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CropLife Europe input for SCOPAFF meeting 21-22 October 2021

- **Guidance documents**
- **MS updated survey on timing of regulatory procedures**
- **News from European Food Safety Authority (EFSA): technical report on rotational crops and IUCLID rules for confidentiality**
- **Improving the efficiency of the process of a.s. approval / renewal**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 21-22 October 2021, CropLife Europe would like to provide input on several issues:

Guidance Documents (A.07)

We note six guidance documents are listed for note taking on the agenda. For several of them a consultation of stakeholders took place more than 2 years ago. We would like to ask the Commission to share the outcome of these consultations and the new versions produced for a last commenting round by the stakeholders before note taking. In addition, in order to enhance transparency, **we believe these documents should be made available prior to the meeting on the comitology register if they are listed for note taking by the Standing Committee.**

We also understand a newer version 9 of the *Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004 rev. 9)* is being used in the context of pilot projects led by Member States. **The final version of the guidance document being neither available to applicants nor noted, we would call for no premature use of unadopted guidance document in order to avoid putting on hold product assessments and discriminant treatment between zones.**

MS updated survey on timing of regulatory procedures (A.17)

CropLife Europe welcomes this exercise of gathering more information on the practical implementation of the authorisation system in Europe. We know Member States are working on solutions to improve timelines and increase resources available and we look forward to seeing the result of the survey and also bring the applicant experience point of view on several procedures and their timings in reality.

News from European Food Safety Authority (EFSA) (A.11)

EFSA technical report on the assessment of residues in rotational crops

CropLife Europe appreciates that the new "*EFSA Technical Report for rotational crops*" intending to support the harmonised interpretation of the relevant OECD Guidance Documents and Test Guidelines is taken up to discussion in both the SCoPAFF Residues and Legislation, and is extensively discussed with Member States and expert groups, as this is going to impact the way residues and MRLs are calculated and set in Europe.

CropLife Europe would appreciate being involved in the evolution of this report, to understand the impact of the changes in our future submissions and to participate with constructive comments and clarification of practical issues, in keeping the harmonized interpretation of the OECD Guidance documents.

Use of IUCLID as new data format and handling of confidential information

CropLife continues to be supportive of the new data format and Industry efforts are continuing, together with EFSA, to obtain a workable system as soon as possible. Nevertheless, we now see that the implementation of IUCLID is not in line with the transparency requirements when it comes to publication of dossiers, and **we foresee a high risk of having confidential information unwillingly disclosed by the system.** It happens already with a recent rule set change in IUCLID for filtering of confidential information: it was only due to one applicant's note that an unintentional publication of CBI was detected (and directly removed and now corrected by EFSA). **This confirms the importance of setting up a proper testing environment when it comes to evolution of IUCLID rules for PPPs and before any use for regulatory submissions**.
A first dossier for an MRL setting is now publicly available (link) but we fail to see any measure preventing a direct access without agreeing to EFSA's terms and conditions, validating a disclaimer or logging in like for other activities on EFSA webpage. **We would call for urgent consideration of any safeguards that could ensure the proper application of the Transparency Regulation principles while protecting published information from any misuse.**

Improving the efficiency of the process of a.s. approval / renewal (A.12)

We would like to reiterate our wish to see a discussion taking place between the European Commission, Member States authorities, EFSA and applicants on how to address the pending issues of delays and assessment capacities in Europe. Similarly to what was done back in 2015 with the workshop in Dublin which notably led to the updated mutual recognition and renewal of authorisations guidance documents we believe a dedicated event could follow up on the REFIT report recommendations and identify possible new common solutions to ensure the EU pesticide regulatory system is improved and further contributes to the objectives of the Green Deal and the Farm to Fork policy.

Yours sincerely

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cc. Karin Nienstedt
Manuela Tiramani
Bénédicte Vagenende

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