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NOTE

From: Presidency
To: Council

Subject: Proposal for a Regulation 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
- Political agreement

1. The Commission submitted the above-mentioned proposal to the Council on 14 July 2010.

The aim of the proposal is to provide for a legal basis in the related EU legal framework in order to authorise Member States to restrict or prohibit the cultivation, in all or part of their territory, of Genetically Modified Organisms (GMOs) that have been authorised at EU level.

2. Discussions on this legislative initiative were held within the Council and its preparatory bodies during various Presidencies. The outcome of these discussions showed that although a significant number of delegations broadly support the proposal, a blocking minority of delegations could not accept it.

In July 2011 the European Parliament adopted a set of amendments at first reading.¹

¹ Document 11037/11.

At its meeting on 9 March 2012, the "Environment " Council noted that no Political Agreement was possible to reach as a blocking minority of delegations continued to express misgivings on the proposed compromise text. Since then, successive Presidencies have noted that this blocking situation had remained.

In February 2014, the "General Affairs" Council held a policy debate during which a significant number of Ministers favoured the revision of the EU legislation governing the authorisation of GMOs for cultivation.

At its meeting on 3 March 2014, the "Environment " Council welcomed the re-examination of the Commission proposal on the basis of a revised text that had been prepared by the Presidency. Following in-depth technical discussions, the Presidency submitted a new revised compromise text to COREPER with a view to reach a Political Agreement.

The new Presidency text is set out in the Annex.

3. At its meeting on 28 May 2014, the COREPER agreed, in principle, on the said Presidency's text and invited the "Environment" Council to adopt a Political Agreement, under a "B" Agenda Item, at its meeting on 12 June 2014.

Presidency compromise proposal

Proposal for 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

(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,

After transmission of the proposal to the national Parliaments,

Having regard to the proposal from the European Commission,

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

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (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 and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed 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 EU as seeds or other plant-propagating material (hereinafter 'GMOs for cultivation').
- (2) Under this set of legislation, GMOs for cultivation shall undergo an individual risk assessment before being authorized to be placed on the Union market in accordance with Annex II of Directive 2001/18/EC. The aim of this 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.
- (3) In addition to the authorization for placing on the market, genetically modified varieties also need to comply with the requirements of EU legislation on the marketing of seed and plant propagating material, as set out in particular in Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed, Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed, Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed, Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes, Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants, Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine, Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants, Council Directive 99/105/EC of 22 December 1999 on the marketing of forest reproductive material and Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production.

Among them 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 parts of its territory or to lay down appropriate conditions for the cultivation of a variety.

- (4) Once a GMO is authorised for cultivation purposes in accordance with the EU legislative framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of EU legislation on the marketing of seed and plant propagating material, Member States are not authorized to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by EU legislation.
- (5) Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed by Member States. Issues related to the placing on the market and the import of GMOs should remain regulated at EU 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, local agricultural structures and to the protection or maintenance of habitats, ecosystems and landscapes. The common authorisation procedure, especially the evaluation process should not be adversely affected by such flexibility.
- (6) To restrict/prohibit GMO cultivation, some Member States have made recourse to the safeguard clauses and emergency measures according to Article 23 of Directive 2001/18/EC and to Article 34 of Regulation (EC) No1829/2003 as a result, depending on the cases, of 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. Others have made use of the notification procedure set out in Article 114(5) and (6) TFEU which requires to put forward new scientific evidence relating to the protection of the environment or of the working environment. In addition, the decision making process has proved to be particularly difficult as regards GMO cultivation, in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs on health or on the environment.

- (7) In accordance with Article 2(2) TFEU Member States should therefore be 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 parts of that Member States territory. In this context, it appears appropriate to grant to 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 Article 26a of Directive 2001/18/EC to avoid the unintended presence of GMOs in other product. Granting this 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 will be preserved whilst providing greater clarity to affected stakeholders concerning cultivation of GMOs in the Union. The present Directive will therefore facilitate the smooth functioning of the internal market.

- (8) During the authorisation procedure of a given GMO and at the latest 30 days from the date of the circulation of the assessment report under Article 14(2) in Directive 2001/18 or 30 days from receiving the opinion of the Authority under Article 6 (6) and Article 18(6) in Regulation (EC) No 1829/2003, the possibility should therefore 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 this Directive or in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 to the effect that parts or all the territory of that Member State be excluded from cultivation. The Commission should facilitate the procedure, by presenting the demand of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to the request within 30 days.

- (9) The geographical scope of the notification/application should be adjusted accordingly if the notifier/applicant explicitly or tacitly agrees within 30 days from the communication, by the Commission, of the request to the notifier/applicant. If the notifier/applicant opposes the request, the notifier/applicant should notify the Commission and the Member States. However, a refusal by the applicant/notifier to adjust the geographical scope of the notification/application is without prejudice to the Commission's power in accordance with Articles 19 of the Directive 2001/18/EC or Articles 7 and 19 of the Regulation 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 Authority.
- (10) In addition, and only where the applicant/notifier 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 their territory, on the basis of grounds distinct from those assessed according to the harmonized set of Union rules (i.e. Directive 2001/18/EC and Regulation (EC) No 1829/2003) which are in conformity with Union law. These grounds may be related to environmental or agricultural policy objectives, or other compelling grounds such as land use, town and country planning, socio-economic impacts, coexistence and public policy. These 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/animal health and of the environment chosen in the EU allows for a uniform scientific assessment throughout the Union and the present Directive should not alter this situation. Therefore, to avoid any interference with the competences which are granted to the risk assessors and risk managers in Directive 2001/18/EC and in 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 the two above mentioned pieces of EU legislation, 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 under this Directive on grounds concerning socio-economic impacts which might arise from the cultivation of a GMO on the territory of the concerned Member State. While co-existence measures have been addressed by the Commission's Recommendation of July 2010, 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. These grounds may be related to the impracticability or the impossibility of implementing coexistence measures due to specific geographical conditions or the need to avoid GMO presence in other products such as specific or particular products or 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 2008 Environmental Council Conclusions, reported to the European Parliament and the Council on socio-economic implications of GMO cultivation. The outcome of this report may provide valuable information for Member States considering taking decisions on the basis of this Directive.
- (13) The restrictions or the prohibitions adopted under 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 Articles 34, 36 and 216(2) of the Treaty on the Functioning of the European Union.

- (14) Member States that intend to adopt measures under this Directive should communicate to the Commission a draft of the measures at least 75 days prior to their adoption. During this 75 days standstill period the Member State should refrain from adopting and implementing those measures. If the Commission considers that the Member State is making an improper use of the powers provided to it under this Directive it should communicate this to the Member State within the 75 days standstill period. The Commission may make suggestions on how these measures should be amended to meet the conditions of this Directive. However, after the 75 days standstill period it is the decision of the Member State whether it amends its measures to take account of the comments received from the Commission or it adopts them as originally proposed. In light of the level of EU scrutiny put in place by this procedure, it is not necessary to foresee, in addition, the application of Directive 98/34/EC laying down a procedure of information in the field of technical standards and regulations². Member States may restrict or prohibit the cultivation of a GMO in all or part of their territory as from the day of entry into force of the EU authorisation and no later than two years after the date that the consent/authorization is granted, provided that the 75 days standstill period has elapsed during which the Commission was given the opportunity to comment on the proposed measures.
- (15) Decisions to restrict or prohibit the cultivation of GMO 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.
- (15a) [NEW] When new and objective circumstances justify an adjustment of the geographical scope of the consent/authorization of a GMO, and no earlier than two years after the date that the consent/authorization is granted, a Member State should be able to request via the Commission the consent/authorization holder to adjust its geographical scope. If the consent/authorization holder does not, tacitly or explicitly agree, the Member State should be given the possibility to adopt reasoned measures restricting or prohibiting the cultivation of that GMO. The concerned Member State should communicate a draft of these measures to the Commission at least 75 days prior to their adoption to give the opportunity to the Commission to comment and during this period it should refrain from adopting and implementing these measures. After that period of 75 days the Member State may adopt the measures as originally proposed or amended to take into account the Commission's comments.

² OJ L 204, 21.7.1998, p. 37.

- (15b) [NEW] A Member State should be able to request the competent authority or the Commission to reintegrate part or all of its territory into the geographical scope of the consent/authorization from which it was previously excluded. In this case, there should be no need to forward the request to the consent/authorization holder and ask for its agreement. Under Directive 2001/18/EC, the competent authority which has issued the written consent or, under Regulation (EC) No 1829/2003, the Commission should respectively amend the geographical scope of the consent or the decision of authorisation accordingly.
- (16) Written consents or decisions of authorisations issued/adopted with a geographical scope limited to certain areas or measures adopted by Member States in accordance with this Directive, to restrict or prohibit GMO cultivation, 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.
- (17) Articles 7(8) and 19(8) of Regulation (EC) No 1829/2003 provide 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 this Directive 2001/18/EC should apply as well to GMOs authorised in accordance with Regulation (EC) No 1829/2003.
- (17a) [NEW] The present 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 legislation and in accordance with the Treaty.

- (17b) [NEW] 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 what 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.
- (18) [NEW] The Commission's Recommendation of 13 July 2010 provides guidance to Member States for the development of coexistence measures, including in border areas.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/18/EC is amended as follows:

The following Articles shall be inserted with effect from the date of entry into force of this Directive:

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 part or all of the territory of that Member State 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) in this Directive or from receiving the opinion of the Authority under Article 6 (6) and Article 18(6) in Regulation (EC) No 1829/2003. The Commission shall communicate the request of the Member State to the notifier/applicant without delay as well as to the other Member States.

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 the request. In case 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 tacitly or explicitly 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, that Member State may adopt measures restricting or prohibiting the cultivation of a that GMO in all or part of its territory once authorised in accordance with Part C of this Directive or 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 Directive 2001/18/EC and Regulation (EC) No 1829/2003;
 - b. town and country planning;
 - c. land use;
 - d. socioeconomic impacts;
 - e. avoidance of GMO presence in other products without prejudice to Article 26a;
 - f. agricultural policy objectives;
 - g. public policy.

These grounds may be invoked individually or in combination, with the exception of the ground in (g) which must be used in combination, 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 Regulation 1829/2003.

4. Member States that intend to adopt measures pursuant to paragraph 3 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 the Directive or under Regulation 1829/2003, has been completed. During a period of 75 days from the date of such communication:
 - the Member State concerned shall refrain from adopting and implementing those measures, and
 - the Commission may make any comments it considers appropriate.

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

5 [NEW]. Where, after the authorisation of a GMO under this Directive or Regulation (EC) 1829/2003 and no earlier than two years after the date that the consent/authorization is granted, a Member State considers that new objective circumstances justify an adjustment of the geographical scope of the consent/authorization, it may apply the procedure of 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 [NEW]. Where a Member State wishes part or all of its territory to be reintegrated into the geographical scope of the consent/authorization from which it was previously excluded pursuant to paragraph 2, it may make a request to that effect to the competent authority which delivered the written consent under this Directive or 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 the decision of authorisation accordingly.

7. [NEW]. For the purposes of an adjustment of the geographical scope of the authorisation of a GMO under paragraphs 5 and 6, and on condition that under paragraph 5 the authorisation-holder tacitly or explicitly agrees to the request of the Member State:

- a. for a GMO 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 authorisation holder, the Commission and the Member States 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 authorisation holder and the Member States accordingly.

8. [NEW]. Where a Member State has revoked measures taken according 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 [NEW]

1. As from [date of entry into force of this Directive] until [date of entry into force of this Directive + 6 months] a Member State may request via the Commission a notifier/applicant to adjust the geographical scope of a notification/application lodged, or authorisation granted, under this Directive or Regulation (EC) 1829/2003 before [date of entry into force of this Directive]. The Commission shall communicate the request of the Member State to the notifier/applicant without delay as well as the other Member States.
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 this request, the geographical scope of its 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 tacitly or explicitly 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 this request, 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 tacitly or explicitly agreed by the authorisation holder and inform the authorisation holder, the Commission and the Member States 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. It shall inform the authorisation holder and the Member States 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. The provisions of this Article are 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.

Article 1a [NEW]

No later than 4 years after *[the entry into force of this 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 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 EFSA guidance on the environmental risk assessment of genetically modified plants.

Article 2

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 Brussels,

For the European Parliament

For the Council

The President
