DRAFT OPINION

of the Committee on Agriculture and Rural Development

for the Committee on the Environment, Public Health and Food Safety


Rapporteur: George Lyon
SHORT JUSTIFICATION

Context of the proposal

Your Rapporteur would like to recall some facts and figures on GMO cultivation as a basis for discussion:

- 2 GMO crops are currently authorised for cultivation in the EU: MON810 maize and Amflora potato
- 17 GMOs are awaiting authorisation for cultivation in the EU
- A total of 94,800 ha. of MON810 maize were grown in 5 Member States in 2009 (Spain, Czech Republic, Portugal, Romania and Slovakia), 80% of which were in Spain (compared to 107,700 ha. in 2008, before Germany discontinued cultivation). Amflora potato is currently cultivated in 3 Member States: Sweden, Germany and Czech Republic.

In 2009, 14 million farmers worldwide planted 134 million ha. of GMOs, with 64 million ha. planted in the USA, over 21 million ha. in Brazil and Argentina respectively, and over 8 million ha. in countries such as Canada and India.

These figures illustrate the current deadlock surrounding the decision-making on GMOs in the EU and the lack of answers to genuine concerns expressed by farmers and consumers.

A science-based approach to new technology

Your Rapporteur believes that best scientific advice and a risk-based approach should be the key principles in determining the safety of new technologies. Without the bedrock of scientific advice to anchor decisions on safety of new methods and practices, society runs the risk of decisions being taken on the basis of what is popular rather than what is safe. Other elements such as socio-economic concerns or ethical considerations cannot substitute for science-based decisions on safety. Your Rapporteur recognises that the Commission's proposal as it stands does not undermine the common scientific GMO authorisation procedure in Europe.

Purpose of the proposal

According to the Commission, in parallel to the comprehensive legal framework for the authorisation of products consisting of or derived from GMOs, the proposal seeks to "facilitate decision making", "take into account all relevant factors" and "grant Member States sufficient flexibility to decide on GMO cultivation after they have been authorised at EU level". While serious concerns have been raised by the Council and European Parliament legal services respectively regarding legal certainty, potential threats to the Single Market and WTO incompatibilities, your Rapporteur has come to the conclusion after weighing up all the arguments, that on balance, the proposal may deliver the Commission's objectives and provide some opportunities for progress in unlocking the deadlock on the decision-making surrounding GMOs in the EU.

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1 Records are taken for maize, soybean, cotton and rapeseed
Position

The general approach taken by your Rapporteur is to strengthen the Commission's proposal in response to concerns about Internal Market and WTO-compliance. Your Rapporteur has also introduced a requirement to respect the principle of proportionality and the freedom of choice for consumers and farmers. He has also sought to give greater protection to those farmers who wish to cultivate GM-free and greater legal certainty to Member States using this flexibility.

Your Rapporteur believes that Member States should be required to adopt a case-by-case approach when deciding to use this new power to ensure the restrictions are crop specific. This would recognise the fact that different GMOs bring both different threats and benefits to different regions, and therefore should be assessed individually to make sure Member States respect the principle of proportionality.

In order to respect the freedom of choice, as recognised in the Council conclusions of 4th December 2008 and the Opinion of the European Economic and Social Committee of 9th December 2010 (NAT 480 - CESE 1623/2010), it is necessary to ensure that Member States have robust co-existence rules in place on their territory. This requires an amendment to Article 26a of Directive 2001/18/EC to give reassurance to non-GM growers and consumers who wish to grow and purchase GM-free products that their right to do so will be respected. Your Rapporteur also believes that Member States should make full use of the flexibility granted under Article 26a and the Commission's new Recommendation on guidelines for co-existence before adopting further restrictive measures under the proposed Article 26b.

In parallel to the co-existence measures, and in order to protect non-GM growers from economic loss due to the adventitious presence of GMOs in their fields and in their seeds, your Rapporteur also asks the Commission to draw up a proposal on technical thresholds for labelling GMO traces in conventional seeds at the lowest practicable, proportionate and functional levels for all economic operators, as asked by the Council Conclusions of 4th December 2008.

Finally, while ensuring that restrictive measures are proportionate and that all necessary practical measures are taken to respect the freedom of choice of farmers and consumers, your Rapporteur proposes to reinforce legal certainty for farmers in the context of this proposal. To achieve this goal, Member States must publicise and implement the restrictions they plan to take using this new power under Article 26b of Directive 2001/187EC at least three months prior to the start of the growing season, so that farmers can plan ahead with some certainty.

Your Rapporteur is therefore ready to grant support to this proposal provided the additional safeguards proposed in this opinion are adopted.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report.
Amendment 1

Proposal for a regulation – amending act
Recital 5

Text proposed by the Commission

(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.

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. Issues related to the placing on the market and the import of GMOs should remain regulated at Union level to preserve the internal market. Cultivation might require more flexibility in certain instances as it is an issue with a strong local/regional dimension. However, the common authorisation procedure should not be adversely affected by such flexibility. 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 Union market, provided that those rules do not adversely affect the free movement and marketing of GMO products and seeds.

Or. en

Justification

It must be ensured that the flexibility granted to Member States under new Article 26b does not disrupt the functioning of the Single Market and the common GMO authorisation procedure.

Amendment 2

Proposal for a regulation – amending act
Recital 6

Text proposed by the Commission

(6) In this context, it appears appropriate to

Amendment

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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.

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 in **parallel with** the measures that Member States must take by application of Article 26a of Directive 2001/18/EC, as amended by this Regulation, to avoid the unintended presence of GMOs in other products.

**Or. en**

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**Amendment 3**

**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, 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.

**Amendment**

(7) Member States should therefore be authorised to adopt measures restricting or prohibiting the cultivation of GMOs **on a case-by-case basis** in all or part of their territory, **as long as those measures are adopted and made publicly available to all operators concerned, including growers, at least three months prior to the start of the growing season**, and respectively amend those measures as they deem appropriate. 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.
material in which adventitious or technically unavoidable traces of EU authorised GMOs are found.

varieties of seed and plant propagating material in which adventitious or technically unavoidable traces of EU authorised GMOs are found.

Justification

National restrictive measures should be crop specific as different GMO crops can bring different threats and benefits to different regions. Making those measures publicly available before the growing season should enable farmers to order their seeds without risking economic loss following an unforeseen ban of those seeds. It will therefore increase legal certainty for operators.

Amendment 4

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 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

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 Union 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 GMOs on a case-by-case basis 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 Union 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, the principle of proportionality and Articles 34 and 36 of the Treaty on the Functioning of the European Union, as well as with the
Union, notably in the context of the World Trade Organisation.

Those measures should also ensure that the freedom of choice of farmers and consumers is duly respected. To achieve that goal, appropriate seed thresholds for labelling GMO traces in conventional seeds should be put in place as a matter of priority. The necessity of such measures was also emphasised in the Council Conclusions of 4 December 2008 on GMOs.

Or. en

Justification

The fundamental principle of freedom of choice for farmers and consumers should be respected as this will ensure that measures are proportionate, that all stakeholders' interests are taken into consideration, and that a debate takes place in regions on cultivation of GMOs.

Amendment 5

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 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

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 flexibility to Member States to invoke other grounds than scientific assessment of health and environmental risks to restrict or prohibit the cultivation of GMOs on their territory in order to ease the decision-making process surrounding the issue of GMOs in the Union. This Regulation, on balance, may therefore benefit the internal market. 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
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.

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 per se, 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.

Or. en

Justification

This clarifies the purpose of the proposal, and therefore legitimises the use of Article 114 TFEU as the right legal basis to use.
Amendment 6

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

Text proposed by the Commission  
Amendment

(-1) Directive 2001/18/EC shall be amended as follows:

Article 26a(1) shall be replaced by the following:

"1. Member States shall take appropriate measures to avoid the unintended presence of GMOs in other products."

Or. en

Justification

It should be made mandatory for Member States to take the appropriate measures to manage co-existence in their territory in order to allow the freedom of choice to apply and to avoid cross-border difficulties arising from lack of management of co-existence.

Amendment 7

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

Text proposed by the Commission  
Amendment

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

(1) The following Articles shall be inserted with effect from the date of entry into force of this Regulation:

Or. en
Amendment 8

Proposal for a regulation – amending act
Article 1 - point 1
Directive 2001/18/EC
Article 26b – 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 seed and plant propagating material, in all or part of their territory, provided that:

Amendment

Member States may adopt measures restricting or prohibiting the cultivation of 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, on a case-by-case basis, in all or part of their territory, provided that:

Or. en

Justification

National restrictive measures should be crop specific as different GMO crops can bring different threats and benefits to different regions, and because crops do not all pollinate the same way.

Amendment 9

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

Text proposed by the Commission

(aa) those measures ensure that the freedom of choice of farmers and consumers is duly respected;

Amendment

Or. en
Justification

The fundamental principle of freedom of choice for farmers and consumers should be respected as this will ensure that measures are proportionate, that all stakeholders' interests are taken into consideration, and that a debate takes place in regions on the cultivation of GMOs.

Amendment 10

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

Text proposed by the Commission

(ab) the objective of those measures could not be achieved more proportionately by the introduction of measures under Article 26a to manage the coexistence of genetically modified crops with conventional and organic crops;

Amendment

Or. en

Justification

Member States should be encouraged to make full use of the flexibility under Article 26a of this Directive before they adopt further restrictions under Article 26b, which should be seen as a last resort instrument if no other less restrictive measures can achieve the objective pursued.

Amendment 11

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

Text proposed by the Commission

(ac) those measures are adopted and made publicly available to all operators concerned, including growers, at least three months prior to the start of the
growing season;

Justification

This amendment aims at increasing legal certainty for farmers by making sure that the broad regulatory environment will not change too close to the start of the growing season. This should enable farmers to order their seeds and prepare their fields without risking economic loss following an unforeseen ban of the crops they intended to grow.

Amendment 12

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

Text proposed by the Commission
(b) that they are in conformity with the Treaties.

Amendment
(b) that those measures are in conformity with the Treaties and the Union’s international obligations.

Amendment 13

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

Text proposed by the Commission

Amendment

Art 26ba

Seed thresholds
The Commission shall assess the need for the establishment of thresholds for labelling GMO traces in conventional seeds at the lowest practicable, proportionate and functional levels for all economic operators. It shall report to the European Parliament and to the Council
by 31 December 2011, accompanied, if appropriate, by relevant legislative proposals.’

Or. en

Justification

The European Commission has announced that they would establish such thresholds, as asked by the Council Conclusions of 4th December 2008. The lowest possible technical seed thresholds should be defined urgently in order to protect the economic interests of those who want to remain 'GM-free' and therefore implement the principle of freedom of choice.