AMENDMENTS 001-026
by the Committee on the Environment, Public Health and Food Safety

Report
Corinne Lepage **A7-0170/2011**
Possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory

Proposal for a regulation (COM(2010)0375 – C7-0178/2010 – 2010/0208(COD))

Amendment 1

Proposal for a regulation – amending act
Citation 1

Text proposed by the Commission	*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,

Justification

See opinion of the JURI committee

Amendment 2

Proposal for a regulation - amending act
Recital 2

Text proposed by the Commission	*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. The aim of this authorisation procedure is to ensure a high level of protection of human life and	(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,***

health, animal health and welfare, the environment and consumer interests, whilst ensuring the effective functioning of the internal market.	***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 3

Proposal for a regulation - amending act
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The Commission and the 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 primarily 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. Until the risk assessment provisions are properly implemented, no new GMO variety should be authorised. 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 4

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

Text proposed by the Commission	*Amendment*
	(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.

Justification

GMOs are evaluated on the basis of data submitted by the applicant. Given the cost and economic boundaries limitations of EFSA, Member States that have the capacity to decide must also take responsibility and work on collecting information and transferring it to Europe.

Amendment 5

Proposal for a regulation - amending act
Recital 5

Text proposed by the Commission	*Amendment*
(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.	(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 an issue of particular importance for the self-determination of Member States***. ***The common authorisation procedure should not be adversely affected by such flexibility. However, the harmonised environmental and health risks assessment might not address all possible impacts of GMO cultivation in different regions and local ecosystems.*** In accordance with Article 2(2) TFEU Member States should therefore be entitled to have a possibility to adopt ***binding legislative provisions*** concerning the 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	*Amendment*
(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	(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

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.	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	*Amendment*
(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***.	(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 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

Proposal for a regulation - amending act
Recital 8

Text proposed by the Commission	*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 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***.	(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. ***Those measures may be based 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. Those measures should be duly justified on scientific grounds or on grounds relating to risk management or other legitimate factors which might arise from the deliberate release or the placing on the market of GMOs.*** Those measures should furthermore be ***proportionate and*** 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.

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 10

Proposal for a regulation - amending act
Recital 9

Text proposed by the Commission	*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 ***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 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	(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

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.	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 11

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

Text proposed by the Commission	*Amendment*
	(9b) 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	*Amendment*
	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.'

Justification

Article 22 should not preclude the possibility for Member States to adopt rules concerning the restriction or prohibition of the cultivation of GMOs on their territory in accordance with the new article 26b.

Amendment 13

Proposal for a regulation – amending act
Article 1 – point -1 a (new)
Directive 2001/18/EC
Article 25 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	(-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.'

Justification

The Environment Council, in December 2008 concluded that 'independent researchers should be given access to all relevant material, while respecting intellectual property rights'. Currently, it is often impossible for independent researchers to conduct research on a GM-variety, as the access to the GM-material is restricted and farmers are obliged not to pass on GM-material for research purposes. In order for Member States to be able to investigate the compatibility of a certain GM-variety with a specific receiving environment, access to the GM material must not be restricted.

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	*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 15

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

Text proposed by the Commission	*Amendment*
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:	Member States may adopt, ***on a case-by case-basis,*** 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 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 16

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

Text proposed by the Commission	*Amendment*
(a) those measures are based on grounds	(a) those measures are based on

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;	
	i) scientifically justified grounds ***relating*** to ***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 of adequate data or the existence of contradictory data or persisting scientific uncertainty concerning the potential negative impacts of the release of GMOs on the environment of a Member State or region, 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;

- the need to ensure seed purity; or

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 18

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

Text proposed by the Commission	*Amendment*
	(ab) those measures respect local agricultural and cultural traditions;

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)

Text proposed by the Commission	*Amendment*
	(ac) those measures have been the subject of a prior public consultation lasting at least 30 days;

Justification

To enable the competent authorities to take informed decisions, the parties concerned must be able to notify their observations before the adoption of such measures, which could have an impact on various sectors.

Amendment 20

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

Text proposed by the Commission	*Amendment*
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 21

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

Text proposed by the Commission	*Amendment*
	Member States shall make publicly available any such measure to all operators concerned, including growers, at least three months before the start of the growing season. In the event that the GMO concerned is authorised less than three 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 b (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	*Amendment*
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*'*.	By way of derogation to Directive 98/34/EC, Member States that intend to adopt 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.

Justification
The word 'reasoned' is not necessary. It is subjective and may unnecessarily restrict possibilities for Member States.

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	*Amendment*
	(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.'

Justification

If different cultivation rules apply in different Member States, it is even more important that each Member State has a strict system in place in order to ensure that the polluter pays for unintended effects or damages. So far, conventional or organic farmers are often not adequately protected from possible contaminations with GMOs.

Amendment 25

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

Text proposed by the Commission	*Amendment*
	(1b) The following Article is inserted:
	'Article 26 bb
	'GMO-free' labelling
	The Commission shall propose harmonised conditions under which operators may make use of terms indicating the absence of GMOs in products.'

Justification

The 13 July 2010 guidelines on the co-existence of crops state that Member States may take measures to avoid the economic implications of the presence of GMOs below the Community 0.9% labelling threshold. To avoid distortions of competition, the conditions under which operators may make use of terms indicating the absence of GMOs in products should be harmonised at Community level.

Amendment 26

Proposal for a regulation – amending act
Article 2

Text proposed by the Commission	*Amendment*
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 enter into force on the ***twentieth*** day following that of its publication in the Official Journal of the European Union.