, can provide a backdrop in that sense. CLE

is willing to explore other venues to maintain a science-based and predictable approach to PPPs authorisation.

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) amending Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

The proposed implementation timeline of the amendment of Regulation 547/2011 is challenging. However, CLE believes it is important to engage with stakeholders to establish workflows on approval of new paper and digital labels from the entry into force of the new regulation. CLE believes that a stakeholder workshop would be a valuable step, working collectively between industry associations and regulatory authorities towards a successful implementation of the new regulation.

Yours sincerely,

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cc. Karin Nienstedt
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/

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

Annex II - CropLife Europe Position on Revised Guidance on the Risk Assessment of Plant Protection Products on Bees and Proposed Changes to Regulation EU 546/2011

Annex III – CLE interpretation of ECJ judgements C-308/22, C-309/22 and C-310/22