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30 September 2016

To: Michael Flüh
DG SANTE
European Commission
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Members of SCoPAFF-phytopharmaceuticals

ECPA input for ScoPAFF meeting on 6-7 October:

- **Genotoxicity**
- **Bee Guidance document**
- **Article 43 Guidance document**
- **Endocrine disruption**
- **Co-formulants**

Dear Dr Flüh
Dear ScoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical of 6-7 October, ECPA would like to take this opportunity to provide our input on a number of issues to be discussed at that meeting.

Genotoxicity

Recent EFSA conclusions have raised issues in the genotoxicity evaluation, that have consequently led to either key data gaps being reported, or an inability to complete the risk assessment and/or to set reference doses. Many of the issues raised by EFSA were unexpected and there are numerous examples where additional data were not considered necessary - and the generation of such data would not have been in line with the legal requirements set out in EU animal testing legislation. ECPA have requested an independent review of recent EFSA evaluation of genotoxicity; this report has been provided to the Commission and highlights a change in EFSA's approach that is not attributable to changes in legislation, guidance or data requirements.

Given the unexpected changes and the lack of consistency between different guidance documents and test methods, ECPA request:

- An urgent scientific review of the process, to be carried out by the relevant EFSA Panel or Scientific Committee;
- Suspension of Regulatory decisions on active substances, based on genotoxicity concerns raised by EFSA, until such a review has been completed;
- Consideration of additional data generated to address data gaps identified during the peer review process within the ongoing review process; and
- The setting of all endpoints in order to allow risk managers to take the correct decision.

Further information in the Zip file annex – ECPA letter (doc.no.26074) and external consultant report (doc.no.26790)

Bee guidance document (Agenda items A.17, B.04 & B.05)

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 However, we still fail to see how the outdated document from 2013 will ensure appropriate risk assessment for pollinators.

We continue to be of the opinion that the current guidance is unworkable and would mean that most insecticides 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. 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. A discussion on suitable protection goals, together with their practical consequences on the availability of solutions for farmers should be organised in light of new findings.

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.

Further information in the Zip file annex – ECPA letter from July 2016 - doc.no.26359

Draft GD on Authorisation Renewal - Article 43 (Agenda item A.08)

ECPA would like to propose a number of amendments and/or clarifications to the draft Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (doc. SANCO/13170/2010 Rev. 13.9), which has been put forward for noting at the meeting. We would like to underline that a practical and flexible process is necessary in order to be able to implement the stringent provisions of Article 43.

As the deadlines for this process are very short, it is of utmost importance that the zonal Rapporteur Member State is agreed in the zonal Steering Committee as early as possible. This will allow for pre-submission meetings, which are essential to agree on data to be submitted. Clarifications are also needed concerning the notification timelines, in particular for those case of products containing other active substances expiring within 1 year.

For the same purpose of complying with deadlines, the implementation of Category 4 data needs to be clarified, as to what should or should not be accepted. In addition, for pending applications submitted under Article 33, applicants should be given the opportunity to update dossiers when the evaluation is still pending, in order to avoid unnecessary reviews and resubmissions.

Additional national or zonal requirements remain a major blocker to the efficient functioning of the zonal process. For the sake of transparency and equal treatment of applications throughout the EU, such requirements should not be requested as category 4 studies during the Article 43 renewal process.

Further information in the Zip file annex – ECPA comments on GD - doc.no.26770

Endocrine disruption (Agenda item A.19)

ECPA would underline the significant concerns we have with the Commission's proposal for the criteria for endocrine disruptors. Many substances, which present little or no concern to human health or the environment will be unnecessarily "identified" as endocrine disruptors by using the WHO/IPCS definition alone (option 2). 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. To do this, the criteria should be based on option 4, incorporating all elements of hazard characterisation, while also including full consideration of potency, severity and lead toxicity. Hazard characterisation is a routine and essential second step in the overall assessment of the hazard properties of any substance and therefore can be built into the criteria for endocrine disrupting properties.

We would also highlight the conclusion of the Commission's Impact Assessment, that **all options under consideration offer the same high level of protection for human health and the environment**. However, **the option put forward by the Commission is assessed as having the greatest negative impact** on the availability of products for farmers, and the most severe and negative impact on sectorial competitiveness, agriculture and trade. . It is therefore incomprehensible why this option was put forward; given its negative repercussions it is unacceptable.

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 which considers both hazard and exposure. A departure from this robust assessment 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 strongly urge the Commission together with Member States to amend the proposal. The Commission should adopt workable, proportionate and science based criteria which ensure regulators have the necessary tools to make informed regulatory decisions and which maintain 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 - doc.no.26411

Co-formulants (Agenda item A.15)

ECPA would like to highlight the 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.

The suggested use of the proposed Tier 2 & 3 hazard classifications (e.g. skin sensitisation) as potential triggers for restricting co-formulants would lead to a disproportionate impact, with substantial additional resource needs and potential restrictions on many important and commonly used co-formulants.

Given the considerable additional complexity proposed, consideration must be given to the development of workable timelines for implementation, transition and grace periods, recognising the potentially vast number of formulations which could be affected with the Annex III listing of a substantial number of co-formulants. Past experience shows that transition periods of several years are required to allow for such formulation changes.

ECPA's aim is to ensure a streamlined process that avoids the duplication of effort - in line with the broader principles of Better Regulation that have been developed by the

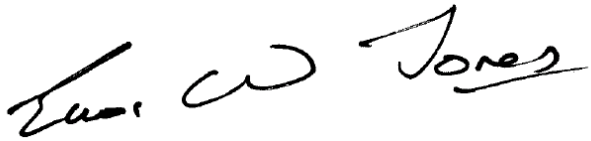
Commission. ECPA will continue to input into the Working Group discussions to take place in the 4th quarter of 2016, to try and support the development of such a streamlined process.

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>

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.

For information, and to ensure full transparency, this letter is being published on the ECPA website and will be available at: <http://www.ecpa.eu/transparency-policy>.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Euros Jones', with a stylized flourish at the end.

Euros Jones
Director, Regulatory Affairs