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To: Members of SCoPAFF-phytopharmaceuticals

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ECPA input for SCoPAFF meeting on 19-20 July:

- **Endocrine disruptors**
- **Residue definition**
- **REFIT evaluation: Regulations 1107/2009 & 396/2005**
- **Re-approval of glyphosate**
- **Article 43**

Dear SCoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical of 19-20 July, ECPA would like to provide input on a number of issues. Reference is made to the meeting agenda item where relevant:

Endocrine disruptors (Agenda item A.17)

We note the outcome of the SCOPAFF vote on 4 July 2017. We are extremely disappointed that the Commission and Member States did not adopt more robust criteria which allow regulators to clearly separate those substances of concern from those that are not. Our concerns with the criteria are set out in our previous letter dated 26 June 2017.

We are also disappointed that the proposed amendment to the derogation, which wasremoved from the proposal, was not tabled for a vote on 4 July given how many Member States recognise the importance of this deroagtion. This amendment is critical to allow a more workable and scientifically defensible process for the regulation of substances considered to have endocrine disrupting properties. We would request the Commission to work with the Member States to urgently retable the amendment and to allow Member States the opportunity to formally vote on the derogation proposal.

Residue definition (Agenda item A.22)

The recently published EFSA guidance document for establishing the Residue Definition for Dietary Risk Assessment increases complexity of the evaluation process for deriving a residue definition, without necessarily increasing consumer protection. The scheme leads to complex residue definitions that are inconsistent with international systems, and will therefore impact 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 for the guidance document is required before its possible adoption by the SCoPAFF to ensure a consistent understanding of the requirements and their implications.
Further information in the Zip file enclosed– ECPA position on EFSA Guidance Document on the Residue Definition for Dietary Risk Assessment (doc.no.27774)

REFIT evaluation: Regulations 1107/2009 & 396/2005 (Agenda item A.23)
ECPA welcomes the start of the consultants' work on a report reviewing both Regulations. The review is an essential step to understand the shortcomings of the legislation and to consider improvements for the future.
Further information in the Zip file enclosed – ECPA position paper (doc.no.22085)

Re-approval of glyphosate (Agenda item A.21)
Following the publication of the ECHA opinion on glyphosate, we urge the Commission to come forward with a proposal for the 15-year re-approval of glyphosate. A 15-year approval would ensure consistency with the approvals of other active substances and would be in line with the initial proposal made in 2016.

Article 43 (Agenda item A.14.2)
ECPA welcomes the efforts made to clarify the process through regular reviews of the guidance document on Article 43 SANCO/2010/13170. However we would like to highlight that issues remain with multiple interpretations of the guidance document within Member States, and late decisions on zRMS allocation and acceptance of Category 4 studies. ECPA supports a rationalised process with early decisions, limited number of submissions and allowance of updates after active substance renewals.
Further information in the Zip file annex – ECPA comments on guidance document (doc.no.28013)

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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