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ECPA input for SCOPAFF meeting 5-6 December 2019

- **Amendment to General Food Law, new transparency rules**
- **Amending Implementation Regulation (EU) No 844/2012**
- **Annex III of Regulation 1107/2009 (unacceptable co-formulants)**
- **EFSA Isomer Guidance Document**
- **Recast of Drinking Water Directive – Council General Approach**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 5-6 December 2019, ECPA would like to provide our input on several key issues on the agenda:

Amendment to General Food Law, new transparency rules (Agenda item A.22)

Regulation 2019/1381 amending the General Food Law (GFL) and associated sectorial legislation was published on 6 September 2019. We have consistently supported the provisions aimed at strengthening consumer confidence and transparency in the EU risk assessment process. The new regulation will nevertheless entail key changes to the process for the evaluation of active substances under Regulation 1107/2009 and Regulation 844/2012 (renewals). Several new procedures will now need to take place well in advance of dossier submission[1] and additional time will need to be planned for by the Applicant, EFSA and RMS for these steps to take place. With the official application date being 27 March 2021 we would highlight the complexity of implementing these new procedures to submissions under the current AIR4 and AIR5 renewal programmes both of which will be ongoing at this time period. We would also highlight the urgent need for early clarity on the designation of the RMS for the AIR6 renewal programme. This is essential to allow applicants to start to prepare their dossiers and to allow sufficient time for the above mentioned new procedures to take place prior to submission.

The procedures employed for making studies public will also be critical to strike the right balance between increasing transparency and protecting from commercial misuse the small part of the dossier which contains legitimate confidential business information. **Given the significant changes that the new regulation will entail, we would reiterate our request that there be sufficient opportunities for industry to be regularly informed and consulted during the course of establishing and implementing these provisions.**

[1] These include the processes related to pre-submission advice, the notification of studies to the database of studies to be established by EFSA, and the submission of the list of intended studies (renewals) and the subsequent public consultation on this list.

Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances (Agenda item B.01)

We support the proposal to align the active substance authorisation process under Regulation 1107/2009 with the harmonised classification of substances under Regulation 1272/2008. ECPA position is that regulatory decisions based on the cut-off criteria laid out under points 3.6.2, 3.6.3 and 3.6.4 of Annex II to Regulation 1107/2009 should be based on a harmonised classification prepared by ECHA according to Regulation 1272/2008 and not on recommended classifications proposed by EFSA.

As a general point, we would like to continue to oppose the 30 days stop-of clock period in regulation 844/2012 as it is not long enough to address all the questions raised by EFSA. We would suggest a stop-the-clock extended to 90 days instead. We fail to see why the 3 months period, coming from regulation 1107/2009, should be restricted to 30 days for the renewal process. We do hope the upcoming amendment of the AIR regulation to adapt it to the GFL rules will be an occasion to make such change.

Annex III of Regulation 1107/2009 (unacceptable co-formulants) (Agenda item C.01)

We understand that the draft Commission regulation modifying Annex III of Regulation 1107/2009 (unacceptable co-formulants) may be placed for public commenting soon after the 5/6th December 2019 SCOPAFF meeting. In advance of the discussion during the meeting, we would reiterate the following 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 are used which have been agreed by the relevant competent authority and have been adopted at the European level, i.e. via ECHA and the CLH process.
- For the consistent interpretation of Annex III, ECPA is supportive of setting a *de minimis* level for impurities in finished formulations. However, we would strongly recommend that full consistency with the declaration cut-offs specified in the REACH and CLP legislation is maintained. In general this is 0.1%, rather than the proposed 0.01%. We are aware of no legislative basis for a lower threshold than 0.1%.
- Due to the lack of harmonised classification for crystalline silica, parallel legislative activities aimed at controlling exposure to this substance, and complexities involving the route of exposure, we believe crystalline silica neither itself nor as an impurity in another co-formulant should be listed in Annex III at this time.

EFSA Isomer Guidance Document

While not included in the agenda of this meeting, we would like to highlight the need for a suitable transition period. We believe the timeframe to perform the new studies, the need to develop additional analytical methods, followed by additional toxicity data for isomeric metabolites and impurities, can take much longer than 2 years. For the period 2019/2020 alone, we estimate that more than 25 ECPA member company submissions are impacted by the new requirements. We would therefore request a pragmatic and workable transition period with an implementation date around mid-2022.

EFSA responses to our comments during the public consultation clarified several part of the text but we have identified remaining questions and interpretation issues. ECPA is preparing a questions document that will be shared with EFSA, Commission and Member States.

We would also highlight an additional aspect which we believe should be taken into account before implementing the guidance document. The additional requirements mentioned above may have an impact on the position of the EU during international reviews. Especially at JMPR/CCPR meetings this may lead to further difficulties in adopting CODEX MRLs (CXL). This could result in a lower international standard recognition rate and may further complicate trade with the EU. Consequently, ECPA would recommend that an analysis be conducted on

the potential implications for international trade before this guidance document is formally adopted.

Commission proposal for a recast of Directive on the quality of water intended for human consumption (Drinking Water Directive)

While not included in the agenda of this SCOPAFF meeting, we would take this opportunity to reiterate our concerns with some of the changes which have been introduced into the Council's General Approach on the Commission proposal[2] for a recast of the Directive on the quality of water intended for human consumption (Drinking Water Directive[3]). The General Approach adopted by the Environment Council on 5 March 2019 includes some concerning amended text on the identification of pesticide relevant metabolites in Annex 1 – Part B – Chemical Parameters - Pesticides.

The amendments, if adopted, would introduce an unnecessary and ambiguous definition of "*relevant metabolites*" which would be incoherent with the current text of Regulation 1107/2009 and existing Commission guidance documents (e.g. guidance document SANCO/221/2000). The proposed amendments and our concerns are explained in more detail in the attached updated position paper (Attachment 1). We understand that trialogues have been ongoing on political and technical level and the topic has been discussed in part already. We would urge the institutions to maintain the wording in the original Commission proposal, which is also reflected in the current position of the European Parliament.

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

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Director of Regulatory Affairs

This letter will published on the ECPA website and will be available at: http://www.ecpa.eu/transparency-policy.

[2] COM(2017) 753 final
[3] Directive 98/83/EC