EUROPEAN COMMISSION

Brussels, 6.4.2016
C(2016) 1853 final

Dear Chairman,

The Commission would like to thank the Vouli ton Antiprosopon 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}.

President Juncker made a clear commitment in his Political Guidelines to review the legislation applicable to the authorisation of Genetically Modified Organisms. This proposal, which would allow Member States to better take into account public views and national contexts when it comes to the use of genetically modified food and feed authorised at European level, honours that commitment.

The legislative proposal provides a legal basis for Member States to restrict or ban the use of Genetically Modified (GM) food and feed after the granting of an EU authorisation, on the basis of compelling grounds other than those relating to safety which 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. We therefore considered that a more subsidiarity-based approach should be adopted, by granting these Member States a possibility to take into account their individual legitimate concerns on such a controversial subject.

The Commission welcomes the support in principle of the Vouli ton Antiprosopon for the aims of the legislative proposal and takes note of its observations and criticisms. The Commission is pleased to have the opportunity to provide, in annex to this letter, some clarifications and trusts that these will allay the concerns of the Vouli ton Antiprosopon.

Mr Adamos ADAMOU
Chairman of the Standing Committee
on the Environment of the
Vouli ton Antiprosopon
CY – 1402 NICOSIA

cc. Mr Yiannakis OMIROU
President of the
Vouli ton Antiprosopon
CY – 1402 NICOSIA

The points made in this letter and its 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.

We are looking 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 carefully considered each of the issues raised by the Vouli ton Antiprosopon in its Opinion and is pleased to offer the following clarifications.

The Commission would like to recall that the authorisation procedure for Genetically Modified Organisms (GMOs) is based on a risk assessment approach, and it is recognised as being among the strictest worldwide. The legislative proposal does not aim to tackle potential risks to human health and the environment, since the decision making process, in its current shape, already achieves this objective in an effective way. Indeed the safety of GMOs is extensively assessed by the European Food Safety Authority (EFSA) prior to their authorisation. Afterwards the Member States also have the capacity to ban authorised GMOs through the adoption of safeguard clauses, should they consider that new scientific evidence shows that the product could pose a risk to health and to the environment.

The objective of the legislative proposal is actually to resolve a long-standing challenge faced by the decision making process for GM food and feed: the Member States until now have always failed to reach a qualified majority in favour or against draft decisions of authorisation, because a number of them abstain or vote against by invoking national considerations – e.g. concerns of their national citizens – which are not related to the safety of the products. The legislative proposal therefore aims to allow the Member States to take into account these non-safety-related motives when deciding on GMOs, without influencing the EU authorisation procedure ensuring an equal level of safety across the EU, and which is therefore not conceived to address these national dimensions. Consequently, the legislative proposal allows for the extension of the range of citizens' concerns, which vary from one country to another, that can be considered when authorising GMOs for food and feed use.

The Commission would like to recall that a comprehensive review of the decision making process has been carried out prior to the publication of the legislative proposal, and its findings were outlined in the Communication of the Commission published concomitantly[1]*. In that Communication it is shown that the situation of systematic "no opinion" is specific to GMO authorisation requests and unique compared to the thousands of implementing decisions adopted via comitology every year, where the Member States usually support the Commission's draft decision in the standing committee. The reasons invoked by Member States to justify their abstentions or negative votes are sometimes scientific in nature, but in majority of the cases are based on other considerations, reflecting the societal debate in their country. Whilst the current legislation allows the Commission to take into consideration "other legitimate factors", in addition to the risk assessment carried out by EFSA, it has not been in a position to justify an EU-wide ban on products considered safe by EFSA on the ground of these*

[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.

factors, due to their wide diversity across Member States. This led the Commission to the conclusion that it is appropriate and proportionate to adopt a subsidiarity-based approach to resolve this challenge very much specific to authorisation of GMOs, and give a legal basis to Member States to make use of these legitimate factors at national level. The Directive (EU) 2015/412 as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs[2], which was adopted with a large majority by the European Parliament and the Council, successfully provides a practical and efficient solution as regards the cultivation of GMOs. Therefore the Commission used the same model for allowing the Member States to decide on the use of GM food and feed.

The national restrictions or bans have to respect a number of substantial conditions directly deriving from article 34 of the Treaty and related case law of the Court of Justice of the EU, including the obligation to demonstrate that the national measures are based on overriding reasons of public interest, proportionate and non-discriminatory. These substantial requirements may indeed be perceived as a constraint, but they aim to guide the Member States in the adoption of subsidiarity-based measures which are defendable in Courts at national, European and international levels.

The absence of definition of the term "use" provides the Member States with a wide margin of discretion as to the scope of the measures they intend to adopt, which needs to be closely connected to the compelling grounds used to justify the measure, and which shall also take into account the principles of subsidiarity and non-discrimination.

Concerning the absence of a list of criteria with respect to the reasons which may be invoked, the Commission would like to recall that Member States are the best placed to identify the compelling grounds/overriding reasons of public interest which best correspond to their specific national contexts. Member States may find in Article 36 of the Treaty, in the related case law, or in secondary legislation – such as Directive (EU) 2015/412 - examples of compelling grounds/overriding reasons of public interest which they may consider appropriate. In view of the variety of national contexts and situations which can be covered by the legislative proposal, the Commission was not in a position to identify precisely the justifications which could be used by the Member States to support their measures, provided that they are compatible with Union law. This approach is compatible with the principle of subsidiarity.

With regards to the concern of the Vouli ton Antiprosopon related to the effectiveness of the national restriction or prohibition measures in the context of the free circulation of GM food and feed implied by the Internal Market, the Commission would like to recall that the traceability and labelling obligations imposed on operators will help Member States to identify the banned GM food/feed and perform targeted controls in their territory. Member States with safeguard clauses also have to ensure the absence of the banned products in food and feed, including when such products transit their territory. The Commission is not aware that these existing obligations – which are not

[2] OJ L 68, 13.3.2015.

substantially different from the ones in the legislative proposal – raise particular feasibility challenges in the Member States.

The legislative proposal does not allow a Member State with a GM food/feed ban to impede the import of food products from animals fed with GMOs (e.g. milk, meat, eggs). Nevertheless, the Member State concerned has means to inform consumers about these products, either by taking advantage of existing obligatory labels allowing a distinction between locally produced and imported animal products (for instance for beef products: country of birth, rearing and slaughtering), or by developing voluntary labelling schemes stressing that no GMOs have been used to feed the animals from which such products are delivered.