

LET/17/LO/28136  
16 June 2017

To: Klaus Berend  
DG SANTE, European Commission  
B-1049 Brussels  
[Klaus.Berend@ec.europa.eu](mailto:Klaus.Berend@ec.europa.eu)

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

**Subject: Review and update of the EFSA Bee Guidance Document**

Dear Dr Berend,

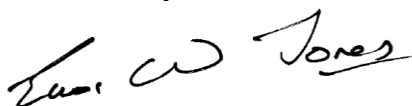
The implementation challenges posed by EFSA's Bee Guidance Document has resulted in significant scientific developments and discussions. Following on from these discussions, an updated approach has been developed by the crop protection industry which we believe to be both a protective and realistic way forward for bee risk assessment. We request that this approach be considered as part of a process to update the 2013 Bee Guidance Document.

We recognize the need to review the bee pollinator risk assessment based on scientific progress. The 2013 guidance document does not however provide an appropriate risk assessment process to allow risk managers to take robust decisions. We continue to be of the opinion that the guidance is unworkable, has an unrealistic level of conservatism resulting in a negative evaluation for most insecticides and a large number of other substances, without demonstrating a positive contribution to improved bee health.

Industry strongly believes that a revision of the assessment scheme for use by regulatory authorities is needed. Building on an analysis of the proposed developments by EFSA, we suggest an approach which we believe to be both proactive and practical. This approach is summarized in the document in annex. It provides a comparable level of protection to the EFSA approach and is based on the current scientific state of the art for bee pollinator risk assessment. Key features of this proposal are the focus on honey bees as a representative species, the definition of core data packages, concentration on main exposure routes and a proposal for more realistic assumptions for the risk assessment process.

We would welcome the opportunity to engage in a technical discussion with Member States experts and EFSA on this topic - in order to rapidly establish a workable and protective solution for the bee risk assessment. We would of course welcome the opportunity to have an initial discussion with you on this issue during our meeting on 7<sup>th</sup> July. Should you have any questions in the meantime, please do not hesitate to contact me.

Yours sincerely



Euros Jones

Cc: Ladislav Miko DG SANTE  
Sabine Juelicher DG SANTE  
Sofie Hofkens DG SANTE  
Jose Tarazona EFSA