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CropLife Europe input for SCOPAFF meeting 13-14 October 2022

- **General issues on regulatory processes - IUCLID**
- **Co-formulants - Implementation of Annex III**
- **Amendment Regulation (EU) No 547/2011**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 13-14 October 2022, CropLife Europe would like to provide input on several issues:

General issues on regulatory processes – IUCLID (A.03)

We still see today key challenges with IUCLID implementation.

- As highlighted in our previous letters, many completeness check processes are still not being completed (more than a year now in some cases instead of the legal 1 month).
- Applicants also receive requests now for CADDY versions of dossier by some Member States acting as Rapporteur Member States, increasing further preparation work.
- Dossiers published on the EFSA website are routinely taken offline after GDPR or CBI concerns have been highlighted. We believe this approach of publishing first and checking later is fundamentally flawed and all actors share responsibility.

CropLife Europe calls on the Commission, EFSA and Member States to take stock of the current situation and initiate a review of the implementation of the Transparency Regulation. For instance, EFSA's own practical arrangement could evolve to reflect ongoing difficulties without negatively impacting the transparency process.

CropLife Europe is also concerned by the initial idea presented when introducing IUCLID for Active Substances and MRLs to expand it, in a second stage to Products. The current situation shows that any development in this direction is premature: there are much more product dossiers than AS/MRL applications, and introduction of this format would only slow down innovation at a time when the EU needs it the most.

Amendment Regulation (EU) No 547/2011 (A.14)

We understand an initial draft proposal will be discussed with Member States during this Committee meeting. CropLife Europe would like to raise the following points when it comes to labels of products on the European market:

- Products labels are already heavily loaded with information and any proposal adding further mandatory elements should be carefully assessed in terms of feasibility, practically and intelligibility by the end user. The situation is even more difficult for very small packaging (e.g., <1L) with less label space.
- As most of the Plant Protection Product users are trained professionals, any proposal should avoid redundant or even misleading information compared to what would have been

learned during the dedicated training (e.g., using an IPM approach when MS will have to design crop-specific rules under the SUR proposal).

- Any revision of the EU rules should be an opportunity to include elements linked to digitalization of labels. It would be a missed opportunity to not render future-proof this piece of legislation and talk about prioritization of what could be printed/online. We believe this could improve readability of the information and conditions of use including precautions, risk mitigation and restrictions where applicable.
- Proposal around categorising products with colours, does not add any value as regards the purpose of a label that is to describe the conditions of use and precautions to take. It adds unnecessary complexity to the label and is unapplicable for products mixing two active substances, or mixed products. It also undermines the entire risk assessment system which guarantees that plant protection product uses are only approved if they present a high level of safety. Finally, it can led to detrimental effects with the wrong perception that “green” means no safety/precautionary measures needed.
- Evolution of label content and design requires time, as well as specific transition measures (e.g., to use existing stocks with former labels). Realistic timelines will need to be discussed with holders of national authorisations.

CropLife Europe calls on the Commission to conduct a detailed assessment of the consequences any proposal would have on a range of representative labels. We are ready to support such exercise directly and transparently, especially to support the transition to smart e-labels.

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:

- There are no legal provisions in Regulation 1107/2009 to arbitrarily include additional substances to those listed in Annex III, either by analogy, read across, or grouping. So called “formaldehyde releasers” are not currently listed on Annex III, and there is no basis to extend to additional CAS numbers. **Both compliance with the Annex III limit on formaldehyde as an impurity (<0.1 %w/w), and with the CLP regulation (<0.1 %w/w for classification due to formaldehyde), effectively achieve a similar result**.
- We wish to highlight that the lists of “formaldehyde releasers” that have been circulated by some Members States contain errors, with incorrectly identified substances, and in particular one which biocide competent authorities have concluded is **not** an intentional formaldehyde releaser, thus exemplifying the call for one-substance one-assessment. For this reason, besides that of legal certainty, only those substances explicitly listed on Annex III should be in scope of any withdrawals.
- To avoid such errors in future, the process to add substances to Annex III must involve peer review and rely on harmonized classifications or REACH SVHC identification only. It is this key feature which ensures the supply chain transparency (via the SDS) that allows for a smooth and efficient implementation. The process should include a public consultation to ensure right of reply by co-formulant manufacturers and ensure that all available information is considered.

CLE request that Commission provides legal clarity on:

- **the legality of the withdrawal of authorized formulations based on substances (i.e., CAS numbers) not otherwise listed in Annex III**
- **whether and under what limitations Member States can continue to maintain national lists of unacceptable co-formulants**

CLE recognizes the difficulties involved in developing a comprehensive regulatory framework for the management of polymers in Europe in an efficient and robust manner, while balancing animal welfare, and sheer practicality of dealing with an estimated 30 000 polymer registrations (Wood 2020 report). **In this respect we encourage Member States to engage with their local REACH**

competent authorities and COM to develop a scheme that serves the needs of all sectors. On the whole, 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.

Yours sincerely

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cc. 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/