COMPROMISE AMENDMENTS
1 - 17

Draft report
Corinne Lepage
(PE456.911v01-00)

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

Proposal for a regulation – amending act
Amendment 1
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard, Oreste Rossi
Compromise amendment replacing Amendments 7, 57, 58, 59, 60, 61, AGRI 8

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

Text proposed by the Commission

Amendment

Directive 2001/18/EC shall be amended as follows:

(-1b) 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 on their territory and in border areas of neighbouring Member States."

Or. en

Amendment 2
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard
Consolidated amendment replacing Amendments 63, 64, 65, 66, AGRI 10

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

Text proposed by the Commission

Amendment

Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of

Member States may adopt, on a case by case basis, measures restricting or prohibiting the cultivation of particular GMOs or of a group of GMOs defined by crop or trait, or of all GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties
seed and plant propagating material, in all or part of their territory, provided that: 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 3
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard, Oreste Rossi
Consolidated amendment replacing Amendments 8, 67-75, 76, 77, 78, 79, 80, 81, 82, 83, 85, AGRI 11, 93

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
(a) those measures are based on i) scientifically justified grounds relating to environmental impacts which might arise from the deliberate release or the placing on the market of GMOs and which are complementary to the environmental impacts examined during the scientific assessment of the impacts on the environment conducted under Part C of this Directive, or grounds relating to risk management; those grounds may include:

- the prevention of the development of pesticide resistance amongst weeds and pests;
- the invasiveness or persistence of a GM-variety, or the possibility of interbreeding with domestic cultivated or wild plants;
- the prevention of negative impacts on the local environment caused by changes
in agricultural practices linked to the cultivation of GMOs;

- the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability,

- the maintenance of local biodiversity including certain habitats and ecosystems, or certain types of natural and landscape features;

- the absence of adequate data or the existence of contradictory data or persisting scientific uncertainty concerning the potential negative impacts of the release of GMOs on the environment of a Member State or region, including on biodiversity;

ii) socio-economic impacts; those grounds may include:

- the impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions such as small islands or mountain zones, or

- the need to protect the diversity of agricultural production

- the need to ensure seed purity,

iii) other grounds that may include land use, town and country planning, or other legitimate factors;

Or. en

Amendment 4
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard, Oreste Rossi
Compromise amendment replacing Amendments 90, 91, 92
Proposal for a regulation - amending act
Article 1 – point 1
Directive 2001/18/EC
Article 26 b paragraph 1 – point a a (new)

Text proposed by the Commission

(aa) in cases where those measures concern crops which are already authorised at Union level, Member States ensure that farmers who cultivated such crops legally have sufficient time to finish the current cultivation season;

Or. en

Amendment 5
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard, Oreste Rossi
Compromise amendment replacing Amendments 105, 106, 107, AGRI 16

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

Text proposed by the Commission

b) those measures are in conformity with the Treaties

Amendment

b) those measures are in conformity with the Treaties in particular the principle of proportionality;

Or. en

Amendment 6
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard
Consolidated amendment replacing Amendments 94, 95, 96, 97, 98, AGRI 15

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

Member States shall make publicly available any such measure to all operators concerned, including growers, at least 3 months ahead of the start of the growing season. In the event that the GMO concerned is authorised less than three months prior to the start of the growing season, Member States shall make those measures publicly available upon their adoption.

Amendment 7
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard
Consolidated amendment replacing Amendments 104

Proposal for a regulation – amending act
Article 1 – point 1
Article 26 b – paragraph 1b (new)

Text proposed by the Commission

Member States shall adopt those measures for a maximum of five years and shall revise them when the GMO authorisation is renewed.

Amendment 8
Corinne Lepage, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard, Oreste Rossi
Consolidated amendment replacing Amendments 1

Proposal for a regulation – amending act
Citation 1
Text proposed by the Commission

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 [...] thereof,

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Justification

See opinion of the JURI committee

Amendment 9

Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard, Oreste Rossi

Compromise amendment replacing Amendments 2, 14, 15, 16, AGRI 1, 18

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. The same high level of protection of health and the environment should be sought and maintained throughout the territory of the Union.

Or. en
Amendment 10
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard, Oreste Rossi
Consolidated amendment replacing Amendments 3, 19, 20, 21

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

*Text proposed by the Commission*

(2a) *The Commission and Member States should ensure, as a priority, the implementation of the Environment Council Conclusions adopted on 4 December 2008, namely a proper implementation of the legal requirements laid down in Annex II of Directive 2001/18/EC for the risk assessment of GMOs. In particular, the long-term environmental effects of GM crops as well as their potential effects on non-target organisms should be rigorously assessed; the characteristics of the receiving environments and the geographical areas in which GM plants may be cultivated should be duly taken into account; the potential environmental consequences brought by changes in the use of herbicides linked to herbicide-tolerant GM crops should be assessed. More specifically, the Commission should ensure that the new guidelines on GMO risk assessment are adopted. These guidelines should not be based primarily on the principle of substantial equivalence or on the concept of a comparative safety assessment, and should make it possible to clearly identify direct and indirect long-term effects, as well as scientific uncertainties. Until the risk assessment provisions are properly implemented, no new GMO variety should be authorised.*

*EFSA and Member States should pursue the formation of an extensive network of scientific organisations representing all disciplines including those related to...*
ecological issues, and cooperate to identify at an early stage any potential divergence between scientific opinions with a view to resolving or clarifying the contentious scientific issues.

The Commission and Member States should ensure that the necessary resources for independent research on the potential risks of GMOs are secured; and that the enforcement of intellectual property rights does not prevent independent researchers from accessing all relevant material.

Amendment 11
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard
Consolidated amendment replacing Amendments 24, 44, 45

Proposal for a regulation - amending act
Recital 4a new

Text proposed by the Commission

(4a) Given the importance of scientific evidence in taking decisions on the prohibition or approval of GMOs, the EFSA and the Member States should collect and publish annually the results of research regarding the risks or evidence of any accidental presence, contamination or danger to the environment or human health of GMOs, on a case by case basis. Due to the high cost of expert consultation, it would be necessary that Member States promote the collaboration of research institutions and national academies.
Justification

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

Amendment 12
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard, Oreste Rossi
Consolidated amendment replacing Amendments 25, 26, 27, AGRI 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 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 EU level to preserve the internal market. Cultivation might require more flexibility in certain instances as it is an issue with a strong local/regional/territorial dimension and an issue of particular importance for the self-determination of Member States. The common authorisation procedure should not be adversely affected by such flexibility. However, the harmonised environmental and health risks assessment might not address all possible impacts of GMO cultivation in different regions and local ecosystems. In accordance with Article 2(2) TFEU Member States should therefore be entitled to have a possibility to adopt binding legislative provisions concerning the cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.

Or. en
Amendment 13
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard, Oreste Rossi
Compromise amendment replacing Amendments 28, 29, 30, 31, 32, 33

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 independently of the measures that Member States are required to take by application of Article 26a of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products on their territory and in border areas of neighbouring Member States.

Or. en

Amendment 14
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard
Consolidated amendment replacing Amendments 4, 34, 35, 36, AGRI 4, 42 (first part)

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

Amendment

(7) Member States should therefore be authorised to adopt, on a case by case basis, measures restricting or prohibiting the cultivation of particular GMOs or groups of GMOs or all GMOs in all or part of their territory, and respectively amend those measures as they deem appropriate, at all stages of the authorisation, re-
concerned GMOs. This should apply as well to genetically modified varieties of seed and plant propagating material which are placed on the market in accordance with relevant legislation on the marketing of seeds and plant propagating material and, in particular, in accordance with Directives 2002/53/EC and 2002/55/EC. Measures should refer to the cultivation of GMOs only and not to the free circulation and import of genetically modified seeds and plant propagating material, as or in products, and of the products of their harvest. Similarly they should not affect the cultivation of non genetically modified varieties of seed and plant propagating material in which adventitious or technically unavoidable traces of EU authorised GMOs are found.

Cultivation is closely linked to land use and the conservation of fauna and flora, areas in which the Member States retain significant powers. The possibility of adopting these measures 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. Those measures should allow all operators concerned, including growers, sufficient time to adapt.

Or. fr

Amendment 15
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard, Oreste Rossi
Consolidated amendment replacing Amendments 5, 37, 38, 39, 40, 41, AGRI 5, 42 (second part)

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

Amendment

(8) According to the legal framework for the authorisation of GMOs, the level of protection of human/animal health and of the environment chosen in the EU cannot be revised by a Member State and this situation must not be altered. However Member States may adopt measures restricting or prohibiting the cultivation of
all or particular GMOs in all or part of their territory on the basis of grounds relating to the public interest other than those already addressed by the harmonised set of EU rules which already provide for procedures to take into account the risks that a GMO for cultivation may pose on health and the environment. Those measures should furthermore be in conformity with the Treaties, in particular as regards the principle of non-discrimination between national and non-national products and Articles 34 and 36 of the Treaty on the Functioning of the European Union, as well as with the relevant international obligations of the Union, notably in the context of the World Trade Organisation.

These national measures should be duly justified on scientific grounds or on grounds related to risk management or other legitimate factors which might arise from the deliberate release or the placing on the market of GMOs. Those measures should furthermore be proportionate, and in conformity with the Treaties, in particular as regards the principle of non-discrimination between national and non-national products and Articles 34 and 36 of the Treaty on the Functioning of the European Union.

Or. en

Amendment 16
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Julie Girling, Kartika Tamara Liotard, Oreste Rossi
Compromise amendment replacing Amendments 43

Proposal for a regulation - amending act
Recital 8 a (new)

Text proposed by the Commission

(8a) Restrictions on or prohibitions of cultivation of particular GMOs by

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Member States should not prevent or restrict the use of authorised GMOs by other Member States, provided effective measures are taken to prevent cross-border contamination.

Amendment 17
Corinne Lepage, Cristina Gutiérrez-Cortines, Justas Vincas Paleckis, Bart Staes, Margrete Auken, Kartika Tamara Liotard, Oreste Rossi
Consolidated amendment replacing Amendments 6, 46, 47, 48, 49, 50, 51, 52, AGRI 6

Proposal for a regulation - amending act
Recital 9

(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 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.

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.