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**To: Members of SCoPAFF-phytopharmaceuticals**

Euros Jones
Director Regulatory Affairs
(+32) 2 663 15 53
euros.jones@ecpa.eu

**ECPA input for SCoPAFF meeting on 22-23 March:**

- **Bee Guidance document**
- **Residue definition guidance document**
- **Review of Genotoxicity evaluation**
- **PBT evaluation**
- **Co-formulants**

Dear SCoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical of 22-23 March, ECPA would like to take this opportunity to provide our input on a number of generic issues. Reference is made to the meeting agenda item where relevant:

## Bee guidance document (Agenda items A.16)

ECPA is supportive of a revision of the pollinator risk assessment. However, we still fail to see how the EFSA document on the risk assessment to honeybees, bumble bees and non-*Apis* bees (2013) will ensure appropriate risk assessment for pollinators and allow risk managers to take robust decisions.

In its current form the document is generating a number of uncertainties and data gaps in the conclusions of risk assessments, as observed in nearly all EFSA conclusions published since January 2016. In addition, this document elaborated between 2011 and 2013 does not rely anymore on the best scientific knowledge. We believe a new way forward is needed.

Since 2013, industry has been active in developing additional research to propose a protective and realistic way forward. Built on an analysis of the proposals included in the EFSA document, several technical suggestions and possible options have been explored for this to become a workable risk assessment process, which are compiled in the presentation enclosed with this letter. More specifically the presentation includes:

- The learning from several years of laboratory testing on honeybees
- The outcome of collaboration with expert groups during workshops, as well as up to date experience in method development.
- Further work on exposure routes
- Possible options to support chronic risk assessment of honeybee and larvae risk assessment.
- Suggestions of refinement options in higher tiers based on available new data and recent modelling developments.

ECPA will continue to ask that the Commission, EFSA and Member States:

- **Not to adopt the guidance document as it currently stands**, on the basis that it is not fit for purpose and does not provide useful support to decision making, and **reject any proposed legislative changes** when the proposed trigger values remain questionable and are not based on the most recent scientific knowledge
- **Review the progress gained in science and knowledge** over the last 3 years, before implementing the measures currently under discussion, which lead to unfeasible additional data requests.

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.
***Further information in the Zip file enclosed – ECPA - New Industry Research and Approaches to improve the risk assessment on bees (doc.no.27576)***

## Residue definition guidance document

The recently published EFSA guidance document for establishing the Residue Definition for Dietary Risk Assessment will increase complexity of the evaluation process for deriving a residue definition. **A critical review of the guidance document is required before it is considered for adoption by the SCoPAFF, to ensure that the document is fit for purpose to support the regulatory process and risk manager decision-making.**

The scheme leads to an inconsistency with other national and international systems, therefore impacting global harmonisation of residue definitions and respective MRLs, import tolerances and trade. The establishment of such complex residue definitions will lead to low acceptance of Codex MRLs in Europe due to the differing residue definitions.

There are a number of areas where specific tools are required to support the implementation of the guidance document. It is essential that these essential tools and the necessary training are put in place before the adoption and application of the guidance document.

Given the significant refinements proposed in the guidance document, a testing phase is also required to understand the requirements and their very broad implications, and what ultimately it means in practice. ECPA has initiated a substance specific review and we will share the results of that review to support a better understanding of the implications of any change in the guidance.

## Review of Genotoxicity evaluation

ECPA welcomes the publication of the recent mandate to the European Food Safety Authority (EFSA) for clarification and consideration of several aspects related to the assessment of genotoxicity. ECPA has identified that over the last several years the assessment of genotoxicity at EFSA has changed and in our view, the current EFSA approach is contrary to the standard global regulatory approach which considers that genotoxicity is a mode of action causal to carcinogenicity.

ECPA is encouraged to see the mandate to EFSA reflecting specific concerns on key issues; detailed written input has been provided by ECPA for consideration by the EFSA Scientific Committee in their review and we hope that the information provided will help support a robust evaluation of the issues raised in the Commission mandate.
***Further information in the Zip file enclosed – ECPA input to EFSA on the genotox mandate (doc.no.27560)***

## PBT evaluation

ECPA have identified recent situations in the evaluation of active substances during the EFSA peer review process, where decisions are based on an ECHA/biocides guidance in the consideration of the persistence of an active substance. The biocides guidance document however contains provisions that conflict with those that apply for PPP evaluations (P evaluations for biocides are carried out at $12^0$C and at $20^0$C for PPPs.). We would take this opportunity to stress that the relevant guidance document should be the basis of PPP evaluations and we would ask DG SANTE and SCoPAFF members to ensure that this continues to be the case.

***Further information included as annex to this letter***

## Co-formulants

ECPA wishes to highlight a potential risk of dual regulation of co-formulants used in Plant Protection Products under REACH, and the (yet to be populated) Regulation 1107/2009 (PPPR) Annex III negative list of co-formulants. The potential issue does not lie with REACH itself, but rather the proper co-ordination between different pieces of EU legislation.

REACH data generation and processes apply to all co-formulants, and ECPA considers that these should be used to populate PPPR 1107/2009 Annex III. The potential problem therefore lies with the fact that PPPR 1107/2009 Annex III fails to make proper links with the relevant REACH provisions.

ECPA has already highlighted the potential for the duplication of work in the evaluation of co-formulants. This concern has again been highlighted within the framework of the REACH REFIT Review. To ensure a streamlined process that avoids the duplication of effort, an EU impact assessment is required to ensure a full understanding of the implications.
***Further information in the Zip file enclosed – ECPA questionnaire response (doc.no.27298) and position paper (doc.no.27240) for the REACH Refit Review.***

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

Euros Jones
Director, Regulatory Affairs

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

## ANNEX

## PBT Assessment – Further input

PBT compounds are cut-off candidates and cannot receive (re)approval under Regulation 1107/2009. Therefore, a very diligent and prudent assessment needs to be done whether a compound meets the PBT criteria or not.

When Regulation 1107/2009 was implemented, deficiencies related to a sound classification of PBT substances were evident already. Therefore, DG SANCO released in 2012 the Working Document on "Evidence needed to identify POP, PBT and vPvB properties for pesticides", rev. 3, 25.09.2012, which has been established with the contribution of EFSA, EChA, DG Enterprise, DG Environment and several Member States (the "DG SANCO Working Document"). This document was noted in the Standing Committee. However, in recent cases EFSA did not apply the criteria set in the DG SANCO Working Document but applied a very restrictive (worst case) interpretation of the newest version of the EChA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.11: PBT/vPVb assessment Version 2, November 2014 (the "EChA Guidance").

The EChA Guidance, however,

- is developed to assist users in complying with their obligations under Regulation (EC) No 1907/2006 (REACH regulation) and typically deals with data poor chemicals. It is not appropriate and not intended to be applied for data rich substances like plant protection products as it is based on lab data and ignores any higher tier field data;
- was passed within the framework of the REACH regime where the consequences of PBT classifications are by far less restrictive compared to the crop protection regime. Under REACH, PBT-classifications trigger a risk assessment and socio-economic assessment to identify risks and mitigation measures for the uses of the related substances, but no automatic ban;
- has neither been discussed nor noted in the Standing Committee to be applied for the PBT assessment of plant protection products

The use of the latest version of the EChA Guidance for PPP evaluations violates several Regulations of the crop protection regime, first and foremost Regulation 1107/2009, and several fundamental principles of EU law, in particular the principles of legal certainty and legitimate expectations and of scientific excellence and the rights of defence. This is mainly because the EChA Guidance is not applicable under the crop protection regime, and, even if it was deemed applicable, it would neither represent a finalized guidance as a new version is currently discussed. Therefore, crop protection industry expects that the evaluation for active substances is done strictly according to the DG SANCO Working Document released in 2012 on "Evidence needed to identify POP, PBT and vPvB properties for pesticides", rev. 3, 25.09.2012. Which is the applicable guidance for the time being.