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CropLife Europe input for SCOPAFF meeting 14-15 July 2022

- **CropLife Europe conference 2023**
- **Guidance documents**
- **Biopesticides**
- **Co-formulants – implementation of Annex III**
- **Transparency Regulation implementation issues**
- **Key legislative proposals affecting future availability of Plant Protection Products**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 14-15 July 2022, CropLife Europe would like to provide input on several issues:

CropLife Europe conference 2023

We would like to inform the European Commission, Member States and EFSA that the 2023 CropLife Europe conference will take place in Brussels on the 7 and 8 March. A save-the-date with more information will be shared later this year.

Guidance documents – availability of final draft and upload of endorsed versions (A.07)

CropLife Europe would like to reiterate its demand to have transparency on the outcome of public consultations that were made on guidance documents as well as on the new resulting versions before they are listed on a SCoPAFF agenda for note taking.
We would also ask for a timely availability of newly endorsed guidance documents on the official European Commission webpage so that all applicants can access the documents and the important information about their application date. Guidance documents endorsed in May are still not uploaded.

Biopesticides (A.16)

CropLife Europe member companies are providing Biopesticide product for European farmers. However, we believe further elements could be put in place to increase their availability on the European market. Recent Commission developments like the amended data requirements for microorganisms, or the Better Training for Safer Food programs are very much welcomed.
While technical capacity and knowledge is being built in evaluating authorities, we would suggest starting a discussion with Commission, Member States and interested stakeholders on:

- The creation of specialized evaluating units for biopesticides within authorities – taking the example of how the US EPA is operating.
- The decoupling within Peer Review meetings of biopesticides from other substances. A precedent was set in 2020 with a focus on microorganisms based biopesticides.
- Allocation of a fixed part of the SCoPAFF agendas for biopesticides.

Co-formulants - Implementation of Annex III (A.15)

CropLife Europe is concerned by the approaches taken in some Member States when it comes to 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 a 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. So called “formaldehyde releasers” are not listed on Annex III, and provided the formaldehyde limit is complied with, there is no legal basis to extend to additional CAS numbers. Furthermore, the ECHA identification of formaldehyde releasers was conducted in relation to certain envisaged exposure scenarios that are irrelevant to plant protection products.
- 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, and therefore there is no justification for information on impurities below 0.1%.

Furthermore, we would like to ask for clarification under what legal basis certain Member States are engaging in extensive compositional data collection activities, outside of the foreseen dossier submission processes.

Transparency Regulation implementation issues (A.17)

The Transparency regulation started to apply as from 27th March 2021. Several dossiers have been submitted by companies, for new active ingredients, for renewal of existing active ingredients or MRL/IT applications in respect of the legal timelines. More than 30 dossiers were submitted under this new system in the course of 2021. Today, only a handful of dossiers have progressed at the RMS/EFSA level, leaving applicants in doubts about how these first dossiers are being evaluated. It is essential for companies to know if previous submissions are considered acceptable and if the approaches taken (e.g., on CBI claims) are workable, in order to prepare for future submissions. Adequate preparation of new dossiers depends on such feedback which is still lacking. This is also to better prepare to facilitate authorities work and avoid unnecessary work by any actor in the system.

More than a year after its implementation, we believe clear feedback by COM, Member States and EFSA is needed on the transparency regulation; the lessons learned, the added value it is bringing to the whole process and what could be adapted collectively so as enhance its efficiency.

Key legislative proposals affecting future availability of Plant Protection Products

CropLife Europe would like to ask the European Commission to include on the Standing Committees agendas regular updates on legislative proposals being discussed in other committees and other Directorate Generals which will have an impact on the availability of plant protection products. We believe this committee should be informed about the impact of certain proposals on its work and on national authorities’ activities. For instance, many initiatives

launched by DG ENVI and DG GROW under the Chemical Strategy for Sustainability are being discussed and will have direct consequences on Plant Protection Products.

Yours sincerely

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cc. Almut Bitterhof
Karin Nienstedt
Manuela Tiramani

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