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CropLife Europe input for SCoPAFF meeting 14-15 May 2025

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Topics

Topics on the Agenda

- Renewal dossier implications of Regulation (EU) 2023/707
- General issues on regulatory process
- Microorganism and low-risk Active Substances
- Unacceptable co-formulants
- Data requirements and uniform Principles
- Draft labelling regulation

Continuation of previous agenda topics - Outstanding topics

- Second mandate to EFSA on TFA
- GD Birds & Mammals
- In Vitro Comparative Metabolism studies
- Safeners and Synergists

Dear SCoPAFF members,

CropLife Europe is pleased to offer feedback on several matters on the agenda or of broader relevance.

Topics on the Agenda

A.03.2 Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008 – Implications for DAR/RAR prepared in the context of renewal dossiers

CropLife Europe notes the point on the inclusion of Delegated Regulation (EU) 2023/707 and its implications for the preparation of DARs/RARs in renewal dossiers. While we understand the evolving landscape of hazard classification under Regulation (EC) No 1272/2008, we are concerned that, in the absence of clear guidance, some Member States may interpret the newly introduced hazard classes in a precautionary or overly conservative manner during the drafting of DRARs. This could lead to the premature flagging of concerns or precautionary risk management proposals that extend beyond the current legal framework of Regulation (EC) No

1107/2009, particularly with respect to cut-off criteria. We therefore strongly recommend that the Commission provide clear direction on how (and to what extent) the new hazard classes should be considered in the context of renewal dossiers, to ensure harmonised, proportionate, and legally sound assessments across Member States.

A.03 General issues on regulatory process

On point 3 “Annual MS report of the authorisations of plant protection products” and point 4 “Delays on regulatory processes”, CropLife Europe is keen to gain a better understanding of this Agenda point. Regarding regulatory delays, these are indeed having a major impact on the functioning of our sector. The delays also significantly affect the whole supply chain, which lacks sufficient solutions to fight pests.

A.09 Microorganism and low risk Active Substances: New DAR/RAR (Draft Assessment Report / Renewal Assessment Report) template

CropLife Europe welcomes more targeted dossiers for microorganisms and low-risk substances. However, we have not seen any indication that a period for public comment has been included for the new DAR/RAR template, and we suggest that this process be carried out before implementation.

B.01 Draft Labelling regulation

On the 16th of April, CropLife Europe sent a letter with key concerns on the draft proposal for a labelling regulation for plant protection products repealing regulation 547/2011, based on the publicly available March 2025 version. Since last week (2nd of May) an updated draft legal text proposal is available on the comitology register.

In this context, CLE would like to emphasize the key messages on provisions for digital labels with the request to include a clear incentive to move forward from currently used label formats, as well as the call for a more concise framing of the scope of transitional measures. Currently, the draft proposal introduces a deviating set of rules, which would be leading to up to three different labels on the market at the same time.

Regarding fold-out label requirements, especially what elements would need to appear on the front page, CropLife Europe appreciates the updated requirements, mainly making reference to Regulation (EC) 1272/2008 (CLP) and having removed the requirement to include further information like e.g. crop information, conditions of use or first aid measures.

C.01 and C03- Exchange of views of the Committee on a draft Commission Regulation on the data requirements and on a draft Commission Regulation as regards uniform principles for evaluation and authorisation of plant protection products

CropLife Europe is aware of the Commission’s exchange with MS on this proposal, and remains available to provide constructive feedback once it is shared with stakeholders. Any clarification on the timing would help.

C.04 “Exchange of views of the Committee on a draft Commission Regulation (EU) amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing further co-formulants which are not accepted for inclusion in plant protection products”

Referring to our letter of 24 April to the European Commission, CropLife Europe would like to highlight that the criteria for listing potential additional unacceptable co-formulants are to be followed, and we are concerned about the accuracy and rigor in the drafting of these lists.

A transition period of a minimum of 5 years would allow full transparency to develop the co-formulant supply chain. This would provide sufficient time, as product development or reformulation due to co-formulant substitution requires 5-6 years, assuming a substitute co-formulant is readily available on the market.

The proposed period is too short [2 years after the entry into force of a new Annex III listing Regulation].

Continuation of previous agenda topics - Outstanding topics

Second mandate to EFSA on TFA

CropLife Europe reiterates the need for the EFSA and MS authorities to make data and science-driven decisions on the potential formation of TFA from soil-degradation studies. The current study-guidelines (as specified by the data requirements regulation 283/2013) are no longer deemed adequate and fit for purpose in some cases. Scientific and regulatory consensus is needed on how open questions on TFA formation can be unambiguously answered. CLE expressed this need, which should be addressed in a targeted mandate to EFSA, in a letter to SANTE (LET/25/CF/3864904 April 2025). CLE is more than willing to offer its views and expertise in expert discussions. It is key on such an important matter which is gaining increased public and regulatory attention, that there is an EU-wide approach guaranteeing regulatory predictability and legal certainty.

It is also key to note that the renewal process for the majority of the relevant active substances is already scheduled or under evaluation. Therefore, an EU-wide evaluation is already due to take place. Any regulatory initiatives and decisions must be based on science and robust data evaluation. As additional information will need to be generated by the applicants (potentially going beyond the established and conventional methodologies), it is important that adequate time is granted for these data to be submitted for each substance within its respective renewal process.

Clarification on EFSA Guidance Risk assessment for Birds and Mammals

EFSA Guidance Risk assessment for Birds and Mammals

CropLife Europe would again like to draw your attention to the following concern relating to the Birds and Mammals guidance document, as endorsed in the October 2024 SCoPAFF.

As we noted previously, we realize the endorsement of this guidance has already taken place, and we have previously provided our CropLife Europe Position on the Revised EFSA Birds and Mammals Guidance Document, especially on the challenges related to the use of BMD and higher tier approaches.

However, the fact that the guidance would be implemented from October 2025 at the same time for active substances and products is of high concern and will lead to significant delays for product evaluations. We believe that these concerns might have been underestimated and we would therefore request SCoPAFF discuss potential procedural consequences for product application dossiers.

More specifically:

1. As an agreed List of Endpoints should be used for product submissions, what is the proposed process regarding the evaluation of BMD10 values and justification for use of fTWA, if they have not yet been evaluated at an EU level?
2. The online EFSA BMD calculator tool is not fit for purpose, because of the lack of version control. Regular updates of the EFSA BMD tool result in different outcomes. This makes the risk assessment non-reproducible.
3. CropLife Europe recognizes that further alignment between Member States is required for a transparent and efficient implementation of the revised EFSA Birds and Mammals Guidance Document. In order to avoid back-and-forth discussions and potentially unharmonized approaches a more consistent interpretation and application of the guidance should be ensured.

Further clarifications and proposals on the topics mentioned above are provided in the attached document (Annex I).

In Vitro Comparative Metabolism Assessment Studies

Crop Life Europe reiterates its request for more clarity on how to address a number of technical challenges that have been identified with implementing the EFSA (2021) Scientific Opinion on testing and interpretation of IVCM studies.

See Annex II (enclosed) for more details.

Safeners & Synergists

CropLife Europe would appreciate further clarification, in particular about:

- The process for product evaluations post approval of safeners.
- Data protection. One could expect 10 years of data protection following approval yet herbicide products with safeners are already on the market. Did the Commission assess the potential legal consequences in that regard? (it is key to maintain the 10-year data protection following approval);
- Transitional period for products already on the market is until 19-12-2030 (5 years from the adoption of the WP) – What are the key aspects to consider?
- Where would an approval for a safener or synergist be listed? Would there be an approval regulation per compound and/or an amendment of the scope of 540/2011?

We remain available in case of any questions,

Yours sincerely,

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Director of Regulatory Affairs



cc. Karin Nienstedt
Mark Williams
Eric Liegeois
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Manuela Tiramani

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