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2009 - 2014

Committee on Agriculture and Rural Development

2010/0208(COD)

15.3.2011

OPINION

of the Committee on Agriculture and Rural Development

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

on the 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)0375 – C7-0178/2010 – 2010/0208(COD))

Rapporteur: George Lyon

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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 GMOs¹, 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.

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 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.

Amendment 2

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

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/***territorial*** dimension, ***and as one of particular importance for the self-determination of Member States.*** In accordance with Article 2(2) TFEU

GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.

Member States should therefore be entitled to have a possibility to adopt **binding legislative provisions** concerning the effective cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.

Amendment 3

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 **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.

Amendment 4

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

Amendment

(7) Member States should therefore be authorised to adopt measures restricting or prohibiting the cultivation of particular GMOs, **a group of GMOs defined by the crop variety, or all GMOs** in all or part of their territory, **provided those measures have been subject to prior impact assessment and public consultation, and as long as those measures are adopted and made publicly available to all operators concerned, including growers,**

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.

at least twelve months prior to the start of sowing. This choice left to Member States is directly linked to their sovereignty on territorial management and development, land use and the need to preserve the diversity of ecosystems. 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.

Amendment 5

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

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 particular GMOs, **a group of GMOs defined by the crop variety, or all GMOs** in all or part of their territory on the basis of **duly justified** grounds relating to the public interest other than those already addressed by the harmonised set of **Union** rules which already provide for procedures

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.

to take into account the risks that a GMO for cultivation may pose on health and the environment. ***The distinct notion of 'risk management', as established in Regulation EC No 178/2002 could be used, however, as a basis to justify those measures. Such measures may be justified on the basis of general policy objectives such as:***

- ***The need to preserve specific types of agriculture such as organic or high nature value farming, as well as traditional types of farming,***
- ***Grounds related to the protection of the diversity of agricultural production,***
- ***The protection of GMO-free areas provided that co-existence measures in place are not sufficient to protect,***
- ***The impossibility to implement co-existence due to specific geographical conditions (e.g. small islands, mountains, small national territory),***
- ***Socio-economic grounds such as the protection of specific mountain products, product quality policy or labels,***
- ***Wider environmental policy objectives such as specific habitats, ecosystems, biodiversity, emergence of resistance and landscape features preservation,***
- ***Territorial management or land use planning,***
- ***Other legitimate grounds in the public interest or addressing public concerns, duly justified, proportionate and non-discriminatory,***

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 relevant international obligations of 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.*

Amendment 6

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 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

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 **duly justified grounds in the public interest which are different from those related to the** scientific assessment of health and environmental risks **carried out pursuant to Part C of Directive 2001/18/EC, such as those grounds listed under Recital 8 of this Regulation, in order to restrict or prohibit the** cultivation of GMOs on **all or part of** their territory **in order to ease the decision-making process on GMOs in the Union**. 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 regulations¹ 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 **per se** the conditions of placing on the market of GMOs authorised under the existing legislation, the

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.

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 7

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

Text proposed by the Commission

Amendment

(9a) In line with the Environmental Council Conclusions of 4 December 2008, and in order to ensure respect for the freedom of choice and full implementation of the principle of proportionality, the Commission should re-evaluate the appropriate seed thresholds level for labelling GMO traces in conventional seeds. This should be accompanied by relevant proposals on harmonised sampling and analysis methods for those traces, in particular the setting up of a minimum performance limit for detection methods.

Amendment 8

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."

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 9

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:

Amendment 10

Proposal for a regulation – amending act

Article 1 - point 1

Directive 2001/18/EC

Article 26 b – 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 11

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

(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

Member States may adopt measures restricting or prohibiting the cultivation of particular GMOs, **a group of GMOs defined by the crop variety, or 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

(a) those measures:

(i) are based on **different** grounds **from** those **covered by the harmonised scientific** assessment of health and **environmental risks carried out pursuant to Part C of Directive 2001/18/EC** which might arise from the deliberate release or the placing on the market of GMOs, **while the distinct notion of 'risk management', as established by Regulation EC No 178/2002, could be used as a basis to justify national/regional restrictive measures;**

(ii) **may be justified on the basis of general policy objectives such as:**

- The need to preserve specific types of agriculture such as organic or high

- nature value farming, as well as traditional types of farming,*
- *Grounds related to the protection of the diversity of agricultural production,*
 - *The protection of GMO-free areas provided that co-existence measures in place are not sufficient to protect,*
 - *The impossibility to implement co-existence due to specific geographical conditions (e.g. small islands, mountains, small national territory)*
 - *Socio-economic grounds such as the protection of specific mountain products, product quality policy or labels,*
 - *Wider environmental policy objectives such as specific habitats, ecosystems, biodiversity and landscape features preservation,*
 - *Territorial management or land use planning,*
 - *Other legitimate grounds in the public interest or addressing public concerns, duly justified, proportionate and non-discriminatory.*

Amendment 12

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

Amendment

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

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 13

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 have been the subject of a prior impact assessment showing them to be necessary and proportional;

Justification

In order to confirm the legal validity of measures to restrict or prohibit the cultivation of GMOs adopted by the Member States, a prior impact assessment should be carried out to demonstrate the necessity and proportionality of the proposed measures. In the event of a dispute before the WTO, such impact assessment would make it easier to defend the measure adopted.

Amendment 14

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 15

Proposal for a regulation – amending act

Article 1 - point 1

Directive 2001/18/EC

Article 26 b – paragraph 1 – point a d (new)

Text proposed by the Commission

Amendment

(ad) those measures are adopted and made publicly available to all operators, including growers, at least twelve months prior to the start of sowing;

Amendment 16

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) that they are in conformity with the Treaties.

b) that they are in conformity with the Treaties, in particular with the principle of proportionality, and the Union's international obligations.

Amendment 17

Proposal for a regulation – amending act

Article 1 – point 1

Directive 2001/18/EC

Article 26 b – paragraph 2 a (new)

Text proposed by the Commission

Amendment

The Commission shall assess the need for harmonisation of the sampling and analysis methods for non-authorised GMOs present at a low level in seed, and in particular for the setting of a minimum

performance limit for detection methods.

Justification

The lack of harmonisation leads the Member States to apply different rules, which inevitably introduce distortions of competition, since firms are able to adjust their marketing channels. Since traces of non-authorized GMOs in batches of imported seeds are frequently found in spite of the measures taken by operators, the same procedure should be envisaged as is proposed by the Commission for animal feed.

Amendment 18

Proposal for a regulation

Article 1 – point 1

Directive 2001/18/EC

Article 26b a (new)

Text proposed by the Commission

Amendment

Article 26b a

'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.

PROCEDURE

Title	Amendment of Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory		
References	COM(2010)0375 – C7-0178/2010 – 2010/0208(COD)		
Committee responsible	ENVI		
Opinion by Date announced in plenary	AGRI 7.9.2010		
Rapporteur Date appointed	George Lyon 30.8.2010		
Discussed in committee	26.10.2010	1.12.2010	1.2.2011
Date adopted	15.3.2011		
Result of final vote	+: 30	–: 4	0: 10
Members present for the final vote	John Stuart Agnew, Richard Ashworth, Liam Aylward, José Bové, Luis Manuel Capoulas Santos, Vasilica Viorica Dăncilă, Michel Dantin, Paolo De Castro, Albert Deß, Herbert Dorfmann, Hynek Fajmon, Lorenzo Fontana, Iratxe García Pérez, Béla Glattfelder, Sergio Gutiérrez Prieto, Martin Häusling, Esther Herranz García, Peter Jahr, Elisabeth Köstinger, Stéphane Le Foll, George Lyon, Gabriel Mato Adrover, Mairead McGuinness, Krisztina Morvai, Mariya Nedelcheva, James Nicholson, Rareş-Lucian Niculescu, Wojciech Michał Olejniczak, Georgios Papastamkos, Marit Paulsen, Britta Reimers, Ulrike Rodust, Alfreds Rubiks, Giancarlo Scottà, Czesław Adam Siekierski, Sergio Paolo Francesco Silvestris, Alyn Smith, Marc Tarabella, Janusz Wojciechowski		
Substitute(s) present for the final vote	Luís Paulo Alves, Christa Klaß, Giovanni La Via, Astrid Lulling, Daciana Octavia Sârbu, Christel Schaldemose, Milan Zver		