



European Economic and Social Committee

NAT/480
GMO – restrictions of
cultivation in Member States

Brussels, 9 December 2010

OPINION

of the
European Economic and Social Committee
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) 375 final – 2010/0208 (COD)

Rapporteur: **Gerfried Gruber**

On 2 and 10 September 2010 respectively the European Parliament and the Council decided to consult the European Economic and Social Committee, under Article 114 of the Treaty on the Functioning of the European Union, 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) 375 final – 2010/0208 (COD).

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 17 November 2010.

At its 467th plenary session, held on 8 and 9 December 2010 (meeting of 9 December), the European Economic and Social Committee adopted the following opinion by 169 votes to 12 with 12 abstentions.

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1. **Conclusions**

- 1.1 The EESC acknowledges that the use of genetically modified organisms in European farming raises major concerns for a large section of the European public. The EESC therefore welcomes the European Commission's intention to address this sensitive issue of Member States' freedom to decide on GMO cultivation with a view to reaching a practicable solution and to endeavour to promote a European framework that is compatible with the smooth operation of the internal market. The EESC considers, however, that the draft proposal that has been submitted, mainly based on ethical and moral criteria, creates more vagueness than certainty and could in practice result in a proliferation of (legally unstable) measures being adopted by the States and regions, which could affect the operation of the EU's internal market, the legal security of operators and the credibility of the system as a whole.
- 1.2 However, the Committee thinks that the present proposal needs to be improved and made more specific, especially with regard to legal certainty for those concerned. In the opinion of the Committee, such legal certainty could be achieved by for example introducing a concrete and enforceable legal basis in secondary EU law, with specific grounds, conditions, and procedures applicable to national measures. More generally, the Committee urges for further clarification of the legal basis of the proposal and the compatibility of possible Member States bans on the basis of Article 26b with EU internal market rules and WTO trade law, and other international legal obligations.

- 1.3 The issue of national restrictions on GMO cultivation is highly intertwined with the issues of coexistence and liability for GMO damages and unintended admixture. The Committee believes that these dossiers should therefore be considered together or in parallel legislative proposals, as part of a more comprehensive review of the EU regulatory framework for agricultural biotechnology, also in line with the December 2008 Environment Council Conclusions.
- 1.4 Given the timing of the Commission's current proposal, ahead of the ongoing overall review of the current legal framework, it is impossible to render a definitive opinion on the proposal, since this can only be evaluated comprehensively in relation to the ongoing review of the authorisation system and overall legal framework. This should not, however, unduly delay the improvements of the current proposal.

2. **The proposal for a regulation and its background**

- 2.1 The European Union (EU) has a comprehensive legal framework for the authorisation of Genetically Modified Organisms (GMOs). The rules on GMO cultivation are to be found in Directive 2001/18/EC¹ and Regulation (EC) No 1829/2003². It is possible for Member States to impose restrictions on the cultivation of GMOs that have already been authorised using the safeguard measures under Article 23 of Directive 2001/18/EC, subject to the conditions set out therein, based on additional scientific information suggesting that a given GMO poses a risk to human health or the environment. In addition, they may also take appropriate measures under Article 26a to avoid the unintended presence of GMOs in other products (coexistence).
- 2.2 In March 2009, an application by the European Commission to lift existing national safeguard measures (in Austria and Hungary) due to a lack of scientific justification was rejected in the Council. Similar Council votes have followed the same pattern, leading to a political stalemate, similar to the situation with the authorization system. In June 2009, thirteen Member States³ issued a joint declaration calling on the European Commission to draft proposals that would permit Member States to decide on GMO cultivation.
- 2.3 In a decision of 13 July 2010, the European Commission, following up on the political guidelines of Commission president Barroso, submitted a legislative proposal intended to enable the Member States to make their own minds up about GMO cultivation. The Commission's proposals consist of a communication on the freedom of the Member States to

¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed; OJ L 268, 18.10.2003, p. 1.

³ AT, BG, IE, EL, CY, LV, LT, HU, LU, MT, NL, PL and SI.

decide on the cultivation of genetically modified crops⁴, and a proposal for a regulation to modify the legal framework accordingly⁵.

- 2.4 In technical terms, a regulation is used to add a new Article 26b to Directive 2001/18/EC. This provision allows the Member States to adopt measures to restrict or prohibit on their territory or parts of it the cultivation of GMOs already allowed in the single market, provided the grounds adduced are not related to environmental or human health risks, which are already covered by the authorisation system in place and are in conformity with the Treaties.
- 2.5 The aim of the draft regulation is to give Member States more leeway to decide on GMO cultivation – in conformity with the subsidiarity principle – and to put in place the required legal certainty. The Commission believes that the proposal for a regulation complies with the rules of the single market and with international obligations. It also takes the view that the new rules are not at odds with the current authorisation system, but merely complement it.
- 2.6 On 5 November, the Council's legal services issued a legal opinion on the choice of legal basis, the national measures that could be adopted and the compatibility of the proposed measures with the GATT agreements. The legal service asserts that the legal basis selected is not valid, expresses serious doubts as to the compatibility with the treaties or with the GATT of the measures that Member States might adopt and emphasises that it would be extremely difficult, at the Court of Justice and at the WTO, to defend a measure adopted by a Member State or region on the basis of ethical or moral criteria. Furthermore, these concerns were partly confirmed by the legal service of the European Parliament, which in its opinion of 17 November 2010 raised similar concerns about the conformity of possible justifications for national restrictions, e.g. based on public morality, with EU internal market rules and WTO trade law.

3. **On the current GMO authorisation system**

- 3.1 The aim of the authorisation procedure established at European level is to ensure a high degree 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.
- 3.2 The current rules on the authorisation and use of GMOs rest on a string of key (legal) principles which the EESC thinks should be respected. These include, in particular:
- an independent, science-based authorisation procedure;
 - a high level of protection for health and the environment, in keeping with the precautionary principle;
 - compatibility with the single market and international obligations;

⁴ COM(2010) 380 final.

⁵ COM(2010) 375 final.

- freedom of choice and transparency along the entire food chain;
- legal certainty; and
- subsidiarity and proportionality.

3.3 The Commission's proposals should be seen in the context and timeframe of the implementation of the conclusions of the December 2008 Council. Among other things, these conclusions call for a review – scheduled for completion by the end of 2010 – of the authorisation system in place. The initiatives concerned here are, in particular: a revision of the EFSA guidelines on assessing potential risks for health and the environment⁶, a Commission report on improving environmental monitoring after authorisation, and a study of the socio-economic and environmental impact of GMO cultivation. There is also a review of the legal framework for genetically modified food and feed and for GMO cultivation. A complete overhaul of the entire GMO authorisation system is set to follow by the end of 2012.

3.4 In addition, further light is to be shed on the relationship between national prohibitions or limits on cultivation and coexistence rules, since the two matters are intertwined and, here too, the Commission would like to give the Member States greater leeway. The Commission's observations in its report of 3 April 2009 on the implementation of the coexistence guidelines⁷ are important in this context.

4. **General comments**

4.1 Although the Committee has not yet, of course, expressed a view on the specifics of national prohibitions on cultivation, it has in the past commented on matters that bear upon the present proposal for a regulation and remain valid as input in to the discussion or as proposals.

4.2 In its own-initiative opinion of 16 December 2004⁸, for example, the Committee went into some detail on the coexistence of GMO, conventional and organic cultivation and put forward proposals regarding regulatory levels. One of the points it made there is that some measures to prevent cross-breeding according to particular regional conditions, as well as regional provisions on cultivation or a ban on cultivation, should be regulated at national level. In addition, it also emphasised the need for EU-level minimum norms for coexistence and liability.

4.3 Particular attention must be paid to measures to protect nature conservation and environmentally sensitive areas. There must also be measures to safeguard regional economic and cultural interests, and other social economical impacts.

6 See the launched public consultation on the EFSA-draft of 12 November, which will run until 24 January 2011, website: www.efsa.europa.eu/en/press/news/gmo101112.htm.

7 COM(2009) 153 final.

8 CESE 1656/2004, OJ C 157, 28.6.2005, p. 155.

4.4 The Committee also pointed out in that opinion that the conditions for coexistence depend on regional circumstances and that parallel cultivation of GMOs and non-GMOs, both conventional and organic, appears to be impracticable within regions, particularly those with small-scale agriculture.

4.5 The opinion also addressed the marketing opportunities that could come from using quality marks and guarantees of origin where – in line with consumer expectations – GMOs had not been used. Along the same lines, many regions have proclaimed themselves GMO-free, prompting the Committee to highlight the legal uncertainties that this entails and that need to be cleared up.

5. **Specific comments/unresolved issues**

5.1 **Criteria for a possible prohibition or restriction of cultivation**

5.1.1 Directive 2001/18/EC harmonised the provisions on GMO authorisation, including the adoption of safeguard measures under Article 23 and coexistence under Article 26a. The basis is Article 114 TFEU (previously Article 95 TEU) on harmonising legal provisions to achieve the goals of the single market. The new Article 26b now provides for Member States to be able to ban GM cultivation notwithstanding EU level authorisation.

5.1.2 The question then arises of the extent to which a national ban can be exempted from the area of harmonised law and does not run counter to the general legal principles of the single market. Even more so, according to a recent opinion from the Council's legal service⁹, the legal basis of Art. 114 TFEU appears invalid given the aims, content and scope of the proposal for Art. 26b. The EP's legal service, on the other hand, does not call Art. 114 TFEU into question as legal basis of the proposal, thereby showing that there are diverging legal interpretations at EU level on this issue, which must be clarified and resolved.

5.1.3 The proposal gives neither a comprehensive nor a partial list of grounds that Member States might invoke for imposing a ban. All that is said – in Article 26b – is that the grounds must be different from those examined in the authorisation procedure. It is not possible, therefore, to put forward reasons that were already used in the environmental and health risk assessment under the EU authorisation system or reasons related to these. In the opinion of the EESC, the legal certainty afforded by the proposal could be strengthened by including in Art. 26b itself, an indicative (though non-exhaustive) list of concrete grounds which Member States may invoke to restrict or prohibit GM crop cultivation. Such grounds might include, in addition to ethical, moral and religious arguments, also certain socio-economic concerns. Such clarification in secondary law would serve as a *lex specialis* viz. the grounds listed in Art. 36 TFEU and developed in ECJ case law, and would thereby improve the compatibility with the internal market rules and the Treaties.

⁹ Opinion of the Legal Service of the Council, 5/11/2010, 2010/0208(COD), 15696/10.

5.2 Legal certainty

5.2.1 The Committee takes the view that a mere reference to primary legislation is not enough to provide legal certainty. It draws attention, for example, to ECJ judgment C-165/08 of 16 July 2009¹⁰, which found a national ban on the authorisation of GMO seeds to be incompatible with EU provisions. This ruling illustrates the difficulty for Member States in basing their case on reasons other than health and environmental protection aspects.

5.2.2 However, the EESC recognises that, given the current legal and political situation, the creation of a clear and solid legal basis could afford the Member States greater legal certainty than at present. Nevertheless, this is better accomplished through a concrete and detailed legal basis in secondary law (i.e. Directive 18/2001/EC) than through reference to the meagre and ill-defined room for manoeuvre afforded by the general rules of the single market.

5.3 Scope of EFSA testing/collaboration with the Member States

5.3.1 The science-based authorisation system should be protected by revising, subject to Member State consent, the EFSA guidelines on assessing potential risks to health and the environment to make them binding. In this connection, the EESC would like to see the system of science-based and independent examination in the authorisation procedure further elaborated in line with the precautionary principle.

5.3.2 The EESC wonders whether the Member States should not be drawn more closely into the EFSA scientific risk assessment procedure where special issues are involved. The EFSA was originally set up in Regulation (EC) No 178/2002¹¹ to deliver scientific opinions on food and feed safety, also taking environmental risks into account. Obviously the environmental effects of GMOs are also monitored in the Member States. However, the Member States themselves can also more thoroughly examine the various environmentally related matters within their own sovereign territory, with the EFSA then acknowledging those findings.

5.3.3 Generally speaking, methodological criteria should be established that all scientific work for and by the EFSA must meet. This should extend to peer reviews and could help ensure better coordination between the EFSA and the Member States¹². The EESC is aware that the EFSA applies formally the highest possible, absolutely scientifically independent risk assessment criteria and that it is therefore also a highly respected EU body internationally. There should be closer cooperation on developing research methods between the EFSA and research institutes, universities and independent researchers involved in risk assessment in the Member States.

¹⁰ Ruling of the European Court of Justice C-165/08 (European Commission v Republic of Poland) of 16 July 2009.

¹¹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.

¹² See Hungary's case against the European Commission regarding Amflora (case T-240/10).

5.3.4 Nevertheless, in order to ensure that the scientific assessment of GMOs is a more transparent, better quality process, the EESC proposes that the EFSA be reformed so that all interest groups are represented on the GMO panel (consumers, industry, traders, organic farmers, consumer cooperatives, nutritionists, doctors, etc.) and not just researchers.

5.4 **Internal Market**

5.4.1 The European Commission takes the view that the possibility of imposing national bans does not disrupt the internal market for GMOs as seed, food or animal feed. This assumption is questionable, since trade in authorised GMO seed could be curtailed, at least in areas or Member States in which a ban has been applied, as ECJ rulings in cases of this kind would seem to suggest¹³.

5.4.2 For the time being, it is difficult to say whether a ban could lead to distortions in competition. However, in the absence of (minimum) EU-level coexistence and liability norms, the level playing-field in the non-GMO agriculture sectors will likely be jeopardised. What is clear is that the measures needed to provide for coexistence entail financial and other outlay that must be anticipated whatever path is taken. On the other hand, GMO-free status could offer marketing advantages, with consumer behaviour governing pricing.

5.4.3 To some extent, genetically modified crops require different culture techniques and cultivation measures – such as different crop protection products – from conventional ones. This could give rise to problems of supply, since the internal market in such products is incomplete and inoperative. This is just one example of how varied the conditions are in which farmers have to make their decisions about what and how they produce.

5.5 **Socio-economic consequences**

5.5.1 A report on the socio-economic effects of GMO authorisation is expected from the Commission at the end of 2010. Its findings should be taken on board in assessing the present proposal, since it is probably the fallout on the economy, the social sphere and the environment that will loom largest in justifications of cultivation bans under Article 26b. Until this report has been completed, it is impossible to render a full opinion on the current proposal.

5.5.2 It is also worth noting that in some cases Regulation (EC) No 1829/2003 already permits other factors than those that pose a risk to health and the environment to be taken into account in individual risk-management assessments.

¹³ See e.g. Cases C-110/05, *Commission v. Italy*; C-142/05, *Mickelsson and Roos*; C-188/04, *Alfa Vita*; and C-416/00, *Morellato*.

5.5.3 Since not enough is known about the economic impact and the impact on competition law, the proposal should include a clause providing for assessment, with the Commission carrying out a prior impact assessment of this kind.

5.6 **International obligations**

5.6.1 One important dimension, in the Committee's view, is clarification regarding the fulfilment of international obligations, especially those of the WTO/GATT and the Cartagena Protocol. Since Member States seeking to impose a ban can now be expected to also cite Article 26b, it is particularly important that decisions on this rest on a sound, internationally secure legal basis.

5.6.2 Given how important this is, the EESC would have welcomed more explanation from the Commission regarding conformity with the EU's international obligations. On the same point, the reports of the legal services of the EU institutions on WTO compatibility should also be heeded, in particular the recent opinion from the Council's legal service¹⁴, which has voiced strong doubts about the compatibility with the Treaties or with the GATT of any measures the Member States might adopt in reliance upon the new article 26b, in the form as proposed by the Commission. Also, the legal service of the European Parliament expresses similar doubts about the conformity of possible justifications based on e.g. public morality under EU internal market rules and WTO trade law.

5.7 **Freedom of choice throughout the food chain**

5.7.1 It is equally important to ensure freedom of choice for both producers and retailers and consumers. Producers are entrepreneurs and should be allowed, as a matter of principle, to make their own choices about cultivation methods. Likewise, importers and traders should be able to carry out their lawful professional activities in spite of the proposed new Article 26b.

5.7.2 National restrictions or prohibitions on cultivation should therefore follow the general principles of the Treaties, especially those of subsidiarity and proportionality.

5.7.3 To provide consumers with a choice between GM and non-GM food, there should be not only a properly functioning traceability and labelling system, but also a range of products on offer that appeals to consumers. It is particularly important here to take account of regional availability of products. The EESC wishes to emphasise the need for European consumers to be fully aware that any ban on GMO cultivation in their region or country will not prevent GMOs from being marketed freely within the same borders and that mass imports of GMOs - for animal feed or human consumption from third countries providing dubious traceability - will continue.

¹⁴ Opinion of the Legal Service of the Council, 5/11/2010, 2010/0208(COD), 15696/10.

5.8 **Interaction with coexistence issues**

- 5.8.1 The aim of coexistence is generally to avoid unintended mixing of conventional or organic products with generically modified ones so that, on the one hand, producers and consumers retain freedom of choice and, on the other, economic damage to businesses is averted.
- 5.8.2 The EESC sees the effective implementation and safeguarding of coexistence as an important factor in the whole question of GM use, noting that much still remains unclear and more knowledge – particularly about long-term consequences – has to be gleaned at all levels.
- 5.8.3 While the possibility of a ban on cultivation under the Commission proposal may diminish the problem of unintended mixing or cross-breeding in the areas concerned, this should not distract us from seeking to design rules for a long-term coexistence of the different forms of cultivation. As the Committee recommended in 2004¹⁵, a minimum-harmonisation at EU-level of coexistence and liability norms (or alternatively in Article 26a a legal requirement for Member States to adopt such rules at national or regional level), will be imperative to securing freedom of choice, a level playing field in the agriculture sector, and to control the socio-economic impacts of GMO cultivation. This will be particularly relevant for border-regions.
- 5.8.4 The more that coexistence rules are worked out at national and regional levels, the more important it will be to exchange knowledge and good practice. The work of the European Coexistence Bureau (ECoB) should therefore be focussed on this and stakeholders enlisted accordingly at all levels.
- 5.8.5 However, the question of a limit for GMOs in seed and for GMOs that are not authorised in the EU but are imported into it (primarily animal feed) also still remains unresolved. Either the European Commission has to answer these questions or a start needs to be made quickly on implementing the proposals it has put forward.

5.9 **Cross-border and liability issues**

- 5.9.1 Also still awaiting clarification are liability rules in the event of unintended mixing with GMOs, especially contamination across national borders. At present, neighbouring Member States are under no obligation to inform one another where GMOs are being cultivated. In many cases, such information is only exchanged through personal contacts.
- 5.9.2 One proposal could be for an obligation on Member States at whose borders GMOs are being cultivated to post a notification of this on the internet in the language of the neighbouring country. A measure of this kind could possibly give greater legal validity to claims beyond national borders in the event of unintended mixing with GMOs and resultant economic losses.

¹⁵ CESE1656/2004, O.J. C 157 du 28.6.2005, page 155.

- 5.9.3 Improvement is at hand in the supplementary protocol to the Cartagena Protocol adopted on 12 October 2010 on common rules on liability and redress for damage to biological diversity resulting from transboundary movement. The obligations it provides for should be implemented without undue delay.
- 5.9.4 The EESC also calls for an examination of the extent to which binding EU minimum standards on coexistence and liability (or alternatively in Article 26a a legal requirement for Member States to adopt such rules at national or regional level) could be made compulsory at least for the border regions of Member States, and could reduce private law liability risks, as well as clarify cases of doubt between Member States. The Committee notes the urgency of such liability rules, given that at present the insurance industry continues to decline offering insurance coverage for GMO-related damages, and the present EU environmental liability regime under Directive 2004/35/EC provides insufficient coverage for this type of damage.

Brussels, 9 December 2010.

The president
of the
European Economic and Social Committee

Staffan Nilsson

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N.B.: Appendix 1 overleaf.

APPENDIX I
to the Committee opinion

The following passage was deleted as a result of an amendment accepted at the plenary session, although more than one quarter of the votes was given in favour of maintaining the deleted text:

Point 5.8.5

The solution to low levels of unauthorised GMOs should be technical in nature, by setting a minimum threshold for such occurrences, covering both animal feed and the food.

Result of the vote

For:	83
Against:	79
Abstentions :	29
