NOTE
from: General Secretariat
to: Permanent Representatives Committee/Council
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
– Outcome of the European Parliament's first reading (Strasbourg, 4 to 7 July 2011)

I. INTRODUCTION

The rapporteur, Ms Corinne LEPAGE (ALDE - FR), presented a report consisting of 26 amendments (amendments 1–26) to the proposal for a Regulation, on behalf of the Committee on the Environment, Public Health and Food Safety (ENVI).
23 further amendments were tabled: the EPP political group tabled one amendment (amendment 34), the ECR political group three amendments (amendments 37-39), the ALDE political group five amendments (amendments 40-44), the EUL/NGL political group two amendments (amendments 45-46), and the Greens/EFA three amendments (amendments 47-48, 51). The EPP and ECR political groups together tabled eight amendments (amendments 27-33, 36).

II. DEBATE

The rapporteur opened the debate, which took place on 5 July 2011, and:

- noted that the proposal aims at allowing Member States to prohibit and to restrict the cultivation of genetically modified organisms (GMOs) in their territory and creating a framework for an opt-out procedure, whilst respecting the principle of subsidiarity and the wishes of Member States, the regions and the citizens. At the same time, the centralised European authorisation procedure for GMOs by the European Food Safety Authority (EFSA) should not be called into question.
- stressed that the ENVI Committee has introduced specific grounds according to which the cultivation of GMOs can be prohibited by Member States. According to the rapporteur, there are three categories:
  - first, environmental grounds complementary to the ones which are assessed at European level in the authorisation procedure, they would treat local and systemic aspects;
  - second, grounds relating to the socio-economic impact, such as the costs of coexistence measures or the impossibility of implementing coexistence measures due to the specific geographical conditions;
  - third, grounds that may include land use, town and country planning or other legitimate factors.
- noted that a change of the legal basis is proposed, from Article 114 to Article 192 with the objective to help Member States to defend the measures taken, if GMO producers were to attack them in court.
- pointed out that accompanying mandatory measures on coexistence would be needed.
- regretted that the position of the EPP political group made it impossible to agree on compromise amendments before the vote in the plenary. Despite this position, the ALDE political group tabled a number of amendments which should be seen as compromises and should be acceptable to other groups, and also to parts of the EPP group.

Commissioner John Dalli:
- welcomed the efforts of the Parliament to clarify the grounds on which restrictions on cultivation may be justified. Though, the possible grounds that could be invoked are open. In order not to restrict Member States’ flexibility the Commission proposal referred only to grounds other than the assessment of adverse effects of GMOs on health or the environment.
- noted that, regarding the concrete grounds for prohibitions, the Commission is very happy to see that they are taken from the list that the Commission developed at the request of the Member States in December 2010
- stressed that the specification of environmental grounds must be further substantiated in order to make it explicit that such environmental reasons or policy objectives are distinct from risks assessed according to GMO legislation. This is essential to preserve the EU authorisation system with the Member States playing an active role during the risk assessment prior to an EU-wide authorisation, but without duplication at national level once the authorisation is given.
- spoke against Amendment 12, in relation to Article 22 on free circulation, as it could weaken the argumentation in the event of EU or WTO litigation, and also against Amendment 24 on a general mandatory system of financial liability.
- argued in favour of Article 114 as the correct legal basis for this proposal whose centre of gravity is the approximation of laws in Member States for the establishment of the internal market.
- noted that the use of safeguard clauses, which is the way several Member States restrict and prohibit the cultivation of GMOs, is illegal under European law.
- regretted that there was no possibility to start the negotiations between Council and Parliament in view of an agreement before the vote in plenary despite the substantive progress in the Council under the Hungarian Presidency.
Speaking on behalf of the Committee on Agriculture and Rural Development, Mr George LYON (ALDE – UK):

- noted that the Committee on Agriculture and Rural Development supports the Commission proposal with some hesitation and with a number of safeguards, such as the respect of the principle of proportionality and the freedom of choice of consumers and farmers. He insisted on the need for farmers and growers to be given proper notice of a ban in order to give them time to adapt.
- stressed the very high importance for introducing obligatory measures on coexistence in order to protect non-GM growers.
- supported a wider definition of environmental grounds provided that they did not undermine the current EU-wide authorisation process.

Speaking on behalf of the EPP political group, Ms Cristina GUTIERREZ-CORTINES (EPP – ES):

- regretted that no agreement between the political groups could be found, but noted at the same time that her own political group is not totally united.
- stated that there is a lot of insecurity regarding the legal issues. Therefore her group is in favour of a strong legal base which should be Article 114 on the internal market.
- stressed that the decisions of EFSA at European level must be based on objective scientific grounds and that they should be adapted to national criteria.
- supported the paper of the Commission of December 2010 on the specific grounds for prohibitions and restrictions of cultivation.

Speaking on behalf of the S&D political group, Mr Justas Vincas PALECKIS (S&D – LT):

- thanked the rapporteur for a very balanced report and congratulated her on the broad support it had received in the ENVI Committee.
- noted that Member States in Council neither find common ground on which they would approve or reject GMOs, nor for the removal of safeguard clauses.
• stressed that this report will bring more legal certainty for Member States and could help to break the existing deadlock. The inclusion of complementary environmental reasons as well as a list of social and economic grounds for the restriction or prohibition of GMOs by Member States will make this report more legally solid.

Speaking on behalf of the ALDE political group, Ms Antonia PARVANOVA (ALDE – BG):
• stressed that the report creates a solid and common European framework under which Member States will be able to restrict and prohibit the cultivation of GMOs in their territory, and it will be strongly supported by her group.
• noted that the proposal does not create an obstacle to the European internal market.
• stated that for such a controversial and debated technology, affecting European territories and biodiversity and regional specificity, the level of discussion should be left as close as possible to the European citizens.

Speaking on behalf of the Greens/EFA political group, Mr Bart STAES (Greens/EFA – BE):
• thanked the rapporteur for her work and stressed the importance of the proposed Regulation for the environment and for the farmers as its creates legal certainty for the restriction and prohibition of cultivation of GMOs.
• expressed his group's support for all the specific grounds presented in the report on the basis of the principle "the polluter pays".
• noted that the freedom of choice of farmers and consumers needs to be respected and protected.

Speaking on behalf of the ECR political group, Mr Miroslav UOZKY (ECR – CZ):
• noted that the report goes far beyond the original Commission proposal and is not acceptable.
• pointed out that the resistance against GMOs and the general opposition in public opinion put European farmers in a disadvantageous position.
• stated that further restrictions for the cultivation of GMOs are not acceptable, and his group will therefore vote against the proposal.
Speaking on behalf of the EUL/NGL political group, Ms Kartika LIOTARD (EUL/NGL – NL):

- noted that the original Commission proposal did not go far enough and the possibilities for Member States to restrict need to be extended.
- supported the introduction of health-, environmental- and socio-economic grounds as justification for the prohibition of GMO cultivation.

Speaking on behalf of the EFD political group, Mr Oreste ROSSI (EFD – IT):

- supported the ban or the restriction of the use of GMOs whilst respecting the freedom to use or not to use GMOs.
- pointed out that the consumer needs to be informed about the presence of GMOs in his food.

III. VOTE

When it voted on 5 July 2011, the parliament adopted 28 amendments (amendments 1-2, 4-14, 17, 19-20, 22-24, 26, 40-44, 46-47 and 51). The text of the amendments adopted and the European Parliament's legislative resolution are annexed to this note.
Possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory


(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2010)0375),
– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0178/2010),
– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
– having regard to Article 294(3) and Article 192(1) of the Treaty on the Functioning of the European Union,
– having regard to the opinion of the European Economic and Social Committee of 9 December 2010¹,
– having regard to the opinion of the Committee of the Regions of 28 January 2011²,
– having regard to Rules 55 and 37 of its Rules of Procedure,
– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0170/2011),

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

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

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

¹ OJ C 54, 19.2.2011, p. 51.
² Not yet published in the Official Journal.
Amendment 1
Proposal for a regulation – amending act
Citation 1

Text proposed by the Commission
Having regard to the Treaty on the
Functioning of the European Union, and in particular Article 114 [...] thereof,

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

Amendment 2
Proposal for a regulation - amending act
Recital 2

Text proposed by the Commission
(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.

Amendment
(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, taking into account, in accordance with Annex II of Directive 2001/18/EC, the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects, on human health and the environment. 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. A uniform high level of protection of health and the environment should be achieved and maintained throughout the territory of the Union.

Amendment 44
Proposal for a regulation – amending act
Recital 2 a (new)

Text proposed by the Commission
(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 GM 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 GM plants 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 GM crops should be assessed. More specifically, the Commission should ensure that the new guidelines on GMO risk assessment are adopted. 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. The European Food Safety Authority (EFSA) and the Member States should aim to establish an extensive network of scientific organisations representing all disciplines including those relating to ecological issues, and should cooperate to identify at an early stage any potential divergence between scientific opinions with a view to resolving or clarifying the contentious scientific issues. The Commission and the Member States should ensure that the necessary resources for independent research on the potential risks of GMOs are secured, and that the enforcement of intellectual property rights does not prevent independent researchers from accessing all relevant material.

Amendment 46
Proposal for a regulation – amending act
Recital 2 b (new)

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<td>(2b) There is a need for the precautionary principle to be taken into account in the framework of this Regulation and when implementing it.</td>
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Amendment 4

Proposal for a regulation - amending act
Recital 4 a (new)

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<td>(4a) Given the importance of scientific evidence in taking decisions on the prohibition or approval of GMOs, EFSA 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, on a case-by-case basis. Due to the high cost of expert consultation, Member States should promote collaboration between research institutions and national academies.</td>
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Amendment 5

Proposal for a regulation - amending act
Recital 5

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<td>(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)</td>
<td>(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. Issues related to the placing on the market and the import of GMOs should remain regulated at EU level to preserve the internal market. Cultivation might require more flexibility in certain instances as it is an issue with a strong local/regional/territorial dimension and</td>
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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.

**Amendment 6**

**Proposal for a regulation - amending act**

**Recital 6**

*Text proposed by the Commission*

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

*Amendment*

(6) In this context, it appears appropriate to grant to Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMO crops on their territory without changing the system of Union authorisations of GMOs and independently of the measures that Member States are required to take by application of Article 26a 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.

**Amendment 7**

**Proposal for a regulation - amending act**

**Recital 7**

*Text proposed by the Commission*

(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.

*Amendment*

(7) Member States should therefore be authorised to adopt, on a case-by-case basis, measures restricting or prohibiting the cultivation of particular GMOs or
Amendment 8

Proposal for a regulation - amending act

Recital 8

Text proposed by the Commission

(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 groups of GMOs or of all 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. Cultivation is closely linked to land use and the conservation of fauna and flora, areas in which the Member States retain significant powers. The possibility for Member States to adopt such measures should also apply 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. Those measures should allow all operators concerned, including growers, sufficient time to adapt.

Amendment

(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 groups of GMOs or of all 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. Cultivation is closely linked to land use and the conservation of fauna and flora, areas in which the Member States retain significant powers. The possibility for Member States to adopt such measures should also apply 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. Those measures should allow all operators concerned, including growers, sufficient time to adapt.
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.

Amendment 9
Proposal for a regulation - amending act Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) Restrictions on or prohibitions of cultivation of particular GMOs by a Member State should not prevent or restrict the use of authorised GMOs by other Member States, provided effective measures are taken to prevent cross-border contamination.

Amendment 47
Proposal for a regulation – amending act Recital 8 b (new)

Text proposed by the Commission

Amendment

(8b) Member States should be allowed to base the measures referred to in Article 26b on duly justified grounds relating to local or regional environmental impacts which might arise from the deliberate release or the placing on the market of GMOs and which are complementary to the environmental impacts examined
during the scientific assessment of the impacts on the environment conducted under Part C of this Directive, or 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 GM variety, or the possibility of interbreeding with domestic 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.

The measures may also be based on grounds relating to socio-economic impacts. Those grounds 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;

- the need to ensure seed purity.

The measures may also be based on other grounds that may include land use, town and country planning, or other legitimate factors.

Amendment 10
Proposal for a regulation - amending act
Recital 9

Text proposed by the Commission

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

Amendment

(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 restrict or prohibit the cultivation of GMOs on their territory on grounds relating to environmental or other legitimate factors such as socio-economic impacts, which might arise from the deliberate release or the placing on the market of GMOs where those factors have not been addressed as part of the harmonised procedure provided for in Part C of Directive 2001/18/EC or in the event of persisting scientific uncertainty. In addition, one 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 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 with their reasons to the Commission and to the other
Amendment 11

Proposal for a regulation - amending act
Recital 9 a (new)

Text proposed by the Commission

(9a) Restrictions or bans on cultivation of GMOs by Member States should not prevent biotechnology research from being carried out provided that, in carrying out such research, all necessary safety measures are observed.

Amendment 12

Proposal for a regulation – amending act
Article 1 – point -1 (new)
Directive 2001/18/EC

Article 22

Text proposed by the Commission

Directive 2001/18/EC is amended as follows:

(-1) Article 22 is replaced by the following:

‘Article 22

Free circulation

Without prejudice to Article 23 or Article 26b, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.’

Amendment 13

Proposal for a regulation – amending act
Article 1 – point -1 a (new)
Directive 2001/18/EC

Article 25 – paragraph 5 a (new)
(-1a) In Article 25, the following paragraph is added:

‘5a. Without prejudice to the protection of intellectual property rights, access to material necessary for independent research on potential risks of GMOs, such as seed material, shall not be restricted or impeded.’

Amendment 14

Proposal for a regulation – amending act
Article 1 – point -1 b (new)
Directive 2001/18/EC

Article 26 a – paragraph 1

Text proposed by the Commission

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

Amendment

(-1b) Article 26a(1) is replaced by the following:

‘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.’

Amendment 40

Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC

Article 26b – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

Member States may adopt, after a case-by case examination, measures restricting or prohibiting the cultivation of particular GMOs or of groups of GMOs defined by crop or trait or of all GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties
seed and plant propagating material, in all or part of their territory, provided that:

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:

Amendment 41

Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26b – paragraph 1 – point a

Text proposed by the Commission

(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;

Amendment

(a) those measures are based on

(i) duly justified grounds relating to local or regional environmental impacts which might arise from the deliberate release or the placing on the market of GMOs and which are complementary to the environmental impacts examined during the scientific assessment of the impacts on the environment conducted under Part C of this Directive, or 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 GM variety, or the possibility of interbreeding with domestic 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;
(ii) grounds relating to socio-economic impacts. Those grounds 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;
(iii) other grounds that may include land use, town and country planning, or other legitimate factors;

Amendment 17
Proposal for a regulation - amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26 b – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment
(aa) in cases where those measures concern crops which are already authorised at Union level, Member States ensure that farmers who cultivated such crops legally have sufficient time to finish the current cultivation season;

Amendment 42
Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26b – paragraph 1 – point a b (new)
(ab) those measures have been subject to a prior independent cost-benefit analysis, taking into account alternatives;

Amendment 19
Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26 b – paragraph 1 – point a c (new)

(ac) those measures have been the subject of a prior public consultation lasting at least 30 days;

Amendment 20
Proposal for a regulation - amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26 b – paragraph 1 – point b

b) those measures are in conformity with the Treaties.

b) those measures are in conformity with the Treaties, in particular the principle of proportionality.

Amendment 51
Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26b – paragraph 1 a (new)

In the same way, regions within Member States may adopt measures restricting or prohibiting the cultivation of GMOs on their territory.
Amendment 43

Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26b – paragraph 1 b (new)

Text proposed by the Commission

Amendment

Member States shall make publicly available any such measure to all operators concerned, including growers, at least six months before the start of the growing season. In the event that the GMO concerned is authorised less than six months before the start of the growing season, Member States shall make those measures publicly available upon their adoption.

Amendment 22

Proposal for a regulation – amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26 b – paragraph 1 c (new)

Text proposed by the Commission

Amendment

Member States shall adopt those measures for a maximum of five years and shall review them when the GMO authorisation is renewed.

Amendment 23

Proposal for a regulation - amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26 b – paragraph 2
Text proposed by the Commission

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.

Amendment 24

Proposal for a regulation - amending act

Article 1 – point 1 a (new)

Directive 2001/18/EC

Article 26 b a (new)

Text proposed by the Commission

(1a) The following Article is inserted:

‘Article 26ba

Liability requirements

Member States shall establish a general mandatory system of financial liability and financial guarantees, for example through insurance, which applies to all business 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.’

Amendment 26

Proposal for a regulation – amending act

Article 2

Text proposed by the Commission

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

Amendment

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