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CropLife Europe input for SCOPAFF meeting 25-26 January 2021

- **Transparency and access to documents to be noted in SCoPAFF meetings**
- **Amendment to the General Food Law and its implementation**

Dear SCOPAFF members,

Since the 6th of January, the European Crop Protection Association (ECPA) operates as CropLife Europe, expanding its mandate to include digital and precision farming, plant biotech innovation and biopesticides alongside conventional pesticides.

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 25-26 January 2021, CropLife Europe would like to provide input on several issues:

Transparency and access to documents discussed within the Standing Committee

CropLife Europe would like to highlight the need to get access to documents which are planned for noting in the Standing Committee meeting. This is especially important for Guidance Documents applicants need to understand and prepare internally for, should the document be noted or not in the end. We acknowledge that some documents might need last minutes changes due to discussions or feedback from Member States. Nevertheless, documents could already be shared openly on the comitology register with a clear indication of their draft nature and non-applicability to regulatory processes yet. Similarly, should a guidance document be noted a rapid communication to all potential applicants (e.g. via DG SANTE webpage) of its implementation date is important.

We would demand a timely publication on the comitology register of all documents listed on the SCoPAFF agendas for possible noting.

New Transparency rules: General Food Law amendment and implementation

The 27th March is approaching rapidly and while applicants received numerous information from DG SANTE and EFSA on the implementation of the revised general food law regulation, we still face a critical lack of responses on important questions - especially on 2021 processes and MRLs. The recently published EFSA Practical Arrangement documents are also not providing answers to all our raised questions.

We would ask for a specific dialogue between all actors of the Plant Protection Product Active Substances approval system so as to clarify as much as possible the future processes. This can take place in a forum involving DG SANTE, EFSA and all associations representing applicants in the EU.

Study notification is an important new process, and **we request the possibility to consult the database before it goes live** (e.g. a beta testing version), so that applicants can determine the work involved to complete these notifications.

We would appreciate clarifications on whether our understanding (described below) on how the future MRL submission process will look like, is correct. We note that these questions were

transferred to EFSA, by DG SANTE, but we have not received any answer; yet the procedure timelines are still maintained for the 27th of March.

- The revised GFL foresees a public consultation after the submission, i.e. the MRL submission, the admissibility check and the publication of a sanitized dossier. Such a public consultation is not part of the Regulation 396/2005. How and when will this happen? How long will these consultations take? Will they increase the overall MRL setting timelines?
- The practical arrangement on pre-submission advice is foreseeing that, studies resulting in MRL submissions must be included in the EFSA notification data base.
    - Studies must be notified before start: this is clear in the case of a new substance approval, or for the renewal process. This task can be done for EU MRLs if products are applied to new crops or according to more critical GAPs..
    - Situation is more complex regarding the development of **new formulations or import tolerances**. We would appreciate any clarification on the process to follow in the following cases:
        - Product submissions are not concerned by the revised GFL; the related studies will not be entered into the EFSA database. However if unexpectedly the conduct of studies result in higher residues, the need of a modification to a higher MRL could raise. How and when the studies should be notified?
        - For import tolerances, frequently the studies are performed for local registrations in exporting countries and are used for the IT submissions into EU, later if needed. They are also not part of the revised GFL. Frequently, it is unknown whether these studies will be needed for an IT submission in the EU, before the results are there (as the need to submit for EU import tolerances depends on two criteria: when significant trade occurs and if residues exceed the level of 0.01 mg/kg).
- MRLs and import tolerances are in full scope of the EFSA / ECHA plans for IUCLID pesticide submissions. During the IUCLID testing phase, we realized that MRL applications can be entered as submission type if an active substance approval is submitted. The situation is different if MRLs are related to product submissions (draft Registration Reports) for the active substances that are already registered or being currently under evaluation (e.g. new active substances, AIR3 or AIR 4). What should the process be? We'd like to avoid duplication of efforts caused by the preparation of an IUCLID dossier and the draft Registration Reports for the zonal submissions.
- **Given the IUCLID pilot exercise and expected training, we would estimate extremely limited the time to adapt for a full implementation for MRL submissions as from March 27th 2021.**

We would welcome a more detailed discussion on these issues. If you have any questions regarding CropLife Europe views, please do not hesitate to contact me.

Yours sincerely

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cc. Karin Nienstedt
Almut Bitterhof
Manuela Tiramani

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