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*Mr Pio GARCÍA-ESCUADERO MÁRQUEZ
President of the Senado
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Dear Presidents,

The Commission would like to thank the Congreso de los Diputados and the Senado for their Reasoned Opinion concerning the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory {COM(2015) 177 final}.

The Congreso de los Diputados and the Senado rightly underline the dependence of EU farming on commodities imported from third countries, where the cultivation of genetically modified organisms (GMOs) is widespread, and the need to preserve these sources of vegetal proteins to maintain EU livestock competitiveness. These elements were also considered in the Commission's Communication,¹ which accompanied the proposal. However, as a matter of fact, even if genetically modified food and feed are used in most Member States, the same Member States have never voted in favour of a draft decision for authorisation proposed by the Commission. This situation is worrying for the reasons mentioned by the Congreso de los Diputados and the Senado and because it generates a feeling of distrust in the system which is perceived by some as non-democratic.

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Reviewing the decision-making process on genetically modified organisms (GMOs), COM(2015) 176 final.

The Commission has endeavoured to analyse the reasons behind the vote of the Member States that abstain or vote against the authorisation decisions and it appears that, in most cases, they do not relate to the quality of the risk assessment, but to other kinds of national societal considerations.

The Commission considers that granting Member States the possibility to take their own decisions at national level on the basis of compelling grounds, other than those linked to the risk assessment of GMOs, should allow these Member States to reflect national considerations and at the same time it may alleviate the tensions around the decision-making process on GMOs. Such a possibility is permitted by the Treaty on the Functioning of the European Union in its Article 36 and in related case-law of the Court of Justice of the EU, allowing derogations from the single market rules justified by compelling grounds or overriding reasons of public interest. It should be noted that the proposed amendment relates to a legal text which is 12 years old: Regulation (EC) No 1829/2003 which entered into force in 2003. The recently adopted Directive (EU) No 2015/412 is not applicable to food and feed, but only to the cultivation of GMOs.

The proposal, read in combination with the Treaty rules, contains substantial safeguards to avoid possible abuse by Member States. The measures should be proportionate, non-discriminatory, and they should be based on compelling grounds in accordance with EU law. As observed by the Congreso de los Diputados and the Senado, the assessment by the Commission does not include the possibility to block the adoption of a restrictive measure by a Member State. However, the Treaty grants the Commission the power to launch an infringement procedure against a measure adopted by a Member State which does not comply with EU law. Such a procedure could be used in cases where the Commission considers that the substantial conditions are not respected.

In addition, several provisions are included in the proposal to ensure that the possible adoption by Member States of restrictive measures will not affect products coming from other Member States or third countries. For instance, the proposal does not allow such measures to ban food and feed in which an adventitious presence of authorised GMOs below the labelling threshold is present. The proposal also does not authorise measures prohibiting or restricting the free circulation and imports of genetically modified food and feed. Moreover, it is clear from the proposal and from Regulation (EC) No 1829/2003, that Member States cannot impose labelling of animal products derived from animals fed with GMOs since these products do not fall under the scope of the GMO legal framework.

Finally, as regards the compliance with the principle of subsidiarity, the Commission would like to point out that the proposal does not transfer the entire competence to decide on the placing on the market of GMOs to Member States. It only proposes to grant the possibility for those Member States which so wish, to adopt measures restricting or prohibiting the use of genetically food and feed on their territory, after the EU authorisation has been issued. The proposal will not affect the elements of the GMO authorisation which are better addressed at EU level, such as the assessment by the European Food Safety Authority and the principle of a risk management decision which is taken at EU level on the basis of this opinion. However, it appears that measures based on legitimate considerations which are not related to the risk assessment could be better handled at national level. It should be noted that if a Member State sees no reason to make use of the possibility offered by this proposal to adopt restrictive measures, that Member State does not need to take any action, thus avoiding any kind of additional administrative burden.

The points made above are based on the initial proposal presented by the Commission which is currently in the legislative process involving both the European Parliament and the Council in which your government is represented.

The Commission hopes that these clarifications address the issues raised by the Congreso de los Diputados and the Senado and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Frans Timmermans
First Vice-President*

*Vytenis Andriukaitis
Member of the Commission*