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CropLife Europe input for SCOPAFF meeting 5-6 July 2021

- **Guidance Documents**
- **Improving the efficiency of the process of a.s. approval / renewal**
- **Safeners and Synergists**
- **Use of the IUCLID new data format and upcoming renewal dossiers**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 5-6 July 2021, CropLife Europe would like to provide input on several issues:

Guidance Documents (A.07)

CropLife Europe would like to emphasize the importance of consulting all stakeholders on draft guidance documents due the important consequences they may have on regulatory assessments and processes. On the other end we would like to highlight the need for all authorities **to respect the implementation date set for new guidance documents when noted in the Standing Committee** and avoid requesting from applicants to do preemptive use of non-noted documents. Guidance documents applicable are the ones available at the time of submission.

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

We would like to reiterate our wish to see a discussion take 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. This exercise could follow up on the REFIT report recommendations and identify possible 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.

Safeners and Synergists (A.14)

In the context of the ongoing Commission work on a regulation establishing a framework for the gradual review of synergists and safeners on the EU market, we believe several regulatory considerations need to be taken into account:

- Safeners have been part of evaluated and authorised formulations on the EU market for several years now, their function in plant protection products is to eliminate or reduce phytotoxic effects, mainly from herbicides. While they are very different from active substances, we believe an adapted and smooth EU regulatory process should be implemented to **ensure continuity in the availability of products already assessed and available on some Member States markets.**
- **CropLife Europe supports considering safeners as new substances** under a new EU framework. These new applications can be attached to a specific work programme considering Member States workload already at a very high resource level. We would

encourage that the extra workload due to evaluation of safeners should be spread over time.

- CropLife Europe supports that **safeners should be aligned with the approval periods currently in place for basic substances.** Any subsequent need for review of safeners due to new data requirements or guidance could be covered by the existing provisions that allow for an active review to be conducted when deemed necessary. This would prevent further pressure on renewal programmes for Member States while maintaining valid endpoints for the safener in relation to the data requirements for use in plant Protection Products authorisations at the Member State level.
- First applications under such a new work programme for safeners should only take place **at least 5 years after the process and the data requirements are clearly set and communicated** to all potential applicants. Appropriate transition period would be required to allow to conduct substantial data generation to address the most recent standards and requirements (refer to below section on Relevant data requirements). **Similarly, the beginning of study notification into EFSA database for safeners should only start when the regime is clearly defined.**

Use of ICULID as new data format and upcoming renewal dossiers

CropLife Europe would like to reiterate its concerns about having a rushed implementation of the IUCLID data format for regulatory purposes[1]. While we support the general uptake of this new format, we see in practice many technical and software issues. Several companies are preparing new active substances dossiers or renewal submissions due by end July. While the EFSA led HYPERCARE program with applicants helped to prepare, **we still see today unresolved issues which will have consequences on the first cases to go through the process**:

- Settings in IUCLID regarding size of dossiers and size of attachments seem to be insufficient for renewal dossiers, creating issues during export and upload into IUCLID as experienced by first submitters already. As the reasons for that are largely unclear, it is impossible for applicants to prepare accordingly and eventually upload of Dossiers in time will be under scrutiny. We therefore recommend a guideline is urgently prepared for applicants and RMS alike how to handle the situation avoiding any legal clarification needs for not meeting a deadline due to insufficient submission technologies.
- IUCLID allows to mark items as potential Confidential Business Information not to be disclosed while the evaluation of confidentiality claims is ongoing by the RMS and EFSA. However, the latest software version recommended for use shows that, in practice, there is a very real risk that some items would still end up being made public regardless of any pending decision on the confidentiality claim. These bugs are being actively discussed with EFSA and need to be resolved as soon as possible in order to avoid unwanted and unauthorised public disclosure of protected information (e.g. composition information or name of a vertebrate study author) and legal consequences. To be clear, any release of confidential information due to such “technical issues” cannot be considered within the terms of the new transparency regime and could expose EFSA and the Commission to significant legal liability. Where members choose to file applications while these issues remain unresolved, we trust that EFSA will be taking all necessary steps to avoid inadvertent release (including, if necessary, delay of publication until manually checked).

The required level of administrative work relating to the justification of confidentiality claims is increasing drastically compared to the previous regime. We understand this development and are ready to assist, including by providing more information. Nevertheless, the IUCLID implementation forces applicants to provide specific justifications for almost every line or paragraph of a given document, often repetitively and without an organised format for submission or review. This process is extremely tedious for applicants and will also create

[1] CropLife Europe letter on the Transparency Regulation implementation status 05 March 2021

resource intensive work for the authority. **We would call for further flexibility in the provision of these claims, in line with the letter of EFSA's own Practical Arrangement document**[2].

We remain concerned that given the immense volume of work, the review of confidentiality claims by different staff at EFSA may not be consistent or transparent, leading to different decisions for similar materials. We would welcome the opportunity to engage with any internal guidance being created.

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/

[2] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-confidentiality-Artt-7-and-16-of-regulation-1107-2009.pdf