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CropLife Europe input for SCoPAFF meeting 11-12 March 2025

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Topics

- **TFA- support for a Second mandate to assess all sources of TFA**
- **Unacceptable co-formulants and Annex III- clarity on the consultation phase and transition period**
- **Labelling regulation – follow up**

Continuation of previous agenda topics - Outstanding topics

- **Outsourcing of risk assessment**
- **Azoles resistance**
- **PMT-vPvM – arguments expressing CROPLIFE EUROPE's position**
- **Clarification on the Efsa Mammals and Birds Guidance Document- timeline and reference to the BDM**
- **In vitro comparative metabolism assessment studies**
- **Safeners and synergists**

Dear SCoPAFF members,

CropLife Europe (CROPLIFE EUROPE) is pleased to offer its feedback on several matters, as is their standard procedure.

A.10 TFA

CropLife Europe understands that Members States have developed concerns that environmental fate data generated according to the current guidelines (e.g. OCED 307) were not always sufficient to prove whether TFA was not formed or not. It has been confirmed that TFA is a relevant metabolite for the groundwater risk assessment (following the submission of data under the REACH process and the subsequent harmonised classification proposal under CLP). Therefore, it has become clear to CLE member companies that additional information will be required, and that time should be made available for these data to be generated, in support of a substance-by-substance evaluation.

A.13 Co-formulants and assessment of formulations.

- Unacceptable coformulants- Implementation of Regulation (EU) 2023/574 - draft Regulation amending Annex III

As the discussion on additional Annex III entries is ongoing in SCoPAFF, potentially based on the public notification list: https://food.ec.europa.eu/document/download/14849519-3139-45d9-9526-a560881879b5_en?filename=pesticides_auth-ppp_notified-unacceptable-coformulants.pdf , CropLife Europe would urge to include a consultation phase for the new draft Regulation amending Annex III as the draft list seems to display quite a number of errors and would benefit from detailed rigor in terms of correct chemical identification and accuracy in allegedly meeting Annex III criteria. In addition, while Regulation (EU) 383/2021 stipulated a transitionary period of 24 months, it seems crucial that a new draft Regulation amending Annex III would allow for a longer reformulation time (up to 5 years) due to a lot of chemicals currently undergoing classification changes following the CLP revision and the implementation timelines for new hazard classes.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) repealing 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

In January 2025 CropLife Europe provided our comments in relation to the public consultation phase of the draft labelling regulation repealing regulation (EU) No 547/2011. Now that the consultation phase is over the Commission will revise the draft to consider the relevant comments from Member States and stakeholders.

CropLife Europe still welcomes the revision of this regulation as we are actively working on the evolution of labels in particular on the digital component with AgriGuide. Yet it is important to have clarity on implementation phases and transition periods of the draft regulation, which is essential for good preparation and implementation of the regulation following adoption.

The provision on the compliance regime for products already on the market at the date of application is clear, although it should clarify that new or renewed authorisations of plant protection products would be in scope of this regulation, while amendments to product authorizations as referenced in Article 33, mutual recognitions in line with Article 41 and emergency authorizations in line with Article 53 of Regulation (EC) No 1107/2009 and Reg. (EC) No 547/2011, as well as extensions of authorisations for minor uses in line with Article 51 of Regulation (EC) No 1107/2009 would be dealt with in a transition period.

Continuation of previous agenda topics - Outstanding topics

General issues on regulatory processes – outsourcing of risk assessment

As the results of the Member States' survey on the outsourcing of risk assessment are expected to be presented during the next SCoPAFF meeting (see A.03(1) of the previous minutes), CropLife Europe would like to voice our preliminary concerns on the treatment of CBI. Although not against outsourcing practices, authorities should be transparent towards applicants concerning data processing agreements with institutes or consultants performing risk assessment tasks on behalf of a MS authority.

Azoles resistance

CropLife Europe welcomes the publication of the EFSA mandate report and commends the coordinators and contributors on their investigation of this highly complex topic. CropLife Europe members advocate for a balanced approach that supports the use of azoles as essential crop protection tools while ensuring their availability for medical applications, following a "One Health" approach.

We have reviewed the report and its annexes, and we appreciate the distinction that is made between environmental “coldspots” and “hotspots,” with a clear focus on prioritization of mitigation efforts in "hotspots". We also support the emphasis on risk assessment in relation to those compartments, although we believe there are opportunities for further refinement of the proposed approach. Specifically, when estimating the potential for resistance selection and amplification in environmental

hotspots, it would be valid to take into account the differential conditions (not typically captured in standard in vitro tests) that influence the reproductive potential of A. fumigatus in those niches.

We recognize that the proposed approach may require substantial testing, and resources for both evaluation and risk assessment at the applicant and member state levels. While we understand that this might present challenges in light of the simplification goals outlined in the 2025 Commission work programme, we would welcome the opportunity to engage in discussions of how the report's recommendations can be effectively and pragmatically implemented, based on the availability of the appropriate technical guidelines and timelines.'

PMT vPvM discussion at SCoPAFF

With the implementation of PMT/vPvM criteria in CLP (EU 2023/707 see point A03 SCoPAFF 4-5 December minutes)- discussions are expected on how these new hazard classes should be considered in sectorial legislation such as the regulation for plant protection products (PPP), EC 1107/2009. CropLife Europe is of the opinion that it is not justified to implement the CLP classification of PMT or vPvM criteria (as per the CLP (EU 2023/707)) into EC 1107/2009.

The CLP regulation classification is aimed at addressing, in broader terms, early signals regarding harmonized classification and does not intend to anticipate more fine-tuned and precautionary regulatory concepts as per 1107/2009.

In that sense, Bioaccumulation (B) is more informative of hazard-based, intrinsic characteristics of crop protection products than Mobility (M), and has been rightfully considered as more relevant to introducing cut-off considerations for non-approval of pesticides. PBT, vPvB and POP classes have long been part of the regulatory toolbox of the policymakers to exclude impact on human health and the environment.

Further to that, in the regulation EC 1107/2009 a comprehensive and sophisticated mobility assessment is carried out for PPP. This includes many aspects such as experimental studies, modelling and monitoring. For EU registration of PPP, it needs to be shown that the substances are not transported and do not impact drinking water sources.

Compared to this, the simple mobility assessment under CLP regulation which is mainly based on the LogKoc-value only represents a screening for mobility and therefore only indicates a potential for mobility.

It is therefore not justified to implement the PMT or vPvM criteria into EC 1107/2009. Classification of a substance as PMT/vPvM under CLP should be used only as an indication to check the mobility information for consistency.

CropLife Europe reminds that the existing cut off criteria for PBT/vPvB/POP currently prevent authorization of PPPs, and that pesticides meeting two out of three criteria of PBT are Candidates for Substitution, with just 7-year authorisation and a *de facto* progressive phasing out – making not attractive for the applicants to invest regulatory resources in short-lived molecules.

Clarification on EFSA Guidance Risk assessment for Birds and Mammals

EFSA Guidance Risk assessment for Birds and Mammals

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

We realize the endorsement of this guidance already took place, and we had 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 important delays for product evaluations. We believe that these concerns might have been underestimated and would therefore request SCoPAFF to 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 on 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).

Comparative in vitro metabolism studies

Scientific opinion of the PPR Panel on testing and interpretation of comparative in vitro metabolism studies. CropLife Europe reiterates the request for clarification on this point as per October's CropLife Europe letter to SCoPAFF representatives. An Annex II with more specific points is here enclosed.

Safeners and Synergists

CropLife Europe intends to feed into the conversation providing further points in response to the ongoing SCoPAFF discussion. Please find here enclosed Annex III.

We remain available in case of any questions,

Yours sincerely,

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Director of 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/