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ECPA input for SCOPAFF phytopharmaceuticals-legislation meeting, 12-13 December 2018

- **EFSA bee guidance document and update of Uniform Principles**
- **Sustainable Use Directive**
- **Endocrine disruptors**
- **Harmonised risk indicators**
- **REFIT evaluation of Regulations 1107/2009 & 396/2005**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 12-13 December 2018, ECPA would like to provide our input on several critical issues. Reference is made to the meeting agenda item where relevant:

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 reiterate our requests for a significant revision of the proposed EFSA guidance document before any type of implementation. ECPA continues to collate information on EFSA conclusions on bees since January 2016 (see Attachment 1). This information indicates 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.**

We believe that the elements suggested by the Commission as ready for implementation require substantial work before being applicable. This is the case for the **field-testing requirements, which are unrealistic and will lead to the rejection of all field and other higher tier studies**. Only a revision of the document would allow a review of the protocols for field and semi-field studies to take into account the latest scientific insights[1].

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:

[1] See attachment 2 - An illustration of the size needed to conduct a study according to the EFSA guidance document Appendix O.

- 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.

Sustainable Use Directive (Agenda item A.17)

In the context of this item, the demands made by the recent European Citizens Initiative on use reduction, and the proposal for vote under item C.01, ECPA would like to express its concern about the number of National Action Plans still not yet approved under the Sustainable Use Directive. We would encourage Member States who do not yet have one in place to submit one as soon as possible. There are rightly demands to ensure that crop protection products are being used in a sustainable way, having the action plans in place is critical to demonstrate that this requirement is being taken seriously by national governments.

Endocrine disruptors (ED) (Agenda item A.22)

Ahead of previous SCOPAFF meetings we have highlighted our significant concerns regarding the EFSA-ECHA guidance document for the assessment of endocrine disrupting properties. One of our key concerns has been the likely impact on the amount of additional vertebrate studies that maybe required. Based on emerging experience with the guidance, it appears these concerns are being realised. We are aware of at least one case where the available information clearly supports that the substance does not have endocrine disrupting properties. Yet in order to comply with the guidance, for purposes of data sufficiency, extensive unnecessary additional testing is being required despite the fact that in this case, a regulatory decision can clearly be made based on the data already available.

We would highlight that Commission Implementing Regulation 2018/1659[2] states that: *"When requesting additional information from the applicant, the Authority should consider that animal testing is to be minimised and tests on vertebrates are to be undertaken only as a last resort, in accordance with Article 62 of Regulation (EC) No 1107/2009."* Regulation 2018/605 laying out the criteria for endocrine disrupting properties also clearly requires a weight of evidence based approach to be used considering the available data.

We therefore urge EFSA and the Member State experts to undertake regulatory evaluations against the criteria for endocrine disrupting properties in a manner as foreseen in Regulation 2018/605 and Regulation 2018/1659 including employing a weight of evidence approach and in a way which minimises the requests for unnecessary additional vertebrate studies.

REFIT evaluation of Regulations 1107/2009 & 396/2005 (Agenda item A.27)

ECPA supports the REFIT evaluation of the functioning of Regulations 1107/2009 and 396/2005, and we welcome the detailed contribution provided by the Ecorys report published in October[3]. ECPA welcomes the key conclusions of this comprehensive report which finds that *"the two Regulations are overall effective and relevant"* in enhancing protection of health and the environment. In developing the Commission's own conclusions we would request that some of the aspects of the Ecorys report be clarified to ensure the current situation is accurately reflected and to help guide possible areas for improvement in implementation. In particular, we would highlight the conclusion that PPP uses are at risk due to difficulties met throughout both approval and MRL processes, which we believe can be overcome by improving the implementation of the current provisions. In due course we will provide our more detailed feedback on these aspects of the Ecorys report.

[2] Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605

[3] Study supporting the REFIT evaluation of the EU legislation on plant protection products and residues (Regulation (EC) 1107/2009 and Regulation (EC) 396/2005).

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

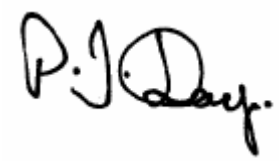
While we support the Commission's commitment to put harmonised risk indicators in place, we are concerned that the proposed indicators (based on sales statistics and number of products approved under Article 53 of Regulation 1107/2009) combined with arbitrary weighting factors, will not on their own provide an accurate indication of the relative risk. Additional factors, such as actual conditions of use, uptake of good agricultural practices, specific risk mitigation measures (where required) and dosages all determine likelihood of exposure, and would need to be included to provide a more accurate assessment and to indicate trends in risk reduction.

We support the use of easy-to-measure, implementation-based risk indicators, and believe that indicators with existing available data (e.g. in the area of water, residue monitoring or empty container collection rates) could already be included in the proposal. Only indicators requiring further work in collecting and establishing information collection systems should be scheduled for a second phase. We would also recommend the inclusion of a deadline for the development of the second phase indicators in the Directive.

Finally, we understand that this draft Directive is scheduled for voting at this SCOPAFF meeting. We would suggest, bearing in mind its own commitment to Better Regulation, that the Commission await the conclusion of the feedback mechanism consultation on 26 December, before proceeding to a vote.

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
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cc. Karin Nienstedt

Attachments:
(1) Excel file with compilation of EFSA conclusions on bees published since 1 January 2016 and up to 11 November 2016.
(2) ECPA infographic illustrating the unrealistic field-test requirements of the proposed EFSA guidance on the risk assessment of plant protection products on bees.