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Members of SCoPAFF-phytopharmaceuticals

ECPA input for ScoPAFF meeting on 6-7 December:
- **Endocrine disruption**
- **Bee Guidance document**
- **Co-formulants**
- **Residue definition guidance document**
- **REFIT evaluation: Regulations 1107/2009 & 396/2005**
- **Stakeholder dialogue with SCoPAFF**

Dear Dr Flüh
Dear ScoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical of 6-7 December, ECPA would like to take this opportunity to provide our input on a number of current issues. Reference is made to the meeting agenda item where relevant:

Endocrine disruption (Agenda item A.18)

ECPA would underline the concerns we have with the proposal for the criteria for endocrine disruptors. For decision making under Regulation 1107/2009, we believe regulators should be provided with the necessary tools to separate out those substances which have the real potential to cause harm, from those that do not. It remains our firm view that endocrine disruptors can and should be regulated like other substances of potential concern and be subject to risk assessment considering both hazard and exposure. A departure from this framework sets a precedent for regulation that neglects the consideration of all information potentially available to ensure the protection of human health and the environment.

We hope that the Commission will look to adopt workable, proportionate and science based criteria which ensure that regulators have the necessary tools to make informed decisions; maintaining the existing high levels of protection for human health and the environment, while also ensuring that European farmers have access to essential crop protection products.

Further information in the Zip file annex – ECPA letter ahead of Nov 18th SCoPAFF/ED meeting - doc.no.27011

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 However, we still fail to see how the outdated document from 2013 will ensure appropriate risk assessment for pollinators and allow risk managers to take robust decisions.

We continue to be of the opinion that the current guidance is unworkable and would mean that all insecticides, and a lot of herbicides, fungicides would fail the first tier laboratory risk assessment and trigger the need for follow up semi-field and field studies despite the fact that the study specifications cannot be met. Today, a year after EFSA's decision to use *de facto* this unapproved document, we see the practical consequences with nearly all EFSA conclusions highlighting risks and data gaps[1]. This clearly demonstrates the inappropriate calibration of the guidance, with the protection goals sustaining the whole document being based on incorrect and extremely conservative assumptions. It also creates unnecessary complexity for many substances that can only be addressed at Member State level.
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.
- **Reject the proposed legislative changes** when the proposed trigger values remain questionable and are not based on the most recent scientific knowledge
- Carry out a **transparent assessment of the impact** of the proposed measures before taking a final decision
- **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.

As industry, we would welcome the opportunity to engage in a technical discussion with risk assessors and risk managers so that solutions to some practical issues could be jointly explored.

Co-formulants

ECPA would again highlight industry concerns with the way forward set out in the Discussion paper on implementation rules for the inclusion of unacceptable co-formulants in Annex III. We would in particular highlight the impact of duplication of work in the evaluation of co-formulants and the potential impact of the suggested triggers which could potential restrict many commonly used co-formulants.

Given the potential impact of this exercise, ECPA believes that an impact assessment is required to ensure a full understanding of the implications. ECPA's aim is to ensure a streamlined process that avoids the duplication of effort - in line with the broader principles of Better Regulation. ECPA will continue to input into the Working Group discussions to support the development of such a streamlined process.

Further information in the Zip file annex – ECPA letter - doc.no.26056. Also, please see separate published paper at https://www.ncbi.nlm.nih.gov/pubmed/27411735

Guidance on the Establishment of the Residue Definition for Dietary Risk Assessment

While we note that the EFSA Guidance Document on the Establishment of the Residue Definition for Dietary Risk Assessment is not on the agenda for the December meeting, ECPA would highlight some issues at this stage, ahead of a possible future discussion and 'noting' of the document. We emphasise the complexity of the evaluation scheme, and we would in particular stress that additional elements (e.g. QSAR tools and databases) are required for the workable implementation of the guidance document - proceeding without such tools will lead to additional toxicological testing including unnecessary vertebrate testing. ECPA has also noted a lack of consistency between the guidance document and the

[1] 24 EFSA conclusions over 27 published in 2016.

approaches in other national and international systems –impacting global harmonisation of MRLs, import tolerances and trade.

ECPA would therefore propose a technical discussion to ensure a high level of understanding and consistency (i) across the Member States and, (ii) with international systems, as well as the provision of a suitable toolkit and respective training requirements, to support the implementation process.

REFIT evaluation: Regulations 1107/2009 & 396/2005 (Agenda items A.26)

ECPA welcomes the publication of the roadmap for the review of both Regulations. The review is an essential step to understand the shortcomings of the legislation and to consider improvement options for the future. ECPA support the roadmap work programme and believes that an essential element of the review will be to consider improvements options for - in the implementation of the current legislation and in future legislative changes.

Further information in the Zip file annex – ECPA view on roadmap (doc.no.27064) and ECPA position paper on review (doc.no.22085 – July 2015)

Stakeholder dialogue with SCoPAFF

ECPA have recently written to DG SANTE requesting greater Stakeholder transparency and participation in the work of the ScoPAFF sections on '*Phytopharmaceuticals*' and '*Pesticide Residues*'. While all discussions in these groups have to date been held without stakeholder participation, we request that this policy to reviewed, in particular to ensure greater consistency with other similar Standing Committees such as the Biocides Committee.

There are two areas where we would request greater transparency:

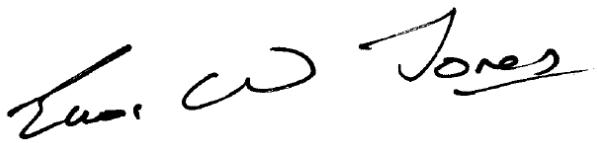
- **Documentation –** create a CIRCABC section with stakeholder access for the documents that are to be discussed in the meeting. While complying with the EU's transparency principle, such access to drafts would also enable commenting on latest versions, and potentially avoid waste of resources in trying to solve subsequent issues.
- **Participation -** Relevant non-confidential discussions in the SCoPAFF section meetings should be opened up to stakeholders to allow dialogue with decision makers.

Our experience from other sectors is that the organised participation of stakeholders has been helpful and have provided a higher level of transparency. We look forward to greater transparency and greater consistency with the committee procedures in similar policy areas.

Further information in the Zip file annex – ECPA letter to DG SANTE - doc.no.26781.

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 with DG SANTE 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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