



EUROPEAN COMMISSION

*Brussels, 15.9.2015
C(2015) 6291 final*

Dear President,

The Commission would like to thank the Bundesrat for its Opinion on 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 Commission takes note of the Bundesrat's critical assessment of the above proposal and would like to offer the following observations in reply.

First, the Commission would like to stress that under the new framework foreseen by the legislative proposal, the procedure for authorising genetically modified organisms (GMOs) at European level will remain risk-based, and the Member States will continue to play an active role during both the risk assessment phase and the risk management phase. Indeed Member States will still have the opportunity to comment on applications which are under risk assessment by the European Food Safety Authority (EFSA) and on adopted opinions presented to them by EFSA in Standing Committee meetings before a vote takes place. EFSA will continue to address all Member States' scientific comments and questions. Therefore, at the time of vote in the Standing Committee, the Member States will continue to have at their disposal all the necessary information about the safety of the GMO at stake to make an informed decision in favour or against the draft authorisation.

Second, Member States will retain the possibility to ban an EU authorised genetically modified food and feed in their territory via safeguard clauses, should they consider that new scientific evidence shows that the product could pose a risk to health and the environment. Austria has already made use of this possibility by adopting safeguard clauses on three genetically modified food and feed, namely maize MON863 and oilseed rapes Ms8xRf3 and GT63.

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The Commission's legislative proposal therefore does not in any way modify or restrict the existing core steps of the genetically modified food and feed authorisation procedure based on risk assessment, nor will it limit the possibility for Member States to adopt safeguard clauses on the basis of safety grounds. On the contrary, the proposal provides a new, legally sound path to the Member States, in addition to the safeguard clauses, to restrict or ban the use of EU authorised genetically modified food and feed on their territory, by allowing them to refer to non-safety related reasons such as national societal concerns, which are frequently invoked by opposing or abstaining Member States when voting in Standing and Appeal Committee meetings. Such a possibility is permitted by Article 36 of the Treaty on the Functioning of the European Union (TFEU) and the related case law of the Court of Justice of the EU, provided that a number of conditions are met, i.e. that the bans are based on overriding reasons of public interest, are proportionate and non-discriminatory. These substantial conditions are not intended to limit the use of this new tool by the Member States, but rather to ensure that the opt out measures are adopted while taking due account of the interests of all concerned parties, are compatible with the Treaty and EU international agreements and are defensible in Courts at national, European and international level.

The Commission would also like to react to the Bundesrat's concern that the legislative proposal may have an impact on the handling of the authorisation procedure, and ultimately on the number of GMOs authorised. It has to be recalled that the European legislation on GMOs and the comitology procedure, which were both adopted by the European Parliament and the Council, set clear procedures and timelines for processing applications for genetically modified food and feed authorisations. The Commission is bound to ensure the proper implementation of these rules. This has led to a situation where the Commission, in accordance with the comitology procedure, has assumed the responsibility of authorising the genetically modified food and feed with a positive EFSA opinion, while following the vote of the Member States – in the Standing Committee and in the Appeal Committee – no qualified majority in favour or against the draft decisions could be obtained. Under the new framework set out in the legislative proposal, EFSA and the Commission will continue to deal with applications with the same level of stringency, and the Member States will keep their right to vote against a draft decision if they consider that their safety concerns have not been properly addressed.

Finally, as regards the doubts expressed by the Bundesrat concerning the practicability of the bans, the Commission would like to recall that the Member States will be responsible for controlling the proper application of their own opt out measures by farmers and food and feed operators in their territory. This duty will not differ substantially from the already existing obligation for the Member States to put in place appropriate control measures to ensure that food and feed marketed in their territory do not contain GMOs which are not authorised in the EU. Likewise, Member States having adopted safeguard clauses against particular GMOs – such as Austria – should already have in place control systems to ensure that these GMOs are not present at any level of the food and feed chain. The Commission is not aware that these existing obligations raise particular feasibility challenges in the Member States. It should also be noted that farmers and food and feed chain operators are already routinely controlled by national inspection authorities on a wide number of safety criteria, which could include specific controls dedicated to the detection of GMOs concerned by a national opt out measure.

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 Bundesrat and looks forward to continuing our political dialogue in the future.

Yours faithfully,

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First Vice-President*

*Vytenis Andriukaitis
Member of the Commission*