European Parliament

Committee on the Environment, Public Health and Food Safety
The Chair

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Mr Vytenis Andriukaitis
Commissioner, Health and Food Safety
European Commission
Rue de la Loi 200
BE - 1049 Brussels

Dear Commissioner Andriukaitis,

On behalf of the ENVI Committee coordinators, I am writing to you to express our serious legal concerns in relation to the draft Commission Regulation setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) No 1107/2009 (C(2016)3751) which was endorsed by the Commission on 15 June 2016.

Based on legal advice from Parliament services, we are led to believe that the mentioned draft Regulation exceeds the implementing powers conferred to the Commission in Article 78(1) of Regulation (EC) No 1107/2009 (the 'PPP Regulation') in that it seeks to amend the conditions for granting a derogation from the ban on substances considered to have endocrine-disrupting properties, as laid down in points 3.6.5 and 3.8.2 of Annex II to that Regulation.

More specifically, the issue arises with regard to the envisaged amendment to the above-mentioned provisions whereby the expressions "*unless the exposure of humans*" (in point 3.6.5) and "*unless the exposure of non-target organisms*" (in point 3.8.2) would then read "*unless the risk from exposure of humans*" and "*unless the risk from exposure of non-target organisms*".

We have been advised that the regulatory approach adopted as regards the conditions for granting approval of active substances (and potential derogations therefrom) - i.e. that derogations can only be granted in case of negligible exposure of humans or non-target organisms to the substance concerned (hazard-based) - must be considered as an essential element of the PPP Regulation, the latter being entirely devoted to lay down harmonised rules for approving active substances and authorising the marketing, use and control of the products consisting of, or containing, the substances in question.

In this regard, it has been brought to our attention that, as is apparent from the very wording of the PPP Regulation, when addressing the complex issue of setting the rules on approving active substances as well as on the marketing, use and control of plant protection products, the legislature had to strike a delicate balance between different and potentially conflicting objectives, i.e. the improvement of agricultural production and the internal market, on the one hand, and the protection of health and the environment, on the other hand. The general ban on the use of endocrine disruptors in plant protection products, as laid down in points 3.6.5 and 3.8.2 of Annex II, and the corresponding derogations, are clearly the result of such balancing exercise.

It has also been brought to our attention that regulatory elements entailing this kind of political choices are to be considered as essential elements of the legislative act, the adoption (or amendment) of which is reserved to the legislature - the Parliament and Council - and may not be delegated to the Commission.

It follows, in our view, that the envisaged amendments to points 3.6.5 and 3.8.2 of Annex II of the PPP Regulation fall beyond the scope of the Commission's implementing powers under Article 78(1) (a) as they touch upon an essential regulatory element of the PPP Regulation.

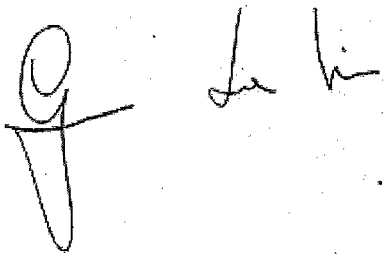
Although the Commission, pursuant to Article 78(1)(a) of the PPP Regulation, is entitled to amend the Annexes to the Regulation, taking into account current scientific and technical knowledge, the Commission's mandate is limited to non-essential elements of those Annexes. A shift from hazard-based to risk-based derogations in order to reflect scientific and technical knowledge (as mentioned in Recitals 5 to 9 of the draft Commission Regulation) could therefore only be undertaken through a legislative procedure to amend the PPP Regulation in accordance with Article 294 TFEU.

Since the draft Commission Regulation at hand is still under consideration in the Standing Committee on Food Chain and Animal Health, we felt it was appropriate to draw your attention on our concerns already at this early stage.

That said, I would like to underline that the concerns outlined above are obviously without prejudice to the position (and any additional concerns) that ENVI Members may take on the scientific criteria for the determination of endocrine disrupting properties, which the Commission envisages to adopt through the same draft Regulation, as well as on those included in the draft delegated act to be adopted pursuant to Article 5(3) of Regulation (EU) No. 528/2012 as regards biocidal products.

I look forward to hearing from you at your earliest convenience.

Yours sincerely,



Giovanni La Via