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CropLife Europe input for SCOPAFF meeting 30-31 March 2022

- **Chemical Strategy for Sustainability and impacts on the PPP regulatory framework**
- **Guidance document on Operator exposure**
- **Guidance document on predicting environmental concentrations in soil**
- **Co-formulants/Annex III**
- **Allocation of Rapporteur Member States to facilitate pre submission meetings**
- **CropLife Europe conference**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 30-31 March 2022, CropLife Europe would like to provide input on several issues:

Chemical Strategy for Sustainability (CSS) and implications for the Plant Protection Products framework

CropLife Europe would like to raise the awareness of the SCoPAFF members on the significant effect which the CSS implementation will have on the availability of plant protection products for European agriculture. While supporting the Commission's objective to deliver safe and sustainable solutions for a greener future, **CropLife Europe is concerned that the implementation of several measures will put at risk the availability of certain chemical substances which are key for plant protection products and, consequently, for productivity of European agriculture.**

For example, the revision of the Classification, Labelling and Packaging regulation might result in a drastic number of substances falling under the scope of the newly proposed hazard classes, particularly due to an overly conservative approach to identifying persistent, mobile and toxic substances (PMT/vPvM) currently under discussion. In an impact assessment performed by CropLife Europe, it is shown that more than 63%-80% of the substances would be classified as PMT/vPvM if the currently discussed criteria are applied (impact assessment in Annex)**. We would call on the Commission and Member States authorities to ensure that future assessment framework should be suitable for all groups of chemicals, taking into account the interlinks with sectorial legislations and the scale of potential impacts.**

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (A.07)

The revised Guidance has been published on 18 January 2022 with its new online calculator for exposure assessment. Since the EFSA guidance was first introduced in 2014, industry has continually strived to improve the data base upon which the old model calculations were derived and looked to provide both EFSA and Member States with information and data to allow for rigorous evaluation prior to inclusion in any further revision. As such, the data call-in requested by EFSA in June 2018 was seen as a great opportunity to introduce additional data to improve the situation on both existing and new scenarios, e.g., worker re-entry exposure in

vineyards (BROV), bystander exposure to drift for low crops (BREAM2). It is therefore somewhat disappointing that only a very limited amount of the new information and data submitted and available to EFSA has been concluded suitable for inclusion into the revised Guidance and updated online calculator. Nevertheless, we welcome the increased clarity about EFSA expectations for future data submissions so whilst certain areas are viewed as a missed opportunity it is hoped future evaluations will be more successful. **Since new and relevant data are already available, but not considered in the current updated Guidance, we would call on the Commission to mandate EFSA to conduct not only periodic but also more frequent reviews of the Guidance and consider available data during a regular review process, i.e., to assess already available data with an aim to incorporate the new knowledge they bring into a limited revision of the Guidance**.

As it was pointed out during public consultation, the online calculator is not considered to be user-friendly and lacks transparency and traceability during the calculation process making re-iterative calculations more difficult and cumbersome. It is hoped that in due course several of the inconsistencies observed between the calculator and the report can also be addressed prior to its regulatory implementation. **Furthermore, since this is an online calculator, data protection is a question that needs clarification – how data entered in the calculator are collected, processed, stored, and who can access them**.

After the online calculator accompanying the Guidance is made fully transparent, user-friendly, and easy-to-use, CropLife Europe would call for a reasonable implementation timeline of at least 6 months, for applicants to be able to prepare the dossiers addressing new data requirements accordingly.

EFSA guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (A.07)

CropLife Europe commented regularly over the lengthy development of this modelling framework. Now that the complete software suite is available to stakeholders, CropLife Europe was able to conduct a specific Impact Assessment exercise with 56 active substances and 56 metabolites currently passing EU evaluations. **These assessments now reveal a considerable increase of conservatism for PECSOIL values: up to x200 for Tier 1, x80 for Tier 2 and x34 for Tier 3.** These significant increases in predicted exposure are driven primarily by non-validated assumptions on soil bulk density and the unrealistic simulation of product application during precipitation events. Please find in annex to this letter a one pager explanation as well as the full underlying scientific report.

Due to the high conservativeness of the new modelling, the uncertainty on how to use these values in a soil risk assessment scheme, and the demonstrated high failure rate of the risk assessment, **CLE recommends to the Commission, Member States and EFSA that further work should be conducted before any regulatory use of this document:**

- **to allow further validation of the modelling methodology and scenario assumptions, and**
- **to allow alignment of the tiered approach with the future soil organism guidance.**

Coformulants - Implementation of Annex III (A.15)

CropLife Europe is concerned by the approaches taken in some Member States when it comes to the implementation of Annex III of Regulation 1107/2009. We would like to remind the following:

- **Annex III has not introduced any requirements that cannot be met through data already previously submitted, or already available on co-formulant supplier safety data sheets (SDS), or on the PPP SDS**. If additional data is requested, it should be limited exclusively to confirmation of those products identified as being candidates for losing the authorisation.

- Polymers are no different to any other co-formulant: if a residual monomer (impurity) that is relevant for Annex III exceeds 0.1%, it is an already existing legal requirement, with penalties for enforcement, that this be listed on the co-formulant supplier SDS.
- The draft procedures for listing additional substances in Annex III must continue to be limited to substances with harmonised classifications under CLP, or otherwise identified as SVHC by REACH. It is this key feature which ensures the supply chain transparency (via the SDS) that allows for a smooth and efficient implementation, and thus avoids any need for Europe wide co-formulant or product information request.
- **There are no legal provisions to arbitrarily include additional substances than those listed in Annex III, either by analogy, read across, or grouping**. Potential degradation to an Annex III listed substance acts via the Annex III provision for a limit of <0.1% in the finished product.
- It is mathematically impossible for the same impurity present in multiple co-formulants at concentrations <0.1% to collectively sum up and exceed a 0.1% threshold. Concentrations expressed as percentages are not additive.

Early definition of RMS to better use the option of pre submission meetings

We recognise the call from the Commission towards applicants to make better use of the new possibilities offered by the Transparency regulation, such as the pre submission meetings ahead of the applicant's obligation to submit a notification of intended studies for active substances renewal. Nevertheless, definition of a RMS is still lacking for several substances. **We would invite the Commission and Member States to consider future allocations of RMS much earlier – at least 5 years before submission date - to facilitate the intended steps defined by the Transparency Regulation as this will benefit the whole evaluation process.**

CropLife Europe conference 2022

On the 9 and 10 March CropLife Europe hosted its Annual Conference 2022. Programme and presentations given can be found on our public website here. Presentations include especially CropLife Europe views on:

- The zonal system implementation, with first results of our survey on product authorisations, covering submissions between January 2014 and December 2021.
- The regulatory translation of Cumulative Risk Assessment.

Yours sincerely

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cc. Karin Nienstedt
Manuela Tiramani

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

Annex 1 – 35109 CropLife Europe position on the proposed new EFSA soil exposure modelling framework.pdf
Annex 2 – CropLife Europe – PEC soil-Risk-Evaluation-Final.pdf
Annex 3 - 35004 - CropLife Europe PMT Impact Assessment.pdf