13/05/2016
LET/16/EJ/26056

Sabine Juelicher
Director
Dir E — Food and feed safety, innovation
DG Sante
Rue Breydel 4
1040 Bruxelles
sabine.juelicher@ec.europa.eu

Euros Jones
European Crop Protection Association
+32 2 663 76 01
euros.jones@ecpa.eu

Subject: Implementation rules for the inclusion of unacceptable co-formulants in Annex III of the Regulation (EC) No 1107/2009

Dear Ms Juelicher

ECPA would like to bring to your attention our serious objections to the "Discussion paper on co-formulants - Implementation rules for the inclusion of unacceptable co-formulants in Annex III of the Regulation (EC) No 1107/2009" as presented by the Commission at the Plenary meeting of the advisory group on the food chain and animal and plant health (Brussels, 29 April 2016).

While we will provide detailed technical comments on the Discussion Paper by the 30th May deadline specified by the Commission, we would already highlight the following objections and concerns:

- The suggested way forward is **completely out of line** with the **regulatory fitness check**, where the stated aim is to make EU law simpler and to reduce regulatory costs. It would lead to duplication of work in the evaluation of co-formulants, as it effectively proposes **parallel REACH & CLP processes** for PPP co-formulants; it also fails to make proper links between Regulation (EC) 1107/2009 and both Regulation (EC) 1907/2006 and 1272/2008. Co-formulants used in plant protection products are commodity chemicals, with broad and wide-spread uses in many applications in the European and global marketplace – such as in cosmetics, fertilisers, food contact materials, house-hold chemicals, etc., and as such are regulated under REACH.

- The extent of the technical issues identified in this document indicate that the full range of existing regulatory mechanisms within Europe's chemical management system have not been properly considered, and **inadequate stakeholder consultation** with chemical regulators, industry, and other stakeholders also points towards an incomplete evaluation of the tools available.

- A **proper impact assessment** is necessary, given that the considerable overall impact across all formulations currently on the European market has not been considered or explained, and that existing regulatory mechanisms have not been properly explored. Such an assessment should fully consider options other than those presented in the Discussion Paper, such as the efficient leveraging of existing REACH approaches.

- While it is to be expected that pre-existing national approaches to regulating co-formulants would have taken a narrower national-scope approach, it would also be expected that the development of an EU-wide approach would take a broader perspective and properly evaluate all existing EU regulatory mechanisms, and in this context leveraging REACH approaches would have been expected to be the starting point for this exercise.

- The proposed approach does not clearly differentiate product assessment from co-formulant assessment, and inappropriately binds risk assessment with a regulatory ban. We would stress that the reuse of the co-formulant risk assessment methodology developed for the Biocidal Products Regulation would be inappropriate as the outcome of that evaluation is linked to the product risk assessment and was not developed for the purpose of banning the co-formulants.

- Suggested use of the proposed **Tier 2 & 3 hazard classifications** (e.g. skin sensitisation) as potential triggers for banning is **unacceptable**. Furthermore, the resulting workload implications for COM/MS/applicants have clearly not been considered, further **adding to the delays and unmanageable workload** which are already a feature of the 1107/2009 authorisation system.
- Europe's chemical management system is based around substances. Accordingly, **only substances should be listed** as unacceptable for use in PPP. The suggestion to list mixtures (presumably by tradename) is unworkable and inconsistent.
- Given the considerable additional complexity proposed, consideration must be given to the development of workable timelines for implementation, transition and grace periods, recognising the potentially vast number of formulations which could be affected with the Annex III listing of a substantial number of co-formulants. Past experience shows that transition periods of several years are required to allow for such formulation changes.

ECPA wishes to stress that there are sufficient mechanisms within the plant protection product regulation (PPPR, Regulation (EC) 1107/2009), classification and labelling (CLP, Regulation (EC) 1272/2008) and REACH (Regulation (EC) 1907/2006) frameworks to regulate co-formulants used in crop protection products. Decision making on the population of Annex III of 1107/2009 should therefore be based on these mechanisms. We strongly oppose any additional process which would use different criteria and unnecessarily increase the resources required to manage the additional complexity to an unworkable level for authorities and notifiers alike.

Attached with this letter is an ECPA letter which was addressed to the Commission in March 2015 suggesting an approach. We hope that this proposal will be given proper consideration to developing a realistic and workable approach.

We remain open to discussions and would be happy to answer any questions you may have.

Yours sincerely

Euros Jones
Director, Regulatory Affairs

Cc:

Michael Flüh	DG SANTE
Wolfgang Reinert	DG SANTE
Jeremy Pinte	DG SANTE
Bjorn Hansen	DG ENVI
Reinhard Buescher	DG GROW
Jack de Bruijn	ECHA
Leana Yla- Mononen	ECHA

Members of the Standing Committee