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Dr Klaus Berend
Head of Unit E.4 - Pesticides and Biocides
DG Sante
European Commission
1049 Brussels
klaus.berend@ec.europa.eu

Peter Day
Director Regulatory Affairs
(+32) 2 663 76 01
peter.day@ecpa.eu

ECPA input for SCOPAFF meeting on 19-20 July 2018:
- **EFSA bee guidance document**
- **Endocrine disruptors**
- **Amending regulation for submission of CLH dossier**
- **Harmonised risk indicators**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 19-20 July 2018, ECPA would like to provide input on certain 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.08.3)

ECPA is supportive of a robust pollinator risk assessment, however we maintain that a significant revision of the draft EFSA guidance document is required to establish a practicable and consistent approach. Since EFSA started to use the current guidance in January 2016 to develop conclusions on active substance evaluations we have observed the practical consequences of this overly conservative document (see chart below and the enclosed Excel file compiling the EFSA bee conclusions published since 1 January 2016). The overview illustrates that for **nearly all conclusions (for conventional as well as non-conventional pesticides) data gaps are identified in the risk assessment,** a situation which does not adequately support risk management decisions.

We have previously raised our concerns especially in relation to the conservatism of the proposed honey bee chronic trigger value (which grossly overestimates risk), and to the lack of acceptable higher tier refinement options with nearly all studies submitted since 2016 being invalidated. Academia, Industry and regulators have gained significantly more knowledge on pollinator risk assessment since the EFSA document was drafted in 2012 and we believe it is now time to move forward towards a protective, realistic and applicable document taking into account these new developments

We would urge the Commission and Member States to engage in an EU level discussion with risk assessors and risk managers to explore possible ways forward, taking in to account new technical/scientific developments. We believe that practical solutions could be jointly assessed in a technical discussion with Member States and EFSA in order to develop a workable, protective and adequately calibrated risk assessment system for pollinators.

Endocrine disruptors (ED) (Agenda item A.18.1, A.18.2, C.11)

A.18.1: We support the concept of a technical guidance document to assist the application of the ED criteria. Such guidance is essential to provide applicants and regulatory authorities with a clear framework and for ensuring consistency in the decision making process. While we acknowledge the significant amount of work undertaken by EFSA and ECHA to develop the final guidance, we still have a number of significant concerns regarding this document. Our concerns are described in more detail in the attached position paper.

We would also highlight the confusion being caused by the fact that the guidance is already being applied, but has not yet been noted in SCOPAFF. Urgent clarity is therefore required on the process and timelines for applying the guidance document against the ED criteria.

A.18.2: Following the commitment given to Member States in early 2017 to revisit the proposed amendment in points 3.6.5 and 3.8.2, Annex II, Reg 1107/2009, we are pleased that this proposal has been placed back on the SCOPAFF agenda for discussion.

In general we do not support the principle of regulation by derogation, as it does not provide the predictability needed for business to operate, and in particular for farmers to plan effectively for the future. However, given that this is the only route by which to make the ED criteria more workable, proportionate and science-based, and to avoid threatening the availability of products for farmers and the competitiveness of EU agriculture, **we support the adoption of this draft regulation, and encourage Member States to strongly support it.**

C.11: We are supportive of the proposal to prepare a regulation to amend Reg 844/2012 to allow for additional data to be submitted where considered necessary to reach regulatory decisions against the ED criteria. We would request that the regulation provide a workable and predictable procedure for managing this process and that this can be agreed and made available to applicants as soon as possible. As mentioned above, **we urgently require clarity on how the process for applying the ED criteria will be implemented in practice** leading up to and after 10 November 2018. In particular, for substances already in the renewal process, what will be the process for deciding if and what additional studies are required? We would also highlight that the complexity of any individual studies required and the global capacity of laboratories to perform these should be taken into account when setting the timeframes for the data to be submitted.

Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances (Agenda item A.21.2)

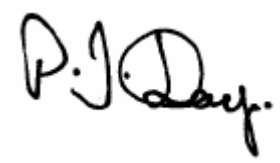
We support the proposal to align the active substance authorisation process under Reg 1107/2009 and the harmonised classification of substances under Reg 1272/2008. We would request that progress be made urgently allowing the amending regulation to Reg 844/2012 to be agreed and adopted. ECPA member companies are willing to support Member State authorities in the process of the development and submission of CLH dossiers.

Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators (Agenda item C.14)

We question whether the Commission proposal on Harmonized Risk Indicators under the Sustainable Use Directive (Dir 2009/128) as presented to Member States, will provide a reliable indication of the potential risk arising from PPP use in Europe. We support the use of easy-to-measure, implementation-based risk indicators. We believe indicators with existing available data (e.g. in the area of water or residue monitoring) should already be included in phase one of the proposal. Only indicators requiring further work in collecting and establishing information collection systems should be scheduled for a second phase.

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

Attached:
(1) Excel file compilation of EFSA conclusions on bees published since 1 January 2016
(2) ECETOC, CEFIC, ECPA comments on 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*