EUROPEAN COMMISSION

Brussels, 15.09.2015
C(2015) 6342 final

Dear President,

The Commission would like to thank the Bundesrat for its 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 Commission welcomes the support of the Bundesrat for increasing the power given to Member States when deciding on the use of genetically modified food and feed but regrets its rejection of the proposal and would like to address the Bundesrat's concerns underlying this rejection.

To ensure that national measures adopted on the basis of the proposal are legally defendable and compatible with EU primary law and international obligations, the proposal provides that measures adopted by Member States have to respect certain substantial conditions. In particular, these measures must be proportionate, non-discriminatory and based on compelling grounds. It is important to note that the notion of compelling grounds of public interest is recognised in Article 36 of the Treaty of the Functioning of the European Union (TFEU) and in the related case law of the Court of Justice, and allows derogations to the single market rules.

No list of grounds has been included in the proposal, because Member States are the best placed to identify these compelling grounds which best correspond to their national context. They can however find in Article 36 of the Treaty, related case law or secondary legislation, examples of compelling grounds which they may consider appropriate.

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As regards the Bundesrat's concern on the absence of an impact assessment prior to the adoption of the proposal, it should be recalled that the proposal only gives a legal basis to the Member States to restrict or ban GM food and feed. Member States will be responsible for their own decisions, after having evaluated their possible impacts at national level. As in the case of Directive (EU) 2015/412 on GMO cultivation, it was neither possible nor relevant to assess ex ante and at European level the practical impacts of the proposal, since these will depend on the national opt-out measures, which could widely differ in scopes and designs, in order to fit national contexts. The Commission therefore considers that it would be up to each Member State, when deciding to make use or not of the possibility offered by the EU legislation, to strike the balance between all relevant impacts, including possible negative effects on national farmers and operators using GM raw materials such as soya, maize or oilseed rape.

The Commission's Communication, adopted the same day as the proposal[1], shows that even if genetically modified food and feed is used in most if not all the Member States, it has never happened that a draft decision of authorisation tabled by the Commission received a qualified majority in favour during the vote in the relevant committees where Member States are represented. In most cases, Member States which abstain or vote against draft decisions of authorisation of genetically modified food and feed do not justify their vote by reasons relating to the quality of the risk assessment, but by national societal considerations. For the moment, the GMO legal framework does not allow these Member States to invoke those societal considerations, which creates a tension in the authorisation procedure of GMOs.

The Commission considers that granting Member States a 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, will allow these Member States to better reflect their national societal considerations while preserving the EU authorisation process for GMOs.

Other ways of addressing the issue have been considered by the Commission before tabling this proposal, including the possibility to change the comitology rules for the adoption of GMO related decisions. However, none of them have been considered as being tenable for institutional reasons. It has to be underlined that the procedure which is followed for the authorisation of GMOs and which allows the Commission to adopt a decision in the absence of a qualified majority in favour or against the draft decision was agreed jointly by the European Parliament and the Council[2]. This procedure is applied in many other areas of EU law without controversy as to its democratic nature. The rules of vote by qualified majority are the same as those which are set in the Treaties.

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[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.

[2] Regulation (EC) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13–18.

EFSA does not operate in isolation for the risk assessment of GMO applications. On the contrary, Member States collaborate closely with EFSA on each submitted application and for applications covering cultivation, the initial risk assessment is performed by the competent authority of a Member State.

Concerning the risk assessment of genetically modified food and feed, Commission Implementing Regulation (EC) 503/2013 on applications for authorisation of genetically modified food and feed was adopted in April 2013 following a qualified majority in favour in the Standing Committee. This Regulation reinforces the risk assessment to be conducted by applicants when submitting a new authorisation file by clearly defining the studies and data to be provided and the protocols to be followed when conducting the studies. The revision of the environmental risk assessment of GMOs for cultivation is ongoing as requested by the 2008 Council conclusions. As indicated in Directive (EU) 2015/412, the Commission will update the Annexes to Directive 2001/18/EC with a view to incorporating and building upon the strengthened 2010 EFSA guidance on the environmental risk assessment of GM plants. This should be finalised by April 2017.

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 its political dialogue in the future.

Yours faithfully,

Frans Timmermans
First Vice-President

Vytenis Andriukaitis
Member of the Commission