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ECPA input for SCOPAFF phytopharmaceuticals-legislation meeting, 23-24 October 2018

- **EFSA bee guidance document and update of Uniform Principles**
- **Endocrine disruptors**
- **Harmonised risk indicators**
- **Amending regulation for submission of CLH dossier**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 23-24 October 2018, ECPA would like to provide input on several critical issues. Reference is made to the meeting agenda item where relevant:

EFSA guidance document on the risk assessment of plant protection products on bees (Agenda item A.08.2 and C.02)

ECPA is supportive of a robust pollinator risk assessment, however we continue to request a significant revision of the proposed EFSA guidance document before any type of implementation. We believe that even the parts suggested by the Commission as ready for use are far from being fit for purpose. This is demonstrated by reviewing the results of all EFSA conclusions on bees prepared since January 2016 (see Attachment 1). The compilation illustrates that for **nearly all substances (being conventional or natural based pesticides) data gaps are identified in the risk assessment and/or no risk assessment conclusion could be completed by EFSA.**

Having a document which fails to properly discriminate between substances in a tiered approach is not workable and will only lead to inadequate risk management decisions and to increasing challenges for Member States in product authorisations at national level. We have previously raised our concerns especially in relation to the conservatism of the proposed honey bee **chronic** trigger value (which grossly overestimates risk¹), and to the lack of acceptable higher tier options. **We do not share the views of EFSA that the proposed higher tier risk assessment options (tier 2 studies and semi-field/field studies) permit refinements to the risk assessment once a substance has failed the first tier of the process.**

Since the EFSA guidance document was drafted in 2012, academia, industry and regulators have gained significant additional knowledge regarding pollinator risk assessment and we

¹ In a ECPA analysis of 10 day honey bee chronic studies it was observed that the EFSA trigger would meet the SPG <7% only 3 times out of 133 studies. This means that for 98% of substances the trigger of 0.03 would overestimate the risk.

believe this should be taken into account in revising the document and preparing an up-to-date, protective, realistic and workable document. As an example, a list of research and data analysis initiated by ECPA is available in Attachment 2 to this letter. We would therefore request the Commission and Member States to:

- **Engage in an EU level discussion with risk assessors and risk managers with the aim of revising the EFSA guidance document before its implementation and adoption.**
- **Avoid legislative changes (adaptation of the Uniform Principles) when the proposed trigger values remain questionable, are not based on the most recent knowledge and lead to unfeasible additional data requests.**

Endocrine disruptors (ED) (Agenda item A.22, B.01)

A.22: We remained highly concerned that with the final ED criteria combined with the text of the EFSA-ECHA guidance document, a significant number of currently approved substances will be considered to have endocrine disrupting properties, and are likely to be unnecessarily removed from the market. This will lead to a further loss of crop protection solutions for EU farmers without providing any demonstratable benefits in the protection of human health and the environment. Consequently, we are pleased that the proposed amendment in points 3.6.5 and 3.8.2, Annex II, Regulation 1107/2009 has been placed on the SCOPAFF agenda for discussion, following the commitment given to Member States. We believe this amendment is the only remaining option by which to make the ED criteria more workable and proportionate and to avoid further threatening the availability of products for growers and the competitiveness of EU agriculture. **We would therefore encourage all Member States to support the adoption of this draft regulation.**

B.01: We are supportive of the principle of preparing a regulation to amend Regulation 844/2012 to allow for additional data to be submitted for pending substances where considered necessary to reach regulatory decisions against the ED criteria. We have submitted our comments on the proposal via the Commission's feedback mechanism, and these are attached for reference. Overall, we would request that the regulation provide a workable and predictable procedure for managing this process. We would also highlight the need for applicants to be consulted in deciding on what additional information, if any, maybe required and the timeframe by which that information should be submitted. The complexity of each requested study and the global capacity of laboratories to perform these tests should be taken into account when setting the appropriate timeframes for submission.

EFSA-ECHA technical guidance document: While not on the agenda for the 23-24 October SCOPAFF meeting, we would reiterate the significant concerns we have regarding this guidance document. We have communicated our concerns ahead of previous SCOPAFF meetings, and these are described in more detail in the attached position paper. We would welcome an opportunity to review the workability of the guidance document with EFSA and Member States after an appropriate period of experience has been gained in applying the document.

Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators (Agenda item C.01)

We question the Commission proposal on the hazard-based harmonised risk indicator under the Sustainable Use Directive (Directive 2009/128) which we understand is based on sales statistics. It does not reflect the safety of the uses that would comply with the regulation, i.e. it needs to be read with complementary information: likelihood of exposure, actual conditions of use, and where required, specific risk mitigation measures in place, uptake of good agricultural practices, dosages, etc. Moreover, the proposed arbitrary based weighting factors of different categories of plant protection products do not support the purpose of calculating the relative risk of using these, but are undermining the regulatory risk assessment procedures behind.

We support the use of easy-to-measure, implementation-based risk indicators. We are convinced that indicators with existing available data (e.g. in the area of water or residue monitoring) should already be included in the proposal. Only indicators requiring further work

in collecting and establishing information collection systems should be scheduled for a second phase. This phase should be clearly indicated as an outstanding amendment to be added to the Directive within a given timeframe.

Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances (Agenda item A.26.2)

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 reiterate 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.

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

Yours sincerely



Peter Day
Director Regulatory Affairs

cc. Karin Nienstedt

Attachments:

- (1) Excel file with compilation of EFSA conclusions on bees published since 1 January 2016
- (2) Research and data analysis initiated by ECPA to provide workable options to review and refine the EFSA guidance document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) – dated 3 October 2018
- (3) ECETOC, CEFIC, ECPA comments on the *Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 prepared by EFSA and ECHA* – dated 5 July 2018
- (4) ECPA comments on Commission Implementing Regulation amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 – dated 12 October 2018