European Commission

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Mr Giovanni La Via, MEP
Chair of the Committee on the Environment,
Public Health and Food Safety
European Parliament
Rue Wiertz, 60
B-1047 Brussels

Dear Chairman,

I would like to thank you for your letter dated 15 September 2016 in which you express the concerns of the ENVI Committee coordinators 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 which was endorsed by the Commission on 15 June 2016.

Based on legal advice from Parliament services, some of you believe that the Commission has exceeded its powers with the amendment to the derogation for endocrine disruptors that it proposed in the context of the Plant Protection Products (PPP) Regulation.

I have several reasons not to share the views of the Honourable Members on this point. First of all, I would like to stress that the draft act that was endorsed by the College on 15 June 2016 had prior to that been subject to an inter-service consultation which involved the Legal Service of the Commission.

I would also recall that the amendment at stake is based on Article 78(1)(a) of the PPP Regulation, which allows the Commission to amend the non-essential elements of the PPP Regulation, taking into account current scientific and technical knowledge.

In your letter you state that you "*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*". In my view this is incorrect, for several reasons.

First, Annex II to the PPP Regulation is among the annexes which may be amended based on Article 78(1)(a). It is the most substantial annex to that Regulation, laying down the "procedure and criteria for the approval" of active substances. These criteria must be subject to amendment in light of scientific knowledge as otherwise the Commission would be able to amend only the procedural elements in Annex II, which would seem to contradict the terms of Article 78(1)(a), namely that the annexes should be amended in light of scientific progress.

Further, the fact that, as you refer to it, the "derogation" is of a hazard-based nature, does not mean that the derogation is an essential element which cannot be changed in light of scientific progress. Neither the recitals nor the basic act suggest that it was the intention of the legislator to maintain the derogation to the non-approval of active substances having endocrine disrupting properties unchanged, without taking account of the latest scientific information on that issue. To the contrary, a careful analysis of the recitals and of the basic act itself makes clear that the derogation should be understood as a "criterion for approval" which reflected the state of science at the time of adoption of the basic act, and which may be amended in light of scientific progress.

Finally, I would like to recall that the legislator explicitly emphasised in recital 10 its intention to establish a system in which the active substances would be approved where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment (recital 11). Currently this high standard on protection of human health is not always ensured because a substance could be approved under restricted conditions on the ground that exposure would be negligible, even though the substance has a very high hazard which may result in a risk to human health. Only the consideration of hazard and exposure together would avoid approving substances which may pose a risk. It is my belief therefore that amending the conditions for granting the derogation would, in the light of the latest science, allow for the highest standard of protection of human health and the environment.

In light of the above, I do not believe the Commission exceeded the powers it has under Article 78(1)(a) of the PPP Regulation. Given that the draft Commission Regulation will be examined by the European Parliament, once voted in the Standing Committee on Plants, Animals, Food and Feed, I thought it was important to give you explanations on this point and I would like to invite you to share these explanations with all the Members of the ENVI Committee.

I hope that I can count on the support of the European Parliament to adopt swiftly the best decision on the criteria.

Yours sincerely,