Committee on the Environment, Public Health and Food Safety

2010/0208(COD)

24.9.2014

*****II**
DRAFT RECOMMENDATION FOR SECOND READING

on the Council position at first reading with a view to the adoption of 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 genetically modified organisms (GMOs) in their territory
(10972/2014 – C8-0145/2014 – 2010/0208(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Frédérique Ries

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not

highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council position at first reading with a view to the adoption of 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 genetically modified organisms (GMOs) in their territory
(10972/2014 – C8-0145/2014 – 2010/0208(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (10972/2014 – C8-0145/2014),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2010)0375),

– having regard to Article 294(7) of the Treaty on the Functioning of the European Union,

– having regard to Rule 69 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A8-0000/2014),

1. Adopts its position at second reading hereinafter set out;

2. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Council position
Citation 1

Council position	*Amendment*
Having regard to the Treaty on the Functioning of the European Union, and in particular ***Article 114*** thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular ***Article 192(1)*** thereof,

Or. en

[1] OJ C 033 E, 5.2.2013, p. 350.

Justification

Re-tabled Amendment 1 which was adopted in plenary with an absolute majority in favour of changing the legal basis. In its letter of 29 March 2011 to the ENVI Committee, the JURI Committee stated: "Taking into account the fact that arguments against the cultivation of GMOs are notably based on grounds related to environment, the correct legal basis for the proposal as amended by the rapporteur would have to be Article 192(1) TFEU".

Amendment 2

Council position
Recital 2

Council position	*Amendment*
(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. 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 and the environment should be achieved and maintained throughout the territory of the Union.	(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.*** 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 and the environment should be achieved and maintained throughout the territory of the Union.

Or. en

Justification

Amendment 2 adopted in first reading re-tabled in part. Clarification of the core content of the risk assessment as laid down in Annex II of the Directive 2001/18/EC.

Amendment 3

Council position
Recital 2 a (new)

Council position	*Amendment*
	(2a) The Commission and Member States should ensure, as a priority, the implementation of the Environment Council Conclusions adopted on 4 December 2008, namely a proper implementation of the legal requirements laid down in Annex II of Directive 2001/18/EC for the risk assessment of GMOs. In particular, the long-term environmental effects of genetically modified crops as well as their potential effects on non-target organisms should be rigorously assessed; the characteristics of the receiving environments and the geographical areas in which genetically modified crops may be cultivated should be duly taken into account; and the potential environmental consequences brought about by changes in the use of herbicides linked to herbicide-tolerant genetically modified crops should be assessed. More specifically, the Commission should ensure that the new guidelines on GMO risk assessment are given normative status. Those guidelines should not be based only on the principle of substantial equivalence or on the concept of a comparative safety assessment, and should make it possible to clearly identify direct and indirect long-term effects, as well as scientific uncertainties.

Or. {EN}en

Justification

Amendment 44 adopted in first reading re-tabled in part. It summarizes the main demands of the Council expressed in its conclusions of 4 December 2008, adopted unanimously. They

request, in particular, a significant improvement in the implementation of the risk assessment as provided for in Directive 2001/18/EC.

Amendment 4

Council position
Recital 2 b (new)

Council position	*Amendment*
	(2b) It is necessary to take into account the political context, and, in particular, the political commitment expressed in July 2014 by the President-elect of the European Commission to rapidly review the existing decision-making process applied to genetically modified organisms in order to confer at least as much weight to the opinions of democratically elected governments as to the views of the scientific community.

Or. en

Justification

On 15 July 2014, the new President-elect of the European Commission at the occasion of the presentation of his political orientations to the Members of the European Parliament stated his intention to review the current authorisation system for genetically modified organisms (GMOs) as he found it unacceptable that under current rules the Commission is legally obliged to authorise the import and processing of new GMOs even in cases where a clear majority of Member States are opposed to their use. He felt that the Commission should be able to give at least as much weight to the opinions of democratically elected governments as to scientific advice Similarly, in his mission letter to the Commissioner-designate, the President-elect emphasised his strong commitment to carry out such a review within the first 6 months of the new Commission. Although the present amendment of Directive 2001/18/EC does, in principle, not touch upon the EU authorisation system of GMOs, the new political context should be taken into account.

Amendment 5

Council position
Recital 5

Council position	*Amendment*
(5) 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. ***The*** common authorisation procedure, in particular the evaluation process, should not be adversely affected by such flexibility.	(5) 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. ***Furthermore, the harmonised assessment of risks to health and the environment might not address all possible impacts of GMO cultivation in different regions and local ecosystems. 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 effective cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the Union market. However, the*** common authorisation procedure, in particular the evaluation process, should not be adversely affected by such flexibility.

Or. en

Justification

Amendment 5 adopted in first reading re-tabled in part, in order to specify that the examination of the national, regional or local impact of the cultivation of GMOs always requires at least some scientific data and touches upon environmental aspects which may - or may not - already have been examined at Union level.

Amendment 6

Council position
Recital 6

Council position	*Amendment*
(6) ***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) of the Treaty on the Functioning of the European Union (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.	(6) ***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) of the Treaty on the Functioning of the European Union (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.

Or. en

Amendment 7

Council position
Recital 7

Council position	*Amendment*
(7) ***In accordance with Article 2(2) TFEU, Member States are therefore 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 part of that Member State's territory.*** 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 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 Directive 2001/18/EC to avoid the unintended presence of GMOs in other products. ***The grant of that 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 should be preserved 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.***	(7) 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 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 ***required*** to take by application of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products ***on their territory and in border areas of neighbouring Member States.***

Or. en

Justification

Related to Amendments 22 and 24 that entitle Member states to optionally use either the negotiation process with the applicant company (so called "phase I") or the national restriction/prohibition process based on specific grounds ("phase II"). Also linked to Amendment 21 in relation to Member States' obligation to take co-existence measures.

Amendment 8

Council position
Recital 7 a (new)

Council position	*Amendment*
	(7a) To ensure that the cultivation of GMOs does not result in the unintended presence of GMOs in other products, effective co-existence measures are needed. Member States should therefore be required, under Directive 2001/18/EC, to adopt rules applicable to their territories to avoid such unintended presence. Particular attention should be paid to any possible cross-border contamination from a Member State or a region where cultivation is allowed into a neighbouring Member State or region where it is prohibited. The Commission Recommendation of 13 July 2010 provides guidance to Member States for the development of national co-existence measures[1a], including in border areas.
	[1a] Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crop (OJ C 200, 22.7.2010, p. 1).

Or. en

Justification

Related to Amendment 21 which reformulates Article 26(a): It should be compulsory for Member States to take measures to avoid the presence of GMOs in other products.

Amendment 9

Council position
Recital 7 b (new)

Council position	*Amendment*
	(***7b) The grant of flexibility to Member States should facilitate the decision-making process regarding GMOs. At the same time, freedom of choice of consumers, farmers and operators should be preserved whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union. This Directive is therefore compatible with the smooth functioning of the internal market.***

Or. en

Amendment 10

Council position
Recital 8

Council position	*Amendment*
(8) During the authorisation procedure of a given GMO, the possibility should 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 Directive 2001/18/EC or in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 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 request of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to that request within an established time-limit.	(8) During the authorisation procedure of a given GMO, the possibility should 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 Directive 2001/18/EC or in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 to the effect that all or part of the territory of that Member State be excluded from cultivation. The Commission should ***present*** the ***justified*** request of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to that request within an established time-limit.

Or. en

Justification

Related to Amendment 22 on Article 26(b) paragraph 1. A Member States requesting an adjustment of the geographical scope of a notification/application to the effect that all or part of the territory of that Member State be excluded from cultivation ("phase I") should be obliged to justify its request (based on specific grounds, as mentioned in Article 26(b) paragraph 3).

Amendment 11

Council position
Recital 10

Council position	*Amendment*
(10) ***In addition, and only where the notifier/applicant 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 its territory, on the basis of grounds ***distinct from 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, socio-economic impacts, co-existence 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.	(10) ***Without prejudice to the possibility provided for a Member State to request the adjustment of the geographical scope of a notification/application,*** there should ***always*** be the possibility for ***a*** Member State to ***act as risk manager and*** adopt reasoned measures restricting or prohibiting the cultivation of ***a*** GMO ***or of groups of GMOs defined by crop or trait or of all GMOs*** once authorised in all or part of its territory, on the basis of grounds ***relating to the public interest***, which are in conformity with Union law. Those grounds may be related to environmental or agricultural policy objectives, or other ***legitimate factors such as socio-economic impacts, where those factors have not been addressed as part of the harmonised procedure provided for in Part C of Directive 2001/18/EC, or to persisting scientific uncertainty. Those measures should be duly justified on scientific grounds or on grounds relating to other legitimate factors which might arise from the deliberate release or the placing on the market of GMOs.*** 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.

Or. en

Amendment 12

Council position
Recital 11

Council position	*Amendment*
(11) 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 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 Directive 2001/18/EC and in Regulation (EC) No 1829/2003***, such as the maintenance of certain type of natural and landscape features, certain habitats and ecosystems, as well as specific ecosystem functions and services***.	(11) The level of protection of human or animal health and of the environment chosen in the Union ***cannot be diverged from by a Member State, and this principle should be maintained***. 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 related to environmental policy objectives which ***are 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.

Or. en

Justification

The list of grounds is too restrictive and does not cover any complementary environmental reasons that a Member State may invoke to justify a ban (such as biodiversity protection).

Amendment 13

Council position
Recital 11 a (new)

Council position	*Amendment*
	(11a) Member States should be allowed to base the measures that restrict or prohibit the cultivation of GMOs on duly justified grounds relating to environmental impacts, or on grounds relating to risk management. Those grounds may include the prevention of the development of pesticide resistance amongst weeds and pests; the invasiveness or persistence of a genetically modified variety, or the possibility of interbreeding with domestically cultivated or wild plants; the prevention of negative impacts on the local environment caused by changes in agricultural practices linked to the cultivation of GMOs; the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability; the maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features; the absence or lack of adequate data concerning the potential negative impacts of the release of GMOs on the local or regional environment of a Member State, including on biodiversity.

Or. en

Justification

Related to key Amendment 24 on Article 26(b) paragraph 3.

Amendment 14

Council position
Recital 11 b (new)

Council position	*Amendment*
	(11b) The grounds relating to socio-

economic impacts may include the impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions such as small islands or mountain zones; the need to protect the diversity of agricultural production; or the need to ensure seed purity.

Or. en

Justification

Specification in relation to socio-economic grounds. Linked with Amendment 24.

Amendment 15

Council position
Recital 11 c (new)

Council position	*Amendment*
	(11c) Member States should be allowed to base measures restricting or prohibiting the cultivation of GMOs also on other grounds that may include land use, town and country planning, or other legitimate factors.

Or. en

Justification

Specification in relation to other types of grounds that may be invoked by Member States to justify a restriction or ban. Linked with Amendment 24.

Amendment 16

Council position
Recital 12

Council position	*Amendment*
(12) Member States should also be able to base the decisions which they adopt pursuant to Directive 2001/18/EC on grounds concerning socio-economic impacts which might arise from the cultivation of a GMO on the territory of the Member State concerned. While co-existence measures have been addressed by the Commission Recommendation of 13 July 2010[1], 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 impracticability or the impossibility of implementing co-existence measures due to specific geographical conditions, the need to avoid GMO presence in other products such as specific or particular products, 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 Council Conclusions of 5 December 2008 on Genetically Modified Organisms, reported to the European Parliament and the Council on socio-economic 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.	***deleted***
[1] Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crop (OJ C 200, 22.7.2010, p. 1).	

Or. en

Amendment 17

Council position
Recital 14

Council position	*Amendment*
(14) Member States' measures adopted pursuant to this Directive should be subject to a procedure of scrutiny and information at Union level. In 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[1]. Member States may restrict or prohibit the cultivation of a GMO in all or part of their territory as from the date of entry into force of the Union authorisation ***and no later than two years after the date when the consent/authorisation is granted***, provided that an established standstill period, during which the Commission was given the opportunity to comment on the proposed measures, has elapsed.	(14) Member States' measures adopted pursuant to this Directive should be subject to a procedure of scrutiny and information at Union level. In 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[1]. Member States may restrict or prohibit the cultivation of a GMO 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 the proposed measures to the Commission at least 75 days prior to their adoption, in order to give the opportunity to the Commission to comment, 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.***
[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204,	[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204,

21.7.1998, p. 37.). 21.7.1998, p. 37.).

Or. en

Justification

The aim of this amendment is to allow MS to take measures during the whole period of authorisation. The last two sentences of this recital ("The MS concerned...") have been moved from deleted recital 16.

Amendment 18

Council position
Recital 15 a (new)

Council position	*Amendment*
	(15a) Given the importance of scientific evidence in taking decisions on the prohibition or approval of GMOs, the Authority and the Member States should collect and publish annually the results of research regarding the risk or evidence of any accidental presence, contamination or danger to the environment or human health of GMOs.

Or. en

Justification

Amendment 4 adopted in first reading, re-tabled in part.

Amendment 19

Council position
Recital 16

Council position	*Amendment*
(16) When new and objective circumstances justify an adjustment of the geographical scope of the	***deleted***

consent/authorisation of a GMO, and in any case no earlier than two years after the date when the consent/authorisation is granted, a Member State should be able to request, via the Commission, the consent/authorisation holder to adjust its geographical scope. If the consent/authorisation holder does not explicitly or tacitly agree, the Member State should be given the possibility to adopt reasoned measures restricting or prohibiting the cultivation of that GMO. The Member State concerned should communicate a draft of those measures to the Commission at least 75 days prior to their adoption, in order to give the opportunity to the Commission to comment, 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.

Or. en

Justification

This deletion is to put into perspective with Amendment 24, which removes the mandatory nature of Phase I (providing for the obligation of a Member State to make a request to the applicant company in order to adjust the geographical scope of the authorisation of a GMO before being allowed to adopt measures restricting or prohibiting the cultivation of GMOs on its territory). This deletion reflects the deletion of Article 26b, paragraph 5 (Amendment 26). The necessary elements which apply to Phase I have already been taken up in recitals 8 and 9. The last two sentences of this recital are moved to the end of recital 14.

Amendment 20

Council position
Recital 22

Council position	*Amendment*
(22) The Commission Recommendation of 13 July 2010 provides guidance to Member States for the development of co-existence measures, including in border areas.	***deleted***

Or. en

Justification

Moved to recital 7a and strengthened.

Amendment 21

Council position
Article 1
Directive 2001/18/EC
Article 26 a – paragraph 1

Present text	*Amendment*
	(1) In Article 26a, paragraph 1 is replaced by the following:
1. Member states ***may*** take appropriate measures to avoid the unintended presence of GMOs in other products.	'1. Member States ***shall*** take appropriate measures to avoid the unintended presence of GMOs in other products ***on their territory and in border areas of neighbouring Member States.***'

Or. en

Justification

The possible cultivation of GMOs should not result in additional costs for farmers working in conventional or organic farming. It should thus be compulsory for Member States to take measures to avoid the presence of GMOs in other products. Specific attention should be paid to any possible cross-border contamination.

Amendment 22

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 1

Council position	*Amendment*
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 all or part of the territory of that Member State is to 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) of this Directive, or from receiving the opinion of the Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall communicate the request of the Member State to the notifier/applicant and to the other Member States without delay.	1. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may 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 Regulation (EC) No 1829/2003, to the effect that all or part of the territory of that Member State is to be excluded from cultivation. ***That request shall be justified on compelling grounds such as those mentioned in paragraph 3 of this Article. That*** request shall be communicated to the Commission at the latest ***60*** days from the date of the circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall communicate the request of the Member State to the notifier/applicant and to the other Member States without delay.

Or. en

Justification

In order to be legally solid, the adjustment of the geographical scope of a notification/application as requested by a Member State during the authorisation procedure shall be justified on the basis of compelling grounds such as those applied in case of Member States restricting/prohibiting the cultivation of GMOs on their territory after authorisation.

Amendment 23

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 2 – subparagraph 1

Council position	*Amendment*
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 that request. In the event 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.	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 that request. ***The Commission shall make public such notification of opposition.*** In the event 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 Commission shall make public such agreement.***

Or. en

Amendment 24

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 3

Council position	*Amendment*
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 of this Article, that*** Member State may adopt measures restricting or prohibiting the cultivation of ***that*** GMO in all or part of its territory once authorised in accordance with Part C of this Directive or	3. ***Without prejudice to paragraph 1, a*** Member State may, ***following the risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003 and acting as risk manager,*** adopt measures restricting or prohibiting the cultivation of ***a*** GMO ***or of groups of GMOs defined by crop or trait or of all GMOs*** in all or part of its territory once authorised in accordance with Part C of

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:	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 ***distinct from the elements assessed*** according to this Directive and Regulation (EC) No 1829/2003***;***	(a) environmental policy objectives ***relating to environmental impacts which might arise from the cultivation of GMOs and which are complementary to*** the ***impacts examined during the scientific risk assessment conducted*** according to this Directive and Regulation (EC) No 1829/2003. ***Those grounds may include:***
	- the prevention of the development of pesticide resistance amongst weeds and pests;
	- the invasiveness or persistence of a genetically modified variety, or the possibility of interbreeding with domestically cultivated or wild plants;
	- the prevention of negative impacts on the local environment caused by changes in agricultural practices linked to the cultivation of GMOs;
	- the 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;
	- the absence or lack of adequate data concerning the potential negative impacts of the release of GMOs on the local or regional environment of a Member State, including on biodiversity;
(b) town and country planning;	(b) town and country planning;
(c) land use;	(c) land use;
(d) socio-economic impacts;	(d) socio-economic impacts ***such as the impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions***

	such as small islands or mountain zones;
(e) avoidance of GMO presence in other products without prejudice to Article 26a;	
(f) agricultural policy objectives***;***	(f) agricultural policy objectives***. Those grounds may include:***
	- the need to protect the diversity of agricultural production;
	- the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability;
	– the need to ensure seed purity.
(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.	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, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003.

Or. en

Justification

This is a key amendment of the Amending Act:

- Member States should be allowed to restrict the cultivation of all or a particular GMO(s) as drafted in the original proposal of the Commission.

- It should also be possible for Member States acting as risk manager to invoke different types of factors (environmental impacts, socio-economic or agricultural impact) to ban the cultivation of the GMO(s) concerned.

- Those grounds should not be too vague and ensure legal certainty.

This amendment contains the key elements of the Parliament's Amendment 40 and 41 adopted in first reading.

Amendment 25

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 4 – subparagraph 2

Council position	*Amendment*
On expiry of the 75-day period referred to in the first subparagraph, ***and no later than two years after the date that the consent/authorisation is granted,*** the Member State concerned may adopt the measures either in the form originally proposed, or as amended to take account of any comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the ***notifier/applicant*** without delay.	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 comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the ***authorisation holder*** without delay.

Or. en

Justification

The aim of this amendment is to allow MS to take measures during the whole period of authorisation.

Amendment 26

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 5

Council position	*Amendment*
5. Where, after the authorisation of a GMO under this Directive or Regulation (EC) No 1829/2003 and no earlier than two years after the date that the consent/authorisation is granted, a Member State considers that new objective circumstances justify an adjustment of the geographical scope of the consent/authorisation, it may apply	***deleted***

the procedure under 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.

Or. en

Justification

With the possibility to adopt national measures during the whole duration of the authorisation (Amendment 25), this provision is not relevant.

Amendment 27

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 5 a (new)

Council position	*Amendment*
	5a. A Member State which intends to adopt measures pursuant to paragraph3 of this Article shall:
	(a) ensure that farmers who cultivated such crops legally have sufficient time to finish the ongoing cultivation season; and
	(b) carry out a prior independent cost-benefit analysis, taking into account any alternatives.

Or. en

Justification

Re-tabled Amendments 17 and 42 adopted in first reading that set up two new criteria to be met by Member States related to GMOs which are already on the market.

Amendment 28

Council position
Article 1
Directive 2001/18/EC
Article 26 b – paragraph 7 – introductory part

Council position	*Amendment*
7. For the purposes of an adjustment of the geographical scope of the consent/authorisation of a GMO under paragraphs ***5 and 6, and on condition that under paragraph 5 the consent/authorisation-holder explicitly or tacitly agrees to the request of the Member State:***	7. For the purposes of an adjustment of the geographical scope of the consent/authorisation of a GMO under ***paragraph 6:***

Or. en

Justification

Linked to Amendment 25 and the deletion of paragraph 5.

Amendment 29

Council position
Article 1
Directive 2001/18/EC
Article 26 b a (new)

Council position	*Amendment*
	'Article 26 b a
	Liability requirements and financial guarantees
	Member States shall establish a general mandatory system of financial liability and financial guarantees which applies to all operators and which ensures that the polluter pays for unintended effects or damage that might occur due to the deliberate release or the placing on the market of GMOs.'

Or. en

Justification

Re-tabled Amendment 24 adopted in first reading.

Amendment 30

Council position
Article 1
Directive 2001/18/EC
Article 26 c – paragraph 2

Council position	*Amendment*
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 that request, 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 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 explicitly or tacitly agreed by the notifier/applicant.	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 that request, 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 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 explicitly or tacitly agreed by the notifier/applicant. ***The Commission shall make public such agreement.***

Or. en

Amendment 31

Council position
Article 26 b – paragraph 3
Directive 2001/18/EC
Article 26 c – paragraph 3

Council position	*Amendment*
3. Where the authorisation has already	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 the request referred to in paragraph (1) of this Article, 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 explicitly or tacitly agreed by the authorisation holder 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.	been granted and the authorisation holder has explicitly or tacitly agreed to a request within 30 days from the communication of the request referred to in paragraph (1) of this Article, 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 explicitly or tacitly agreed by the authorisation holder 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. ***The Commission shall also make public such agreement.***
	Or. en

Amendment 32

Council position
Article 1
Directive 2001/18/EC
Article 26 c – paragraph 4

Council position	*Amendment*
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.	4. If a notifier/applicant or, as the case may be, an authorisation holder opposes such a request, ***the Commission shall make public such notification of opposition. Paragraphs*** 3 to 9 of Article 26b shall apply mutatis mutandis.
	Or. en

Amendment 33

Council position
Article 2

Council position	*Amendment*
No later than 4 years after…[+], 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 Authority guidance on the environmental risk assessment of genetically modified plants.	No later than 4 years after…[+], 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. ***During this period the*** Commission shall also ***give*** normative status to the strengthened 2010 Authority guidance on the environmental risk assessment of genetically modified plants.
[+] OJ: please insert the date of entry into force of this Directive.	[+] OJ: please insert the date of entry into force of this Directive.

Or. en

Justification

In 2010, EFSA adopted (strengthened) guidelines on the environmental risk assessment of genetically modified plants. As they are currently not legally binding, the Commission should be requested to give them a normative status no later than four years as of the entry into force of this Amending Act.

EXPLANATORY STATEMENT

I. Background

On 23 July 2014, the 28 Environment Ministers adopted the Council position concerning the restriction or prohibition of the cultivation of GMOs in the territory of the Member States.

In practice, they were seeking to amend Directive 2001/18/EC on the deliberate release into the environment of GMOs, adding a new article widening the powers of the Member States to justify legally a national or regional ban on GMO cultivation. This amendment would also apply to the cultivation of GMOs authorised under Regulation (EC) No 1829/2003 covering food and feed containing or produced from GMOs.

The provisions of these two legislative texts establish a strict legal framework, authorising the marketing of GMOs only after approval based on a scientific assessment of the risks to human and animal health and to the environment.

It must be specified that the text under discussion concerns only the cultivation of GMOs for harvesting or on-farm research. In other words, GMO imports intended mainly for livestock are not covered by this legislation.

The compromise adopted by the Member States has entered into effect three years after the Parliament vote at first reading on 5 July 2011.

While such progress is welcomed by all, the underlying situation has become increasingly sensitive:

1. The European groundswell of opposition to GMOs is particularly pronounced with regard to their presence in food intended for human consumption, as reflected in the special Eurobarometer survey (no 354) of December 2010 regarding food-related risks, revealing that only 21% of Europeans concurred with the proposition that *'GMO foods are safe for future generations'* (as opposed to 58% against).

An updated survey would be particularly welcome. It would very probably indicate that a large majority is still opposed to GMO cultivation in Europe.

2. In February 2014, the controversy surrounding TC1507 genetically modified maize, opposed by 19 governments out of 28, received intensive media coverage. Only five Member States (Spain, the United Kingdom, Estonia, Finland and Sweden) voted in favour of authorising this new GMO variety, leaving the Commission to take the final decision, which it has not yet done.

3. A backlog of applications has accumulated in the centralised EU authorisation system. In addition to the application for authorisation of TC 1507 maize, six other GMO authorisation procedures (five for maize and one for soya) are pending, a favourable opinion having been issued by the EFSA. Given the strong opposition of most of the Member States, the Commission is hesitating to put it to the vote.

4. It was against this background that the new Commission President Jean-Claude Juncker, outlining Commission policy to the MEPs on 15 July 2014, set out his intentions: *'I also intend to review the current legislation authorising the use of genetically modified organisms. I consider it unacceptable that, under current rules, the Commission is legally obliged to authorise the import and processing of new GMOs, even in cases where a clear majority of Member States are opposed to their use'*.

This was confirmed in the mission statement sent to the new European Commissioner responsible for health and food safety, who will be required to review, in the first six months of his term of office, the existing decision-making process applicable to GMOs.

The rapporteur must therefore take account of the new political climate in drawing up his draft recommendation.

In this, he has the joint backing of the European Parliament, most of the Member States and the new Commission President, who are anxious to 'extricate' the GMO issue from the morass of bureaucracy that is proving so exasperating to all concerned.

II. Objectives and limits of the Council common position

It should be remembered that the principal objective of the this modification to the legislative framework is to provide greater latitude and greater legal security to Member States wishing to prohibit in all or part of their territory the cultivation of GMOs authorised at European level. This is specified by the Council in the fifth recital.

While the Council has adopted a number of Parliament's amendments thereby endorsing its objectives, it has at the same time introduced a procedure imposing fresh obligations on the national authorities.

A Member State is initially required to submit a specific request (paragraphs 1 and 2 of Article 26b (new) to an undertaking seeking to market GMOs in the EU (phase I) so as to ensure that the authorisation does not encompass its national territory.

It is only if this initial phase is unsuccessful and the request opposed by the undertaking that the single (phase II) procedure will be applied (paragraph 3 of Article 26b (new)), enabling a Member State to invoke legal justifications in a bid to prohibit GMO cultivation.

In other words, this involves two consecutive phases, the second conditioned by the first, instead of the procedure set out in the original Commission proposal as amended by the EP and which should remain at the core of the amended version of the 2001 Directive.

However, the Council's version, which runs counter to the European Parliament objective in its vote of 5July 2011, gives the uncomfortable impression of putting the cart before the horse.

This was why the rapporteur tabled Amendment 24 to paragraph 3 of Article 26b, which is essential if recourse to the phase I procedure by a Member State is to be optional.

Another restriction of the rights of Member States is the strict two-year deadline for procedures to be initiated at national level to prohibit GMO cultivation once EU authorisation

has been accorded.

The rapporteur fails to see the reasons for this and considers that ten years, the statutory duration of authorisation, would be an appropriate deadline. That is the reason behind Amendment 25 to paragraph 4 of Article 26b.

The compensatory procedure provided for in paragraph 5 of by Article 26b is therefore no longer needed and Amendment 26 accordingly seeks deletion thereof.

Furthermore, regarding the open-ended list of reasons which may be invoked to justify a ban on GMO cultivation, the rapporteur takes the view that the absence of specific examples weakens the legal framework and has accordingly tabled Amendment 24 closely resembling the text adopted by absolute majority at first reading, except that it includes five categories of justification:

- Environmental criteria in addition to those outlined by the EFSA at European level, relating to local or systemic aspects of GMO utilisation in a given agronomic context;
- Regional development criteria;
- Land-use criteria;
- Socio-economic criteria, for example the high cost of contamination for conventional and/or organic farmers;
- Criteria relating to agricultural policy objectives.

These criteria will give Member States the necessary flexibility to take suitable measures without altering or undermining current EU risk assessment procedures.

III. Other amendments by the rapporteur

At first reading, the European Parliament adopted 28 amendments in its modified proposal, most of which were uncontroversial or supported by an absolute majority. The rapporteur accordingly tabled a total of 33 amendments, including the principal amendments adopted at first reading and not included in the Council common position.

In view of this:

- It is necessary to reaffirm the legal basis chosen by the European Parliament relating to the environment (Amendment 1). This new legislation seeks to modify not only Directive 2001/18/EC but also Regulation (EC) No 1829/2003, where the request for authorisation from a company relates to cultivation and food or feed. While the legal basis relating to the internal market was selected for the 2001 directive, the, legislators selected no less than three, relating to agriculture, the internal market and public health, for the 2003 regulation.

The text also seeks to achieve a major objective: giving greater flexibility to Member States to prohibit GMO cultivation within their territory on a number of grounds, including environmental considerations, such as the protection of biodiversity, habitats and ecosystems.

- It is necessary to improve risk evaluation procedures. Amendment 3 seeks to ensure implementation of the conclusions adopted by the 'Environment' Council of 4 December 2008 calling for comprehensive and effective assessment methods, bearing in mind that insufficient account has been taken to date of the long-term impact of GMO cultivation.

The rapporteur notes with satisfaction that this matter is included in the provisions of the Council text, which nevertheless needs to be improved. Amendment 33 accordingly seeks to make EFSA guidelines binding.

- It is necessary specify compulsory measures to safeguard the coexistence of different types of cultivation.

That was the purpose of the amendment to Article 26a tabled in plenary in July 2011, which the rapporteur wishes to re-table with Amendment 21.

It is important to include in this legislation compulsory provisions requiring Member States to safeguard the coexistence of different types of cultivation and to prevent any cross-border dissemination, a requirement heartily endorsed by most European farmers.

Modifications have also been proposed to guarantee the transparency of the procedure to restrict or prohibit GMO cultivation and ensure that such major decisions are made public.