

Proposal for a

**DIRECTIVE (EU) 2015/412 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 11 March 2015**

**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**

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 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 and Regulation (EC) No 1829/2003 of the European Parliament and of the Council 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 taking into account the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects, on human health and the environment. That risk assessment provides scientific advice to inform the decision-making process and is followed by a risk management decision. 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, the environment and consumers should be achieved and maintained throughout the territory of the Union. The precautionary principle should always be taken into account in the framework of Directive 2001/18/EC and its subsequent implementation.
- (3) Pursuant to the conclusions adopted by the Council on 4 December 2008 on Genetically Modified Organisms ('2008 Council conclusions'), it is necessary to look for improvement of the implementation of the legal framework for the authorisation of GMOs. In this context, the rules on risk assessment should be, where needed, regularly updated to take account of continuous developments in scientific knowledge and analysis procedures, in particular regarding the long-term environmental effects of genetically modified crops as well as their potential effects on non-target organisms, the characteristics of receiving environments and the geographical areas in which genetically modified crops may be cultivated, and the criteria and requirements for assessing GMOs producing pesticides and herbicide tolerant GMOs. Therefore, the Annexes to Directive 2001/18/EC should be amended accordingly.

- (4) In addition to the authorisation for placing on the market, genetically modified varieties also need to comply with the requirements of the Union law on the marketing of seed and plant propagating material, as set out in particular in Council Directives 66/401/EEC <sup>(1)</sup>, 66/402/EEC <sup>(2)</sup>, 68/193/EEC <sup>(3)</sup>, 98/56/EC <sup>(4)</sup>, 1999/105/EC <sup>(5)</sup>, 2002/53/EC <sup>(6)</sup>, 2002/54/EC <sup>(7)</sup>, 2002/55/EC <sup>(8)</sup>, 2002/56/EC <sup>(9)</sup>, 2002/57/EC <sup>(10)</sup> and 2008/90/EC <sup>(11)</sup>. 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.
- (5) 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.
- (6) 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. In accordance with Article 2(2) of the Treaty on the Functioning of the European Union (TFEU), Member States are entitled to have the possibility to adopt legally binding acts restricting or prohibiting the cultivation of GMOs in their territory after such GMOs have been authorised to be placed on the Union market. However, the common authorisation procedure, in particular the evaluation process conducted primarily by the European Food Safety Authority (the 'Authority'), should not be adversely affected by such flexibility.
- (7) In the past, 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) 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.
- (8) 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 GMOs 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 cultivating GMOs are entitled or required 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 is likely to improve the process for authorisations of GMOs and, at the same time, is also likely to ensure freedom of choice of consumers, farmers and operators 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.
- (9) In order to ensure that the cultivation of GMOs does not result in their unintended presence in other products and whilst respecting the principle of subsidiarity, particular attention should be paid to the prevention of possible cross-border contamination from a Member State where cultivation is

allowed into a neighbouring Member State where it is prohibited, unless the concerned Member States agree that particular geographical conditions render it unnecessary.

- (10) The Commission Recommendation of 13 July 2010 provides guidance to Member States for the development of coexistence measures, including in border areas. The recommendation encourages Member States to cooperate with each other to implement appropriate measures at the borders between Member States so as to avoid unintended consequences of cross-border contamination.
- (11) During the authorisation procedure of a given GMO, the possibility should be provided for a Member State to demand that the geographical scope of the 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 be adjusted 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 demand of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to that demand within an established time limit.
- (12) The geographical scope of the notification/application should be adjusted accordingly unless the notifier/applicant confirms the geographical scope of its notification/application within an established time limit from the communication by the Commission of that demand. Such confirmation, however, 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 Authority.
- (13) Whilst it is expected that most restrictions or prohibitions adopted pursuant to this Directive will be implemented at the stage of consent/authorisation or renewal thereof, there should, in addition, also be the possibility for Member States to adopt reasoned measures restricting or prohibiting the cultivation in all or part of their territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised, on the basis of grounds distinct from and complementary to 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, socioeconomic impacts, coexistence 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.
- (14) 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 with respect to environmental policy objectives relating to impacts which are distinct from and complementary to 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 and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability, or maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features, as well as specific ecosystem functions and services.
- (15) Member States should also be able to base the decisions which they adopt pursuant to Directive 2001/18/EC on grounds concerning socioeconomic impacts which might arise from the cultivation of a GMO on the territory of the Member State concerned. While coexistence measures have been addressed by the Commission Recommendation of 13 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. Those grounds may be related to the high cost, impracticability or impossibility of implementing coexistence measures due to specific geographical

conditions, such as small islands or mountain zones, or the need to avoid GMO presence in other products such as specific or particular products. Furthermore, the Commission has, as requested in the 2008 Council conclusions, reported to the European Parliament and the Council on socioeconomic 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. Grounds relating to agricultural policy objectives may include the need to protect the diversity of agricultural production and the need to ensure seed and plant propagating material purity. Member States should also be allowed to base their measures on other grounds that may include land use, town and country planning, or other legitimate factors including those relating to cultural traditions.

- (16) The restrictions or 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.
- (17) Member States' measures adopted pursuant to this Directive should be subject to a procedure of scrutiny and information at Union level. In the 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 Council (<sup>1</sup>). Member States may restrict or prohibit the cultivation of GMOs in all or part of their territory as from the date of entry into force of the Union authorisation and for the whole duration of the consent/authorisation, provided that an established standstill period, during which the Commission was given the opportunity to comment on the proposed measures, has elapsed. The Member State concerned should therefore communicate a draft of those measures to the Commission at least 75 days prior to their adoption, in order to give the Commission an opportunity to comment thereon, 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.
- (18) During the established standstill period, the authorisation applicant/holder who would be affected by measures restricting or prohibiting the cultivation of a GMO in a Member State should refrain from all activities related to the cultivation of that GMO in that Member State.
- (19) 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 relating to human and animal health and environmental protection are observed and that the activity does not undermine the respect of the grounds on which the restriction or prohibition has been introduced. Moreover, the Authority and the Member States should aim to establish an extensive network of scientific organizations representing all disciplines including those relating to ecological issues, and should cooperate to identify at an early stage any potential divergence between scientific opinions with a view to resolving or clarifying contentious scientific issues. The Commission and the Member States should ensure that the necessary resources for independent research on the potential risks arising from the deliberate release or the placing on the market of GMOs are secured, and that independent researchers should be given access to all relevant material, while respecting intellectual property rights.
- (20) Given the importance of scientific evidence in taking decisions on the prohibition or approval of GMOs, the Authority should collect and analyse the results of research regarding the risk or danger to human health or the environment of GMOs and inform the risk managers of any emerging risks. Such information should be made available to the public.

- (21) 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.
- (22) Written consents or decisions of authorisation 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.
- (23) 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.
- (24) 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.
- (25) In order to guarantee a high level of consumer protection, Member States and operators should also take effective labelling and information measures pursuant to Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 of the European Parliament and of the Council to guarantee transparency with regard to the presence of GMOs in products.
- (26) 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.
- (27) The provisions laid down in Articles 26b and 26c of Directive 2001/18/EC apply without prejudice to Article 23 of that Directive as well as Article 34 of Regulation (EC) No 1829/2003.
- (28) Directive 2001/18/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:



Directive 2001/18/EC is amended as follows:

(1) In Article 26a, the following paragraph is inserted:

‘1a. As from 3 April 2017 Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in the light of particular geographical conditions. Those measures shall be communicated to the Commission.’

(2) The following Articles are inserted:

*‘Article 26b*

### **Cultivation**

- a. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation. That demand shall be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay. The Commission shall make the demand publicly available by electronic means.
- b. Within 30 days from the presentation by the Commission of that demand, the notifier/applicant may adjust or confirm the geographical scope of its initial notification/application.

In the absence of confirmation, the adjustment of the geographical scope of the notification/application shall be implemented in the written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 of this Directive as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003.

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

Where a demand in accordance with paragraph 1 of this Article is communicated to the Commission after the date of circulation of the assessment report under Article 14(2) of this Directive, or after receipt of the opinion of the European Food Safety Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003, the timelines set out in Article 15 of this Directive to issue the written consent or, as the case may be, in Articles 7 and 19 of Regulation (EC) No 1829/2003 to submit to the Committee a draft of the decision to be taken, shall be extended by a single period of 15 days regardless of the number of Member States presenting such demands.

- c. Where no demand was made pursuant to paragraph 1 of this Article, or where the notifier/applicant has confirmed the geographical scope of its initial notification/application, a Member State may adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by

crop or trait, 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;
- (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.

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;
- (b) the Member State concerned shall ensure that operators refrain from planting the GMO or GMOs concerned; and
- (c) the Commission may make any comments it considers appropriate.

On expiry of the 75-day period referred to in the first subparagraph, the Member State concerned may, for the whole duration of the consent/authorisation and as from the date of entry into force of the Union authorisation, adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the authorisation holder without delay. Member States shall make publicly available any such measure to all operators concerned, including growers.

- 5. 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.
- 6. For the purposes of an adjustment of the geographical scope of the consent/authorisation of a GMO under paragraph 5:
  - (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.

7. 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.
8. Measures adopted under this Article shall not affect the free circulation of authorised GMOs as, or in, products.

#### *Article 26c*

##### **Transitional measures**

1. From 2 April 2015 until 3 October 2015, a Member State may demand that the geographical scope of a notification/application submitted, or of an authorisation granted, under this Directive or Regulation (EC) No 1829/2003 before 2 April 2015 be adjusted. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay.
2. Where the notification/application is pending and the notifier/applicant has not confirmed the geographical scope of its initial notification/application within 30 days from the communication of the demand referred to in paragraph 1 of this Article, 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 of this Directive as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003 shall then be issued on the basis of the adjusted geographical scope of the notification/application.
3. Where the authorisation has already been granted and the authorisation holder has not confirmed the geographical scope of the authorisation within 30 days from the communication of the demand referred to in paragraph 1 of this Article, the authorisation shall be modified accordingly. For a written consent under this Directive, the competent authority shall amend the geographical scope of the consent accordingly 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. Where no demand was made pursuant to paragraph 1 of this Article, or where a notifier/applicant or, as the case may be, an authorisation holder has confirmed the geographical scope of its initial application or, as the case may be, authorisation, paragraphs 3 to 8 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.

#### *Article 2*

No later than 3 April 2019, 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.

By the same date as referred to in the first paragraph, the Commission shall also report to the European Parliament and to the Council on the actual remediation of environmental damages that might occur due to the cultivation of GMOs, on the basis of information made available to the Commission pursuant to Articles 20 and 31 of Directive 2001/18/EC and Articles 9 and 21 of Regulation (EC) No 1829/2003.

#### *Article 3*

No later than 3 April 2017, the Commission shall update the Annexes to Directive 2001/18/EC in accordance with Article 27 of that Directive as regards the environmental risk assessment, with a view to incorporating and building upon the strengthened 2010 Authority guidance on the environmental risk assessment of genetically modified plants.

#### *Article 4*

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 Belgrade,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*