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Proposal for a

**REGULATION (EU) No .../... OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL**

of [...]

**modifying Directive 2001/18/EC as regards the possibility for the Member States to
prohibit, restrict or impede the cultivation of GMOs in their territory**

(Text with EEA relevance)

THIS DOCUMENT DOES NOT REPRESENT THE VIEWS OF THE COMMISSION

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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,

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

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

After transmission of the proposal to the national Parliaments,

Acting in accordance with the ordinary legislative procedure³,

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/EEC⁴ and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁵ provide for a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which is fully applicable to

GMOs which may be used for cultivation purposes throughout the Union 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 authorised to be placed on the Union market. 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.

(3) In addition to the authorisation for placing on the market, genetically modified varieties need also 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 species⁷, Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed⁸, Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed⁹, Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes¹⁰, Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants¹¹, Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine¹², Council Directive 1998/56/EC of 20 July 1998 on the marketing of fruit plant propagating material of ornamental plants¹³, Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material¹⁴ and Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production¹⁵. 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 cultivation of those varieties.

(4) Once a GMO is authorised for cultivation purposes in accordance with 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 authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by EU legislation.

(5) Increased emphasis has been put in the last years on the idea that the appropriate level of action to take decisions regarding the effective cultivation of GMOs is that of the Member States and that they should be entitled to conserve a possibility to adopt rules concerning the effective cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.

1 OJ C [...], [...], p. [...]
2 OJ C [...], [...], p. [...]
3 OJ C [...], [...], p. [...]
4 OJ L 106, 17.4.2001, p. 1.
5 OJ L 268, 18.10.2003, p. 1.
6 OJ L 268, 18.10.2003, p. 1.

7 OJ L 268, 18.10.2003, p.
8 OJ L 193, 20.7.2002, p. 12-32
9 OJ L 193, 20.7.2002, p. 33.
10 OJ L 193, 20.7.2002, p. 60.
11 OJ L 193, 20.7.2002, p. 74.
12 OJ L 93, 17.4.1968, p. 15-23
13 OJ L 226, 13.8.1998, p. 16-23
14 OJ L 11, 15.11.2000, p. 17-40
15 OJ L 267, 8.11.2008, p. 8.

- (6) In this context, it appears appropriate to clarify EU legislation in order to grant, in accordance with the principle of subsidiarity, Member States more freedom to decide whether or not they wish to cultivate GMO crops on their territory without changing the system of Union authorisations 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.
- (7) Member States should thus be authorised to adopt measures prohibiting, restricting or impeding the cultivation of all or particular GMOs in all or part of their territory and restrictively amend those measures as they deem appropriate, at all stages of the authorisation, re-authorisation or withdrawal from the market of the concerned GMOs. This should apply as well to genetically modified varieties of seed of agricultural plant species and vegetables which are placed on the market in accordance with Directives 2002/53/EC and 2002/55/EC.
- (8) To avoid that these measures undermine the EU system of authorisation, they shall be taken on grounds other than those already addressed by the harmonised set of EU rules which already provide for procedures to take into account the risks that a GMO for cultivation may pose on environment and health. Moreover, given that Article 26a of Directive 2001/18/EC already provides a legal base for the Member States to adopt measures to avoid the unintended presence of GMOs in other products, measures taken on the basis of this Regulation should not be based on that ground as well. These measures shall also be in conformity with the Treaties, in particular as regards the principle of non discrimination between national and non national products. The other Member States and the Commission should be informed of the adoption of these measures by a Member State prior to their adoption
- (9) 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 shall be considered as applying equally to GMOs authorised under that Regulation. Accordingly, measures adopted by the Member States in accordance with this Regulation should apply as well to GMOs authorised in accordance with Regulation (EC) No 1829/2003.
- (10) Directive 2001/18/EC, should be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Modification of Directive 2001/18/EC

In Directive 2001/18/EC, the following Article shall be inserted with effect from the date of entry into force of this Regulation:

Article 26b

Cultivation

Authorisations granted under Part C and Regulation (EC) No 1829/2003 shall not affect the possibility for a Member State to adopt measures prohibiting, restricting or impeding the cultivation of all or particular GMOs, and including genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of its territory, provided that these measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs or related to the need to avoid the unintended presence of GMOs in other products and that they are in conformity with the Treaties.

The Member States that intend to adopt measures under this Article shall inform the other Member States and the Commission thereof prior to their adoption.'

Article 2

Entry into force

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

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels, [...]

For the European Parliament

The President

[...]

For the Council

The President

[...]