AMENDMENTS
1 - 55

Draft report

(PE560.784v01-00)

The possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory

Proposal for a regulation
Amendment 1
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft legislative resolution
Citation 4 a (new)

Draft legislative resolution Amendment
- having regard to the opening statement of Jean-Claude Juncker, at that time candidate for President of the European Commission, in his speech in the European Parliament Plenary Session, Strasbourg, 15 July 2014¹a;

¹a"I will make sure that the procedural rules governing the various authorisations for GMOs are reviewed. I would not want the Commission to be able to take a decision when a majority of Member States has not encouraged it to do so."

Or. en

Justification

Amendment 2
Guillaume Balas

Draft legislative resolution
Citation 4 a (new)

Draft legislative resolution Amendment
- having regard to the speech by the president-elect of the European
Amendment 3
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group
Eleonora Evi, Piernicola Pedicini, Marco Affronte

Draft legislative resolution
Citation 4 b (new)

Draft legislative resolution
- having regard to the Commission work programme, adopted on 16 December 2014\(^1\);

\(^1\) See Annex I of the Commission work programme 2015 ("New initiatives"), point 23: Review of the GMO decision-making process: "The review will look at how the rules could be changed to better ensure the majority view of Member States is taken into account".

Justification

http://ec.europa.eu/atwork/key-documents/index_en.htm)

Amendment 4
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group
Eleonora Evi, Piernicola Pedicini, Marco Affronte
Draft legislative resolution
Citation 4 c (new)

Draft legislative resolution
Amendment

- having regard to the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests, and the related votes in both regulatory committee (February 2009) and Council (February 2014), where no opinions were delivered;

Or. en

Justification

These "no opinion" votes, regarding a GMO event for cultivation (http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%2016120%202013%20INIT%204)
http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/EN/genaff/140991.pdf) prompted Mr Juncker to suggest that the EU authorisation rules need to be changed. It is obvious that the "democratic deficit" as regards GMO authorisations is not restricted to applications for food and feed use.

Amendment 5
Bart Staes
on behalf of the Verts/ALE Group

Lynn Boylan
on behalf of the GUE/NGL Group

Eleonora Evi, Piernicola Pedicini, Marco Affronte

Draft legislative resolution
Citation 4 d (new)

Draft legislative resolution
Amendment

- having regard to the January 2014 European Parliament's resolution on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive
2001/18/EC, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests, by which the European Parliament opposes the adoption of the proposal;

Or. en

Justification


Amendment 6
Sirpa Pietikäinen

Draft legislative resolution
Paragraph 2

<table>
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<td>2. Calls on the Commission to withdraw its proposal;</td>
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Or. en

Amendment 7
Bart Staes
on behalf of the Verts/ALE Group
Lynn Boylan
on behalf of the GUE/NGL Group
Eleonora Evi, Piernicola Pedicini, Marco Affronte

Draft legislative resolution
Paragraph 2

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Jean-Claude Juncker, candidate for President of the European Commission, in his speech in the European Parliament Plenary Session, Strasbourg, 15 July 2014, promised to change the rules for authorising GMOs ("I will make sure that the procedural rules governing the various authorisations for GMOs are reviewed. I would not want the Commission to be able to take a decision when a majority of Member States has not encouraged it to do so."
http://ec.europa.eu/priorities/docs/pg_en.pdf). Keeping the rules on EU level, as suggested in the Commission proposal, is not a solution.

Amendment 8
Guillaume Balas

Draft legislative resolution
Paragraph 2

2. Calls on the Commission to withdraw its proposal; 2. Calls on the Commission to withdraw its proposal and submit a new one, fully taking into account the opposition expressed by the majority of EU Member States to GMO authorisations;

Amendment 9
Marijana Petir, Norbert Erdős, Ivana Maletić, Romana Tomc, Andrej Plenković, Alojz Peterle, Patricija Šulin, Milan Zver

Draft legislative resolution
Paragraph 2 a (new)

2a. Calls on the Commission, within six months after the adoption of the decision of the European Parliament on this
proposal, to submit a legislative proposal which would allow Member States to independently restrict or prohibit the use of genetically modified food and feed on their territory;

Or. en

Amendment 10
Bart Staes
on behalf of the Verts/ALE Group

Lynn Boylan
on behalf of the GUE/NGL Group

Eleonora Evi, Piernicola Pedicini, Marco Affronte

Draft legislative resolution
Paragraph 2 a (new)

Draft legislative resolution

Amendment

2a. Calls on the Commission to ensure that its new proposal provides for the European Parliament’s voice being adequately taken into account when it comes to decisions about GMO authorisations;

Or. en

Amendment 11
Bart Staes
on behalf of the Verts/ALE Group

Lynn Boylan
on behalf of the GUE/NGL Group

Eleonora Evi, Piernicola Pedicini, Marco Affronte

Draft legislative resolution
Paragraph 2 b (new)

Draft legislative resolution

Amendment

2b. Calls on the Commission not to propose to authorise any new GMO variety and not to renew old ones until the new proposal is agreed upon;
Amendment 12
Bart Staes
on behalf of the Verts/ALE Group

Draft legislative resolution
Paragraph 2 c (new)

Draft legislative resolution
Amendment

2c. Calls on the Commission to take a long-term view in reviewing its policy on proteins, and to introduce adequate measures and instruments that support farmers in improving crop rotation systems and locally-grown fodder so as to substantially reduce the current dependence on feed imports;

Or. en

Amendment 13
Bart Staes
on behalf of the Verts/ALE Group

Draft legislative resolution
Paragraph 2 d (new)

Draft legislative resolution
Amendment

2d. Calls on the Commission to provide a balanced basis for democratic decision-making, in particular by improving risk assessment, as GMOs still pose many risks and uncertainties, and by ensuring the necessary resources for independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs;

Or. en
Amendment 14
Bart Staes
on behalf of the Verts/ALE Group

Draft legislative resolution
Paragraph 2 e (new)

Draft legislative resolution Amendment

2e. Calls on the Commission to increase transparency and choice for consumers by ensuring that products stemming from animals that were fed with GM feed are adequately labelled;

Or. en

Amendment 15
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Citation 1

Text proposed by the Commission Amendment

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

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 291(3) thereof,

Or. en

Justification

In order to improve the authorisation procedure for GMOs, there is a need to change Regulation 182/2011 which is based on Article 291(3).

Amendment 16
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Citation 1
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Or. it

Amendment 17
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) Both Directive 2001/18/EC and Regulation (EC) No 1829/2003 establish a centralised procedure at Union level whereby the Commission is empowered to adopt implementing decisions granting or refusing application for the authorisation of GMOs and GM food and feed, based on an assessment of the potential risks that they could pose to human or animal health, or the environment. Regulation (EC) No 1829/2003 also provides that other legitimate factors may be taken into account, where appropriate.

Amendment

(2) Both Directive 2001/18/EC and Regulation (EC) No 1829/2003 establish a centralised procedure at Union level whereby the Commission is empowered to adopt implementing decisions granting or refusing application for the authorisation of GMOs and GM food and feed, based on an assessment of the potential risks that they could pose to human or animal health, or the environment. Both Regulation (EC) No 1829/2003 and Regulation (EC) No 178/2002 of the European Parliament and of the Council require the Commission to take other legitimate factors into account, when submitting a draft decision.


Or. en
Justification

Amendment adds reference to the General food law, where the "other legitimate factors" are also referred to.

Amendment 18
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 4

Text proposed by the Commission

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and this is reflected in the decision-making process leading to the authorisation of GMOs and GM food and feed. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Therefore, authorisations have been adopted by the Commission at the end of the procedure, in accordance with applicable legislation, without the support of the Member States' committee opinion.

Amendment

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Authorisations have been adopted by the Commission, in accordance with applicable legislation, without the support of the Member States' committee opinion.

Or. it

Amendment 19
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 4

Text proposed by the Commission

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and

Amendment

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and
this is reflected in the decision-making process leading to the authorisation of GMOs and GM food and feed. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Therefore, authorisations have been adopted by the Commission at the end of the procedure, in accordance with applicable legislation, without the support of the Member States’ committee opinion.

However, as the area is very sensitive for European citizens, the Commission needs a clear indication on how to act in such cases. Regulation (EU) No 182/2011 therefore needs to be changed accordingly.

Or. en

Justification

As promised by the President of the Commission, the rules for authorising GMOs must be changed. Keeping the rules on EU level as they are is not a solution.

Amendment 20
Lynn Boylan

Proposal for a regulation
Recital 4

Text proposed by the Commission

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and this is reflected in the decision-making process leading to the authorisation of GMOs and GM food and feed. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Therefore, authorisations have been adopted by the Commission at

Amendment

(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and this is reflected in the decision-making process leading to the authorisation of GMOs and GM food and feed. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Therefore, authorisations have been adopted by the Commission at
the end of the procedure, in accordance with applicable legislation, without the support of the Member States' committee opinion.

This has led to a democratic deficit which the then-candidate for President, Jean-Claude Juncker, committed himself to solve, pledging to democratise the authorisation procedure.

**Justification**

President Juncker in his speech in the EP in Strasbourg on 15 July 2014 said: "I will make sure that the procedural rules governing the various authorisations for GMOs are reviewed. I would not want the Commission to be able to take a decision when a majority of Member States has not encouraged it to do so”.

**Amendment 21**

Bart Staes

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 5**

**Text proposed by the Commission**

(5) Once a GMO or a GM food and feed is authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the Member States may not prohibit, restrict or impede the free circulation of that product within their territory, except in accordance with strict conditions which are laid down by Union law —and require to provide evidence of a severe risk to health or to the environment. Some Member States have had recourse to the safeguard clauses and the emergency measures provided for respectively in Articles 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003. Other Member States have made use of the notification procedure provided for in Article 114(5) and (6) of TFUE which also is required to

**Amendment**

deleted
be based on new scientific evidence relating to the protection of the environment or the working environment. Other Member States have adopted unilateral prohibitions. Some of these measures have been challenged before national jurisdictions or the Court of justice.

Or. en

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 22
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) Once a GMO or a GM food and feed is authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the Member States may not prohibit, restrict or impede the free circulation of that product within their territory, except in accordance with strict conditions which are laid down by Union law—and require to provide evidence of a severe risk to health or to the environment. Some Member States have had recourse to the safeguard clauses and the emergency measures provided for respectively in Articles 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003. Other Member States have made use of the notification procedure provided for in Article 114(5) and (6) of TFUE which also is required to be based on new scientific evidence relating to the protection of the environment or the working environment.

Amendment

(5) The authorisation at EU level, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003 of a GMO or a GM food and feed should be without prejudice to Member States' right to prohibit, restrict or impede the placing on the market of one or more foods or feeds containing GMOs on their territory without impeding their free circulation.
Other Member States have adopted unilateral prohibitions. Some of these measures have been challenged before national jurisdictions or the Court of justice.

Amendment 23
Lynn Boylan

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) Once a GMO or a GM food and feed is authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the Member States may not prohibit, restrict or impede the free circulation of that product within their territory, except in accordance with strict conditions which are laid down by Union law – and require to provide evidence of a severe risk to health or to the environment. Some Member States have had recourse to the safeguard clauses and the emergency measures provided for respectively in Articles 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003. Other Member States have made use of the notification procedure provided for in Article 114(5) and (6) of TFUE which also is required to be based on new scientific evidence relating to the protection of the environment or the working environment. Other Member States have adopted unilateral prohibitions. Some of these measures have been challenged before national jurisdictions or the Court of justice.

Amendment

(5) Once a GMO or a GM food and feed is authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the Member States may not prohibit, restrict or impede the free circulation of that product within their territory, except for its placing on the market and in accordance with strict conditions which are laid down by Union law – and require to provide evidence of a severe risk to health or to the environment. Some Member States have had recourse to the safeguard clauses and the emergency measures provided for respectively in Articles 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003. Other Member States have made use of the notification procedure provided for in Article 114(5) and (6) of TFUE which also is required to be based on new scientific evidence relating to the protection of the environment or the working environment. Other Member States have adopted unilateral prohibitions. Some of these measures have been challenged before national jurisdictions or the Court of justice.
Amendment 24
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) That situation was changed recently as regards GMOs for cultivation due to the adoption, on 13 March 2015, of Directive (EU) 2015/412\(^\text{14}\) which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory, without affecting the risk assessment provided in the system of Union authorisations of GMOs. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It was also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.


Amendment

deleted

Or. en

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation
procedure on EU level, as suggested by the President of the Commission.

Amendment 25
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) That situation was changed recently as regards GMOs for cultivation due to the adoption, on 13 March 2015, of Directive (EU) 2015/412\(^\text{14}\) which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory, without affecting the risk assessment provided in the system of Union authorisations of GMOs. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It was also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.

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Amendment

(6) As regards GMOs for cultivation, Directive (EU) 2015/412\(^\text{14}\) which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory was adopted on 13 March 2015. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory, without affecting the risk assessment provided in the system of Union authorisations of GMOs. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003.

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Or. it
Text proposed by the Commission

(6) That situation was changed recently as regards GMOs for cultivation due to the adoption, on 13 March 2015, of Directive (EU) 2015/412\(^\text{14}\) which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory, without affecting the risk assessment provided in the system of Union authorisations of GMOs. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It was also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.

Amendment

(6) That situation was changed recently as regards GMOs for cultivation due to the adoption, on 13 March 2015, of Directive (EU) 2015/412\(^\text{14}\) which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It was also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.


Justification

The risk assessment for GMOs at EU level needs to be improved. EFSA must undertake reforms to ensure that the authorisation procedure for GMOs provides the highest level of
protection for the health of citizens and the environment and includes therefore the assessment of long-term effects of GMOs, effects on non-target organisms, negative impacts on biodiversity and inclusion of diverging scientific opinions, as outlined in the Council Conclusions on GMOs in December 2008.

Amendment 27
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) The reasons for the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412 as regards GMOs for cultivation are also relevant for other GMOs and GM food and feed covered by Regulation (EC) No 1829/2003. Indeed, the results of the vote on the implementing decision for the authorisation of products covered by Regulation (EC) No 1829/2003 which are not intended for cultivation in the relevant committee, or in the Council, is always “no opinion” (no qualified majority either in favour of or against the authorisation) and there are also Member States in which the use of these products is prohibited. Taking those matters into account, it is appropriate to amend Regulation (EC) No 1829/2003 in order to provide the possibility for the Member States to restrict or prohibit the use of GMOs and GM food and feed in all or part of their territory, on the basis of compelling grounds compatible with Union law - not related to risks to human and animal health and to the environment, as those are already assessed at Union level, pursuant to Regulation (EC) No 1829/2003. This possibility should not apply to GMOs for cultivation which are already covered by the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412.

Amendment

deleted
Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 28
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) The reasons for the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412 as regards GMOs for cultivation are also relevant for other GMOs and GM food and feed covered by Regulation (EC) No 1829/2003. Indeed, the results of the vote on the implementing decision for the authorisation of products covered by Regulation (EC) No 1829/2003 which are not intended for cultivation in the relevant committee, or in the Council, is always “no opinion” (no qualified majority either in favour of or against the authorisation) and there are also Member States in which the use of these products is prohibited. Taking those matters into account, it is appropriate to amend Regulation (EC) No 1829/2003 in order to provide the possibility for the Member States to restrict or prohibit the use of GMOs and GM food and feed in all or part of their territory, on the basis of compelling grounds compatible with Union law - not related to risks to human and animal health and to the environment, as those are already assessed at Union level, pursuant to Regulation (EC) No 1829/2003. This possibility should not apply to GMOs for cultivation which are already covered by the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412.

Amendment

(7) The reasons for the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412 as regards GMOs for cultivation are also relevant for other GMOs and GM food and feed covered by Regulation (EC) No 1829/2003. Indeed, the results of the vote on the implementing decision for the authorisation of products covered by Regulation (EC) No 1829/2003 which are not intended for cultivation in the relevant committee, or in the Council, is always “no opinion” (no qualified majority either in favour of or against the authorisation) and there are also Member States in which the use of these products is prohibited. Taking those matters into account, it is appropriate to amend Regulation (EC) No 1829/2003 in order to provide the possibility for the Member States to restrict or prohibit the use of GMOs and GM food and feed in all or part of their territory, in particular GMOs in respect of which the risk assessment has not provided conclusive evidence of there being no environmental and health risks. This possibility should not apply to GMOs for cultivation which are already covered by the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412.

Amendment 29
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 30
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.
prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

Amendment 31
Tibor Szanyi
Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

Amendment

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised.

Or. en

Amendment 32
Lynn Boylan
Proposal for a regulation
Recital 8
Text proposed by the Commission

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the use in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

Amendment

(8) Member States should therefore be allowed to adopt measures restricting or prohibiting the placing on the market in all or part of their territory of a GMO or a GM food and feed, or group of GMOs or of GM food and feed, once authorised, provided that such measures are reasoned, based on compelling grounds in accordance with Union law, and are in line with the principles of proportionality and non-discrimination between national and non-national products, and Article 34, Article 36 and Article 216(2) of TFEU.

Or. en

Justification

The term 'place on the market' is the mostly commonly used term and from a legal point of view more appropriate, as in article 2 par.14 of the Reg 1829/2003, there is already the definition of the term. Additionally, apart from legal uncertainty, it would create implementation and compliance problems, as we might have the situation where a MS bans the use, but nothing is foreseen for the placing on the market. For legal and practical reason, the appropriate term should be 'place on the market'.

Amendment 33
Bart Staes on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) The restrictions or prohibitions adopted pursuant to this Regulation should refer to the use and not to the free circulation and imports of genetically modified food and feed.

Amendment

deleted

Or. en
Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 34
Tibor Szanyi

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) The restrictions or prohibitions adopted pursuant to this Regulation should refer to the use and not to the free circulation and imports of genetically modified food and feed.

Amendment

deleted

Or. en

Amendment 35
Lynn Boylan

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) The restrictions or prohibitions adopted pursuant to this Regulation should refer to the use and not to the free circulation and imports of genetically modified food and feed.

Amendment

(9) The restrictions or prohibitions adopted pursuant to this Regulation should refer to the placing on the market and not to the free circulation and imports of genetically modified food and feed.

Or. en

Justification

The term 'place on the market' is the mostly commonly used term and from a legal point of view more appropriate, as in article 2 par.14 of the Reg 1829/2003, there is already the definition of the term. Additionally, apart from legal uncertainty, it would create implementation and compliance problems, as we might have the situation where a MS bans the use, but nothing is foreseen for the placing on the market. For legal and practical reason, the appropriate term should be 'place on the market'.
Amendment 36
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 10

Text proposed by the Commission

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.

Amendment

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 37
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 10

Text proposed by the Commission

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.

Amendment

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.
animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.

However, in the absence of conclusive scientific evidence that no environmental and health risks are associated with the use of GMOs, Member States should be responsible for taking national risk management measures.

Or. it

Amendment 38
Lynn Boylan
Proposal for a regulation
Recital 10

Text proposed by the Commission

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union and this Regulation should not alter that situation. Therefore to avoid any interference with the competences which are granted to the risk assessors and risk managers under Regulation (EC) No 1829/2003, Member States should not be authorised to use grounds which are related to risks to health and to the environment which should be dealt with in accordance with the procedure already established in Regulation (EC) No 1829/2003, and in particular its Articles 10, 22 and 34.

Amendment

(10) The level of protection of human and animal health and of the environment achieved through the authorisation procedure provided for by Regulation (EC) No 1829/2003 requires a uniform scientific assessment throughout the Union which, in line with the Council Conclusions on GMOs adopted by the Environment Council on 4 December 2008 must be reformed to improve the quality of the procedure. Until then Member States should be permitted to use grounds which are related to risks to health and to the environment, especially when they are acting based on the concerns of civil society in their country.
Justification

The risk assessment for GMOs at EU level needs to be improved. EFSA must undertake reforms to ensure that the authorisation procedure for GMOs provides the highest level of protection for the health of citizens and the environment and includes therefore the assessment of long-term effects of GMOs, effects on non-target organisms, negative impacts on biodiversity and inclusion of diverging scientific opinions, as outlined in the Council Conclusions on GMOs in December 2008.

Amendment 39
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 11

Text proposed by the Commission  
Amendment

(11) Member States's measures adopted pursuant to this Regulation should be subject to a procedure of scrutiny and information at Union level with a view to the functioning of the internal market. In light of the level of scrutiny and information provided in this Regulation, it is not necessary to provide, in addition, for the application of Directive 98/34/EC of the European Parliament and of the Council. The amendments being made to Regulation (EC) No 1829/2003 by this Regulation provide that Member States may restrict or prohibit the use of GMOs or GM food and feed in all or part of their territory for the whole duration of the authorisation, provided that an established standstill period, during which the Commission and the other Member States are given the opportunity to comment on the proposed measures, has elapsed. The Member State concerned should therefore communicate a draft of those measures to the Commission at least 3 months prior to their adoption, in order to give the opportunity to the Commission and the other Member States to comment,
and should refrain from adopting and implementing those measures during that period. On the expiry of the established “standstill” period, the Member State should be able to adopt the measures as originally proposed or amended to take into account the Commission’s or the Member States' comments. Member States should be allowed to notify to the Commission measures pursuant to this Regulation before that the product concerned by the measures is authorised so that the restriction or the prohibition starts its effects as from the date of entry into force of the Union authorisation.


Or. en

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 40
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Recital 11

Text proposed by the Commission
(11) Member States’s measures adopted pursuant to this Regulation should be subject to a procedure of scrutiny and information at Union level with a view to the functioning of the internal market. In light of the level of scrutiny and

Amendment
(11) Member State measures adopted pursuant to this Regulation should be subject to a procedure of scrutiny and information at Union level with a view to the functioning of the internal market. In light of the level of scrutiny and
information provided in this Regulation, it is not necessary to provide, in addition, for the application of Directive 98/34/EC of the European Parliament and of the Council. The amendments being made to Regulation (EC) No 1829/2003 by this Regulation provide that Member States may restrict or prohibit the use of GMOs or GM food and feed in all or part of their territory for the whole duration of the authorisation, provided that an established standstill period, during which the Commission and the other Member States are given the opportunity to comment on the proposed measures, has elapsed. The Member State concerned should therefore communicate a draft of those measures to the Commission at least 3 months prior to their adoption, in order to give the opportunity to the Commission and the other Member States to comment, and should refrain from adopting and implementing those measures during that period. On the expiry of the established “standstill” period, the Member State should be able to adopt the measures as originally proposed or amended to take into account the Commission’s or the Member States’ comments. Member States should be allowed to notify to the Commission measures pursuant to this Regulation before that the product concerned by the measures is authorised so that the restriction or the prohibition starts its effects as from the date of entry into force of the Union authorisation.


information provided in this Regulation, it is not necessary to provide, in addition, for the application of Directive 98/34/EC of the European Parliament and of the Council. The amendments being made to Regulation (EC) No 1829/2003 by this Regulation provide that Member States may restrict or prohibit the use of GMOs or GM food and feed in all or part of their territory for the whole duration of the authorisation, provided that an established standstill period, during which the Commission and the other Member States are given the opportunity to submit non-binding comments on the proposed measures, has elapsed. The Member State concerned should therefore communicate a draft of those measures to the Commission at least 3 months prior to their adoption, in order to give the opportunity to the Commission and the other Member States to submit non-binding comments, and should refrain from adopting and implementing those measures during that period. On the expiry of the established “standstill” period, the Member State should be able to adopt the measures as originally proposed or amended to take into account the Commission’s or the Member States’ comments. Member States should be allowed to notify to the Commission measures pursuant to this Regulation before that the product concerned by the measures is authorised so that the restriction or the prohibition starts its effects as from the date of entry into force of the Union authorisation.


Or. it
Amendment 41
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In the case where a product was lawfully used before a Member State adopts measures pursuant to this Regulation, sufficient time should be given to operators to allow the phasing out of the product from the market.

Amendment

deleted

(12) In the case where a product was lawfully used before a Member State adopts measures pursuant to this Regulation, sufficient time should be given to operators to allow the phasing out of the product from the market.

Or. en

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 42
Lynn Boylan

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In the case where a product was lawfully used before a Member State adopts measures pursuant to this Regulation, sufficient time should be given to operators to allow the phasing out of the product from the market.

Amendment

(12) In the case where a product was lawfully placed on the market before a Member State adopts measures pursuant to this Regulation, sufficient time should be given to operators to allow the phasing out of the product from the market.

Or. en

Justification

The term 'place on the market' is the mostly commonly used term and from a legal point of view more appropriate, as in article 2 par.14 of the Reg 1829/2003, there is already the
definition of the term. Additionally, apart from legal uncertainty, it would create implementation and compliance problems, as we might have the situation where a MS bans the use, but nothing is foreseen for the placing on the market. For legal and practical reason, the appropriate term should be 'place on the market'.

Amendment 43
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) Measures adopted pursuant to this Regulation, which restrict or prohibit the use of GMOs or GM food and feed should not affect the use in other Member States of these products as well as of products derived from their consumption. In addition, this Regulation and the national measures adopted pursuant to it should be without prejudice to Union law requirements concerning unintended and adventitious presence of GM material in other products and should not affect the placing on the market and use of products complying with these requirements.

Amendment

Or. en

Justification

Deleting this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 44
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 14
Text proposed by the Commission  

(14) Regulation (EC) No 1829/2003 should be amended accordingly,

Amendment

(14) Regulation (EU) No 182/2011 should be amended accordingly,

Or. en

Justification

Changing this recital is necessary in the context of the amendments changing the authorisation procedure on EU level, as suggested by the President of the Commission.

Amendment 45
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a

Text proposed by the Commission  

[...] deleted

Amendment

Or. en

Justification

Linked to amendment 46. As promised by the President of the Commission, the rules for authorising GMOs must be changed. It has been acknowledged by the Commission that the authorisation of GMOs is a special case, as "no opinion" is the standard outcome of votes in the committees. It is therefore necessary to change Regulation 182/2011, in order to provide for a clear indication to the Commission in those cases. Keeping the rules on EU level as they are is not a solution.

Amendment 46
Bart Staes
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 a (new)
Text proposed by the Commission

Amendment

Article 1a

Regulation (EU) No 182/2011 is hereby amended as follows:

(1) The following recital 11a (new) is inserted:

(11a) (new) The area of GMO authorizations, be it via Directive 2001/18/EC or via Regulation (EC) No 1829/2003, is the only field where regularly neither the responsible committee, nor the Council comes to an opinion (no qualified majority either in favour or against the authorisation). As the area is very sensitive for European citizens, the Commission needs a clear indication on how to act in such cases.

(2) Recital 14 is changed as follows:

(14) When considering the adoption of other draft implementing acts concerning particularly sensitive sectors, notably taxation, consumer health, food safety and protection of the environment, the Commission, in order to find a balanced solution, will, as far as possible, act in such a way as to avoid going against any predominant position which might emerge within the appeal committee against the appropriateness of an implementing act. With regard to the sensitive field of GMO authorisations, no draft implementing act authorising a GMO should be adopted if a simple majority of the component members of the committee opposes it.

(3) In Article 6, the following paragraph 3a (new) is inserted:

(3a) (new) 'Where no opinion is delivered in accordance with the second subparagraph of paragraph 3, and where the draft implementing act concerns an application for authorisation of a GMO, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the
Commission shall not adopt the draft implementing act.'

(4) In Article 11, the following second subparagraph is inserted:

'Where the draft implementing act concerns an application for authorisation of a GMO, in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, and where the European Parliament has spoken out against the authorisation, e.g. by means of a resolution, the Commission shall not adopt the draft implementing act.'

Or. en

Justification

Linked to amendment 45. As promised by the President of the Commission, the rules for authorising GMOs must be changed. It has been acknowledged by the Commission that the authorisation of GMOs is a special case, as "no opinion" is the standard outcome of votes in the committees. It is therefore necessary to change Regulation 182/2011, in order to provide for a clear indication to the Commission in those cases. Keeping the rules on EU level as they are is not a solution.

Amendment 47
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Art.34a – paragraph 1

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>1. Member States may adopt measures restricting or prohibiting the use of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation provided that such measures are:</td>
<td>deleted</td>
</tr>
<tr>
<td>a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this</td>
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Regulation;
b) proportional and non-discriminatory.

Amendment 48
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 1 – introductory part

Text proposed by the Commission
1. Member States may adopt measures restricting or prohibiting the use of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation provided that such measures are:

Amendment
1. Member States may, in their capacity as risk managers, adopt measures restricting or prohibiting the use of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation where the findings of the risk assessment have not conclusively ruled out the possibility of any environmental and health risks being associated with those products. Those measures shall be based on grounds compatible with Union law and shall be proportionate and non-discriminatory.

Amendment 49
Lynn Boylan

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2002
Article 34a – paragraph 1 – introductory part

Text proposed by the Commission
1. Member States may adopt measures restricting or prohibiting the use of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation provided that such measures

Amendment
1. Member States may adopt measures restricting or prohibiting the placing on the market of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation provided that such measures
The term 'place on the market' is the mostly commonly used term and from a legal point of view more appropriate, as in article 2 par.14 of the Regulation 1829/2003, there is already the definition of the term. Additionally, apart from legal uncertainty, it would create implementation and compliance problems, as we might have the situation where a MS bans the use, but nothing is foreseen for the placing on the market. For legal and practical reason, the appropriate term should be 'place on the market'.

Amendment 50
Eleonora Evi, Marco Affronte, Piernicola Pedicini

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 1 – point a

Text proposed by the Commission

a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation;

Amendment

deleted

Or. it

Amendment 51
Rikke Karlsson, Jørn Dohrmann

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 1 – point a

Text proposed by the Commission

a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the

Amendment

a) reasoned and based on requirements for product integrity, nutrition, health-protection and safety sovereignly

Or. en
risk assessment carried out pursuant this Regulation;

evaluated by the Member State according to the risk assessment set up by its competent authorities;

Or. en

Amendment 52
Aldo Patriciello

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 1 – point a

Text proposed by the Commission

a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation;

Amendment

a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation, so as to avoid any interference with the competences assigned to risk managers;

Or. it

Amendment 53
Eleonora Evi

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 1 – point b

Text proposed by the Commission

b) proportional and non-discriminatory.

Amendment

deleted

Or. it

Amendment 54
Aldo Patriciello
Proposal for a regulation
Article 1 – paragraph 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 1 – point b a new

Text proposed by the Commission

(ba) not at odds with the principle of free movement of goods established in the Treaty on the Functioning of the European Union, provided that compliance with the specific labelling rules for GMO food and feed laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 is ensured.

Or. it

Amendment 55
Rikke Karlsson, Jørn Dohrmann

Proposal for a regulation
Article 1
Regulation (EC) No 1829/2003
Article 34a – paragraph 5 a new

Text proposed by the Commission

5a. This regulation does not prevent the Member States from sovereignly deciding to retain or introduce, on their territory, restrictions and prohibitions of private and public GMO testing if necessary to ensure compliance with requirements for public health and safety, biodiversity and existing organic farming productions.

Or. en