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Brussels, 20 October 2022

Dear Chair, *dear Pascal*,

Thank you for your letter of 29 June 2022 sent on behalf of the coordinators of the Committee on the Environment, Public health and Food safety in which you suggest further action concerning the evaluation of the long-term toxicity of plant protection products (PPPs) by either amending the provisions of Commission Regulation setting out the data requirements for plant protection products ((EU) No 284/2013) or adopting non-binding instruments such as guidelines.

I agree with you that the judgment of the Court of Justice in Case C-616/17 recalls the obligation of the Member States to thoroughly assess the long-term toxicity and carcinogenicity in the context of the assessment of potential impacts on human health of PPPs.

As regards the risk assessments for PPPs which Member States need to perform, the aforementioned Commission Regulation provides that these have to consider not only the information submitted in the application dossiers, but also data obtained under other regulatory frameworks, for example – as referred to in your letter – Regulation 1907/2006 (REACH). If the information is insufficient to conclude on the long-term toxicity, Member States are empowered to require applicants to submit the necessary additional information up to the same level as for active substances. As regards the EU level assessment of active substances, the Rapporteur Member State or EFSA can, if justified, require specific tests in accordance with the existing data requirements, either for the complete PPP or for the individual components.

Therefore, and in particular, also in the light of the judgement in Case C-616/17, I agree with you that in case insufficient information is provided by applicants, the Member States and EFSA have an obligation to request further information. Regulation (EU) 284/2013 sets out the obligations for applicants in terms of data submission in their respective application dossiers, and these data requirements give scope to Member States to require additional data,

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and it is as an obligation to do so if such data are needed to ensure safety, as made clear in paragraph 116 of the Court's decision in Case C-616/17.

Let me also recall that an important step forward in this context was made in 2021, when the Commission amended Annex III to the Regulation on the placing of plant protection products on the market ((EC) No 1107/2009) and listed 144 co-formulants which are banned from use in PPPs. Most of these were listed because of long-term toxicity concerns. As of 24 March 2023 at the latest, such co-formulants cannot be used in any PPP in the EU. In addition, a draft Implementing Regulation which sets out a procedure and harmonised criteria for identifying further unacceptable co-formulants to be added to this list is in preparation and will be subject to public consultation via the feedback mechanism portal in the coming months.

I would also like to inform you that the Commission has initiated a discussion with the Member States and EFSA on this topic, and some Member States have already confirmed that they have requested additional information or studies in the context of evaluations of applications for authorisation of PPPs. In addition, EFSA has recently published a report providing an overview of 182 co-formulants that were part of PPPs submitted in active substances dossiers since January 2019 and further analysis and discussion on how to document more transparently what has been done with regard to the assessment of co-formulants will be held in the future.

Let me reassure you that we will continue working with Member States and EFSA as regards the assessment of long-term toxicity of PPPs and, in line with your suggestion, we will propose to Member States to update the guidance document on Zonal Evaluation and Mutual Recognition.

I would like to take this opportunity to thank you again for your letter and your interest in this matter.

Yours sincerely,

D. Kyriakides