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Subject: Phased implementation of the EFSA Bee Guidance Document and proposal to amend the Uniform Principles regulation

Dear Dr 5.1.2.e Woo

I am writing to you regarding the EFSA Bee Guidance Document and the discussion that will take place during the July Standing Committee meeting and where the Commission will look to enact the use of the EFSA document and propose an amendment of the uniform principles despite the opposition of a majority of Member States.

ECPA is supportive of a revision of the existing pollinator risk assessment. New elements agreed by the scientific community needs to be adequately considered in the regulatory process. However, we still fail to see how this now outdated document from 2013 will ensure risks to pollinators are realistically evaluated.

We continue to be of the opinion that the document as currently drafted is unworkable in a regulatory context and if implemented, even partially, would lead almost all insecticides to fail the first tier laboratory risk assessment along with many herbicides and fungicides. The disproportionality of this document could even lead to a failure in the first tier for substances not toxic to bees and for those only used on crops that are not bee attractive.

- **We would ask that a proper calibration needs to be conducted as the tiered approach is meant to provide meaningful differentiation between compounds with high or low risk potential to bees:**

The only way for a substance to then pass the risk assessment would be through the conduct of semi-field and field studies. However, the Guidance Document requires them to be conducted on a scale which is totally unfeasible and without agreed scientific methodologies in place for undertaking them. A fact even confirmed by companies selling such testing services to applicants¹.

We know EFSA disagree with our analysis of the impact of the document. We already underlined the severe limitations of EFSA's own analysis² but we never received information on why or where our calculations would be incorrect and the impact overestimated. Our assumptions are now confirmed by most of the EFSA conclusions being published since January 2016³ where several risks cannot be excluded for bees and data gaps are identified in nearly all cases, as well as by revised analysis based on the data industry generated over the last two years.

¹ See the annex 2 to our previous letter from 10th May 2016.

² See our letter from 13 November 2013.

³ See Annex 1 with a compilation of information extracted from EFSA journals published in 2016.

- **Given the current status of the discussions on this issue, we would ask if the downstream consequences for Member States of using the document have been considered, especially regarding:**
- the volume of data that would need to be provided and the increase in resources that will be required from Member States to assess dossier submissions.
 - the impact in terms of decision making for product re-registration in the context of Article 43 of Regulation 1107/2009.
 - the impact on the quality of evaluations and decision making by risk managers.
 - the availability of solution for European Agriculture and the competitiveness of EU Farmers.

As industry, we would repeat our offer to engage in a technical discussion with risk assessors and risk managers so that solutions to practical issues could be jointly explored. This would be an opportunity to review the new scientific elements available since 2013 in order to get a fit for purpose and scientifically sound risk assessment scheme for pollinators. As an illustration, a first listing of these new scientific data and information is enclosed in an annex to this letter.

In respect of the principle of proportionality and the commitment for “Better Regulation” we would ask the Commission, EFSA and Member States to consider the following requests before adopting the guidance or making any legislative change:

- ***Review the progress in science and knowledge gained over the last 3 years, before the implementation of the measures currently under discussion, which lead to unfeasible additional data requests.***
- ***Use the most recent scientific knowledge to revise the questionable trigger values.***
- ***Carry out a transparent “ex-ante” assessment of the impact of the proposed measures.***

Should you have any questions please do not hesitate to contact me.

Yours sincerely

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