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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: 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 genetically modified organisms (GMOs) in their territory

DIRECTIVE .../.../ EU
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of...

**amending Directive 2001/18/EC as regards the possibility for the Member States
to restrict or prohibit the cultivation of genetically modified organisms (GMOs)
in their territory**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure³,

¹ OJ C 54, 19.02.2011, p. 51.

² OJ C 102, 2.4.2011, p. 62.

³ Position of the European Parliament of 5 July 2011 (OJ C 33 E, 5.2.2013, p. 350) and position of the Council at first reading of ... (not yet published in the Official Journal). Position of the European Parliament of ... (not yet published in the Official Journal) and decision of the Council of ...

Whereas:

- (1) Directive 2001/18/EC of the European Parliament and of the Council¹ and Regulation (EC) No 1829/2003 of the European Parliament and of the Council² establish a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which is fully applicable to GMOs to be used for cultivation purposes throughout the Union as seeds or other plant-propagating material ('GMOs for cultivation').
- (2) Under that legal framework, GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market in accordance with Annex II to Directive 2001/18/EC. The aim of that authorisation procedure is to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumer interests, whilst ensuring the effective functioning of the internal market. A uniform high level of protection of health and the environment should be achieved and maintained throughout the territory of the Union.

¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

- (3) In addition to the authorisation for placing on the market, genetically modified varieties also need to comply with the requirements of Union law on the marketing of seed and plant propagating material, as set out in particular in Council Directives 66/401/EEC¹, 66/402/EEC², 68/193/EEC³, 98/56/EC⁴, 99/105/EC⁵, 2002/53/EC⁶, 2002/54/EC⁷, 2002/55/EC⁸, 2002/56/EC⁹, 2002/57/EC¹⁰ and 2008/90/EC¹¹. Among those Directives, Directives 2002/53/EC and 2002/55/EC contain provisions which allow the Member States to prohibit, under certain well defined conditions, the use of a variety in all or in part of their territory or to lay down appropriate conditions for the cultivation of a variety.

¹ Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ P 125, 11.7.1966, p. 2298).

² Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ P 125 11.7.1966, p. 2309).

³ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁴ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

⁵ Council Directive 99/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ L 11, 15.1.2000, p. 17).

⁶ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁷ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁸ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

⁹ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

¹⁰ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

¹¹ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

- (4) Once a GMO is authorised for cultivation purposes in accordance with the Union legal framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of Union law on the marketing of seed and plant propagating material, Member States are not authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by Union law.
- (5) Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed at Member State level. Issues related to the placing on the market and the import of GMOs should remain regulated at Union level to preserve the internal market. Cultivation may however require more flexibility in certain instances as it is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems and landscapes. The common authorisation procedure, in particular the evaluation process, should not be adversely affected by such flexibility.

- (6) In order to restrict or prohibit the cultivation of GMOs, some Member States had recourse to the safeguard clauses and emergency measures pursuant to Article 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003 as a result of, depending on the cases, new or additional information made available since the date of the consent and affecting the environmental risk assessment, or of the reassessment of existing information. Other Member States have made use of the notification procedure set out in Article 114(5) and (6) of the Treaty on the Functioning of the European Union (TFEU) which requires putting forward new scientific evidence relating to the protection of the environment or the working environment. In addition, the decision-making process has proved to be particularly difficult as regards the cultivation of GMOs in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment.

- (7) In accordance with Article 2(2) TFEU, Member States are therefore entitled to have a possibility, during the authorisation procedure and thereafter, to decide to restrict or prohibit the cultivation of a GMO on their territory with the effect of excluding cultivation of a specific GMO in all or part of that Member State's territory. In that context, it appears appropriate to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMO crops on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs, either in the course of the authorisation procedure or thereafter, and independently of the measures that Member States are entitled to take by application of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products. The grant of that possibility to Member States should facilitate the decision-making process in the GMO field. At the same time, freedom of choice of consumers, farmers and operators should be preserved whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union. This Directive should therefore facilitate the smooth functioning of the internal market.
- (8) During the authorisation procedure of a given GMO, the possibility should be provided for a Member State to request the Commission to present to the notifier/applicant its demand to adjust the geographical scope of its notification/application submitted in accordance with Part C of Directive 2001/18/EC or in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 to the effect that all or part of the territory of that Member State be excluded from cultivation. The Commission should facilitate the procedure by presenting the request of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to that request within an established time-limit.

- (9) The geographical scope of the notification/application should be adjusted accordingly if the notifier/applicant explicitly or tacitly agrees with the Member State's request within an established time-limit from the communication by the Commission of that request. If the notifier/applicant opposes the request, the notifier/applicant should notify the Commission and the Member States. However, a refusal by the notifier/applicant to adjust the geographical scope of the notification/application is without prejudice to the Commission's powers in accordance with Article 19 of Directive 2001/18/EC or Articles 7 and 19 of Regulation (EC) No 1829/2003, as the case may be, to make such an adjustment, where appropriate, in the light of the environmental risk assessment carried out by the European Food Safety Authority ('the Authority').
- (10) In addition, and only where the notifier/applicant has refused to adjust the geographical scope of the notification/application of a GMO as requested by a Member State, there should be the possibility for that Member State to adopt reasoned measures restricting or prohibiting the cultivation of that GMO once authorised in all or part of its territory, on the basis of grounds distinct from those assessed according to the harmonized set of Union rules, that is Directive 2001/18/EC and Regulation (EC) No 1829/2003, which are in conformity with Union law. Those grounds may be related to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socio-economic impacts, co-existence and public policy. Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region or area in which those measures will apply.

- (11) The level of protection of human or animal health and of the environment chosen in the Union allows for a uniform scientific assessment throughout the Union and this Directive should not alter that situation. Therefore, to avoid any interference with the competences which are granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a Member State should only use grounds related to environmental policy objectives which do not conflict with the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures provided in Directive 2001/18/EC and in Regulation (EC) No 1829/2003, such as the maintenance of certain type of natural and landscape features, certain habitats and ecosystems, as well as specific ecosystem functions and services.

- (12) Member States should also be able to base the decisions which they adopt pursuant to Directive 2001/18/EC on grounds concerning socio-economic impacts which might arise from the cultivation of a GMO on the territory of the Member State concerned. While co-existence measures have been addressed by the Commission Recommendation of 13 July 2010¹, there should also be the possibility for Member States to adopt measures restricting or prohibiting cultivation of authorised GMOs in all or part of their territory under this Directive. Those grounds may be related to the impracticability or the impossibility of implementing co-existence measures due to specific geographical conditions, the need to avoid GMO presence in other products such as specific or particular products, the need to protect the diversity of agricultural production, or the need to ensure seed and plant propagating material purity. Furthermore, the Commission has, as requested in the Council Conclusions of 5 December 2008 on Genetically Modified Organisms, reported to the European Parliament and the Council on socio-economic implications of GMO cultivation. The outcome of that report may provide valuable information for Member States considering taking decisions on the basis of this Directive.

¹ Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crop (OJ C 200, 22.7.2010, p. 1).

- (13) The restrictions or the prohibitions adopted pursuant to this Directive should refer to the cultivation, and not to the free circulation and import, of genetically modified seeds and plant propagating material as, or in, products and of the products of their harvest, and should furthermore be in conformity with the Treaties, in particular as regards the principle of non- discrimination between national and non- national products, the principle of proportionality and Article 34, Article 36 and Article 216(2) TFEU.
- (14) Member States' measures adopted pursuant to this Directive should be subject to a procedure of scrutiny and information at Union level. In light of the level of Union scrutiny and information, it is not necessary to provide, in addition, for the application of Directive 98/34/EC of the European Parliament and of the Council¹. Member States may restrict or prohibit the cultivation of a GMO in all or part of their territory as from the date of entry into force of the Union authorisation and no later than two years after the date when the consent/authorisation is granted, provided that an established standstill period, during which the Commission was given the opportunity to comment on the proposed measures, has elapsed.
- (15) Decisions to restrict or prohibit the cultivation of GMOs by Member States in all or part of their territory should not prevent biotechnology research from being carried out provided that, in carrying out such research, all necessary safety measures are observed.

¹ Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37.).

- (16) When new and objective circumstances justify an adjustment of the geographical scope of the consent/authorisation of a GMO, and in any case no earlier than two years after the date when the consent/authorisation is granted, a Member State should be able to request, via the Commission, the consent/authorisation holder to adjust its geographical scope. If the consent/authorisation holder does not explicitly or tacitly agree, the Member State should be given the possibility to adopt reasoned measures restricting or prohibiting the cultivation of that GMO. The Member State concerned should communicate a draft of those measures to the Commission at least 75 days prior to their adoption, in order to give the opportunity to the Commission to comment, and should refrain from adopting and implementing those measures during that period. On the expiry of the established standstill period, the Member State should be able to adopt the measures as originally proposed or amended to take into account the Commission's comments.
- (17) A Member State should be able to request the competent authority or the Commission to reintegrate all or part of its territory into the geographical scope of the consent/authorisation from which it was previously excluded. In that case, there should be no need to forward the request to the consent/authorisation holder and ask for his agreement. The competent authority which has issued the written consent or the Commission under Directive 2001/18/EC or Regulation (EC) No 1829/2003 respectively, should amend the geographical scope of the consent or of the decision of authorisation accordingly.

- (18) Written consents or decisions of authorisations issued or adopted with a geographical scope limited to certain areas or measures adopted by Member States, in accordance with this Directive, which restrict or prohibit the cultivation of GMOs, should not prevent or restrict the use of authorised GMOs by other Member States. In addition, this Directive and the national measures adopted pursuant to it should be without prejudice to Union law requirements concerning unintended and adventitious presence of GMOs in non-genetically modified varieties of seed and plant propagating material, and should not prevent the cultivation of varieties complying with these requirements.
- (19) Regulation (EC) No 1829/2003 provides that references made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive are to be considered as applying equally to GMOs authorised under that Regulation. Accordingly, measures adopted by the Member States in accordance with Directive 2001/18/EC should also apply to GMOs authorised in accordance with Regulation (EC) No 1829/2003.
- (20) This Directive is without prejudice to Member States' obligations as regards the free movement of conventional seeds, plant propagating material and of the product of the harvest pursuant to relevant Union law and in accordance with the TFEU.

- (21) In order to reconcile the objectives of this Directive with the legitimate interests of economic operators in relation to GMOs which have been authorised, or which were in the process of being authorised, before the entry into force of this Directive, provision should be made for appropriate transitional measures. Transitional measures are also justified by the need to avoid creating potential distortions of competition by treating existing authorisation holders differently from future applicants for authorisation. In the interests of legal certainty, the period during which such transitional measures may be adopted should be limited to that which is strictly necessary in order to ensure a smooth transition to the new regime. Such transitional measures should therefore allow Member States to apply the provisions of this Directive to products which have been authorised or which were in the process of being authorised before the entry into force of this Directive, provided that authorised genetically modified varieties of seed and plant propagating material already lawfully planted are not affected.
- (22) The Commission Recommendation of 13 July 2010 provides guidance to Member States for the development of co-existence measures, including in border areas.
- (23) Directive 2001/18/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

In Directive 2001/18/EC, the following Articles are inserted:

"Article 26b

Cultivation

1. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may request, via the Commission, the notifier/applicant to adjust the geographical scope of its notification/application submitted in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, to the effect that all or part of the territory of that Member State is to be excluded from cultivation. This request shall be communicated to the Commission at the latest 30 days from the date of the circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall communicate the request of the Member State to the notifier/applicant and to the other Member States without delay.

2. Where the notifier/applicant opposes a request of a Member State in accordance with paragraph 1, the notifier/applicant shall notify the Commission and the Member States within 30 days from the communication by the Commission of that request. In the event of explicit or tacit agreement of the notifier/applicant, the adjustment of the geographical scope of the notification/application shall be implemented in the written consent or authorisation.

The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003, shall be issued on the basis of the adjusted geographical scope of the notification/application as explicitly or tacitly agreed by the notifier/applicant.

3. Where the notifier/applicant opposes the adjustment of the geographical scope of its notification/application corresponding to a request made by a Member State in accordance with paragraph 1 of this Article, that Member State may adopt measures restricting or prohibiting the cultivation of that GMO in all or part of its territory once authorised in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to:
- (a) environmental policy objectives distinct from the elements assessed according to this Directive and Regulation (EC) No 1829/2003;
 - (b) town and country planning;
 - (c) land use;
 - (d) socio-economic impacts;
 - (e) avoidance of GMO presence in other products without prejudice to Article 26a;
 - (f) agricultural policy objectives;
 - (g) public policy.

Those grounds may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003.

4. A Member State which intends to adopt measures pursuant to paragraph 3 of this Article shall first communicate a draft of those measures and the corresponding grounds invoked to the Commission. This communication may take place before the GMO authorisation procedure under Part C of this Directive or under Regulation (EC) No 1829/2003 has been completed. During a period of 75 days starting from the date of such communication:
- (a) the Member State concerned shall refrain from adopting and implementing those measures; and
 - (b) the Commission may make any comments it considers appropriate.

On expiry of the 75-day period referred to in the first subparagraph, and no later than two years after the date that the consent/authorisation is granted, the Member State concerned may adopt the measures either in the form originally proposed, or as amended to take account of any comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the notifier/applicant without delay.

5. Where, after the authorisation of a GMO under this Directive or Regulation (EC) No 1829/2003 and no earlier than two years after the date that the consent/authorisation is granted, a Member State considers that new objective circumstances justify an adjustment of the geographical scope of the consent/authorisation, it may apply the procedure under paragraphs 1 to 4, *mutatis mutandis*, provided that such measures do not affect the cultivation of any authorised GMO seeds and plant propagating materials which were planted lawfully before those measures were adopted.
6. Where a Member State wishes all or part of its territory to be reintegrated into the geographical scope of the consent/authorisation from which it was previously excluded pursuant to paragraph 2, it may make a request to that effect to the competent authority which issued the written consent under this Directive or to the Commission if the GMO has been authorised under Regulation (EC) No 1829/2003. The competent authority which has issued the written consent or the Commission, as the case may be, shall amend the geographical scope of the consent or of the decision of authorisation accordingly.

7. For the purposes of an adjustment of the geographical scope of the consent/authorisation of a GMO under paragraphs 5 and 6, and on condition that under paragraph 5 the consent/authorisation-holder explicitly or tacitly agrees to the request of the Member State:
- (a) for a GMO which has been authorised under this Directive, the competent authority which has issued the written consent shall amend the geographical scope of the consent accordingly and inform, the Commission, the Member States and the authorisation holder once this is complete;
 - (b) for a GMO which has been authorised under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorisation accordingly, without applying the procedure set out in Article 35(2) of that Regulation. The Commission shall inform the Member States and the authorisation holder accordingly.
8. Where a Member State has revoked measures taken pursuant to paragraphs 3 and 4, it shall notify the Commission and the other Member States without delay.
9. Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.

Article 26c

Transitional measures

1. As from...^{*} until ...^{**} a Member State may request, via the Commission, a notifier/applicant to adjust the geographical scope of a notification/application submitted, or of an authorisation granted, under this Directive or Regulation (EC) No 1829/2003 before...^{*}. The Commission shall communicate the request of the Member State to the notifier/applicant and to the other Member States without delay.

2. Where the application is pending and the notifier/applicant has explicitly or tacitly agreed to such a request within 30 days from the communication of that request, the geographical scope of the notification/application shall be adjusted accordingly. The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003 shall be issued on the basis of the adjusted geographical scope of the notification/application as explicitly or tacitly agreed by the notifier/applicant.

3. Where the authorisation has already been granted and the authorisation holder has explicitly or tacitly agreed to a request within 30 days from the communication of the request referred to in paragraph (1) of this Article, the authorisation shall be as agreed by the authorisation holder. For a written consent under this Directive, the competent authority shall amend the geographical scope of the consent accordingly as explicitly or tacitly agreed by the authorisation holder and shall inform the Commission, the Member States, and the authorisation holder once this is complete. For an authorisation under Regulation (EC) No 1829/2003, the Commission shall amend the decision of authorisation accordingly, without applying the procedure set out in Article 35(2) of that Regulation. The Commission shall inform the Member States and the authorisation holder accordingly.
4. If a notifier/applicant or, as the case may be, an authorisation holder opposes such a request, paragraphs 3 to 9 of Article 26b shall apply *mutatis mutandis*.
5. This Article is without prejudice to the cultivation of any authorised GMO seeds and plant propagating materials which were planted lawfully before the cultivation of the GMO is restricted or prohibited in the Member State.
6. Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.

* OJ: please insert the date of entry into force of the Directive in document st 10972/14.

** OJ: please insert the date of entry into force of the Directive in document st 10972/14+ 6 months."

Article 2

No later than 4 years after...⁺, 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 of 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 Authority guidance on the environmental risk assessment of genetically modified plants.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Directive is addressed to the Member States.

Done at ...

For the European Parliament
The President

For the Council
The President

⁺ OJ: please insert the date of the entry into force of this Directive.