



EUROPEAN COMMISSION

*Brussels, 19.11.2015  
C(2015) 7728 final*

*Dear President,*

*The Commission would like to thank the Narodno Sabranie 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 legislative proposal delivers on one of the priorities of the Political Guidelines on the basis of which the Commission was appointed, namely to allow Member States to better take into account public views and national contexts when it comes to the use of Genetically Modified (GM) food and feed authorised at European level. As President Juncker remarked in his State of the Union address to the European Parliament: “European problems require European solutions, national problems require national solutions. In this regard, and because citizens' concerns about Genetically Modified Organisms (GMOs) may vary greatly among Member States, the Commission proposed to return the power to restrict or prohibit the use of GM food and feed to national authorities.”*

*The legislative proposal provides a legal basis allowing Member States to restrict or ban the use of GM food and feed after the granting of an EU authorisation on the basis of compelling grounds other than risks relating to health and to the environment, since these aspects are assessed at EU level. This proposal was made following the observation that Member States which abstain or vote against draft decisions of authorisation of GM food and feed tabled by the Commission, usually do not justify their votes by reasons relating to the quality of the risk assessment, but by other kinds of considerations strongly tied to national contexts. It was therefore considered that adopting a more subsidiarity-based approach and granting these Member States a decisional power to take into account individual legitimate concerns on such a controversial subject would alleviate the tensions surrounding the EU GMO authorisation system.*

*Ms Tsetska TSACHEVA  
President of the  
Narodno Sabranie  
2, Narodno Sabranie Square  
BG – 1169 SOFIA*

*The Commission welcomes the Narodno Sabranie's support as regards the initiative to review the authorisation process for GM food and feed in order to increase the power given to Member States when deciding on their use on their territory. The Commission also welcomes the Narodno Sabranie's acknowledgement that the legislative proposal is compliant with the principles of subsidiarity and proportionality laid down in Article 5(3) and (4) of the Treaty of the European Union (TFUE). The Commission has nevertheless noted the concerns highlighted by the Narodno Sabranie relating to several provisions of the legislative proposal and is pleased to have this opportunity to provide, in annex to this letter, a number of clarifications regarding its proposal which it trusts will allay the Narodno Sabranie's concerns.*

*The points made above and in annex 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 Narodno Sabranie and looks forward to continuing our political dialogue in the future.*

*Yours faithfully,*

*Frans Timmermans  
First Vice-President*

*Vytenis Andriukaitis  
Member of the Commission*

## Annex

*The Commission has taken note of the reservations expressed by the Narodno Sabranie in its Opinion as regards several elements of the legislative proposal. The Commission has carefully considered each of the issues raised and is pleased to offer the following clarifications.*

*The Commission would like to stress that granting Member States the possibility to take their own decisions on GM food and feed use, at national level and on the basis of compelling grounds, is permitted by the Treaty on the Functioning of the European Union (TFEU) and is compatible with the principles of the internal market, including the free movement of goods. Indeed, Article 36 of the TFEU, and related case-law of the Court of Justice of the EU, allow derogations from the single market rules specified in Article 34 of the TFEU, if justified by compelling grounds or overriding reasons of public interest. The Commission therefore invites the Narodno Sabranie to consider the aforementioned provisions, as well as the recently adopted Directive (EU) 2015/412 on GMO cultivation, for an indication of compelling grounds – as distinct from risks to health and the environment – which could be used to justify national opt-out measures. The Commission chose not to include a list of compelling grounds in its legislative proposal as it considers the Member States are best placed to identify the grounds that best correspond to their national context and needs.*

*The Commission would also like to recall that, under the current legislative framework, Member States can adopt national emergency measures to ban an authorised GM food and feed on their territory, should they consider that new scientific evidence shows that the product poses a serious risk to health and to the environment. The legislative proposal does not put into question these abilities whatsoever. It aims to give the Member States an additional possibility to restrict or prohibit the use of GM food and feed, based on overriding reasons of public interest not related to health and safety.*

*In addition, several provisions are included in the proposal to ensure that the impact of any opt-out measures on the movement of GM food and feed is limited to what is necessary to achieve the objectives of the Member States. Consequently, a Member State's opt-out measure cannot prohibit the import and transit of products coming from other Member States or third countries. Furthermore, the proposal does not allow opt-out measures banning food and feed with an adventitious presence of authorised GMOs below the labelling threshold. Finally, the proposal, like Regulation (EC) No 1829/2003, does not permit Member States to impose the labelling of animal products derived from animals fed with GMOs, since these products do not fall under the scope of the GMO legal framework.*

*As regards the Narodno Sabranie's concern relating to the absence of an impact assessment prior to the adoption of the proposal, it should be recalled that the proposal only gives Member States a legal basis to restrict or ban GM food and feed. In accordance with the principle of subsidiarity, it will therefore be for each Member State to decide whether or not a measure is needed on its territory, and what its features should be. To this end, a Member State might decide to carry out an evaluation of all relevant impacts, including possible negative effects on national farmers and operators using GM raw materials, and strike the balance where it considers appropriate. Consequently, Member States may adopt opt out measures which differ widely in scope and design, in order to fit their national contexts. In light of these elements, it was neither possible nor relevant for the Commission to assess ex ante and at European level the practical impacts of the proposal.*