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ECPA input: SCOPAFF phytopharmaceuticals-legislation meeting, 24-25 January 2019

- **EFSA bee guidance document and update of Uniform Principles**
- **Endocrine disruptors**
- **Harmonised risk indicators**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 24-25 January 2019, ECPA would like to provide our input on several critical issues on the agenda:

EFSA guidance document on the risk assessment of plant protection products on bees (Agenda item A.08.1 and C.01)

ECPA is supportive of a robust pollinator risk assessment, however we would maintain our request for a significant revision of the proposed EFSA guidance document before any type of implementation. ECPA continues to collate public information on EFSA conclusions on bees published since January 2016 (see Attachment 1, up to 14 January 2019). This information demonstrates that for **nearly all substances (being conventional or natural based pesticides), data gaps are identified in the risk assessment and/or no risk assessment conclusion could be completed by EFSA.** Such a situation is also creating more difficulties for Member State authorities at product authorisation level.

We believe that the elements suggested by the Commission as ready for implementation require substantial work before being applicable. This continues to be the case for the **field-testing requirements, which are unrealistic and lead to the rejection of all field and other higher tier studies**. Only an update of the document would allow a review of the protocols for field and semi-field studies to take into account the latest scientific insights.

Since the EFSA guidance document was drafted in 2012, academia, industry and regulators have gained significant additional knowledge regarding pollinator risk assessment and we believe this should be taken into account in revising the document and preparing an up-to-date, protective, realistic and workable document.

We would therefore request the Commission and Member States to:

- Engage in an EU level discussion with risk assessors and risk managers with the aim of revising the EFSA guidance document before its implementation and adoption.
- Avoid legislative changes (adaptation of the Uniform Principles) when the proposed changes remain questionable, are not based on the most recent knowledge and lead to unfeasible additional data requests.

Endocrine disruptors (ED) (Agenda item A.03.3(j), A.21)

Following the application date of the ED criteria (10 November 2018 as laid down in Regulation 2018/605), ED evaluations are starting for submissions of new and renewal active substances as well as for substances with confirmatory data requests related to ED properties. We recognise the complexity of applying the criteria and that each substance will be evaluated on a case by case basis, including decisions on what, if any, additional data or information may be requested for pending applications according to Regulation 2018/1659. However, it is essential that applicants have clarity on the timelines and process for the evaluation of their substances; they should be clearly informed of when ED assessments are expected to be completed and when final regulatory decisions are anticipated.

We understand that discussions on the application of the ED criteria took place during the October and December 2018 SCOPAFF meetings. If procedural decisions were taken during these meetings we would request that these be clearly communicated to industry so that there is clarity on the relevant processes and timelines for all applicants.

Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators (Agenda item B.01)

We support the Commission's commitment to put harmonised risk indicators in place under the Sustainable Use Directive (Directive 2009/128). However, we do not support the current proposal using a hazard-based harmonised risk indicator which we understand is based on sales statistics and the number of authorisations granted by Member States under Article 53 of Reg 1107/2009. The proposal does not reflect the safety of the uses that would comply with the regulation, i.e. it should be read with complementary information such as the likelihood of exposure, actual conditions of use, and where required, specific risk mitigation measures in place, uptake of good agricultural practices and actual dosages. We are also concerned that the proposed arbitrary weighting factors for different categories of plant protection products do not support the purpose of calculating the relative risk of using these products, and will undermine the regulatory risk assessment procedures behind their authorisation.

Our detailed comments on the Commission proposal are included as Attachment 2. We would request that the proposal be amended to take into account our concerns prior to formal adoption.

We would welcome a more detailed discussion on these issues. If you have any questions regarding the ECPA views, please do not hesitate to contact me.

Yours sincerely

Peter Day
Director Regulatory Affairs

cc. Karin Nienstedt

Attachments:
(1) Excel file with compilation of EFSA conclusions on bees published since 1 January 2016 and up to 14 January 2019.
(2) ECPA position on the European Commission proposal for Harmonised Risk Indicators, 18 December 2018.