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Members of SCoPAFF - Phytopharmaceuticals

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ECPA input for SCoPAFF meeting on 23-24 January:
- **Endocrine disruption**
- **Bee Guidance document**
- **Co-formulants**

Dear Dr Flüh
Dear SCoPAFF members

Ahead of the SCoPAFF-phytopharmaceuticals of 23-24 January, ECPA would like to take this opportunity to provide our input on a number of current issues. Reference is made to the meeting agenda item where relevant:

Criteria for endocrine disrupting properties (Agenda item A.18)

In the revised Commission proposal presented ahead of the SCOPAFF meeting on 21 December 2016, two separate acts were put forward, with one covering the criteria and one on the amendment to the derogation provided in Regulation 1107/2009. We fail to understand the rationale for separating the proposal in this way. This decision only brings more uncertainty and a lack of predictability to this process. **Setting aside our significant concerns with the proposed criteria, ECPA believes that the two draft acts must be managed as a combined package of the criteria together with the amendment to the derogation.** The changes to the derogation are an integral part of the proposal and essential to ensure coherence across EU chemicals legislation.

We note that the draft criteria themselves have not substantially changed and we would reiterate our serious concerns as stated in our previous letters of 30 September 2016 and 10 November 2016. For decision making, regulators should be provided with the necessary tools to clearly separate those substances which have the real potential to cause harm, from those that do not. To do this, the criteria should incorporate all elements of hazard characterisation, including potency.

We strongly urge the Commission together with Member States to amend the proposed criteria to take our concerns into account and to manage the proposal as a combined package of the criteria with the amendment to the derogation.

Bee guidance document (Agenda item A.16)

ECPA is supportive of a revision of the pollinator risk assessment. However, we still fail to see how the outdated document from 2013 will ensure appropriate risk assessment for pollinators and allow risk managers to take robust decisions.

We continue to be of the opinion that the current guidance is unworkable and would mean that insecticides will no longer be registerable in Europe, and most herbicides, fungicides

with no inherent bee toxicity will fail the first-tier laboratory risk assessment and trigger the need for follow higher-tier assessments up semi-field and field studies despite the fact that the EFSA Bee Guidance specifications for such studies cannot be met.

The unilateral use by EFSA of this document for more than one year now, reveals the practical consequences, with nearly all EFSA risk assessment conclusions highlighting risks and data gaps. Recent state of the art data packages, generated to provide confirmatory data for 3 neonicotinoid insecticides on crops that are not even attractive to bees, also failed to comply with this document. Impossible and unrealistic protection goals result in the whole document being based on incorrect and extremely conservative assumptions. It also creates unnecessary complexity for many substances that can only be addressed at Member State level.

ECPA will continue to ask that the Commission, EFSA and Member States:

- **Do not adopt the guidance document** as it currently stands, on the basis that it is not fit for purpose;
- **Reject the proposed legislative changes** when the proposed trigger values remain questionable and are not based on the most recent scientific knowledge;
- Carry out a **transparent assessment of the impact** of the proposed measures before taking a final decision;
- **Review the progress gained in science and knowledge** over the last 3 years, before implementing this document and associated measures currently under discussion, which will lead to disproportionate regulatory decisions and additional data requests that are not feasible.
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We would welcome the opportunity to engage in a technical discussion with risk assessors and risk managers so that solutions to some of the practical issues could be further explored.

Further information in the Zip file annex – EFSA conclusions published in 2016 and using the EFSA Bee Guidance Document

Co-formulants

Given the potential for the duplication of work in the evaluation of co-formulants, and the impact of the suggested triggers which could potentially restrict many commonly used co-formulants, **ECPA believes that an impact assessment is required to ensure a full understanding of the implications**. Our aim is to ensure a streamlined process that avoids the duplication of effort - in line with the broader principles of Better Regulation.

Further information in the Zip file annex – ECPA overview letter (doc.no.26056), and ECPA input to consultation (doc.no.26144). Also, please see separate published paper at https://www.ncbi.nlm.nih.gov/pubmed/27411735

To ensure transparency, this letter is being published on the ECPA website and will be available at: http://www.ecpa.eu/transparency-policy. We would welcome a more detailed discussion with DG SANTE on these issues. If you have any questions about ECPA's views, please do not hesitate to contact me.

Yours sincerely

Euros Jones
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