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ECPA input for SCOPAFF meeting - 20-21 May 2019

- **EFSA bee guidance document and update of Uniform Principles**
- **Endocrine disruptors**
- **Amendment to General Food Law**
- **Annex III of Regulation 1107/2009 (unacceptable co-formulants)**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 20-21 May 2019, ECPA would like to provide our input on several critical issues on the agenda:

EFSA guidance document on the risk assessment of plant protection products on bees (Agenda item A.08.1 and C.01)

ECPA is supportive of a robust pollinator risk assessment, and welcomes the Commission mandate to EFSA to update the document to take into account new scientific elements available since 2012.

However, we continue to be of the opinion that the EFSA 2013 document should not be implemented, even partially. We believe that the elements suggested by the Commission as ready for implementation require substantial work before being applicable. This is especially the case for the **field-testing requirements, which are unrealistic and lead to the rejection of all field and other higher tier studies**.

We would therefore request the Commission and Member States to reconsider the implementation plan and avoid legislative changes (adaptation of the Uniform Principles) when the proposed changes are not based on the most recent knowledge.

ECPA work on practical solutions to update the risk assessment is continuing[1] and reports and interim findings are being presented in scientific forums, including the IUPAC and SETAC conferences in May 2019. We will continue to suggest practical solutions to ensure that a protective and workable assessment scheme can be agreed, and we welcome EFSA's approach to invite all stakeholders to engage in such a discussion.

[1] See ECPA letter to the European Commission and SCOPAFF members dated 17 October 2018.

Defining Specific Protection Goals for environmental risk assessment (Agenda item A.09)

ECPA welcomes the process initiated by the European Commission to establish specific protection goals for environmental risk assessment. While risk managers will have the task to set the protection level applicable in guidance documents, we will contribute our technical expertise to the planned workshops and provide our views on the importance of selecting appropriate protection goals and clearly understanding their practical consequences; being on the environment, the availability of crop protection solutions or EU agriculture.

Endocrine disruptors (ED) (Agenda item A.22)

We recognise the complexity of applying the ED criteria to both new and pending active substance evaluations. We would reiterate our request that Applicants be kept informed of when ED assessments are expected to be completed for their respective substances and when final regulatory decisions are anticipated.

Amendment to General Food Law (Agenda item A.26)

We understand that the final Commission proposal to amend the General Food Law (GFL) and associated sectorial legislation is likely to be published during the course of the summer period. We have consistently supported the provisions aimed at strengthening consumer confidence in the current risk assessment process. Those elements intended to improve transparency are consistent with the crop protection's own global commitment made in March 2018 to make safety-related studies publicly available[2].

The proposal will entail key changes to the current process for the evaluation of active substance under Reg 1107/2009 and Reg 844/2012 (renewals). The provisions related to pre-submission advice, the notification of studies and the public consultation on the list of intended studies (renewals) will all be required prior to dossier submission and will require close and earlier coordination between EFSA and the RMS (and co-RMS).

The procedures employed for making studies public will also be critical for ensuring the correct balance between increasing transparency and protecting from commercial misuse the small part of the dossier which contains legitimate confidential business information. The European Medicines Agency (EMA) already has an established system for making clinical trial information available[3] and which provides a useful template.

Given the significant changes that the GFL proposal will entail in the evaluation procedures, we would request that industry be kept regularly informed and consulted during the course of establishing and applying these provisions.

Annex III of Regulation 1107/2009 (unacceptable co-formulants) (Agenda item C.02)

We understand that the draft Commission regulation modifying Annex III of Regulation 1107/2009 (unacceptable co-formulants) is likely to be placed for public commenting soon after the SCOPAFF meeting. While we welcome this opportunity to provide our input, in advance of the discussion during the SCOPAFF meeting, we would like to highlight the following key issues

- An adequate transition time for reformulation of any impacted formulations must be provided, acknowledging that using hazard based cut-off criteria does not equate to a risk with using these co-formulants.
- ECPA has consistently requested a transparent and consistent process for the identification of unacceptable co-formulants for addition to Annex III. If hazard based cut-off criteria are used for identification purposes, it is essential that only harmonised classifications which have been agreed by the relevant competent authority and have been adopted at the European level, are used, i.e. via ECHA and the CLH process.

[2] https://www.ecpa.eu/industry-data-transparency
[3] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication ; https://clinicaldata.ema.europa.eu/web/cdp/home

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

Yours sincerely

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cc. Karin Nienstedt

To ensure full transparency, this letter will published on the ECPA website and will be available at: http://www.ecpa.eu/transparency-policy.