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

Euros Jones
Director Regulatory Affairs
(+32) 2 663 15 53
euros.jones@ecpa.eu

ECPA input for SCoPAFF meeting on 12-13 December:
- **Endocrine disruptors**
- **Neonicotinoids**

Dear Dr Berend

Ahead of the SCoPAFF-phytopharmaceutical meeting of 12-13 December, ECPA would like to provide input on two issues. Reference is made to the relevant meeting agenda item:

Criteria for endocrine disrupting properties (Agenda item B.14)

We note that the draft criteria put forward for possible Committee opinion are largely the same as those agreed during the SCOPAFF meeting on 4 July 2017. We would reiterate our previous concerns, that the criteria will not allow authorities to clearly separate those substances that have the real potential to cause harm from those that do not. This cannot be achieved without incorporating elements of hazard characterisation. We would also highlight the growing inconsistency in the approaches to managing ED properties that is now apparent between Reg 528/2012 for biocides and Reg 1107/2009 for PPPs, especially around the derogations. We would urge the Commission to re-table a discussion on the amendment to the derogation for PPPs (shift to negligible risk) and to promptly come forward with a proposal for this essential modification.

In relation to the EFSA/ECHA technical guidance document, we believe such guidance is essential to provide applicants and regulatory authorities with a clear framework as to how evaluations against the criteria should be undertaken, and for ensuring consistency in the decision making process. Our key expectation is that the final document must accurately reflect the legislative text and intent of the Commission's proposal for the criteria. In particular, substances should only be considered as having endocrine disrupting properties where the weight of scientific evidence clearly shows that all three elements of the WHO/IPCS (2002) definition are met.

We would also reiterate our significant concerns with the interim criteria. These criteria are widely recognised as not fit for purpose nor suitable for regulatory decision-making.

Neonicotinoids (Agenda items B.08, B.09, B.10)

It is ECPA's view that disproportionate restrictions are being proposed on the use of the 3 substances, Imidacloprid, Clothianidin and Thiamethoxam; **and we would urge Member States to vote against the Commission's proposals**. The proposal to further restrict these

substances to uses under permanent greenhouses fails to make a full risk analysis, being based on the un-approved EFSA bee guidance document and identifying theoretical risks, without due considerations of the EU context of bee health for which we know much more since the guidance document was published in 2013. Given that we are still waiting the report of EFSA - originally expected in February 2017 - and the outcome of separate court cases on the legality of the current partial restrictions, it would seem premature for a vote at this point without the complete scientific and legal picture, as well as being in contradiction with the Commission's own principles of Better Regulation.

It is unnecessary to further restrict uses on crops that are not attractive to bees, or on crops at stages where no flowers are even present. **A proper risk management discussion is needed to identify which of the theoretical risks identified are likely to happen under field conditions and need to be managed.** Such restrictions would put unnecessary additional pressure on European farmers, especially for those growing non-greenhouse crops such as sugar beet, potatoes, winter cereals or fruit and vegetables.

From recent experience, it is clear that with the continued use of the unapproved methodology in EFSA conclusions, a range of risks to bees will be identified for most insecticides, and a lot of herbicides and fungicides, including those used in organic agriculture. ECPA does not agree with a process whereby a proposal is based on an assessment built using an unapproved guidance document. We therefore ask SCoPAFF members **not adopt the proposals and ask the Commission to initiate a revision of the assessment methodology to consider scientific and technical developments, as well as knowledge on bee health, gathered in the last 5 years**.

We would of course 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

Euros Jones
Director, Regulatory Affairs

Cc: Members of SCoPAFF-phytopharmaeuticals

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