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ECPA input for SCoPAFF-residues meeting on 21-22 November:
- **Import tolerances**
- **Residue definition**

Dear Dr Berend

Ahead of the SCoPAFF-residues meeting on 21-22 November, ECPA would like to provide input on two specific issues mentioned in the agenda:

Import tolerances & hazard criteria of Reg.1107/2009 *(Agenda item A.06.3 & A.17)*

ECPA has previously highlighted its concerns with the proposed policy whereby 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; it would also be contrary to the principles set out in the WTO SPS agreement, with a substantial impact on international trade.

Regarding the potential trade impact, in a recent study carried out by BryantChristie, it is suggested that agricultural imports with a total value of €70 billion in 2016 would be affected (directly or in-directly) by a loss of MRLs resulting from hazard-based non-approval of identified active substances. This includes commodity groups such as cocoa, coffee, tea, and spices which are significant exports for many less wealthy export countries.

Given the significance of the proposed policy approach, ECPA is calling on the European Commission to:
- Formally notify the WTO to ensure that this approach is evaluated for compliance with the SPS agreement
- Carry out an impact assessment to understand the implications for exporting countries and EU businesses[1].'

Further information in the Zip file annex – Bryant Christie Report and Executive Summary on the impact of (doc.nos. 28751 & 28754).

[1] In line with the EU's Interinstitutional Agreement on Better Law making: which 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)

Residue definition *(Agenda item A.10)*

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 also leads to more complex residue definitions, inconsistent with international systems, and 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 to ensure a common understanding between risk assessors, risk managers and stakeholders. A testing phase should be based on real case studies and ECPA would be willing to provide concrete examples as a basis for such a process.

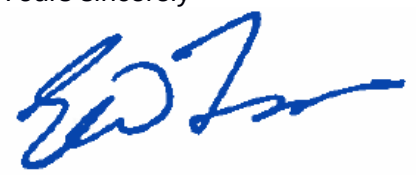
In addition, given the inconsistency with national and international systems, and in particular the potential impact on the acceptance of CODEX MRLs, we believe that this issue requires further consideration at the international level in order to look for harmonised methodologies; in particular, we would welcome a discussion on this issue within JMPR and OECD.
Further information in the Zip file enclosed– ECPA position on EFSA Guidance Document on the Residue Definition for Dietary Risk Assessment (doc.no.27774)

We would request that our views are made available to the Member State participants of the SCoPAFF-residues meeting.

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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