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ECPA input: SCOPAFF phytopharmaceuticals-legislation meeting, 21-22 March 2019

- **Endocrine disruptors**
- **EFSA bee guidance document and update of Uniform Principles**
- **Minor Uses Coordination Fund**
- **Importance of resistance management**
- **Annex III of Regulation 1107/2009 (unacceptable co-formulants)**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 21-22 March 2019, ECPA would like to provide our input on several critical issues on the agenda:

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

We recognise the complexity of applying the ED criteria to both new and pending active substance evaluations. However, we would reiterate our request that applicants have clarity on the anticipated timelines for the evaluation of their substances against the new criteria; they should be clearly informed of when ED assessments are expected to be completed and when final regulatory decisions are anticipated.

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 request for a significant revision of the proposed EFSA guidance document before any type of implementation. ECPA is collating public information on EFSA conclusions on bees since January 2016 (see Attachment 1 – up to 25 February 2019). This information demonstrates **that for 67 active substances where the current draft bee guidance document was used in peer review process, there were only 2 cases having a completed bee risk assessment** (see Figure 1 in Attachment 2); 65 active substances could not pass the proposed assessment scheme.

The above situation is in spite of specific data being generated and submitted in an to attempt to pass the proposed assessment. Contrary to what has been claimed by some parties, Industry is continuously generating new studies to address and better understand the potential impact of substances and to comply with regulatory data requirements and guidance documents. For example, since 2013 when the new data requirements were put in place, **114 studies have been generated to assess larval toxicity and 130 studies for honey bee chronic oral toxicity** (see Table 1 in in Attachment 2).

Nevertheless, as shown by the last 3 years of EFSA conclusions, nearly all substances have data gaps identified in the risk assessment and/or no risk assessment conclusion could be completed by EFSA. This is creating unnecessary difficulties for risk managers and at a later stage for Member State authorities at product authorisation level. The lack of calibration in the EFSA guidance document puts at risk solutions for conventional farmers as well as organic farmers (see conclusions summary for Copper or Spinosad in Attachment 1).

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.

Minor Uses (A. 18)

We would highlight the urgent need to secure long term funding to maintain the Minor Use Coordination Facility (MUCF). The work of the MUCF is critical to Member States, grower and foodchain organisations and plant protection producers alike. Key plant protection solutions for speciality crop growers have been found due to the work of the facility, but its future is unfortunately at risk due to limited funding for 2019. We hope a solution can be urgently found with the support of the European Commission and Member States.

Importance of resistance management (Agenda item B.02)

Given the public health significance of exposure to certain natural contaminants and toxins, it is essential that farmers continue to have the means to control moulds and fungi that can affect cereals, maize, fruit and vegetables. Access to reliable solutions is important not only for efficiency and yield, but to ensure that consumers and farm animals have minimal exposure to naturally occurring, potent contaminants.

There are currently 3 main conventional crop protection substances authorised for use in the EU which are considered essential for managing resistance: Chlorothalonil (item B.02 on the SCOPAFF agenda) Folpet, and Mancozeb. These substances continue to be highly effective in preventing the development of resistant pathogens and are frequently used in combination with other active ingredients to help manage resistance. We are highly concerned that non-renewal of any of these substances would significantly reduce the efficacy, and therefore the effective lifespan, of other active ingredients currently available in the EU and would further reduce the crop protection tools available to European growers.

Our member companies are determined to engage the necessary resources to demonstrate that these substances are suitable for renewal. They will gladly provide complementary studies or data if provided the necessary time to do so.

We understand that several ECPA member companies, as well as independent expert institutions, have already written to the Commission to express their concern regarding resistance and importance of having effective tools to manage this issue.

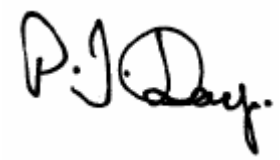
Annex III of Regulation 1107/2009 (unacceptable co-formulants) (Agenda item C.02)

We understand that the draft Commission regulation modifying Annex III of Regulation 1107/2009 (unacceptable co-formulants) is likely to be placed for public commenting after the SCOPAFF meeting. While we welcome this opportunity to provide our input, in advance of the discussion during the SCOPAFF meeting, we would like to highlight several key issues

- An adequate transition time for reformulation of any impacted formulations must be provided, acknowledging that using hazard based cut-off criteria does not equate to a risk with using these co-formulants.
- ECPA has consistently requested a transparent and consistent process for the identification of unacceptable co-formulants for addition to Annex III. If hazard based cut-off criteria are used for identification purposes, it is essential that only harmonised classifications which have been agreed by the relevant competent authority and have been adopted at the European level, are used, i.e. via ECHA and the CLH process.
- We are concerned at suggestions that crystalline silica present as an impurity may be proposed as a criteria for listing of unacceptable co-formulants in Annex III. Crystalline silica is a ubiquitous naturally occurring substance, and the typical concentration based cut-offs for organic substances are unlikely to be practically achievable, or relevant for the health effects associated with crystalline silica.

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 25 January 2019.
(2) Data on risk assessment conclusions according to bee guidance document and on chronic and larval testing

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