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ECPA input for SCOPAFF meeting - 16-17 July 2019

- **EFSA bee guidance document and update of Uniform Principles**
- **Defining specific protection goals**
- **Amendment to General Food Law, new transparency rules**
- **Annex III of Regulation 1107/2009 (unacceptable co-formulants)**
- **Recast of Drinking Water Directive – concerns with Council General Approach**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 16-17 July 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 B.07)

ECPA is supportive of a robust pollinator risk assessment, and welcomes the Commission mandate to EFSA to update the guidance document to take into account new scientific elements available since 2012. ECPA work on practical options to update the risk assessment is continuing. An updated table listing reports and interim findings is available in an annex to this letter (Attachment 1). We will continue to suggest practical solutions for a protective and workable assessment scheme, and we welcome EFSA's approach to invite all stakeholders to engage in such a discussion.

However, we continue to be of the opinion that the EFSA 2013 guidance 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.

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

ECPA welcomes the process initiated by the Commission to establish specific protection goals for environmental risk assessment. While risk managers will ultimately be responsible for deciding on the level of protection 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. We believe it is essential to clearly understand the

practical consequences of selecting protection goals for environmental risk assessment; being for the environment, the availability of crop protection solutions or EU agriculture.

Amendment to General Food Law, new transparency rules (Agenda item A.23)

We understand that the final Commission proposal to amend the General Food Law (GFL) and associated sectorial legislation is likely to be published shortly after the summer holiday period. We have consistently supported the provisions aimed at strengthening consumer confidence in the risk assessment process and 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[1].

The proposal will entail key changes to the current process for the evaluation of active substance under Regulation 1107/2009 and Regulation 844/2012 (renewals). In particular, we would highlight the processes related to pre-submission advice[2], the notification of studies to the database of studies to be established by EFSA[3], and the submission of the list of intended studies (renewals) and the subsequent public consultation on this list[4]. All these processes must take place prior to dossier submission and additional time will need to be planned for by the Applicant, EFSA and RMS alike to allow these steps to take place. With the anticipated official application date being March or April 2021 we would highlight the complexity of implementing these new procedures to submissions under the current AIR4 and AIR5 renewal programmes both of which will be ongoing at this time period. We would also highlight the urgent need for early clarity on the designation of RMS for the AIR6 renewal programme. This is essential to allow Applicants to start to prepare their dossiers and to allow sufficient time for the above mentioned new GFL procedures to take place prior to submission.

The procedures employed for making studies public[5] 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[6] and which provides a useful template.

Given the significant changes that the GFL proposal will entail in the evaluation procedures, we would request that there be sufficient opportunities for industry to 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.01)

We understand that the draft Commission regulation modifying Annex III of Regulation 1107/2009 (unacceptable co-formulants) maybe 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 reiterate 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.

[1] https://www.ecpa.eu/industry-data-transparency
[2] Article 32a of Commission proposal 2018/0088(COD)
[3] Article 32b of Commission proposal 2018/0088(COD)
[4] Article 32c of Commission proposal 2018/0088(COD)
[5] Article 38 of Commission proposal 2018/0088(COD)
[6] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication ; https://clinicaldata.ema.europa.eu/web/cdp/home

Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances (Agenda item C.02)

We support the proposal to align the active substance authorisation process under Regulation 1107/2009 with the harmonised classification of substances under Regulation 1272/2008. We are hopeful that urgent progress can be made allowing the amending regulation to Regulation 844/2012 to be agreed and adopted.

We would highlight our position that regulatory decisions based on the cut-off criteria laid out under points 3.6.2, 3.6.3 and 3.6.4 of Annex II to Regulation 1107/2009 should be based on a harmonised classification prepared by ECHA according to Regulation 1272/2008 and not on recommended classifications proposed by EFSA.

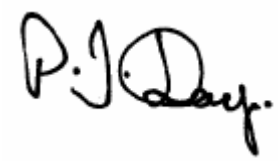
Commission proposal for a recast of Directive on the quality of water intended for human consumption (Drinking Water Directive)

While not included in the agenda of this SCOPAFF meeting, we would take this opportunity to reiterate our concerns with some of the changes which have been introduced into the Council's General Approach on the Commission proposal[7] for a recast of the Directive on the quality of water intended for human consumption (Drinking Water Directive[8]). The General Approach adopted by the Environment Council on 5 March 2019 includes some concerning amended text on the identification of pesticide relevant metabolites in Annex 1 – Part B – Chemical Parameters - Pesticides.

The amendments, if adopted, would introduce an unnecessary and ambiguous definition of "relevant metabolites" which would be incoherent with the current text of Regulation 1107/2009 and existing Commission guidance documents (e.g. guidance document SANCO/221/2000). The proposed amendments and our concerns are explained in more detail in the attached updated position paper (Attachment 2). We understand that the trialogue negotiations are expected to commence after the summer break under the term of the new Commission. We would urge the institutions to maintain the wording in the original Commission proposal, which is also reflected in the current position of the European Parliament.

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



Peter Day
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cc. Karin Nienstedt

Attachments:

Attachment 1 - Bee guidance document - Research and data analysis initiated by ECPA (9 July 2019)
Attachment 2 – ECPA Position Paper on recast of Drinking Water Quality Directive (updated)

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

[7] COM(2017) 753 final
[8] Directive 98/83/EC