REASONED OPINION 1/2015 OF THE JOINT COMMITTEE FOR EU AFFAIRS, DATED JUNE 16, 2015, ON THE NON COMPLIANCE WITH THE PRINCIPLE OF SUBSIDIARITY BY 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) (2015/0093 (COD))

BACKGROUND

A. The Protocol on the application of the principles of subsidiarity and proportionality attached to the Lisbon Treaty of 2007, in force since December 1st, 2009, establishes a procedure allowing national parliaments to verify European legislative initiatives' compliance with the subsidiarity principle. The said Protocol has been developed in Spain by Act 24/2009, of December 22, amending Act 8/1994, of May 19. In particular, new articles 3 j), 5 and 6 of Act 8/1994 are the legal basis for this report.

B. 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, has been adopted by the European Commission and conveyed to national parliaments, which have a deadline of eight weeks to verify the subsidiarity check of the initiative, being the deadline June 23, 2015.

C. The Bureau and the Spokespersons of the Joint Committee for EU Affairs agreed on May 20, 2015, to examine the said European legislative initiative, appointing to that end as Rapporteur Senator Mr. Ángel Pintado Barbanoj, and requesting the Government the report envisaged in section 3 j) of Act 8/1994.

D. The Government has conveyed its report, indicating that this Proposal amending the Regulation affects the due observance of the subsidiarity principle, since the responsibility is transferred to an Administration which lacks the necessary capacity to achieve the objectives pursued by the proposed action, reason for which it does not comply with the subsidiarity principle.

E. The Joint Committee for EU Affairs, in its meeting held on June 16, 2015, adopted the following:

REASONED OPINION

1.- Article 5 (1) of the Treaty on the European Union indicates that "*the use of Union competences is governed by the principles of subsidiarity and proportionality*", and adds in Article 5 (3) of the same Treaty that "*under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall only act in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level".*

2.- The legislative proposal examined is based on Article 114 of the Treaty on the Functioning of the European Union, which lays down the following:

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it

shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure.

3.- The European Union has in place a comprehensive legal framework for the authorisation, traceability and labeling of GM food and feed. Regulation (EC) No 1829/2003 on GM food and feed covers food, food ingredients, and feed containing, consisting of or produced from GMOs. It also covers GMOs for other uses such as cultivation, if they are to be used as source material for the production of food and feed. These different products are designated in this document as “GMOs and GM food and feed”.

Regulation (EC) No 1829/2003 has put in place an authorisation procedure whose aim is to ensure that the placing on the market of the products concerned will not pose a risk to human and animal health and the environment. In order to do so, a scientific risk assessment is at the centre of the procedure: every authorisation for the placing on the market of a product has to be duly justified and the main ground on which such a justification can rely is scientific assessment. The legislation gives responsibility for this scientific risk assessment to the European Food Safety Authority (EFSA), in cooperation with the scientific bodies of the Member States.

Regulation (EC) No 1829/2003 contains provisions allowing the Commission or Member States to adopt emergency measures against the placing on the market/use of an authorised GMO, where it appears that the product is likely to constitute a serious risk to health or to the environment. These measures require scientific evidence demonstrating that the product is likely to pose a serious risk to health or to the environment.

4.- The Proposal amending Regulation 1823/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, generates some confusion as to the objectives pursued by the European Commission since these are not adequately specified. We are aware of the difficulties for the Commission to determine a clear policy with the support of all Member States. We understand that this is no obstacle to try and find a balanced position that will provide guarantees to consumers, to the feeding stuff manufacturing sector, the livestock and the beef sectors. This proposal amending a regulation causes legal uncertainty, unforeseeable costs and the fracturing of the single market. We would move from a system based on scientific evidence to another where private interests and political or ideological positions shall prevail. Our dependence on raw materials (cereals, oilseeds and protein crops) is important enough to safeguard the future of this manufacturing sector.

The European Union is the largest importer of agricultural products in the world. In average, the EU food sector uses 225 million tons of feed material per year. Europe is highly dependent on genetically modified protein sources for its animal products. The European Union would need a soya cultivated area of 15, 5 million hectares to be self-sufficient. Currently we have 0, 6 million.

After 19 years cultivating genetically modified organisms, currently 18 million farmers work 181 million hectares with genetically modified organisms, especially in 28 countries, the main ones being the United States, Brazil, Canada, Argentina and India.

Competitiveness of European agricultural production clearly depends on maintaining agricultural production provision sources with guarantees and certainty as to the rules to be established by the EU and the Member States. The endless fluctuations as regards decision making by European authorities generate the opposite effect to that being

pursued, namely, confusion for consumers, uncertainties for the manufacturing sector and economic damage which takes a toll on the development of Research, Development and Innovation of a sector which is key for our economy.

The European Food Safety Authority is responsible for the risk assessment, from a scientific perspective. At the same time, even if Regulation (EC) No 1829/2003 allows the Commission to take into consideration, in addition to the risk assessment, "other legitimate factors", the Commission has not been in a position to refer to those factors in order to justify a refusal of the authorisation of products considered safe by EFSA and, in any case, it could only do so for the EU as a whole. This argument leads us to consider that it jeopardises the market unity in the EU and might affect free trade and the transit of goods. The fact that there is no detailed determination of the reasons justifying the adoption of exclusion clauses (omission of a "negative or positive list"), as well as the fact that no legal mechanisms are envisaged for the suspension of national measures that might be considered abusive, not adequately justified or of discriminatory nature, entails a clear risk of legal uncertainty.

At the same time, it entails that animal products from animals fed with genetically modified feed do not have to be labeled as such: the re-nationalisation of the GM authorisation can give rise to this "national" labeling request in order to protect the farmers of Member States who have decided to prohibit the use of feed made with GMO products. Such measure can represent a barrier for the import of the animal products of those Member States who have not decided to adopt this prohibition.

The prohibition to "use" GM products could also be extended by some Member States to operations such as the "transit, storage or processing" through its territory.

Another risk of multiple labeling or of greater complexity of the analysis, is that if every EU Member State implements some specific national requirements, consumers shall have a greater lack of trust in foreign products, thus creating a double market based on non-homogeneous criteria within Member States.

A deep divide can be generated in the concept of open market and free movement of goods within the EU as laid down in articles 34 and 36 of the TFEU. In our view, decision making must be always based on science.

5.- As regards the compliance by the Proposal with the principle of subsidiarity, it must be noted that we are in a field, namely the regulation of the use of genetically modified food and feed, which recently has undergone in-depth amendments by means of Directive (EU) 2015/412 of the European Parliament and of the Council, of March 11, 2015, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms in their territory. The current Proposal modifies again the legal framework according to which Member States can adopt measures to prohibit or restrict the use of certain genetically modified

products just a few months after this sector's regulations have been altered. Before going into the content of the Proposal, it must be noted that the legal uncertainty generated by regulatory fluctuations is an indication that points to the incompliance with the principle of subsidiarity, since, regardless of the objective pursued by the European Commission, it could have been attained with a more stable legal framework.

On the other hand, it must be underlined that, since the examined proposal transfers the responsibility of the decision to restrict or prohibit the use of GMO to the States, it compromises the compliance with the principle of subsidiarity, since the States do not always have the capacity to adopt these decisions in such a way as not to damage the functioning of the internal market. The potential unbalances that might be generated between Member States' legislations pose a threat to the functioning of the European Union food and feed market and entail the risk that the effects of this Proposal be opposite to those pursued by the Commission.

CONCLUSION

For the aforementioned reasons, the Joint Committee for EU Affairs considers that 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, does not comply with the subsidiarity principle laid down in the Treaty on the European Union in force.

This reasoned opinion shall be conveyed to the European Parliament, to the Council and to the European Commission, within the framework of the political dialogue between national parliaments and the institutions of the European Union.