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ECPA input for SCOPAFF meeting 16-17 Juy 2020

- **EFSA Isomer Guidance Document**
- **EFSA practical arrangements on Transparency/confidentiality and Pre-submission phase**
- **IUCLID as IT tool for notification and submission of application**
- **Impact of covid-19 situation on regulatory timelines**
- **Annex III of Regulation 1107/2009 (unacceptable co-formulants)**
- **Draft Commission Implementing Regulation repealing Regulation 844/2012**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 16-17 July 2020, ECPA would like to provide input on several key issues on the agenda:

EFSA Guidance on the risk assessment of PPP A.S. and their transformation products that have stereoisomers (A.07)

ECPA would like to emphasize 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. **We would request a pragmatic and workable transition period with an implementation date by end 2022.**

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.**

We would also like to reiterate our demand for a dedicated information session by Commission or EFSA to bring clarifications on this complex guidance document. Many questions are still unanswered and would need timely response due to the need for applicants to adapt internal study planning. A detailed list of questions was shared with our previous letter dated 17th March[1].

EFSA practical arrangements on Transparency/confidentiality and Pre-submission phase (GFL Regulation) (A.12)

In the context of the implementation of the General Food Law amendment, ECPA continues to support the EFSA and Commission work towards more transparency. During the last meeting of the DG SANTE advisory forum meeting focused on GFL implementation, it was made clear by

[1] https://www.ecpa.eu/about-us/eu-transparency-register

EFSA that **no consultation of stakeholders are foreseen on the two practical arrangements being prepared by EFSA. These arrangements can have severe practical consequences on applicants capacity to prepare, submit and defend dossiers in Europe and we believe that stakeholder input should be gathered on the basis of a draft proposal.** We understand it is not a co-creation process, but nevertheless, having those arrangements not carefully developed with practical implications fully understood by all stakeholders, might have unforeseen consequences. **Taking the example of the confidentiality claims related arrangements, the impact could be very direct on companies' ability to submit innovative technologies in Europe.**

We continue to believe specific discussion is needed on several implementation elements for the pesticide sector as a whole, and ECPA together with other associations representing applicants, is ready to engage and provide direct information.

IUCLID as IT tool for notification and submission of application (A.14)

ECPA supports the use of IUCLID as new data format and continues to contribute to the EFSA technical group activities. However, our key concern remains the envisaged timeline for implementing this new data format to active substance dossiers.

The EFSA pilot work looking at converting an existing dossier into the new format is now completed and it confirmed that having something functional by March 2021 will not be possible: it demonstrated that more than 800 hours were needed to convert (not entirely) a rather simple dossier (clodinafop) into the new format. The current lack of clear specifications is putting applicants in a difficult situation as they need to plan internal resources and make significant investment decisions already to cope with the potential conversation workload for the numerous submissions taking place in the 2021.

We would recommend to limit the burden of applicants and Member States authorities by first using the format for certain areas of the dossier like in physico-chemical properties and potentially toxicology regarding data submitted also under REACH and CLH processes. We'll continue to support EFSA and OECD efforts in fully developing this new format.

COVID-19 situation impact on regulatory deadlines

In view of the current situation due to the covid-19 pandemic, ECPA member companies are continuing to closely monitor the existing and future impact on several regulatory deadlines, and will continue to keep competent authorities informed on those developments in a timely and documented manner.

Similarly to what ECHA has announced, we invite the Commission, EFSA and Member States to consider which flexibility measures could be adopted to keep the regulatory system functional while avoiding the negative consequences of missed or incomplete submissions beyond applicants' control. Such flexibility will be essential for companies submitting incomplete substance renewal dossiers, in the hope missing elements could be submitted later in the Stop-the-Clock period.

Annex III of Regulation 1107/2009 (unacceptable co-formulants) (B.01)

We understand that the draft Commission regulation modifying Annex III of Regulation 1107/2009 (unacceptable co-formulants) is on the SCoPAFF agenda for a possible opinion.

We consider that the draft Annex III list of substances as proposed would provide for a workable and robust framework supporting product authorisation, and will contribute to ensuring a continued high level of protection for both operators and the environment.

Regarding the criteria to further populate this initial list, detailed arguments have been submitted previously to SCoPAFF (see our previous letter dated 17th March 2020[2]) and more recently in our letter to DG SANTE dated 24 June 2020 – in annex.

[2] https://www.ecpa.eu/about-us/eu-transparency-register

Draft Commission Implementing Regulation repealing Regulation 844/2012 (C.01)

ECPA welcomes the proposal which will translate elements from the revised General Food Law regulation into the renewal process. We would like to highlight key points to ensure a smooth transition from the current regime.

- It is important for applicants to be clear which substances will be affected or not by the new regulation. We are concerned several substances from AIR4 and AIR5 might fall in-between and require substantial work to be compliant on time. **Several substances already faced reductions of their timelines via the adaption of the renewal regulation to the CLP requirements (minus 3 months). Any further reduction should at least be accompanied by adequate transition measures.**
- The revised GFL includes a new 6 months penalty period in cases of inadmissibility followed by resubmission. Those cases would include situations where mismatches occur between dossier content and the list of studies notified in the EFSA database, unless "valid justification" is provided by the applicant. **It will be important to receive clarity on what can constitute a valid justification, as well as illustrative examples in advance.**
- As correctly identified in the REFIT report, having "*a short window for applicants to submit comments and further information on the draft EFSA conclusions to address aspects that were raised only late during the peer review process and could not be foreseen by the applicant (…)*" . **We fully support the inclusion of such windows in the draft renewal regulation as it can only help to avoid unfair situations.**

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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cc. Karin Nienstedt
Manuela Tiramani

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https://www.ecpa.eu/about-us/eu-transparency-register