

LET/16/PD/27156
15 December 2016

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Members of SCOPAFF-phytopharmaceuticals

Criteria for endocrine disrupting properties, SCOPAFF meeting 21 December 2016

Dear Dr Flüh
Dear SCOPAFF members

Ahead of the SCOPAFF-Phytopharmaceuticals meeting on 21 December 2016 focussed on the Commission's proposal for the criteria for endocrine disrupting properties, ECPA would like to take this opportunity to provide our views on this critical issue.

Revised proposal, December 2016

We fail to understand the Commission's rationale for separating the proposal and putting forward two draft acts, one covering the proposed criteria and one on the amendment to the current derogation provided in Regulation 1107/2009. Unfortunately, this decision brings even 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 with the criteria and the amendment to the derogation.**

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:

Absence of hazard characterisation and risk assessment

Under the criteria put forward many substances, which present little or no concern to human health or the environment will be unnecessarily identified as endocrine disruptors by using the WHO/IPCS definition alone (option 2). For decision making under Regulation 1107/2009, 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 be based on option 4, incorporating all the elements of hazard characterisation.

It remains our firm view that endocrine disruptors can and should be regulated like other substances and be subject to risk assessment considering both hazard and exposure. Moving away from this framework sets a precedent that neglects the consideration of all available and relevant information necessary to ensure the protection of human health and the environment.

Severe negative impact on agriculture, competitiveness and trade

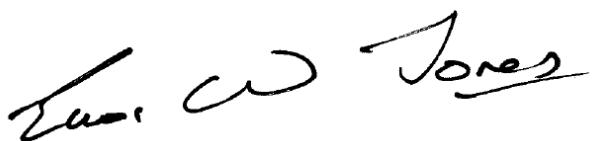
We would again highlight the conclusion of the Commission's Impact Assessment, that all policy options evaluated offer the same high level of protection for human health and the environment. However, the option chosen (option 2) will have the greatest negative impact on the availability of products for farmers, and the most severe and negative impact on sectorial competitiveness, agriculture and trade. We therefore question why this option has

been selected which appears to contradict Recital 8 of Regulation 1107/2009 and the Commission's own principles of Better Regulation.

Workable, proportionate and science based criteria

We strongly urge the Commission together with Member States to amend the proposal to take into account our concerns. We believe that the Commission should adopt workable, proportionate and science based criteria which ensure that regulators have the necessary tools to make informed decisions and which maintain the existing high levels of protection for human health and the environment, while also ensuring that European farmers have access to essential crop protection products.

Your sincerely

A handwritten signature in black ink, appearing to read "Euros Jones". The signature is written in a cursive style with a large initial "E" and a long horizontal stroke extending to the right.

Euros Jones
Director, Regulatory Affairs