February 2014 Presidency compromise proposal (revised)

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 authorization 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 authorization 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 authorized 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 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 authorizations 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, it should therefore be provided the possibility for a Member State to request the applicant 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.

(9) Under Directive 2001/18/EC, this possibility for the notifier/applicant to adjust the geographic scope of its application upon request of one or several Member States and corresponding to that request should be provided from the date when the notification is lodged until 60 days after the circulation of the assessment report referred to under Article 15 (1) where the standard procedure applies. Under Regulation (EC) No 1829/2003 this possibility should be granted until 60 days after the publication of the Authority opinion in accordance with Article 6(6) and 18(6) therein. The adjustment of the scope of the notification/application takes effect from the moment when it is notified by the applicant to the Commission and the other Member States and the written consent and(or) the decision of authorisation shall be issued with respect to the notification/application as adjusted by the notifier/applicant.

(10) In addition, and ~~independently of the possibility for a Member State to ask~~ only where the applicant/notifier has refused to adjust the ~~geographic~~geographical scope of ~~a GMO during the authorisation procedure, it~~the application as requested by a Member State, , there should be ~~provided~~ the possibility for ~~a~~that Member State to adopt reasoned measures restricting or prohibiting the cultivation of ~~an authorised GMO on a case by case basis, or a particular group of authorised GMOs defined by crop or by trait or all GMOs where appropriate,~~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 policy objectives, or other legitimate grounds such as land use, town and country planning, socio-economic impacts, and coexistence.

(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 still be the possibility for Member States to adopt measures restricting or prohibiting cultivation of authorised GMOs on their territory. 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) These grounds may be invoked individually or in combination to support decisions on restricting the cultivation of a GMO in light of the particular circumstances of the Member State/region/area in which the restriction will apply. Those restrictions 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 and 36 of the Treaty on the Functioning of the European Union, as well as with the relevant international obligations of the Union, in particular obligations pursuant to the WTO Agreement.

(14) Member States that intend to adopt measures under this Directive shall communicate to the Commission a draft of the measures 3 months prior to their adoption. During this 3 months standstill period the Member State shall 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 shall communicate this to the Member State within the 3 months standstill period. The Commission may make suggestions on how these measures should be amended to meet the conditions of this Directive. However, after the 3 month 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 regulations[1].

(15) Decisions to restrict the cultivation of GMO by Member States should not prevent biotechnology research from being carried out provided that, in carrying out such research, all necessary safety measures are observed.

(16) Written consents or decisions of authorisations issued/adopted with a geographic 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 authorized 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~~(17) Transitional measures should be foreseen to 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 this Directive is applicable.

(18) 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 authorized under part C of that Directive are to be considered as applying equally to GMOs authorized under that Regulation. Accordingly, measures adopted by the Member States in accordance with this Directive 2001/18/EC should apply as well to GMOs authorized in accordance with Regulation (EC) No 1829/2003.

[1] OJ L 204, 21.7.1998, p. 37.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2001/18/EC is amended as follows:

(1) The following Article shall be inserted with effect from the date of entry into force of this Directive:

Article 26b Cultivation

1. During the authorization procedure of a given GMO a Member State may request the notifier/applicant to adjust the geographical scope of its notification 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.

2. Following the request of a Member State in accordance with paragraph 1, the notifier/applicant may notify to the Commission and the other Member States an adjustment of the geographic scope of its notification/application corresponding to that request at the latest 60 days from the date of the circulation of the assessment report under Article 15 (1) in this Directive or 60 days from receiving the opinion of the Authority under Article 6 (6) and Article 18(6) in Regulation (EC) No 1829/2003. The adjustment of the geographic scope of the notification/application shall take effect from the moment of this notification.

   The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 18 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 scope of the notification/application as adjusted by the notifier/applicant.

3. ~~Without prejudice~~Where the notifier/applicant does not notify an 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 ~~States~~State may adopt measures

restricting or prohibiting the cultivation of ~~a~~that GMO ~~on a case by case basis, or a particular group of GMOs or where appropriate of all GMOs~~once authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, ~~and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation,~~ provided that such ~~a decision is~~measures are in conformity with Union law, reasoned, proportional and nondiscriminatory and ~~does~~do not 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 to the Commission. During a period of 3 months from the date of such communication, the Member State concerned shall refrain from adopting and implementing those measures. In the light of any comments received from the Commission, the Member States concerned may adopt the measures either in the form originally proposed, or as amended to take account of the comments received.

5. As a transitional measure, a Member State may, before [60 days after entry into force of this Directive] request adjustment of the geographical scope of an application lodged, or authorisation granted, under this Directive or Regulation (EC) 1829/2003 before [date of entry into force of this Directive].

Where the notifier/applicant agrees to a request, it shall notify the Commission and the Member States of the adjustment of the geographic scope of its notification/application within 60 days and the adjustment shall take effect from the moment of this notification. The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 18 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 scope of the notification/application as adjusted by the notifier/applicant.

Where the authorisation holder agrees to a request, it shall notify the Commission and the Member States of the adjustment of the geographic scope of its authorisation within 60 days. The authorisation shall be amended solely in relation to the geographical scope 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 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. They shall inform the authorisation holder and the Member States accordingly.

If a notifier/applicant or, as the case may be, an authorisation holder does not agree to such a request, paragraphs 3 and 4 of this article shall apply mutatis mutandis.

The provisions of this paragraph are without prejudice to the cultivation of any authorised genetically modified varieties of seed and plant propagating material which were planted lawfully before this paragraph enters into force

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