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PROPOSAL

from:	European Commission
dated:	14 July 2010
Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Pierre de BOISSIEU, Secretary-General of the Council of the European Union.

Encl.: COM(2010) 375 final

EUROPEAN COMMISSION

Brussels, 13.7.2010
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2010/0208 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{COM(2010) 380 final}

EXPLANATORY MEMORANDUM

1. Context of the proposal

The European Union (EU) has adopted a comprehensive legal framework for the authorisation of products consisting of or derived from Genetically Modified Organisms (GMOs). The authorisation procedure covers the use of GMOs for food and feed purposes, industrial processing and cultivation, and their derived products for food and feed uses.

The European Union authorisation system is aimed at avoiding adverse effects of GMOs on human and animal health and the environment while establishing an internal market for those products. Two pieces of legislation, namely Directive 2001/18/EC on the environmental release of GMOs[1] and Regulation (EC) No 1829/2003 on GM food and feed[2], provide for the pre-marketing authorisation of GMOs. Both establish science based standards for the assessment of potential risks for human health, animal health and the environment as well as labelling requirements. In addition, Regulation (EC) No 1830/2003[3] provides rules on the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs.

The Council Conclusions of December 2008 considered the existing legislative framework on GMOs comprehensive and underlined the need to better implement the existing provisions, notably as concerns cultivation. It also noted the necessity of continuing processing applications without undue delays. In March 2009, the Council rejected Commission's proposals requesting Austria and Hungary to repeal their national safeguard measures, as according to the European Food Safety Authority (EFSA) they lacked the necessary scientific support needed under the EU legislation. Subsequently, a group of 13 Member States[4] called on the Commission to prepare proposals to give freedom to Member States to decide on cultivation of GMOs[5].

In September 2009 the political guidelines for the new Commission set out by President Barroso made reference to the principle of subsidiarity in the GMO area as an example where the balance may not be always right between an EU framework and the need to take account of diversity in an EU of 27 Member States. According to these guidelines, it should be possible to combine a European Union authorisation system for GMOs, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory.

The proposed Regulation aims at implementing these guidelines by providing a legal base in the EU legal framework on GMOs to authorise Member States to restrict or prohibit the cultivation of GMOs that have been authorised at EU level in all or part of their territory. Those prohibitions or restrictions shall be based on grounds other

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1 OJ L 106, 17.4.2001, p. 1.
2 OJ L 268, 18.10.2003, p. 1.
3 OJ L 268, 18.10.2003, p. 24.
4 AT, BG, IE, EL, CY, LV, LT, HU, LU, MT, NL, PL and SI.
5 Respective discussions took place at Council meetings of 2 March, 23 March and 25 June 2009.

than those covered by the environmental and health risk assessment under the EU authorisation system.

2. Preferred option and assessment of its impacts

2.1. Reasons for modification of EU legislative framework compared to other options

A. The current legislative framework does not fully address the need to give more freedom to Member States on cultivation of GMOs, as it does not grant them sufficient flexibility to decide on GMO cultivation after they have been authorised at EU level.

The replacement of the Recommendation for co-existence[6] by a Recommendation on guidelines for the development of national measures to avoid the unintended presence of GMOs in conventional and organic crops complements the steps towards recognising Member States' need for flexibility to take into consideration the particular conditions of agriculture in their territory. However the scope of the new Recommendation, which mirrors Article 26a of Directive 2001/18/EC[7], can only refer to measures aimed at avoiding the unintended presence of GMOs in other crops, which offer fewer margins for Member States to decide than under a comprehensive legal amendment.

Some further elements linked to the EU framework of GMO authorisations could give margin to consideration of specific conditions of cultivation in Member States. Those could be (i) the consideration of regional aspects under the risk assessment and conditions of authorisations or (ii) the consideration of other legitimate factors under the Regulation. However those options would only have an impact on the way in which authorisations are adopted at EU level. Moreover the framework within which those elements may be applied appears too restrictive. Therefore they would not fulfil the central notion of allowing Member States to decide on GMO cultivation taking into consideration their specific conditions.

The fact that Member States have currently no margin of appreciation on cultivation of authorised GMOs has led in several cases some Member States to vote on the basis of non-scientific grounds. Some of them have also invoked the available safeguard clauses, or used the special notification procedures of the Treaty under the internal market, as ways to prohibit the cultivation of GMOs at national level.

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6 Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming .

7 According to Article 26a(1) of Directive 2001/18/EC, *"Member States may take appropriate measures to avoid the unintended presence of GMOs in other products".*

B. Therefore an amendment to the existing EU legislative framework would be necessary to facilitate decision making and take into account all relevant factors. It is also expected to reduce the recourse of Member States to safeguard measures, which according to the legislation must only be based on new or additional scientific evidence with regards to the health and environment safety of the GMO. This would reduce the institutional burdens on the Commission as well as on EFSA. Moreover Member States would not invoke the procedure of Article 114(5) of the Treaty on the Functioning of the European Union (TFEU) in order to prohibit or restrict the cultivation of GMOs in their territories on the basis of considerations other than health and environmental protection. Moreover, the proposed amendment is expected to provide legal certainty to Member States that wish to restrict or prohibit GMO cultivation. Finally it will offer greater clarity to affected stakeholders (e.g. GMO farmers, organic farmers, conventional farmers, seed producers/exporters/importers, livestock breeders, feed processors and consumers and biotechnology companies,) about cultivation of GMOs in the EU and will possibly increase the predictability of the decision-making process.

2.2. Economic, social and environmental impacts of the proposal

GMO cultivation in the EU has been very limited up to date. Therefore it is difficult to make *ex ante* a precise quantification of the possible economic, social and environmental impacts in case Member States are allowed to decide to prohibit/restrict cultivation.

2.2.1. *Economic impacts*

The proposal does not affect the EU authorisation process for GMOs and the Commission will continue to process applications for cultivation in accordance with existing rules. Therefore the proposal will not entail any direct impacts for applicants. This concerns 17 applications currently pending for authorisation or re-authorisation (mainly maize)[8].

A. Continuation of existing trends - GM crop and seed production in the EU

On the basis of the current limited experience of cultivation in the EU, it is expected that the production of GM seeds and cultivation of GMOs in the EU will mainly take place in the Member States which have already experienced cultivation on their territories. The overall pace at which GM cultivation could proceed in the EU is alreadyunclear under different scenarios established on the basis of the existing legislative framework[9]. Farmers' adoption will be the result of a trade-off between, on the one hand, expected productivity gain or market opportunities and, on the other hand,

[8] 14 for maize, one for soybean, one for sugar beet and one for potato.

[9] "The economics of adventitious presence thresholds in the EU seed market", Kalaitzandonakes, Magnier; working paper, June 2007.

possible constraints such as higher prices for GM seeds, premium for non-GM products, possible market rejection[10] and cost of national co-existence and liability measures. Managing segregation will be more demanding in regions where conventional seed production overlaps with high shares of GM seed or GM crop production.

B. Marketing of GM seeds

This proposal concerns the freedom of Member States to prohibit/restrict the act of cultivation of GM varieties only, but not the free marketing of authorised GM seeds throughout the EU or imports of such seeds from third countries once they have been authorised at EU level.

C. Effects on other types of production and downstream operators / users

With regards to other types of production, the possibility to exclude GMOs from specific areas and the clustering of different production chains may benefit operators and consumers of organic or conventional products and reduce the segregation costs. It is difficult to assess the effect on final consumer prices. However it is expected that consumers' and operators' choice between three different types products - organic, conventional and GM - would increase.

D. Effects on administrative costs

This option is expected to reduce the number of national safeguard measures, therefore reducing the administrative burden for Member States, EFSA or the Commission and the procedures linked to them. On the other hand, it might increase the administrative costs for Member States in their endeavours to enforce potential restrictions or prohibitions of GMO cultivation. As under the current situation, in Member States, where cultivation would take place, resources for inspections, controls and monitoring, especially at field level, will be required to ensure that post-market requirements are properly implemented.

2.2.2. *Social impacts*

As the overall cultivation surface is not expected to change under the current proposal, it is expected that the proposal will have no significant impact on jobs.

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[10] According to the 2006 Commission implementation report of Regulation (EC) No 1829/2003, the EU market shares of labelled GM food and feed products appear to be contrasted. Labelled GM feed products are much more placed on the market than GM food. This situation is mainly governed by factors that are not related to the legislative framework as such but by other elements including consumer demand, relative availability and costs of different commodities on the world market, and the policies of food producers and retailers.

Given the more national or regional approach towards GMO cultivation, it is also expected that the level of public involvement in the national and regional decision making will increase and Member States will allocate more resources and time to involve their public with regards to their decisions. Social, economic and ethical aspects are expected to be put on the table and provide the platform for the respective decisions at national, regional or local level.

2.2.3. *Environmental impacts*

Potential health and environmental risks of each GMO will continue being assessed by EFSA at EU level and on a case-by-case basis. EFSA will adopt the respective opinions after taking into account the scientific contributions of the national competent authorities, especially with respect to regional aspects.

As under the current situation, in the areas where GMO cultivation will take place, risk management and monitoring of potential environmental effects may be needed on the basis of the respective risk assessments. This might require the active involvement of national/regional authorities and other networks (e.g. farmers or scientists) to provide the most effective possible results.

2.3. Conclusion

The Commission considers that the amendment of the legislation is necessary to get the right balance between maintaining the EU system of authorisations based on the scientific assessment of health and environmental risks and the need to grant freedom to Member States to address specific national or local aspects raised by the cultivation of GMOs. This approach, while preserving the EU authorisation system of GMOs as well as the free circulation and import of GM food, feed and seeds, is expected to address the demands of several Member States and receive public support. It is also estimated that the potential economic and social benefits of this proposal are likely to outweigh the potential disadvantages.

Member States may be in a more appropriate position to carry out their own impact assessments to justify their decisions about cultivation of GMOs in their territories at national/regional/local levels.

3. Legal elements of the proposal

3.1. Content of the proposal

The proposal amends Directive 2001/18/EC by introducing a new Article which allows Member States to restrict or prohibit the cultivation of authorised GMOs in part or all of their territories on grounds other than those covered by the environmental risk assessment under the EU authorisation system and those related to avoiding the unintended presence of GMOs in other products.

This amendment will apply to GMOs authorised for cultivation either under Directive 2001/18/EC or Regulation (EC) No 1829/2003 which also covers applications for cultivation if they concern GMOs that are intended as source materials for the further production of food and feed. It will equally apply to cultivation of all varieties of seed and plant propagating material placed on the market in accordance with relevant EU legislation[11].

The freedom which Member States will obtain will only concern the act of GMO cultivation, but not the placing on the market and import of authorised GM seeds which must continue unimpeded within the framework of the internal market and the respective international obligations of the Union. The proposal sets out two series of conditions under which Member States can take measures:

1. As the assessment of the safety of GMOs for human/animal health and the environment is carried out at EU level, Member States have the possibility under the existing legal framework to invoke the special procedures of the safeguard clause of Directive 2001/18/EC (Article 23) or the emergency measure of Regulation (EC) No 1829/2003 (Article 34) in case they have serious grounds to consider that the authorised product is likely to constitute a serious risk to health and environment. Consequently, the proposal stipulates that Member States cannot invoke protection of health and environment to justify a national ban of cultivation of GMOs outside these special procedures. This condition aims at preserving the authorisation system based on science set out in EU legislation.

2. Member States can thus invoke grounds (other than those covered by the environmental risk assessment under the EU authorisation system) to restrict or prohibit cultivation of GMOs in their territories. The measures taken by the Member States have to be in conformity with the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU), in particular as regards the principle of non-discrimination between national and non-national products and the provisions on quantitative restrictions of trade between Member States (Articles 34 and 36 TFEU). They should finally be consistent with the international obligations of the EU, and in particular with the ones established under the World Trade Organisation (WTO).

[11] Directives 2002/53/EC and 2002/55/EC.

3.2. Choice of the instrument

The proposal is under the form of a Regulation, even though it amends a Directive.

The reason of this choice is that the proposal has general application, is binding in its entirety and is directly applicable in all Member States. In addition, it does not contain in substance any provision that would require transposition as it only provides to the Member States a legal base to adopt measures.

3.3. Subsidiarity and proportionality principle

3.3.1. *Conformity of the proposal with the principle of subsidiarity.*

According to Article 5(3) TEU, under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but rather, by reason of the scale of effects of the proposed action, be better achieved at Union level.

Following Article 2(2) TFEU, when the Treaties confer on the Union a competence shared with the Member States in a specific area, the Union and the Member States may legislate and adopt legally binding acts in that area. In accordance with the last sentence of this provision, Member States shall again exercise their competence to the extent that the Union decides to cease its competence.

The current EU legal framework fully harmonises cultivation of GMOs. Member States are thus allowed to adopt reasoned measures restricting or prohibiting the cultivation of GMOs only under the conditions set out in that legal framework (essentially the safeguard clauses and emergency measures provisions when a serious risk to health and environment is identified, and Article 26a of Directive 2001/18/EC to avoid the presence of authorised GMOs in other products).

Experience however has shown that cultivation of GMOs is an issue which is more thoroughly addressed by Member States, either at central level or at regional and local level. It is closely linked to land use and the requirements of local agricultural structures, separate production chains and consumers' demands. Contrary to the safety assessment of GMOs, whose principles are common throughout the EU, or to issues related to the imports and marketing of GMOs, which should remain regulated at EU level, GMO cultivation has been acknowledged as an issue with a strong local/regional dimension. As such, national, regional or local levels of decision making are considered to be the most appropriate frameworks to address the particularities linked to GMO cultivation.

In line with the principle of subsidiarity and by application of Article 5(3) last sentence of the TEU, Member States should therefore be entitled to conserve a possibility to adopt rules concerning cultivation of GMOs in their territories after the GMO has been legally placed on the

EU market, provided that these measures do not affect their placing on the market and import and that they are in conformity with the Treaties and with the EU international commitments, and more particularly the obligations under the World Trade Organisation (WTO).

3.3.2. *Conformity of the proposal with the principle of proportionality*

According to Article 5(4) TEU, under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

The content of the Union action in the proposal is limited to allow Member States to adopt reasoned measures on cultivation of GMOs. Within the limits foreseen by the proposal (namely that national measures taken by Member States shall not be based on grounds covered by the environmental risk assessment under the EU authorisation and shall respect the Treaties and relevant international obligations) it should not prevent the EU to achieve the objectives of the Treaties. Measures adopted by Member States could refer to the cultivation of GMOs only and not to the free circulation and import of genetically modified seeds and plant propagating material, as or in products, and the products of their harvest.

In addition, it is expected to bring about no additional costs to involved stakeholders (such as biotech companies or farmers) and consumers compared to the current situation. Some Member States might need to allocate some more administrative resources to address potentially increased needs for inspections and controls; however those costs are not expected to be excessive or unjustifiable. The further economic, social and environmental impacts indicated above indicate that no excessive burdens, costs or disadvantages are going to be caused to operators, consumers or any other side in comparison to the current situation.

4. Budgetary implications

This proposal for a European Parliament and Council Regulation has no financial implications for the Union budget.

This proposal will have no impact on small or medium-sized undertakings different than the impact of the current situation.

2010/0208 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 […] thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[12],

Having regard to the opinion of the Committee of the Regions[13],

After transmission of the proposal to the national Parliaments,

Acting in accordance with the ordinary legislative procedure[14],

Whereas:

(1) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[15] and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[16] 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 EU as seeds or other plant-propagating material (hereinafter 'GMOs for cultivation').

(2) Under this set of legislation, GMOs for cultivation shall undergo an individual risk assessment before being authorised to be placed on the Union market. The aim of this authorisation procedure is to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumer interests, whilst ensuring the effective functioning of the internal market.

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12 OJ C , , p. .
13 OJ C , , p. .
14 OJ C , , p. .
15 OJ L 106, 17.4.2001, p. 1.
16 OJ L 268, 18.10.2003, p. 1.

(3) In addition to the authorisation for placing on the market, genetically modified varieties also need to comply with the requirements of EU legislation on the marketing of seed and plant propagating material, as set out in particular in Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed[17], Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed, Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species[18], Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed[19], Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed[20], Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes[21], Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants[22], Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine[23], Council Directive 98/56/EC of 20 July 1998 on the marketing of fruit plant propagating material of ornamental plants[24], Council Directive 99/105/EC of 22 December 1999 on the marketing of forest reproductive material[25] and Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production[26]. Among them Directives 2002/53/EC and 2002/55/EC contain provisions which allow the Member States to prohibit, under certain well defined conditions, the use of a variety in all or in parts of its territory or to lay down appropriate conditions for the cultivation of a variety.

(4) Once a GMO is authorised for cultivation purposes in accordance with the EU legislative framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of EU legislation on the marketing of seed and plant propagating material, Member States are not authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by EU legislation.

(5) Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed by Member States, either at central or at regional and local level. Contrary to issues related to the placing on the market and the import of GMOs, which should remain regulated at EU level to preserve the internal market, cultivation has been acknowledged as an issue with a strong local/regional dimension. In accordance with Article 2(2) TFEU Member States should therefore be entitled to have a possibility to adopt rules concerning the effective cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.

(6) In this context, it appears appropriate to grant to Member States, in accordance with the principle of subsidiarity, more freedom to decide whether or not they wish to cultivate GMO crops on their territory without changing the system of Union authorisations of GMOs and independently of the measures that Member States are

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17 OJ L 125, 11.7.1966, p. 2298.
18 OJ L 268, 18.10.2003, p. 1.
19 OJ L 193, 20.7.2002, p. 12.
20 OJ L 193, 20.7.2002, p. 33.
21 OJ L 193, 20.7.2002, p. 60.
22 OJ L 193, 20.7.2002, p. 74.
23 OJ L 93, 17.4.1968, p. 15.
24 OJ L 226, 13.8.1998, p. 16.
25 OJ L 11, 15.1.2000, p. 17.
26 OJ L 267, 8.1.2008, p. 8.

entitled to take by application of Article 26a of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products.

(7) Member States should therefore be authorised to adopt measures restricting or prohibiting the cultivation of all or particular GMOs in all or part of their territory, and respectively amend those measures as they deem appropriate, at all stages of the authorisation, re-authorisation or withdrawal from the market of the concerned GMOs. This should apply as well to genetically modified varieties of seed and plant propagating material which are placed on the market in accordance with relevant legislation on the marketing of seeds and plant propagating material and, in particular, in accordance with Directives 2002/53/EC and 2002/55/EC. Measures should refer to the cultivation of GMOs only 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. Similarly they should not affect the cultivation of non genetically modified varieties of seed and plant propagating material in which adventitious or technically unavoidable traces of EU authorised GMOs are found.

(8) According to the legal framework for the authorisation of GMOs, the level of protection of human/animal health and of the environment chosen in the EU cannot be revised by a Member State and this situation must not be altered. However Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs in all or part of their territory on the basis of grounds relating to the public interest other than those already addressed by the harmonised set of EU rules which already provide for procedures to take into account the risks that a GMO for cultivation may pose on health and the environment. Those measures should furthermore be in conformity with the Treaties, in particular as regards the principle of non discrimination between national and non national products and Articles 34 and 36 of the Treaty on the Functioning of the European Union, as well as with the relevant international obligations of the Union, notably in the context of the World Trade Organisation.

(9) On the basis of the subsidiarity principle, the purpose of this Regulation is not to harmonize the conditions of cultivation in Member States but to grant freedom to Member States to invoke other grounds than scientific assessment of health and environmental risks to ban cultivation of GMOs on their territory. In additionone of the purposes of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[27] which is to allow the Commission to consider the adoption of binding acts at EU level would not be served by the systematic notification of Member States' measures under that Directive.. Moreover, since measures which Member States can adopt under this Regulation cannot have as a subject the placing of the market of GMOs and thus does not modify the conditions of placing on the market of GMOs authorised under the existing legislation, the notification procedure under Directive 98/34/EC does not appear the most appropriate information channel for the Commission. Therefore, by derogation, Directive 98/34/EC should not be applicable. A simpler notification system of the national measures prior to their adoption appears to be a more proportionate tool for the Commission to be aware of these measures. Measures which Member States intend to adopt should thus be communicated together

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

with their reasons to the Commission and to the other Member States one month prior to their adoption for information purposes.

(10) Articles 7(8) and 19(8) of Regulation (EC) No 1829/2003 provide that references made in parts A and D of Directive 2001/18/EC to GMOs authorised under part C of that Directive are to be considered as applying equally to GMOs authorised under that Regulation. Accordingly, measures adopted by the Member States in accordance with this Regulation should apply as well to GMOs authorised in accordance with Regulation (EC) No 1829/2003.

(11) Directive 2001/18/EC, should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1
Modification of Directive 2001/18/EC

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

'Article 26b
Cultivation

Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that:

(a) those measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs;

and,

(b) that they are in conformity with the Treaties.

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

Article 2
Entry into force

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

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President