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Committee on the Environment, Public Health and Food Safety

2010/0208(COD)

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COMPROMISE AMENDMENTS

1 - 7

Draft recommendation for second reading

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(PE541540v01-00)

on the Council position at first reading with a view to the adoption of a directive 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 genetically modified organisms (GMOs) in their territory

Council position at first reading

(10972/2014 – C8-0145/2014 – 2010/0208(COD))

AM_Com_LegCompr

Amendment 1

EPP, S&D, ALDE, GREENS, GUE, EFDD

Compromise amendment replacing Amendments 8, 78, 79, 80, 81,123

Council position

Recital 7 a + Article 26 a paragraph 1

Council position

Amendment

(7a) To ensure that the cultivation of GMOs does not result in the unintended presence of GMOs in other products, effective co-existence measures are indispensable. Member States should therefore be required, under Directive 2001/18/EC, to adopt rules applicable to their territories to avoid such unintended presence. Particular attention should be paid to the prevention of any possible cross-border contamination from a Member State or a region where cultivation is allowed into a neighbouring Member State or region where it is prohibited (e.g. by implementing appropriate 'buffer zones'). For a coherent implementation of such rules, Member States should refer to the guidelines provided by the Commission in its Recommendation of 13 July 2010^{1a}. In order to guarantee the effective functioning of co-existence measures in border areas of Member States, the Commission should develop guidelines and Member States should cooperate with neighbouring Member States in order to ensure appropriate information sharing.

1a Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (OJ C 200, 22.7.2010, p. 1).

Or. en

Compromise amendment replacing Amendments 21, 160 – 166, 282

<i>Council position</i>	<i>Amendment</i>
1. Member states may take appropriate measures to avoid the unintended presence of GMOs in other products.	(- 1) In Article 26a, paragraph 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. Such measures shall be communicated to the Commission. The Commission shall develop guidelines to guarantee the effective functioning of co-existence measures in border areas of Member States.

Or. en

Amendment 2

EPP, S&D, ALDE, GREENS, GUE, EFDD

Compromise amendment replacing Amendments 2, 36- 40, 44- 46

Council position

GMOs long-term effects and precautionary principle

<i>Council position</i>	<i>Amendment</i>
(2) Under that legal framework, GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market in accordance with Annex II to Directive 2001/18/EC. The aim of that 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	(2) Under that legal framework, GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market in accordance with Annex II to Directive 2001/18/EC taking into account the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects, on human health and the environment. That risk assessment provides scientific advice to inform the decision making process and is followed by a risk management decision that also takes into account other legitimate factors relevant

territory of the Union.

to the matter.

The aim of that 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, the environment *and consumers* should be achieved and maintained throughout the territory of the Union. *The precautionary principle should always be taken into account in the framework of this Directive and its subsequent implementation.*

Or. en

Amendment 3

EPP, S&D, ALDE, GREENS, GUE, EFDD

Compromise amendment replacing Amendments 3, 41, 43, 48, 51

Council position

Risk assessment improvement and future Regulation on environmental risk assessment of GMOs

Council position

Amendment

(2 a) As reflected in the Council Conclusions on GMOs adopted by the Environment Council on 4 December 2008 ("2008 Council conclusions"), the implementation of the risk assessment as laid down in Annex II to Directive 2001/18/EC needs improvement, in particular regarding the long-term environmental effects of genetically modified crops as well as their potential effects on non-target organisms, the characteristics of the receiving environments and the geographical areas in which genetically modified crops may be cultivated, the potential environmental consequences brought about by changes

in the use of herbicides linked to herbicide-tolerant genetically modified crops, direct and indirect long-term effects, as well as scientific uncertainties. Therefore, the Commission should, in particular, ensure that the implementing Regulation on environmental risk assessment of GMOs, taking into account the above considerations, is adopted no later than one year after the entry into force of this Directive.

Or. en

Council position

Article 2

Compromise amendment replacing Amendments 33, 304 - 308

Council position

No later than 4 years after...+, the Commission shall present a report to the European Parliament and to the Council regarding the use made by Member States of this Directive including the effectiveness of the provisions enabling Member States to restrict or prohibit the cultivation of GMOs in all or part of their territory and the smooth functioning of the internal market. That report may be accompanied by any legislative proposals the Commission considers appropriate.

The Commission shall also report on the progress towards giving normative status to the strengthened 2010 Authority guidance on the environmental risk assessment of genetically modified plants.

+ OJ: please insert the date of the entry into force of this Directive.

Amendment

No later than 4 years after...+, the Commission shall present a report to the European Parliament and to the Council regarding the use made by Member States of this Directive including the effectiveness of the provisions enabling Member States to restrict or prohibit the cultivation of GMOs in all or part of their territory and the smooth functioning of the internal market. That report may be accompanied by any legislative proposals the Commission considers appropriate.

OJ: Please insert the date: ***1 year after*** the date of entry into force of this Directive.

Council position

Article 2

Compromise amendment replacing Amendment 309

Council position

Amendment

No later than +, the Commission shall adopt an implementing Regulation on environmental risk assessment of GMOs, building upon the 2010 EFSA guidelines on environmental risk assessment of genetically modified plants and strengthening them along the lines of the 2008 Council conclusions.

Amendment 4

◀EPP, S&D, ALDE, GREENS, GUE, EFDD▶

Compromise amendment replacing Amendments 5, 59, 60, 62, 63

Council position

Cultivation of GMOs and application of the article 2 (2) of the TFEU

Council position

Amendment

(5) Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed at Member State 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 may however require more flexibility in certain instances as it is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems **and** landscapes. **The** common authorisation procedure, in particular the evaluation process, should not be adversely affected by such flexibility.

(5) Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed at Member State 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 may however require more flexibility in certain instances as it is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems, landscapes **and natural plant genotypes**. **Furthermore, the harmonised assessment of risks to health and the environment might not address all possible impacts of GMO cultivation in different regions and**

local ecosystems. In accordance with Article 2(2) of the Treaty on the Functioning of the European Union (TFEU), Member States are entitled to have the possibility to adopt legally binding acts restricting or prohibiting the cultivation of GMOs or of groups of GMOs defined by crop or trait or of all GMOs in their territory after such GMOs have been legally authorised to be placed on the Union market. However, the common authorisation procedure, in particular the evaluation process conducted primarily by the European Food Safety Authority should not be adversely affected by such flexibility.

Or. en

Amendment 5

◀EPP, S&D, ALDE, GREENS, GUE, EFDD▶

Compromise amendment replacing Amendments 9, 83

Council position

Freedom of choice and smooth functioning of the internal market

Council position

Amendment

(7b) The grant of flexibility to Member States should facilitate the decision-making process regarding GMOs, but in no way influence the position of Member States when it comes to decisions on authorisations of GMOs. At the same time, freedom of choice of consumers, farmers and operators should be preserved whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union.

This Directive is therefore compatible with the smooth functioning of the internal market.

Amendment 6

◀EPP, S&D, ALDE, GREENS, GUE, EFDD▶

Compromise amendment replacing Amendments 22, 23, 168-187, 189, 190

Council position**Article 26 b paragraphs 1 and 2 (PHASE I)**

<i>Council position</i>	<i>Amendment</i>
<p>1. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may request, <i>via the Commission, the notifier/applicant</i> to adjust the geographical scope <i>of its notification/application submitted in accordance with Part C of this Directive or Regulation (EC) No 1829/2003</i>, to the effect that all or part of the territory of that Member State is to be excluded from cultivation. <i>This</i> request shall be communicated to the Commission at the latest 30 days from the date of the circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall communicate the request of the Member State to the notifier/applicant and to the other Member States without delay.</p> <p>2. <i>Where the notifier/applicant opposes a request of a Member State</i> in accordance with paragraph 1, <i>the notifier/applicant shall notify the Commission and the Member States within 30 days from the communication by the Commission of that request. In the event of explicit or tacit agreement of the notifier/applicant, the</i></p>	<p>1. During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may <i>demand</i> to adjust the geographical scope of <i>the written consent or authorisation</i> to the effect that all or part of the territory of that Member State is to be excluded from cultivation. <i>The request</i> shall be communicated to the Commission <i>and, if applicable, to the competent authority responsible for issuing the written consent under this Directive</i> at the latest 60 days from the date of the circulation of the assessment report under Article 14(2) of this Directive, or from receiving the opinion of the Authority under Article 6(6) and Article 18(6) of Regulation (EC) No 1829/2003. The Commission shall communicate the request of the Member State to the notifier/applicant, the other Member States <i>and to the public</i> without delay.</p> <p>2. <i>Where a demand is submitted</i> in accordance with paragraph 1, the adjustment of the geographical scope of the <i>written consent/authorisation, as approved by the Commission or, if applicable, the competent authority</i>, shall be implemented <i>as a condition set out</i> in the written consent or authorisation.</p>

adjustment of the geographical scope of the notification/application shall be implemented in the written consent or authorisation.

The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003, shall be issued on the basis of the adjusted geographical scope of the notification/application ***as explicitly or tacitly agreed by the notifier/applicant.***

The written consent issued under this Directive and, where applicable, the decision issued in accordance with Article 19 as well as the decision of authorisation adopted under Articles 7 and 19 of Regulation (EC) No 1829/2003, shall be issued on the basis of the adjusted geographical scope of the notification/application.

Compromise amendment replacing Amendments 10, 85 - 91

Council position

(8) During the authorisation procedure of a given GMO, the possibility should be provided for a Member State to request the Commission to ***present to the notifier/applicant its demand*** to adjust the geographical scope of ***its*** notification/application submitted in accordance with Part C of Directive 2001/18/EC or in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 to the effect that all or part of the territory of that Member State be excluded from cultivation. ***The Commission should facilitate the procedure by presenting the request of the Member State to the notifier/applicant without delay and the notifier/applicant should respond to that request within an established time-limit.***

Amendment

(8) During the authorisation procedure of a given GMO, the possibility should be provided for a Member State to ***demand*** the Commission ***or, if applicable, the competent authority responsible for issuing the written consent under this Directive,*** to adjust the geographical scope of ***a written consent or authorisation delivered*** in accordance with Part C of Directive 2001/18/EC or in accordance with Articles 7 and 19 of Regulation (EC) No 1829/2003 to the effect that all or part of the territory of that Member State be excluded from cultivation. ***Where such demand is submitted, the Commission or, if applicable, the competent authority, should adjust the geographical scope of the written consent/authorisation accordingly.***

Compromise amendment replacing Amendments 92 - 96

Council position

(9) ***The geographical scope of the notification/application should be adjusted accordingly if the***

Amendment

Delete

notifier/applicant explicitly or tacitly agrees with the Member State's request within an established time-limit from the communication by the Commission of that request. If the notifier/applicant opposes the request, the notifier/applicant should notify the Commission and the Member States. However, a refusal by the notifier/applicant to adjust the geographical scope of the notification/application is without prejudice to the Commission's powers in accordance with Article 19 of Directive 2001/18/EC or Articles 7 and 19 of Regulation (EC) No 1829/2003, as the case may be, to make such an adjustment, where appropriate, in the light of the environmental risk assessment carried out by the European Food Safety Authority ('the Authority').

Or. en

Amendment 7

◀EPP, S&D, ALDE, GREENS, GUE, EFDD▶

Council position

Phase II (right for Member States to adopt measures restricting or prohibiting the cultivation of GMOs once authorised)

Compromise amendment replacing Amendments 24, 191 – 243, 245

Council position

3. Where the notifier/applicant opposes the adjustment of the geographical scope of its notification/application corresponding to a request made by a Member State in accordance with paragraph 1 of this Article, that Member State may adopt measures restricting or prohibiting the cultivation of that GMO in all or part of its territory once authorised in

Amendment

3. Without prejudice to paragraph 1, a Member State may, following the risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003 and acting as risk manager, adopt measures restricting or prohibiting the cultivation of a GMO or of groups of GMOs defined by crop or trait or of all GMOs in all or part of its territory once

accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on **compelling** grounds such as those related to:

(a) environmental policy objectives **distinct from the elements assessed** according to this Directive and Regulation (EC) No 1829/2003;

(b) town and country planning;

(c) land use;

(d) socio-economic impacts;

(e) avoidance of GMO presence in other products without prejudice to Article 26a;

(f) agricultural policy objectives;

(g) public policy

Those grounds may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003.

authorised in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on grounds such as those related to:

(a) environmental policy objectives **relating to impacts which might arise from the deliberate release or the placing on the market of GMOs and which are complementary to the impacts concretely examined during the scientific risk assessment conducted** according to this Directive and Regulation (EC) No 1829/2003.

(b) town and country planning;

(c) land use;

(d) socio-economic impacts;

(e) avoidance of GMO presence in other products;

(f) agricultural policy objectives;

(g) public policy.

Those grounds may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003.

Council position

Compromise amendment replacing Amendments 11, 98 - 109

Council position

(10) ***In addition, and only where the notifier/applicant has refused to adjust the***

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Amendment

(10) There should be the possibility for a Member State to ***act as risk manager and***

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geographical scope of the notification/application of a GMO as requested by a Member State, there should be the possibility for *that* Member State to adopt reasoned measures restricting or prohibiting the cultivation of *that* GMO once authorised in all or part of its territory, on the basis of grounds *distinct from those assessed according to the harmonized set of Union rules, that is Directive 2001/18/EC and Regulation (EC) No 1829/2003*, which are in conformity with Union law. Those grounds may be related to environmental or agricultural policy objectives, or other *compelling grounds such as town and country planning, land use, socio-economic impacts, co-existence and public policy*. Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region or area in which those measures will apply.

adopt reasoned measures restricting or prohibiting the cultivation of *a GMO or of groups of GMOs defined by crop or trait or of all GMOs* once authorised in all or part of its territory, on the basis of grounds *relating to the public interest*, which are in conformity with Union law. Those grounds may be related to environmental or agricultural policy objectives, or other *legitimate factors such as socio-economic impacts, where those factors have not been addressed as part of the harmonised procedure provided for in Part C of Directive 2001/18/EC, or to persisting scientific uncertainty*. *Those measures should be duly justified on scientific grounds or on grounds relating to other legitimate factors which might arise from the deliberate release or the placing on the market of GMOs*. Those grounds may be invoked individually or in combination, depending on the particular circumstances of the Member State, region or area in which those measures will apply.

Council position

Compromise amendment replacing Amendments 12, 111 – 113

Council position

(11) The level of protection of human or animal health and of the environment chosen in the Union *allows for a uniform scientific assessment throughout the Union and this Directive should not alter that situation*. Therefore, to avoid any interference with the competences which are granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a Member State should only use grounds related to environmental policy objectives which *do not conflict with* the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures provided in Directive 2001/18/EC and in Regulation (EC) No

Amendment

(11) The level of protection of human or animal health and of the environment chosen in the Union cannot be diverged from by a Member State, and this principle should be maintained. Therefore, to avoid any interference with the competences which are granted to the risk assessors and risk managers under Directive 2001/18/EC and Regulation (EC) No 1829/2003, a Member State should only use grounds related to environmental policy objectives which are complementary to the assessment of risks to health and the environment which are assessed in the context of the authorisation procedures provided in Directive 2001/18/EC and in

1829/2003, *such as the maintenance of certain type of natural and landscape features, certain habitats and ecosystems, as well as specific ecosystem functions and services.*

Regulation (EC) No 1829/2003.

Council position

Compromise amendment replacing Amendments 13, 77, 115, 116

Council position

Amendment

(11a) Member States should be allowed to base the measures that restrict or prohibit the cultivation of GMOs on duly justified grounds relating to environmental impacts. Those grounds may include the prevention of the development of pesticide resistance amongst weeds and pests; the invasiveness or persistence of a genetically modified variety, or the possibility of interbreeding with domestically 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 as well as specific ecosystem functions and services; scientific uncertainties in relation to the grounds mentioned above; or the lack of adequate data concerning the potential negative impacts of the release of GMOs on the local or regional environment of a Member State, including on biodiversity.

Council position

Compromise amendment replacing Amendments 14, 114, 117, 118

Council position

Amendment

(11b) The grounds relating to socio-economic impacts 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.

**Council position
Recital 11 c new**

Council position

Amendment

(11c) The grounds relating to agricultural policy objectives may include the need to protect the diversity of agricultural production, the maintenance and development of agricultural practices which offer a better potential to reconcile production with eco-system sustainability, and the need to ensure seed purity.