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**To: Members of SCoPAFF-
phytopharmaceuticals**

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ECPA input for SCoPAFF meeting on 5-6 October:

- **Residue definition**
- **Endocrine disruptors**
- **Bee guidance document**
- **REFIT evaluation of Regulations 1107/2009 & 396/2005**
- **Import tolerances**
- **Glyphosate**

Dear SCoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical meeting of 5-6 October, ECPA would like to provide input on a number of issues. Reference is made to the meeting agenda item where relevant:

Residue definition (*Agenda item A.08.8*)

EFSA's guidance document for establishing the Residue Definition for Dietary Risk Assessment increases complexity of the evaluation process for deriving residue definitions, without increasing consumer protection. The scheme leads to more complex residue definitions, inconsistent with international systems. This will impact negatively on global harmonisation of MRLs and import tolerances, with a lower acceptance of Codex MRLs in the EU. We would also highlight our concern that the increased complexity will unnecessarily increase testing on vertebrate animals.

Given the significant refinements proposed in the guidance document, a testing phase is essential and should include the interpretation and application of the GD through jointly coordinated training with EFSA, MSs and industry to ensure a common understanding based on real examples. ECPA would be willing to provide concrete examples as a basis for any testing and training.

Further information in the Zip file enclosed– ECPA position on EFSA Guidance Document on the Residue Definition for Dietary Risk Assessment (doc.no.27774)

Endocrine disruptors (*Agenda item A.17*)

We recognise that the draft ED criteria are still within the Parliament and Council scrutiny phase. However, we would reiterate our request for the Commission to work with the Member States to urgently re-table the amendment to the derogation and to allow SCOPAFF members to formally vote on this proposal. This amendment is critical to allow a workable and scientifically defensible process for the regulation of substances considered to have endocrine disrupting properties as well as to ensure regulatory coherence and consistency with the Biocidal Products Regulation.

In relation to the EFSA/ECHA technical guidance document, ECPA supports the development of this document to facilitate the implementation of the ED criteria. This 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 and predictability in the decision making process.

While we acknowledge the complexity of the topic and that work is continuing by EFSA, ECHA and JRC, we would highlight our key expectation 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 evidence clearly shows that **all** three elements of the WHO/IPCS definition are met.

Bee guidance document

While ECPA is supportive of a revision of the pollinator risk assessment, we continue to believe a new way forward is needed. Earlier this year, ECPA sent to the European Commission, EFSA and Member States new research and approach proposals that could improve the bee risk assessment, building on the work done by EFSA in 2013 (see ECPA letters from 10th March and 16th June).

We would welcome the opportunity to engage in a technical discussion with risk assessors and risk managers to discuss some of our suggestions and present available new data. We strongly believe that practical solutions could be jointly explored in a technical discussion with Member States and EFSA.

REFIT evaluation: Regulations 1107/2009 & 396/2005 (Agenda item A.23)

ECPA welcomed the opportunity to exchange views on the review of both Regulations during the 12 September workshop. As part of the REFIT exercise, we would like to share with you an analysis for a 'data call-in' system for the review of active substances. The review process currently represents a significant resource burden on both regulatory Authorities and industry and we believe that a data call-in system would have significant advantages. Such a data call-in process is already in place in countries such as Canada and has shown to be an effective way of reviewing existing authorisations while avoiding the unnecessary generation and repletion of data.

Further information in the Zip file enclosed – ECPA position paper (doc.no.28417)

Import tolerances (Agenda item A22)

ECPA is extremely concerned with the conclusion of the SCoPAFF Residues meeting on 12 and 13 June 2017, where the Commission services stated their view that MRLs would be lowered to the limit of detection (LOD) when a substance's hazard classification is given as the reason for the non-renewal.

While Regulation 1107/2009 introduces hazard based cut-off criteria as part of the process of approval and re-approval of active substances, hazard based restrictions on the setting of import tolerances would be contrary to the risk assessment based provisions set out in Regulation 396/2005. The provisions of Regulation 1107/2009 should not prevent the legal decision making process in setting import tolerances in the EU.

Hazard based restrictions on setting import tolerances would also be contrary to principles set out in the WTO SPS agreement, with a substantial impact on international trade. The WTO SPS requires that decisions are based on the assessment of risk and it is imperative that the EU continues to comply with these principles. A violation of the agreement by the EU could encourage other WTO members to use their own criteria and presents a significant threat to the future use of the SPS agreement itself. We therefore believe the Commission should notify and consult with WTO members before taking any decision.

We request the Commission to ensure that MRLs and its continue to be decided on the basis of an assessment of risk, in line with Regulation 396/2005, ensuring that the EU meets its obligations under the SPS agreement. Given the significant impacts of implementing the

policy option currently being put forward, the Commission should carry out an impact assessment, in line with the EU's Interinstitutional Agreement on Better Law making¹.
Further information in the Zip file annex – ECPA paper on setting import tolerances in the EU (doc.no.28029).

Glyphosate (Agenda item A.21)

Following the Commission proposal for a 10-year re-approval, based on the scientific evidence available ECPA believes it should in fact be approved for 15-years. It is worth reminding Member States that last year the Commission was content to put forward a proposal for a 15-year approval without the opinion of ECHA. Now that ECHA has confirmed glyphosate is not carcinogenic, we believe the scientific case is beyond doubt. On this basis **we request the Member States to ask the Commission to revise the proposal to provide a full 15-year re-approval.** Glyphosate has been used safely for 40 years, and regulatory authorities around the world have approved its use. We strongly believe clear support for re-approval is essential for the credibility of a science-based EU evaluation process.

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

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



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¹ Interinstitutional Agreement on Better Law making: states that 'The Commission will carry out impact assessments of its legislative and non-legislative initiatives, delegated acts and implementing measures which are expected to have significant economic, environmental or social impacts...' (see - III. TOOLS FOR BETTER LAW-MAKING – point 13; [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016Q0512\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016Q0512(01)&from=EN))