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 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 [...]thereof in relation to Article 26b of this Directive,
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 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 changing the system of Union authorizations of GMOs 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 products. 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 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) Under Directive 2001/18/EC an undertaking who applies for a written consent under Part C can limit the scope of its application to geographical areas within the EU where the product is intended to be cultivated. [This possibility is recognized in the format established in the Annex of Council Decision 2002/812/EC (part 1.A.4f).] Similarly, under Regulation (EC) No 1829/2003, it is the undertaking who applies for an authorization which defines the scope of the application as regards specific products, intended uses, and geographical scope. Therefore, the possibility exists for a Member State to ensure with the agreement of the notifier/applicant, that the scope of a written consent excludes certain geographical areas with the effect that it will not cover the cultivation of the GMO in all or parts of the territory of the Member State.

(9) This possibility, however, does not allow the Member State to modify the scope of a written consent without the agreement of the notifier/applicant. It is therefore necessary to ensure greater flexibility for Member States to grant them the possibility to adopt on a case by case basis measures restricting the cultivation of a GMO on its territory. Member States should therefore be authorized to adopt decisions restricting the cultivation of a GMO, in all or part of their territory, on the basis of grounds distinct from those concretely assessed according to the harmonized set of Union rules (i.e. Directive 2001/18/EC and Regulation (EC) No 1829/2003).

(10) These grounds should be invoked individually or in combination with others 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.

(11) 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.

(12) Decisions to restrict the cultivation of a particular GMO by a Member State should not prevent or restrict the use of authorized GMOs by other Member States.

(13) On the basis of the subsidiarity principle, the purpose of this Directive is not to harmonize the conditions of cultivation in Member States but to grant freedom to Member States to invoke other environmental grounds complementary and distinct from those already assessed according to the harmonized set of Union rules as grounds to restrict the cultivation of a GMO on their territory with the effect of excluding parts or all of the territory of the concerned Member State from the geographical area where the GMO in question can be cultivated. Besides the complementary environmental grounds the Member States should also be allowed to invoke other legitimate factors such as land use, town and country planning, socio-economic impacts, ensuring the agro-economic viability of production of quality products or geographically protected products and grounds in conformity with Article 36 of the Treaty on

the Functioning of the European Union, such as public morality and public policy, to restrict the cultivation of a GMO on their territory.

(14) 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, it is important to stress that the grounds relating to environmental impact which may arise from the cultivation of a GMO must be complementary and distinct from the environmental impact examined during the scientific assessment on the impact on the environment conducted under Part C of this directive. Such grounds may include the prevention of negative impacts on the local environment caused by change in agricultural practice linked to the cultivation of GMOs or the maintenance and development of agricultural practice which offer a better potential to reconcile production with ecosystem sustainability or the maintenance of local biodiversity including certain habitats and ecosystems, or certain types of natural and landscape features or the absence or lack of adequate data concerning the potential negative impact of the release of GMOs on the local or regional environment of a member State including on biodiversity or the maintenance of ecosystem services (e.g. ground water) or the absence of target organisms.

(15) In addition to complementary environmental grounds the Member States should also be able to base their decisions adopted under this Directive on grounds concerning negative socio-economic impacts which might arise from the cultivation of a GMO on the territory of the concerned Member State. These grounds may be related to socio-economic impacts or coexistence which may include the impractibility or the impossibility of implementing coexistence measures due to specific geographical conditions or related to avoidance of GMO presence in other products or grounds related to the need to protect the diversity of agricultural production or the need to ensure seed purity. Furthermore, the Commission has, as requested in the 2008 Council Conclusions reported to the European Parliament and the Council on socio-economic implications of GMO cultivation. The report and subsequent discussion can provide valuable information for Member States considering taking decisions on the basis of the this Directive.

(16) 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.

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 scope of its notification submitted in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, with respect to the geographic conditions of the cultivation of a specific GMO, restricting the cultivation of the GMO to the effect that all or parts of the territory of that Member State be excluded.

2. The member State consultation with the notifier/applicant in accordance with paragraph 1 shall be brought to conclusion at the latest 30 days from the date of the circulation of the assessment report under Article 15 (1) in this Directive or from receiving the opinion of the Authority under Article 6 (6) in Regulation (EC) No 1829/2003.

3. Where the Member State referred to in paragraph 1 is able to reach an agreement with the notifier/applicant within the deadline set out in paragraph 2 it shall immediately inform the Commission and the other Member States of the agreement. The written consent under Article 15 where the standard procedure applies, or the EU Decision of authorization or the written consent under article 18 of the Directive where the Community procedure applies or the authorisation under Article 7(2) and Article 19(2) where Regulation 1829/2003 applies shall reflect the agreed limitation of the geographical scope of the notification or application

4. Without prejudice to paragraph 1, Member States may adopt on a case by case basis measures restricting or prohibiting the cultivation of a GMO, or a particular group of GMOs 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 can be justified on one or more of the grounds listed in paragraph 5 and provided that such a decision is reasoned, proportional and non-discriminatory.

5. The grounds referred to in paragraph 4 shall be any of the following:
   a. Complementary environmental impacts, distinct from those concretely assessed by EFSA pursuant to this Directive or Regulation (EC) No 1829/2003.

b. Grounds related to land use, town and country planning

c. Grounds related to socio-economic impacts

d. Grounds related to ensuring the agro-economic viability of production of quality products or geographically protected products, without prejudice to article 26a, particularly due to the impracticability of other coexistence measures or the impossibility of implementing less restrictive coexistence measures due to specific geographical conditions.

e. Other grounds which are in conformity with Union law

6. By way of derogation to Directive 98/34/EC, Member States that intend to adopt reasoned measure under paragraph 4 shall communicate them to the other Member States and to the Commission one month prior to their adoption for information purposes.

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
The President

For the Council
The President