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**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

concerning the

position of the Council at first reading with a view to the adoption of a Directive of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory

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1. BACKGROUND

Date of transmission of the proposal to the European Parliament and to the Council (document 2010/0208 COD):	14 July 2010
Date of the opinion of the European Economic and Social Committee:	9 December 2010
Date of the position of the European Parliament, first reading:	5 July 2011
Date of transmission of the amended proposal:	[*]
Date of adoption of the position of the Council:	23 July 2014

* The Commission did not prepare an amended proposal but expressed its views on the Parliament amendments in the "*Commission Communication on the action taken on opinions and resolutions adopted by Parliament at the July 2011 part-session*" (document SP (2011)8072) sent to the European Parliament on 8 September 2011.

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The European Union (EU) has adopted a comprehensive legal framework for the authorisation of products consisting of or derived from Genetically Modified Organisms (GMOs). The authorisation procedure covers the use of GMOs for food and feed purposes, industrial processing and cultivation, and their derived products for food and feed uses.

The EU authorisation system is aimed at avoiding adverse effects of GMOs on human and animal health and the environment while establishing an internal market for those products. Two pieces of legislation, namely Directive 2001/18/EC on the environmental release of GMOs[1] and Regulation (EC) No 1829/2003 on GM food and feed[2], provide for the pre-marketing authorisation of GMOs. Both establish

[1] OJ L 106, 17.4.2001, p. 1.
[2] OJ L 268, 18.10.2003, p. 1.

science based standards for the assessment of potential risks for human health, animal health and the environment as well as labelling requirements. In addition, Regulation (EC) No 1830/2003[3] provides rules on the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs.

In March 2009, the Council rejected Commission's proposals requesting Austria and Hungary to repeal their national safeguard measures, as according to the European Food Safety Authority (EFSA) they lacked the necessary scientific support needed under the EU legislation. Subsequently, a group of 13 Member States[4] called on the Commission to prepare proposals to give freedom to Member States to decide on cultivation of GMOs[5].

In September 2009 the political guidelines for the new Commission set out by President Barroso made reference to the principle of subsidiarity in the GMO area as an example where the balance may not be always right between an EU framework and the need to take account of diversity in an EU of 27 Member States. According to these guidelines, it should be possible to combine a European Union authorisation system for GMOs, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory.

The proposed Regulation reflects these political guidelines by providing a legal base in the EU legal framework on GMOs for Member States to restrict or prohibit in all or part of their territory the cultivation of GMOs that have been authorised at EU level. Those prohibitions or restrictions shall be based on grounds other than those covered by the environmental and health risk assessment under the EU authorisation system.

3. COMMENTS ON THE POSITION OF THE COUNCIL

3.1. General comments

The Commission's proposal was transmitted to the European Parliament and to the Council on 14 July 2010. The European Parliament adopted its position at first reading on 5 July 2011 and supported the main goals of the Commission's proposal, subject to 28 amendments.

No modified Commission's proposal was issued. In the "*Commission Communication on the action taken on opinions and resolutions adopted by Parliament at the July 2011 part-session*" (document SP (2011)8072) sent to the European Parliament on 8 September 2011, the Commission indicated that it could accept in full, in part, in principle or subject to rewriting 21 of the 28 amendments, as it considered that these amendments could clarify or improve the Commission's proposal and were consistent with its general aims.

Prior and following adoption of the European Parliament's first reading position, discussions took place in Council with a view to finding a common position. These discussions were finalised by the adoption with qualified majority of a political agreement at the Environment Council of 12 June 2014, which was translated into a common position of the Council at the Council of 23 July 2014.

The Commission considers that the Council's common position reflects the original goals of the Commission's proposal. Although on certain elements, the common

[3] OJ L 268, 18.10.2003, p. 24.

[4] AT, BG, IE, EL, CY, LV, LT, HU, LU, MT, NL, PL and SI.

[5] Respective discussions took place at Council meetings of 2 March, 23 March and 25 June 2009.

position differs from the Commission's proposal, the Commission is satisfied that it covers all issues considered essential by the Commission when adopting its proposal.

3.2. Amendments of the European Parliament accepted by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading

- ***Recitals***

  Amendment 2, which explains ***particular aspects of the EU harmonised environmental risk assessment*** required under Directive 2001/18/EC, is accepted by the Commission. The Council's common position incorporates in part this amendment in the amended **recital (2)**, by making a general reference to the Annex II of Directive 2001/18/EC.

  Amendment 11, referring to the ***importance of avoiding that national measures restricting or banning GMO cultivation prevent biotechnology research*** from being carried out, is accepted by the Commission. This amendment has been incorporated in full in the new recital (15) of the Council's common position.

  Amendment 44 includes a ***call for adoption of updated guidelines on environmental risk assessment***, as a follow up to conclusions of the Environment Council of 4 December 2008. It specifies that these guidelines should not be based only on the principle of substantial equivalence or on the concept of a comparative safety assessment. This part of the amendment can be accepted subject to rewording to clarify that the legal reference for the environmental risk assessment remains Annex II to Directive 2001/18/EC, which reads *"a comparison of the characteristics of the GMO(s) with those of the non-modified organism under corresponding conditions of the release or use will assist in identifying the particular potential adverse effects arising from the genetic modification"*. In the environmental risk assessment, it is appropriate to draw on previous knowledge and experience and to use the appropriate comparator in order to highlight differences associated with the GM plant in the receiving environment(s). Furthermore, the risk assessment guidance developed under the Cartagena Protocol on Biosafety in 2012 follows an approach that is consistent with that of EFSA i.e. step-wise and case-by-case, using a comparative analysis and covering the same seven areas of risk. The Council's common position incorporates in part this section of amendment 44 in the new **Article 2** of the amending Directive, which requires the Commission to report on the progress towards giving normative status to the strengthened 2010 EFSA guidance on the environmental risk assessment of GM plants.

- ***Enclosure of an indicative list of grounds for justifying opt-out measures***

  The assessment of potential risks on human and animal health and on the environment of the deliberate release of GMOs is fully harmonised through Annex II to Directive 2001/18/EC. The scope of the assessment of GMOs for cultivation covers all possible areas of environmental risks on the whole EU territory, including at regional or local levels. It considers for instance the assessment of invasiveness or persistence of a GM event, possibility of cross-breeding with domestic cultivated or wild plants, preservation of biodiversity and persistent scientific uncertainty. A GMO can be authorised only if the risk

assessment concludes, in particular after examination of the above elements, that the GMO is safe for human and animal health and for the environment.

The Commission's proposal provides that Member States' measures restricting or banning the cultivation of GMOs on the basis of that proposal (so called "opt out measures") have to be based on grounds other than those related to the assessment of the adverse effects on health and the environment which might arise from the deliberate release or the placing on the market of GMOs. Therefore **amendments 5, 8, 10, 41, 47** can be accepted by the Commission subject to rewording to make clear that grounds invoked by Member States to justify opt out measures do not conflict with the EU wide environmental risk assessment. The Council's common position introduces in amended **recitals (10) and (11)**, and in the new **Article 26b(3)** of the amended Directive, a different definition of the environment related ground which ensures that there is no interference with the EU wide risk assessment at Member State level: "*environmental policy objectives distinct from the elements assessed according to Directive 2001/18/EC and Regulation (EC) 1829/2003"*. The Commission considers that the wording proposed by the Council is in line with the objective of the proposal. Otherwise, the Commission can accept the grounds not related to environmental dimensions proposed either by the European Parliament or the Council, as these are broadly similar in substance.

- ***Other modifications of the proposed new Article 26b of the amended Directive***

  The Commission agrees with the European Parliament about the importance of making available to operators (including growers), in a timely manner, ***necessary information about any restriction or prohibition*** of GMO cultivation in the territory of a Member State, and to give them sufficient time to adapt and finish the current cultivation season when the measures concern GMOs already authorized at Union level (**amendments 7**, **17, 43**). The Council's common position incorporates the provisions of these amendments in the new **recital (21),** and the new **Articles 26b(4), 26b(5), 26c(3) and 26c(5)** of the amended Directive (with the exception of information obligations towards growers).

  The Commission accepts the particular reference to the importance of national measures being in conformity with the ***principle of proportionality*** (**amendment 20**). This amendment has been incorporated in full by the Council, in the new **recital (13)** and in the new **Article 26b(3)** of the amended Directive.

- ***Modification of other articles of Directive 2001/18/EC***

  Amendment 26 relating to the ***entry into force of the Regulation*** is accepted by the Commission. The Council's common Position incorporates in full this amendment in the new **Article 3** of the amending Directive.

3.3. Amendments of the European Parliament rejected by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading

- ***Modification of other articles of Directive 2001/18/EC***

  The Commission does not accept **amendment 12** modifying Article 22 of Directive 2001/18/EC on ***free circulation***, because the proposal will allow Member States to restrict exclusively the cultivation of GMOs on their territory and not the trade or import of GM or conventional seeds, food and feed. However, the Commission acknowledges the usefulness of stating clearly that the proposal is not affecting the functioning of the internal market. Therefore it accepts the Council's modified wording of **recitals (13) and (18)** and the new **Articles 26b(9) and 26c(6)** of the amended Directive on free circulation and import of authorised GMOs in all Member States and their use in Member States which do neither restrict nor prohibit GMO cultivation, and the new **recital (20)** as regards the free movement of conventional seeds, plant propagating material and of the product of the harvest.

3.4. Amendments of the European Parliament accepted by the Commission in full, in part or in principle, but not incorporated in the position of the Council at first reading

- ***Recitals***

  Amendment 4 referring to the importance of ***collecting the results of research***, is accepted.

  The Commission accepts the provisions of **amendment 44** referring to establishment of an ***extensive network of scientific organisations***, and to ***independent research*** on the potential risks arising from the deliberate release or the placing on the market of GMOs.

- ***Modifications of the proposed new Article 26b of the amended Directive***

  Amendment 40, clarifying the ***need for a case by case examination*** prior to the adoption of national measures, can be accepted.

  Amendment 42, asking for a ***prior independent cost-benefit analysis*** of national measures taking into account alternatives, can be accepted.

  Amendment 19, which requires national measures to be subject to a ***prior public consultation*** of at least 30 days, can be accepted.

  However, the Commission considers that the relevance of the three abovementioned amendments should be reviewed in light of the Council's common position which proposes to transform the Regulation into a Directive, which leaves to the Member States the choice of forms and methods.

- ***Modification of other articles of Directive 2001/18/EC***

  The Commission accepts in principle the modification of Article 26a of the Directive (**amendments 6, 14**) to oblige Member States to establish ***co-existence measures*** to avoid the unintended presence of GMOs on their territory and in border areas of neighbouring Member States, although the current legislation does not set obligations in this field. **Amendment 9,** underlining the importance of effective ***measures to prevent cross-border contamination***, can also be accepted. The Council's common Position also

addresses coexistence measures by making a reference, in new **recital (22)**, to the Commission Recommendation of 13 July 2010 which provides non-compulsory guidance to Member States for the development of coexistence measures, including in border areas. The Commission accepts this wording, which mirrors the existing legislation and reflects the diversity of Member States' positions on this matter.The Commission would like to observe that the modification of Article 25 of the Directive referring to the importance of ***making seed material available for independent research*** is not related to the objectives of the proposal (**amendment 13**). However the Commission accepts in principle this amendment provided that it is compatible with the legal basis of the act.

3.5. Amendments of the European Parliament rejected by the Commission and not incorporated in the position of the Council at first reading

- ***Legal basis***

  The Commission considers that the proposal should be based on Article 114 TFUE, since it amends Directive 2001/18/EC, which is itself based on Article 114 TFUE, and because it aims at ensuring a smoother functioning of the internal market while guaranteeing protection of the environment, in line with Art. 114(2) TFUE. Even if **amendments 8 and 47** of the European Parliament, which introduce the possibility to ban cultivation based on environment related grounds, were to be adopted, the centre of gravity of the proposal and of the Directive as amended would still remain the smooth functioning of the internal market. Therefore the Commission does not accept **amendment 1**.

- ***Recitals***

  The objective of the Commission proposal is to ***allow national restrictions or prohibitions on the basis of grounds other than risks***, which are addressed under the EU-wide environmental risk assessment. The precautionary principle should be taken into account in the implementation of Directive 2001/18/EC (in line with its recital 8), but it is not relevant for the proposed Regulation. Therefore, the Commission does not accept **amendment 46**.

- ***Modifications of the proposed new Article 26b of the amended Directive***

  Amendment 51 refers to the ***possibility of regions within Member States to adopt restrictions or prohibitions*** on their territory. This is an aspect that concerns the distribution of competences between central governments and regional/local entities within Member States, which is a matter belonging to their constitutional law and in which EU law cannot interfere. Therefore, the Commission does not accept this amendment.

  Amendment 22 ***limiting the duration of Member States' measures to five years*** – whereas the duration of the authorization granted to a given GMO under EU law is of 10 years - is inconsistent with the objectives of the proposal – which is to offer to Member States the widest margin of legally sound solutions to restrict or ban GMO cultivation - and with the fact that these measures are justified by reasons of public interest, which may remain unchanged over the five year period. Therefore, the Commission does not accept this amendment.

Amendment 23 ***deletes the word "reasoned" when referring to measures adopted by Member States***. The Commission does not accept this deletion because restrictions or prohibitions need to be well reasoned and justified in line with national conditions.

- ***Addition of a new article to Directive 2001/18/EC***

Amendment 24 introducing in Directive 2001/18/EC a new article on ***liability requirements*** is not directly linked with the objective of the proposal. The Commission would like to recall that GMOs are covered by Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damages[6]. This Directive takes due account of the polluter pays principle as indicated in the Treaty and in line with the principle of sustainable development. Under current EU legislation, questions of liability and compensation due to situations covered by Article 26a of Directive 2001/18/EC (i.e. economic losses of farmers/operators due to unintended presence of authorized GMOs in other products) are let to the competence of Member States, as acknowledged in the Recommendation of the Commission of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs. Indeed, although there are examples of EU legislation setting provisions on financial liability and financial compensations in certain areas falling within the scope of the Treaties, these matters are usually not addressed in EU law, in view of the principle of subsidiarity and due to large differences between Member States' civil and penal laws. The Commission supports the setting by Member States of rules establishing systems of compensation for economic losses due to adventitious presence of authorized GMOs. However, the current formulation of the amendment needs to be clarified as it mixes issues related to liability and compensation and can hence not be accepted in this form.

3.6. New provisions introduced by the Council

- ***Directive instead of a Regulation***

The Council's common position transforms the proposed Regulation into a Directive, by application of the legal principle of formal parallelism. The Commission notes that the proposal is an atypical act which does not impose direct obligations to third parties (as a Regulation would normally do) and does not set either a result that Member States would have to reach (as a Directive would normally do); it only provides to Member States a faculty to act if they wish so. Under these circumstances, the Commission considers that applying the principle of formal parallelism, i.e. modifying Directive 2001/18/EC by a Directive, is acceptable.

- ***Restriction of the geographical scope of the application (step 1)***

The Council's common position establishes a two consecutive steps procedure to allow Member States to restrict or prohibit cultivation of a GMO:

First the Council's common position foresees in **new Articles 26b(1) and 26b(2)** of the amended Directive that Member States, should they wish to restrict or ban cultivation of a GMO on part of or all their territory, have to request the applicant, via the Commission, to exclude their territory from the

[6] see point 11 of Annex III to Directive 2004/35/EC.

scope of the application with respect to cultivation (so-called “step 1”). Secondly, the Council's common position foresees in the new **Article 26b(3)** of the amended Directive that in the case of an explicit refusal of the applicant in step 1, Member States would be allowed to adopt measures restricting or banning the cultivation of a given GMO after it has been authorized (so-called “step 2” or “opt out measures”) on the basis of a list of grounds distincts from the environmental risk assessment, in line with the original proposal.

The Commission accepts the Council’s common position establishing a two consecutive steps procedure (at the time of the definition of the scope of the application by the applicant and after the GMO has been authorized) to allow Member States to restrict or ban GMO cultivation since it enlarges the range of tools to restrict or ban GMO cultivation and preserves the right of Member States to decide on GMO cultivation based on grounds of public interest independently of the position of the applicant/authorisation holder. Furthermore, the deadline for introducing a step 1 geographical scope restriction request (no later than 30 days after the scientific opinion of EFSA) leaves sufficient time to Member States to decide on whether they want to make use of this possibility, since they can introduce a request at any moment during the risk assessment by EFSA, which is a process that can last several months/years.

- ***Opt out measures – procedures to follow prior to adoption***

  The Council’s common position foresees in the new **Article 26b(4)** of the amended Directive that Member States that intend to adopt (a) post authorisation opt out measure(s) (step 2) shall first communicate a draft of this(ese) measure(s) to the Commission, which will have 75 days to make any comment if deemed appropriate. During that period, the Member State shall refrain from adopting and implementing this(ose) measure(s). At the expiry of the 75 days standstill period the Member State concerned may adopt the measure(s) either in the form originally proposed, or as amended to take account of any comments received from the Commission. The Commission accepts this amendment in the Council’s common position which is in line with the Commission's proposed approach.

- ***2 year deadline for adoption of opt out measures***

  The Council’s common position provides in **amended recital (14) and the new Article 26b(4)** of the amended Directive that the Member States shall adopt opt out measures no later than 2 years after the date that the GMO consent/authorisation has been granted. The Commission accepts this provision which aims at providing increased visibility/predictability to operators (including farmers) on opt out measures to be adopted by Member States.

- ***Transitional measures***

  The Council’s common position provides in **recital (21) and the new Article 26c** of the amended Directive for a 6 months transitional measure allowing Member States to apply the provisions of the Directive to GMOs already authorized before its entry into force (maize MON 810), or for which an application is already at an advanced stage at that moment. The Commission accepts this provision as it is needed in the context of linkage between steps 1 and 2: 1) it is not possible to apply step 2 without having used first step 1, and

2) step 1 can only be applied when the application is pending for a limited period of time.

The Council's common position also foresees that the transitional measures are without prejudice to the cultivation of any authorized GMO seed and propagating materials which were planted lawfully before the cultivation of the GMO is restricted or prohibited. The Commission supports this provision, which provides legal security to farmers that planted and harvested the concerned GMOs before the measures retricting or prohibiting cultivation apply.

- ***Possibility for a Member State to change its position on cultivation of a GMO during the term of validity of the authorisation***

The Council's common position provides in new **Article 26b(5) and 26b(7)** of the amended Directive that, after authorisation of a GMO and no earlier than two years after this date, a Member State is allowed to (re)initiate a step 1-step 2 procedure to implement or extend a cultivation ban on part of or all its territory, should new objective circumstances justify it. The Council's common position also provides that this possibility given to the Member States shall be "*without prejudice to the cultivation of any authorised GMOs seeds and plant propagating materials which were planted lawfully before the adjustment was adopted".*

The Council's common position also provides in new **Article 26b(6) and 26b(7)** of the amended Directive that Member States wishing to have part of or all their territory reintegrated into the geographical scope of a GMO authorisation, could do it via a simplified procedure.

The Commission accepts these new provisions since they contribute to enlarge the range of possibilities offered to Member States to restrict or ban GMO cultivation, whilst preserving the rights of farmers who lawfully planted GMOs before their ban.

- ***Reporting obligation***

The Council's common position foresees in new **Article 2** of the amending Directive that "no later than four years after the entry into force of the Directive, the Commission shall present a report to the European Parliament and to the Council regarding the use made by Member States of this Directive including the effectiveness of the provisions enabling Member States to restrict or prohibit the cultivation of GMOs in all or part of their territory and the smooth functioning on the internal market. That report may be accompanied by any legislative proposals the Commission considers appropriate. The Commission shall also report on the progress towards giving normative status to the strengthened 2010 EFSA guidance on the environmental risk assessment of genetically modified plants". The Commission accepts this amendment in the Council's common position.

4. CONCLUSION

The Commission considers that the common position adopted by the Council with qualified majority on 23 July 2014 reflects the original goals of the Commission's proposal and takes into account many concerns of the European Parliament.

For the reasons outlined above the Commission accepts the Council common position.