European Crop Protection

LET/17/AD/28446
29 September 2017

To: Members of SCoPAFF-phytopharmaceuticals

[redacted]
(+32) [redacted] [Art. 4.1 b]
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ECPA input for SCoPAFF meeting on 5-6 October:

- [redacted]
- [redacted] OUT OF SCOPE
- [redacted]
  - **REFIT evaluation of Regulations 1107/2009 & 396/2005**
  - **Import tolerances**
- [redacted]

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:

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OUT OF SCOPE

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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 making[1].'
Further information in the Zip file annex – ECPA paper on setting import tolerances in the EU (doc.no.28029).

OUT OF SCOPE

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

[Art.4.1 b]

[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)