

LET/17/PD/29004  
18 January 2018

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

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

**ECPA input for SCoPAFF meeting on 25-26 January 2018:**

- **Endocrine disruptors**
- **Glyphosate**

Dear SCoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical meeting on 25-26 January 2018, ECPA would like to provide input on some critical issues. Reference is made to the meeting agenda item where relevant:

**Endocrine disruptors (Agenda item A. 17)**

We note that following the vote which took place during the SCOPAFF meeting on 12-13 December 2017, the revised proposal for the ED criteria has been transferred back to the Council and Parliament for scrutiny. While the focus is currently on adopting the criteria we would take this opportunity to urge the Commission to re-table a discussion on the amendment to the derogation (shift to negligible risk) and to promptly come forward with a proposal for this essential modification. This proposal is critical to ensure a proportionate application of the criteria and to ensure coherence with the biocides regulation (Reg 528/2012), consistent with the principles of Better Regulation.

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 document must accurately reflect the legislative text and intent of the ED 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 underline our request that the guidance document be workable and fit for purpose to facilitate consistent regulatory decisions. We therefore support ongoing efforts to thoroughly test the guidance using a series of case studies and welcome the workshop with Member State authorities planned for 1-2 February 2018.

We note the agenda point on the implementation of the final criteria in the context of the renewal procedure. We support this discussion and the development of a clear process for how the criteria will be applied to substances already submitted for renewal. Clarity is especially needed on how the process will be managed for requesting additional studies considered necessary to complete an assessment and decision against the ED criteria.

**Glyphosate (Agenda item A. 21)**

We take note of the Commission's response to the European Citizens Initiative (ECI) on glyphosate and also the increasing societal demands for greater transparency in the risk assessment process. We are supportive of the Commission's initiative on "*Transparency and sustainability of the EU risk assessment model in the food chain*" as recently published on 22 December 2017. As an industry we are reflecting how these provisions could be put in place. It is important that we have a clear and collective understanding of what constitutes confidential business information (CBI). We will actively and constructively contribute to the forthcoming discussion on this initiative.

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

A handwritten signature in black ink, appearing to read 'P. J. Day'.

Peter Day  
Director Regulatory Affairs

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