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ECPA input for SCOPAFF meeting 18-19 May 2020

- **Guidance document on significant and non-significant changes of the chemical composition of PPPs**
- **EFSA Isomer Guidance Document**
- **Guidance document on Time dependant sorption / Aged sorption**
- **Amendment to General Food Law, new transparency rules**
- **Impact of covid-19 situation on regulatory timelines**
- **Annex III of Regulation 1107/2009 (unacceptable co-formulants)**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 18-19 May 2020, ECPA would like to provide input on several key issues on the agenda:

Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (A.07)

ECPA welcomes the revision of this guidance document and the clear improvements made compared to previous versions, especially on how to address composition changes and assessment of co-formulants equivalence. However, we believe more discussions are needed to clarify what appears to be misunderstandings and different ways of thinking in the new draft.

Today, even after a zonal evaluation, the final composition registered in neighbor countries of the same or different zone are not exactly the same regarding the authorization of use of alternative source of co-formulants. This artificially increase product supply chain complexity and create additional expert workload. **In order to harmonize composition of the formulated pesticides within the EU, ECPA would favor an inter-zonal approach, similar to what is being done in the biocide sector. A common evaluation could be latter the basis for the product registration in all countries across the EU.**

We also believe it is fundamental to fully align the rules for identity, composition and classification with the REACH and CLP regulations when it comes to the assessment of equivalence of co-formulant. Having a list of equivalently assessed co-formulants would also facilitate harmonisation.

We would welcome any opportunity to further engage, at technical level, with the European Commission and Member States on this important document, also considering the need to comply with FAO specifications and principles.

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

ECPA 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. **We would**

request a pragmatic and workable transition period with an implementation date by end 2022.

We would also like to reiterate our demand for a dedicated information session with applicants 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 accordingly. A detailed list of questions was shared with our previous letter dated 17th March[1].

Guidance document on Time dependant sorption / Aged sorption (not on the agenda)

We would like to ask for a SCoPAFF level discussion and noting of this long lasting document providing specific guidance to assess these higher tier studies. The document was started by the UK authorities colleagues and went two times to EFSA for review and further adaptions. **After nearly 10 years in the making we believe the noting at EU level should take place** – thus resuming the use of these valuable studies for refinement of the risk assessment.

New Transparency rules: General Food Law amendment and implementation (A.14)

In the context of the implementation of the General Food Law amendment, ECPA continues to be an active member of the EFSA technical groups working on the pilot project to use IUCLID for pesticide dossier and the notification of studies database. While we fully support the need for increased transparency and standardisation of formats we would like to raise again our concerns on the envisaged timing for implementation and the lack of engagement on other crucial aspects.

One specific concern is the envisaged timeline for adopting a **new data format for plant protection product dossier**. The EFSA pilot work raised lots of gaps and needs for adaptions, and we fear that having something fully functional by March 2021 will not be possible. We'd like to get clarity as soon as possible on what will be requested and by when. Applicants need to prepare internal resources accordingly and the pilot showed us that more than 500 hours were needed by a dedicated team to convert a rather simple dossier (and with missing elements in the end). **It has to be noted that at least 5 active substances submissions are planned within a week after the GFL amendment regulation entry into force, and many more in the course of 2021. Having clarity by September 2020 latest is essential.**

We understand the wish to start in March 2021, but 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.

We also see a lack of information regarding the development of **modalities linked to the disclosure of documents**. As this will be on documents owned by applicants, we would like to be part of the discussion. We estimate that a pesticide dossier can contain around 300-400 submitted studies, which is very different from others sectors (e.g. GMO dossier has an average of 30-40 studies). **Confidentiality claims** is also a topic for which we believe applicants view should be considered already.

Given the significant changes that the new regulation will entail, We believe a 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.

COVID-19 situation impact on regulatory deadlines (A.16.2)

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. A list of examples was shared with DG SANTE on the 27th of March[2]. Deadlines being already, or about to be, impacted by the current lockdown across Europe are:

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

[2] Link to download the letter dated 27 March 2020 and its annex.

- Company organizations operating on essential functions only mode, with reduced capacity to generate data, complete ongoing studies, initiate new studies and prepare regulatory dossiers
- Reduced national authorities' ability to process applications.
- Contract research organisations and third party laboratories temporarily suspending operations, with severely reduced capacity to generate information for companies.
- The lack of testing materials and inability to conduct labs/field trials due to missing equipment (e.g. delivery on site), plus the inability to transport materials, which are blocked by customs in several countries worldwide.
- Long-term studies (e.g. field/seasonal studies) due to start in 2020, which have been cancelled for the above reasons. Hoping studies can start in 2021, but this will impact submission timelines for submissions in 2020. More impacts are also foreseen now on submissions for 2021.

ECPA member companies will continue to keep competent authorities informed on those developments in a timely and documented manner. The processes and associated deadlines to be affected may concern any of the following:

- Submission of active substance and plant protection products dossiers, whether supporting new applications or renewals. Looking only at renewals of active substances, more than 90 submissions are expected between 1st June 2020 and end 2021.
- Provision of confirmatory data
- Submission of MRL dossiers
- Provision of information to EFSA
- No possibility to conduct meetings including pre-submission discussions even by phone with the rapporteur member state (or zonal RMS).

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 an exchange of views and possible opinion.

We consider that the draft Annex III 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.

However, in advance of the exchange of views during the meeting, we would reiterate the following key principles for placing substances on the Annex:

- 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.
- A transparent and consistent process for the identification of unacceptable co-formulants for future addition to Annex III is required. 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. These should be consistent with the cut-offs specified in the REACH and CLP legislation. In general this is 0.1%.

Detailed arguments underpinning these points have been submitted previously to SCoPAFF, see our previous letter dated 17th March 2020[3].

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

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

cc. Karin Nienstedt
Manuela Tiramani

This letter will published on the ECPA website and will be available at:
https://www.ecpa.eu/about-us/eu-transparency-register