# Procedure file

## Basic information

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| COD - Ordinary legislative procedure (ex-codecision procedure)<br>Regulation | 2010/0208(COD) |
| Genetically modified organisms (GMOs): possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory<br><br>Amending Directive 2001/18/EC 1998/0072(COD)<br><br>Subject<br>3.10.06 Crop products in general, floriculture<br>3.10.09.06 Agro-genetics, GMOs<br>3.10.10 Foodstuffs, foodstuffs legislation<br>4.60.04.04 Food safety | Procedure completed |

## Key players

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|---|---|---|---|
| European Parliament | Committee responsible | Rapporteur | Appointed |
| | ENVI Environment, Public Health and Food Safety | | 17/07/2014 |
| | | ALDE RIES Frédérique | |
| | | Shadow rapporteur | |
| | | PPE KÖSTINGER Elisabeth | |
| | | S&D PARGNEAUX Gilles | |
| | | ECR GIRLING Julie | |
| | | GUE/NGL BOYLAN Lynn | |
| | | Verts/ALE STAES Bart | |
| | | EFDD EVI Eleonora | |
| | | PPE KÖSTINGER Elisabeth | |
| | Former committee responsible | | |
| | ENVI Environment, Public Health and Food Safety | | 10/09/2010 |
| | | ALDE LEPAGE Corinne | |
| | Former committee for opinion | | |
| | ITRE Industry, Research and Energy | The committee decided not to give an opinion. | |
| | AGRI Agriculture and Rural Development | | 30/08/2010 |
| | | ALDE LYON George | |
| | JURI Legal Affairs | The committee decided not to give an opinion. | |
| | Former committee for opinion on the legal basis | | |
| | JURI Legal Affairs | | 09/03/2011 |
| | | S&D GERINGER DE OEDENBERG Lidia Joanna | |
| Council of the European Union | Council configuration | Meeting | Date |
| | General Affairs | 3331 | 23/07/2014 |
| | Environment | 3297 | 03/03/2014 |
| | Environment | 3173 | 11/06/2012 |
| | Environment | 3152 | 09/03/2012 |

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|---|---|---|---|
| European Commission | Environment | 3139 | 19/12/2011 |
| | Environment | 3103 | 21/06/2011 |
| | Commission DG | Commissioner | |
| | Health and Food Safety | ANDRIUKAITIS Vytenis Povilas | |

## Key events

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|---|---|---|---|
| 13/07/2010 | Legislative proposal published | COM(2010)0375 | Summary |
| 07/09/2010 | Committee referral announced in Parliament, 1st reading/single reading | | |
| 12/04/2011 | Vote in committee, 1st reading/single reading | | Summary |
| 20/04/2011 | Committee report tabled for plenary, 1st reading/single reading | A7-0170/2011 | |
| 21/06/2011 | Debate in Council | 3103 | Summary |
| 05/07/2011 | Results of vote in Parliament | | |
| 05/07/2011 | Debate in Parliament | | |
| 05/07/2011 | Decision by Parliament, 1st reading/single reading | T7-0314/2011 | Summary |
| 19/12/2011 | Debate in Council | 3139 | Summary |
| 09/03/2012 | Debate in Council | 3152 | Summary |
| 03/03/2014 | Debate in Council | 3297 | Summary |
| 23/07/2014 | Council position published | 10972/3/2014 | Summary |
| 18/09/2014 | Committee referral announced in Parliament, 2nd reading | | |
| 11/11/2014 | Vote in committee, 2nd reading | | |
| 11/11/2014 | Committee decision to open interinstitutional negotiations at 2nd reading | | |
| 19/11/2014 | Committee recommendation tabled for plenary, 2nd reading | A8-0038/2014 | Summary |
| 17/12/2014 | Approval in committee of the text agreed at 2nd reading interinstitutional negotiations | PE618.197<br>GEDA/T/(2017)007441 | |
| 13/01/2015 | Debate in Parliament | | |
| 13/01/2015 | Decision by Parliament, 2nd reading | T8-0004/2015 | Summary |
| 02/03/2015 | Act approved by Council, 2nd reading | | |
| 11/03/2015 | Final act signed | | |
| 11/03/2015 | End of procedure in Parliament | | |
| 13/03/2015 | Final act published in Official Journal | | |

## Technical information

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| Procedure reference | 2010/0208(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| | Amending Directive 2001/18/EC 1998/0072(COD) |
| Legal basis | Treaty on the Functioning of the EU TFEU 114-p1 |
| Stage reached in procedure | Procedure completed |
| Committee dossier | ENVI/8/00574 |

## Documentation gateway

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|---|---|---|---|---|---|
| Legislative proposal | | COM(2010)0375 | 13/07/2010 | EC | Summary |
| Document attached to the procedure | | COM(2010)0380 | 13/07/2010 | EC | Summary |
| Document attached to the procedure | | SEC(2010)1454 | 22/11/2010 | EC | Summary |
| Economic and Social Committee: opinion, report | | CES1623/2010 | 09/12/2010 | ESC | |
| Committee draft report | | PE456.911 | 27/01/2011 | EP | |
| Committee of the Regions: opinion | | CDR0338/2010 | 28/01/2011 | CofR | |
| Committee opinion | AGRI | PE454.352 | 15/03/2011 | EP | |
| Amendments tabled in committee | | PE460.799 | 17/03/2011 | EP | |
| Amendments tabled in committee | | PE460.969 | 21/03/2011 | EP | |
| Specific opinion | JURI | PE462.539 | 29/03/2011 | EP | |
| Committee report tabled for plenary, 1st reading/single reading | | A7-0170/2011 | 20/04/2011 | EP | |
| Text adopted by Parliament, 1st reading/single reading | | T7-0314/2011 | 05/07/2011 | EP | Summary |
| Commission response to text adopted in plenary | | SP(2011)8072/2 | 08/09/2011 | EC | |
| Council statement on its position | | 11435/2014 | 16/07/2014 | CSL | |
| Council position | | 10972/3/2014 | 23/07/2014 | CSL | Summary |
| Commission communication on Council's position | | COM(2014)0570 | 10/09/2014 | EC | Summary |
| Committee draft report | | PE537.550 | 24/09/2014 | EP | |
| Amendments tabled in committee | | PE539.851 | 21/10/2014 | EP | |
| Amendments tabled in committee | | PE541.301 | 21/10/2014 | EP | |
| Amendments tabled in committee | | PE541.540 | 07/11/2014 | EP | |
| Committee recommendation tabled for plenary, 2nd reading | | A8-0038/2014 | 19/11/2014 | EP | Summary |
| Text adopted by Parliament, 2nd reading | | T8-0004/2015 | 13/01/2015 | EP | Summary |
| Commission opinion on Parliament's position at 2nd reading | | COM(2015)0083 | 25/02/2015 | EC | Summary |

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|---|---|---|---|---|---|
| Draft final act | | 00001/2015/LEX | 11/03/2015 | CSL | |
| Coreper letter confirming interinstitutional agreement | | GEDA/T/(2017)007441 | 31/07/2017 | CSL | |

## Additional information

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| National parliaments | IPEX |
| European Commission | EUR-Lex |

## Final act

Directive 2015/412
OJ L 068 13.03.2015, p. 0001 Summary

Corrigendum to final act 32015L0412R(03)
OJ L 082 26.03.2018, p. 0017

# 2010/0208(COD) - 13/07/2010 Legislative proposal

PURPOSE: to amend Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and Regulation (EC) No 1829/2003 on genetically modified food and feed establish a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which is fully applicable to GMOs to be used for cultivation purposes throughout the EU as seeds or other plant propagating material.

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.

Once a GMO is authorised for cultivation purposes in accordance with the EU legislative framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of EU legislation on the marketing of seed and plant propagating material, Member States are not authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by EU legislation.

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.

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.

IMPACT ASSESSEMENT: the Commission considers that the amendment of the legislation is necessary to get the right balance between maintaining the EU system of authorisations based on the scientific assessment of health and environmental risks and the need to grant freedom to Member States to address specific national or local aspects raised by the cultivation of GMOs.

This approach, while preserving the EU authorisation system of GMOs as well as the free circulation and import of GM food, feed and seeds, is expected to address the demands of several Member States and receive public support. It is also estimated that the potential economic and social benefits of this proposal are likely to outweigh the potential disadvantages.

Member States may be in a more appropriate position to carry out their own impact assessments to justify their decisions about cultivation of GMOs in their territories at national/regional/local levels.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal amends Directive 2001/18/EC by introducing a new Article which allows Member States to restrict or prohibit the cultivation of authorised GMOs in part or all of their territories on grounds other than those covered by the environmental risk assessment under the EU authorisation system and those related to avoiding the unintended presence of GMOs in other products.

This amendment will apply to GMOs authorised for cultivation either under Directive 2001/18/EC or Regulation (EC) No 1829/2003 which also covers applications for cultivation if they concern GMOs that are intended as source materials for the further production of food and feed. It will equally apply to cultivation of all varieties of seed and plant propagating material placed on the market in accordance with relevant EU legislation.

The freedom which Member States will obtain will only concern the act of GMO cultivation, but not the placing on the market and import of authorised GM seeds which must continue unimpeded within the framework of the internal market and the respective international obligations of the Union. The proposal sets out two series of conditions under which Member States can take measures:

1. As the assessment of the safety of GMOs for human/animal health and the environment is carried out at EU level, Member States have the possibility under the existing legal framework to invoke the special procedures of the safeguard clause of Directive 2001/18/EC (Article 23) or the emergency measure of Regulation (EC) No 1829/2003 (Article 34) in case they have serious grounds to consider that the authorised product is likely to constitute a serious risk to health and environment. Consequently, the proposal stipulates that Member States cannot invoke protection of health and environment to justify a national ban of cultivation of GMOs outside these special procedures.
2. Member States can thus invoke grounds (other than those covered by the environmental risk assessment under the EU authorisation system) to restrict or prohibit cultivation of GMOs in their territories. The measures taken by the Member States have to be in conformity with the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU), in particular as regards the principle of non-discrimination between national and non-national products and the provisions on quantitative restrictions of trade between Member States (Articles 34 and 36 TFEU). They should finally be consistent with the international obligations of the EU, and in particular with the ones established under the World Trade Organisation (WTO).

BUDGETARY IMPLICATIONS: this proposal has no financial implications for the Union budget. It will have no impact on small or medium-sized undertakings different than the impact of the current situation.

## 2010/0208(COD) - 13/07/2010 Document attached to the procedure

This communication accompanies the proposal aiming to amend Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. It aims to specify the conditions according to which a certain amount of freedom is given to the Member States to decide on the cultivation of genetically modified crops.

The political guidelines for the new Commission set out by President Barroso in September 2009 and endorsed by the Commission in March 2010, indicated that it should be possible to combine a European Union authorisation system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory.

A more flexible approach under the existing legislation: in line with Article 26a of Directive 2001/18/EC, Member States are entitled to take appropriate measures to avoid the unintended presence of GMOs in other products. Given the diversity of national, regional and local conditions under which European farmers work, the Commission has always considered that measures to avoid the unintended presence of GMOs in conventional and organic crops should be developed and implemented by the Member States.

In an attempt to support Member States in the process of developing national measures to avoid that presence, the Commission published in 2003 Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming. The purpose of such national measures is to avoid the potential economic impact of the admixture of GM and non-GM crops (conventional and organic).

Experience gained over the last years shows that the approach applied on the basis of Recommendation 2003/556/EC does not exhaust the provisions of Article 26a of Directive 2001/18/EC, notably as concerns the Member States' entitlement to set measures to avoid the unintended presence of GMOs in other products. At present some Member States have adopted national co-existence measures that aim at reaching levels of presence of GMOs in other crops lower than 0.9%. Other Member States have provided different isolation requirements for organic production. In concrete terms, experience with the implementation of the 2003 Recommendation shows that the potential loss of income for organic and (sometimes) conventional producers is not limited to exceeding 0.9%.

Since certain types of agriculture production such as organic production are often more costly, the possibility of losing the associated price premium due to unintended presence of GMOs may entail important economic damages to these types of production. It appears that it is appropriate to revise the 2003 Recommendation on co-existence and replace it with a new one to reflect the experience gained with national measures on GMO cultivation so far and make it more flexible.

To these ends, the new Recommendation on guidelines for the development of national co-existence measures (annexed) limits its content to the main general principles for the development of measures to avoid GMO admixture thereby recognising the flexibility for Member States to take into account their regional and national specificities and the particular local needs of organic, conventional and other types of crops. This Recommendation is adopted by the Commission together with this Communication. The Commission will continue to develop together with Member States best practices for co-existence (work of the European Coexistence Bureau).

Legislative amendment to introduce an ?opt-out? clause: a certain number of Member States want to have the possibility to opt-out from GM cultivation. So far, several of these Member States have banned the cultivation of GMOs on the basis of the safeguard clause set out in Article 23 of Directive 2001/18/EC or the emergency measures referred to in Article 34 of Regulation (EC) No 1829/2003.

The reasons for banning GMOs in a country or declaring a region GM-free appears to be diverse. These reasons vary from agronomic justifications related to difficulties of ensuring co-existence to political or economic motivations such as meeting the demand of GM-free markets.

The Netherlands submitted a declaration to the 23 March 2009 Agriculture and Environment Councils asking the Commission to come forward with a solution on cultivation while taking into account the socio-economic dimension of GMO cultivation and keeping the internal market for GM food and feed products. Austria, supported by twelve Member States, presented in the Environment Council of 25 June 2009 a paper that underlined the subsidiarity issue linked to cultivation and suggested an opt-out clause for cultivation to be introduced in the legislation.

In this context it appears appropriate to amend EU legislation in order to provide in the EU legislative framework on GMOs an explicit legal base to authorise Member States to restrict or prohibit the cultivation of all or particular authorised GMO in part or all of their territories on the basis of their specific conditions.

Therefore, and on the basis of the above principles, the Commission has decided to submit to the European Parliament and the Council a legislative proposal which takes the form of a Regulation amending Directive 2001/18/EC as regards the possibility for the Member States to

restrict or prohibit the cultivation of GMOs in their territory.

The Commission considers that this new approach - (i) to revise the existing Recommendation on co-existence (2003/556/EC); (ii) to adopt the legislative proposal providing the possibility for Member States to restrict or prohibit, under certain conditions, the cultivation of all or particular GMOs in part or all their territory - is necessary to achieve the right balance between maintaining the EU system of authorisations based on scientific assessment of health and environmental risks and the need to grant freedom to Member States to address specific national, regional or local issues raised by the cultivation of GMOs.

## 2010/0208(COD) - 22/11/2010 Document attached to the procedure

The Commission presents a Staff Working Document which gives consideration to the legal issues on GMO cultivation raised by the Council?s Legal Service. It recalls that the initial proposal in question amends Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The amendment inserts a new provision which would provide Member States a legal base to adopt if they wish measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of the Directive or Regulation (EC) No 1829/2003 in all or parts of their territory, subject to certain conditions.

The Council?s Legal Service examined several issues related to the choice of legal basis for the proposal, type of national measures that could lawfully be adopted by Member States on the basis of the proposal, and the compatibility of any such measures with the GATT. It concluded that the proposal as it stands is not validly based on Article 114 TFEU; and that there were strong doubts about the compatibility with the Treaties or with the GATT of any measures the Member States might adopt in reliance upon the new provisions of Directive 2001/18/EC.

This document sets out the reasons why the Commission's services disagrees with these conclusions, and with the main legal reasoning provided in support thereof.

## 2010/0208(COD) - 12/04/2011 Vote in committee, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Corinne LEPAGE (ALDE, FR) on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

It recommended that the European Parliament?s position at first reading, under the ordinary legislative procedure, should be to amend the Commission proposal as follows:

Free circulation: without prejudice to Article 23 (Safeguard clause) or Article 26b, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.

Confidentiality: without prejudice to the protection of intellectual property rights, access to material necessary for independent research on potential risks of GMOs, such as seed material, shall not be restricted or impeded. According to Members, in order for Member States to be able to investigate the compatibility of a certain GM-variety with a specific receiving environment, access to the GM material must not be restricted.

Unintended presence of GMOs: Member States shall take appropriate measures to avoid the unintended presence of GMOs in other products on their territory and in borderareas of neighbouring Member States.

Culture: according to the text, Member States may adopt, on a case-by case-basis, measures restricting or prohibiting the cultivation of particular GMOs or of groups of GMOs, provided that: those measures are based on:

- scientifically justified grounds relating for example to pesticide resistance; the invasiveness or persistence of a GM variety; the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability; the maintenance of local biodiversity;
- grounds relating to socio-economic impacts for example 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; the need to protect the diversity of agricultural production; the need to ensure seed purity;
- other grounds that may include land use, town and country planning, or other legitimate factors.

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.

Measures must respect local agricultural and cultural traditions and they must have been the subject of a prior public consultation lasting at least 30 days.

In addition, Member States shall: (i) make publicly available any such measure to all operators concerned, including growers, at least three months before the start of the growing season; (ii) adopt those measures for a maximum of five years and shall review them when the GMO authorisation is renewed.

Liability requirements: the report calls on the Member States to establish a general mandatory system of financial liability and financial guarantees, for example through insurance, which applies to all business operators and which ensures that the polluter pays for unintended effects or damage that might occur due to the deliberate release or the placing on the market of GMOs.

?GMO-free? labelling: the Commission shall propose harmonised conditions under which operators may make use of terms indicating the absence of GMOs in products.

## 2010/0208(COD) - 21/06/2011 Debate in Council

The Council examined progress with a proposal that would allow Member States to ban or restrict the cultivation of genetically modified organisms (GMOs) in their territory.

Member States are still examining the draft act that would give EU countries the possibility to ban or restrict the cultivation of one or several GMOs in all or part of their territory. In view of the doubts about the conformity of national GMO bans adopted under the proposed legislation with the internal market and WTO rules, some delegations consider that further reflection and analyses are needed.

In light of the discussions in the Council meetings and in the Ad hoc Working Party and taking into consideration the report of the Committee on the Environment, Public Health and Food Safety of the European Parliament, the Presidency prepared a compromise proposal.

In the course of the discussions the Presidency was keen on encouraging an exchange of views on possible overlaps and/or inconsistencies of the environmental considerations that could be used as grounds. The Presidency was also aiming at clarifying the question of likeness with regard to the national treatment obligation imposed by Article III.4 GATT.

Discussions identified the following main issues and concerns of delegations:

- the majority of delegations pointed to the need to advance this file in view of forging an agreement with the European Parliament and expressed support for the Presidency approach;
- it was pointed out by several that the position of the Committee on the Environment, Public Health and Food Safety of the European Parliament shared sufficient common ground with the Presidency?s suggestions to engage informal trialogues with the European Parliament;
- a large number of delegations restated the importance of such opt-out possibility as a step in the right direction and invited the upcoming presidencies to move forward;
- some delegations rejected the proposal in general insisting on leaving the science based decision-making on GM-cultivation at EU level, and opposing the flexibility of Member States to decide on GM cultivation in their territory;
- a large number of delegations noted that the Presidency proposal was a good basis for further work and acknowledged that further fine-tuning of some parts (acceptable grounds, importance of avoiding possible overlaps and/or inconsistencies between the risk assessment at EU level and national measures using "General/complementary environmental policy objectives?, recitals) might be welcomed;
- several delegations asked for more time to address doubts in relation to the legal compatibility of some of the grounds contained in the suggested list with WTO and EU internal market rules; others questioned the choice of the legal base and the modification of the form of the legal act;
- some voiced concerns with regard to the impact on the internal market and the Common Agriculture Policy and questioned whether the proposal constitutes a legally sound and workable option.

At its meeting on 25 May 2011 Coreper considered the Presidency's new compromise proposal a good basis for further work within the Council. Discussions showed that although a large number of delegations supported the Presidency's compromise text, it was felt nevertheless that, at this stage, more time was needed to address questions and concerns by several delegations.

It was pointed out by several that the position of the Committee on the Environment, Public Health and Food Safety of the European Parliament was not far from the Presidency?s suggestions; therefore a unique momentum was provided to reach a compromise which was also supported by the European Commission.

## 2010/0208(COD) - 05/07/2011 Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 548 votes to 84, with 31 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

Parliament adopted its position at first reading, under the ordinary legislative procedure, which amends the Commission proposal as follows:

Legal basis:Parliament considers that the proposal should be based on Article 192(1) of the Treaty on the Functioning of the European Union (as opposed to Article 114).

Free circulation: without prejudice to Article 23 (Safeguard clause) or Article 26b, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.

Confidentiality: without prejudice to the protection of intellectual property rights, access to material necessary for independent research on potential risks of GMOs, such as seed material, shall not be restricted or impeded. According to Members, in order for Member States to be able to investigate the compatibility of a certain GM-variety with a specific receiving environment, access to the GM material must not be restricted.

Unintended presence of GMOs: Member States shall take appropriate measures to avoid the unintended presence of GMOs in other products on their territory and in borderareas of neighbouring Member States.

Culture: according to the amended text, Member States may adopt, on a case-by case-basis, measures restricting or prohibiting the cultivation of particular GMOs or of groups of GMOs, provided that: those measures are based on:

- duly justified grounds relating for example to pesticide resistance; the invasiveness or persistence of a GM variety; the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability; the maintenance of local biodiversity;
- grounds relating to socio-economic impacts for example 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; the need to protect the diversity of agricultural production; the need to ensure seed purity;
- other grounds that may include land use, town and country planning, or other legitimate factors.

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.

Measures put forward by the Member States should have been subject to a prior independent cost-benefit analysis, taking into account alternatives and a prior public consultation lasting at least 30 days.

In addition, Member States shall: (i) make publicly available any such measure to all operators concerned, including growers, at least six months before the start of the growing season; (ii) adopt those measures for a maximum of five years and shall review them when the GMO authorisation is renewed.

Members suggest that regions within Member States may adopt measures restricting or prohibiting the cultivation of GMOs on their territory.

Liability requirements: Parliament calls on the Member States to establish a general mandatory system of financial liability and financial guarantees, for example through insurance, which applies to all business operators and which ensures that the polluter pays for unintended effects or damage that might occur due to the deliberate release or the placing on the market of GMOs.

Research: a new recital states that restrictions or bans on cultivation of GMOs by Member States should not prevent biotechnology research from being carried out provided that, in carrying out such research, all necessary safety measures are observed.

## 2010/0208(COD) - 19/12/2011 Debate in Council

The Council was informed by the Presidency about the state of play on the proposal for a regulation amending directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

The proposal was presented to the Council in July 2010, both at its "Agriculture" and "Environment" configurations, and has been subject to an in-depth technical examination by the competent Council bodies since then. Although progress has been made in this file, it has not yet been possible to reach an agreement on a compromise text.

The Polish Presidency prepared a compromise proposal that takes into account discussions held and delegations' written comments after the last meeting of the Working Party, thus providing the incoming Danish Presidency with the technical basis to pursue this work.

## 2010/0208(COD) - 09/03/2012 Debate in Council

The Council discussed, on the basis of a compromise text from the Presidency, the proposal for a regulation amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) that have been authorised at EU level in all or part of their territory.

The compromise proposal, inspired by the approach in the newly adopted Biocide Regulation, allowed for two options:

- during the GMO authorisation procedure: upon request of a Member State, the notifier/applicant has the possibility to adjust the geographical scope of the authorisation, thus excluding part or all of the territory of that Member State from cultivation;
- after the authorisation procedure: the Member State has the option to restrict or prohibit the cultivation of an authorised GMO, provided that the national measure does not conflict with the environmental risk assessment carried out at EU level.

Although a large number of Member States could accept the Presidency proposal, it was not yet possible to reach agreement in the Council. Some Member States still had concerns regarding:

- the legal compatibility of some provisions in the proposal with WTO and EU internal market rules;
- how to avoid possible overlaps and/or inconsistencies between the mandatory risk assessment at EU level and national environmental measures;
- the implementation of the Environment Council conclusions adopted on 4 December 2008 (doc 16882/08).

## 2010/0208(COD) - 03/03/2014 Debate in Council

The Council held a public exchange of views on the draft regulation amending directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation, in all or part of their territory, of genetically modified organisms (GMOs) that have been authorised at EU level.

The exchange of views confirmed the Member States' willingness to re-open discussions on this legislative proposal on the basis of the presidency compromise text. The Presidency aims to reach a political agreement and prepare the adoption of this important legislation by the end of 2014.

The GMO cultivation proposal presented in July 2010 has already been examined during several presidencies. The Environment Council of 9 March 2012 was not able to reach a political agreement as a blocking minority of delegations still had concerns regarding some issues.

## 2010/0208(COD) - 23/07/2014 Council position

The Council adopted its common 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.

The Council followed the general direction of Parliaments amendments in certain key respects (e.g. the introduction of specific grounds on which to base national restrictions). However, in most other respects the Council has preferred a different approach.

The Council's position at first reading also includes a number of changes other than those envisaged in the European Parliament's position :

- the Council's position is based on Article 114 TFEU, not Article 192 TFEU. The Council considers that the main purpose of the proposal is ensuring the smooth functioning of the internal market, whilst allowing Member States to make their own decisions regarding the cultivation of authorised GMOs. To the extent that other considerations are involved, such as those relating to the environment, these are secondary in relation to the main purpose ;
- although the proposal was initially made in the form of a regulation, the Council changed the legal form to that of a directive, albeit one without a transposition period given the optional nature of the provisions in question ;
- with a view to ensuring the least possible disturbance to the internal market whilst at the same time facilitating the authorisation process of GMOs, the Council considered it appropriate to provide for a mechanism whereby Member States could agree on restrictions with economic operators (via the Commission). The new provisions relate to the procedure for ensuring that this mechanism is capable of working in practice ;
- in the event that agreement with the economic operator cannot be reached, Member States will be entitled to adopt measures restricting or prohibiting cultivation, subject to certain important conditions. Like the European Parliament, the Council has also considered it appropriate to include a non-exhaustive list of grounds in the text. The grounds invoked to restrict the cultivation should not conflict with the scientific risk assessment conducted by European Food Safety Authority ;
- the Council has followed the Parliament in introducing appropriate provisions to respect the legitimate expectations of farmers who have already planted GM crops prior to the adoption of national measures. However, the Council considered that it was not necessary to amend Article 22 of Directive 2001/18, as suggested by the Parliament. On the contrary, it is important to ensure that restrictive measures regarding cultivation do not inadvertently lead to the trading of authorised GMOs, including propagating material, becoming unlawful ;
- as regards coexistence, a new recital has been inserted referring to the most recent Commission Recommendation on this field. This Recommendation provides guidance to Member States with a view to avoiding the unintended presence of GMOs in other products on their territory and in border areas ;
- in view of the fact that authorisation procedures may reasonably be expected to be underway when the proposal is finally adopted, it seemed necessary to introduce appropriate transitional provisions.

Lastly, the Council did not consider it appropriate to introduce an obligation to impose a regime of financial liability.

## 2010/0208(COD) - 10/09/2014 Commission communication on Council's position

The Commission considers that the common position adopted by the Council with qualified majority reflects the original goals of the Commission's proposal and takes into account many concerns of the European Parliament.

The Commission indicated that it could accept in full, in part, in principle or subject to rewriting 21 of the 28 amendments proposed by Parliament.

The main amendments accepted by the Commission and incorporated in full, in part or in principle in the position of the Council at first reading include the following points:

- explanation of particular aspects of the EU harmonised environmental risk assessment required under Directive 2001/18/EC ;
- the importance of ensuring that national measures restricting or banning GMO cultivation do not prevent biotechnology research being carried out ;
- a call for adoption of updated guidelines on environmental risk assessment ;
- the inclusion of an indicative list of grounds for justifying opt-out measures, subject to rewording to make clear that grounds invoked by Member States to justify opt out measures do not conflict with the EU wide environmental risk assessment. The Commission considers that the wording proposed by the Council is in line with the objective of the proposal.
- the importance of making available to operators (including growers), in a timely manner, the information necessary about any restriction or prohibition of GMO cultivation in the territory of a Member State, and to give them sufficient time to adapt and finish the current cultivation season when the measures concern GMOs already authorised at Union level ;
- particular reference to the importance of national measures being in conformity with the principle of proportionality ;
- the entry into force of the Regulation.

The Commission does not accept the amendment modifying Article 22 of Directive 2001/18/EC on free circulation, because the proposal will allow Member States to restrict exclusively the cultivation of GMOs on their territory and not the trade or import of GM or conventional seeds, food and feed.

However, the Commission does accept the Councils modified wording of recitals 13 and 18 and the new Articles 26 b (9) and 26 c (6) of the amended Directive on free circulation and import of authorised GMOs in all Member States and their use in Member States which neither restrict nor prohibit GMO cultivation, and the new recital 20 as regards the free movement of conventional seeds, plant propagating material and of the product of the harvest.

The Commission also accepts new provisions inserted by the Council regarding the proposal, these being the following :

- replacement of the regulation by a directive;

- restriction of the geographical scope of the application (step 1) : the Commission accepts the Councils common position establishing a two consecutive steps procedure (at the time of the definition of the scope of the application by the applicant and after the GMO has been authorised) to allow Member States to restrict or prohibit cultivation of a GMO ;
- the procedures to follow prior to adoption of opt-out measures ;
- the 2 year deadline for adoption of opt-out measures ;
- a 6 months transitional period allowing Member States to apply the provisions of the Directive to GMOs already authorised before its entry into force (maize MON 810), or for which an application is already at an advanced stage ;
- the option for a Member State to change its position on cultivation of a GMO during the term of validity of the authorisation ;
- the Commissions obligation to present a report no later than four years after the entry into force of the Directive, regarding the use made by Member States of the Directive accompanied by any legislative proposals the Commission considers appropriate.

For these reasons, the Commission accepts the Councils common position.

## 2010/0208(COD) - 19/11/2014 Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Frédérique RIES (ADLE, BE) containing a recommendation for second reading 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.

The committee recommended that the position adopted at second reading by the Parliament should amend the Council position as follows:

Legal basis: the Directive should be based on Article 192, paragraph 1 of the TFEU (environment legal basis) and not Article 114 of the TFEU.

Co-existence measures: Members called for Member States to be required to take the necessary 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.

Culture: during the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand to adjust the geographical scope of the written consent or authorisation to the effect that all or part of the territory of that Member State is to be excluded from cultivation. Members proposed that the request be communicated to the Commission and, if applicable, to the competent authority responsible for issuing the written consent under this Directive at the latest 60 days from the date of the circulation of the assessment report.

Grounds for such a prohibition of GMOs: according to Members, these grounds are related to:

- 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 on genetically modified food and feed;
- town and country planning;
- land use;
- socio-economic impacts;
- avoidance of GMO presence in other products;
- agricultural policy objectives;
- public policy.

Time-limit: Member States may restrict or prohibit the cultivation of a GMO or of groups of GMOs defined by crop or trait or of all GMOs in all or part of their territory prior to the date of entry into force of the Union authorisation and for the whole duration of the consent/authorisation, provided that an established standstill period, during which the Commission was given the opportunity to comment on the proposed measures, has elapsed.

The Member State concerned should therefore communicate the proposed measures to the Commission at least 75 days prior to their adoption, in order to give the opportunity to the Commission 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 comments.

During the standstill period, the authorisation applicant/holder who would be affected by measures restricting or prohibiting the cultivation of a GMO or group of GMOs in a Member State should refrain from all activities related to the cultivation of that GMO or a group of GMOs in that Member State.

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

Liability requirements and financial guarantees: Member States shall establish a general mandatory system of financial liability, and financial guarantees in their national laws on GMOs which applies to all operators and which ensures that the polluter pays for unintended effects or damage that might occur due to the deliberate release or the placing on the market of GMOs.

Implementing measures: no later than a year after the date of entry into force, 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.

Transposition: Members called for the Directive to be transposed 12 months after its entry into force.

## 2010/0208(COD) - 13/01/2015 Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution 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.

Parliament adopted its position at second reading following the ordinary legislative procedure amending the Council position as follows:

Risk assessment: GMOs for cultivation are to undergo an individual risk assessment before being authorised to be placed on the Union market, 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. The precautionary principle should always be taken into account in the framework of Directive 2001/18/EC and its subsequent implementation.

According to the Members, the rules on risk assessment should be, where needed, regularly updated to take account of continuous developments in scientific knowledge and analysis procedures, in particular regarding the long-term environmental effects of genetically modified crops.

Co-existence measures: Parliament called for Member States to be required to take the necessary measures to avoid the unintended presence of GMOs in other products on their territory and in border areas of neighbouring Member States. The amended text stated that as from two years after the entry into force, Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in light of particular geographical conditions. Those measures shall be communicated to the Commission.

Culture: during the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand to adjust the geographical scope of the written consent or authorisation to the effect that all or part of the territory of that Member State is to be excluded from cultivation.

That demand shall be communicated to the Commission at the latest 45 days from the date of the circulation of the assessment report. The Commission shall present the demand of the Member State to the notifier/applicant and to the other Member States without delay. It shall make the demand publicly available by electronic means.

Within 30 days from the presentation by the Commission of that demand, the notifier/applicant may adjust or confirm the geographical scope of its initial notification/application.

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

The written consent issued under this Directive and, where applicable, the decision issued in accordance with this Directive.

Time-limit: Member States may restrict or prohibit the cultivation of a GMO or of groups of GMOs defined by crop or trait or of all GMOs in all or part of their territory prior to the date of entry into force of the Union authorisation and for the whole duration of the consent/authorisation, provided that an established standstill period, during which the Commission was 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 75 days prior to their adoption, in order to give the opportunity to the Commission to comment, and should refrain from adopting and implementing those measures during that period.

During the standstill period, the authorisation applicant/holder who would be affected by measures restricting or prohibiting the cultivation of a GMO in a Member State should refrain from all activities related to the cultivation of that GMO in that Member State.

On expiry of the 75-day period, the Member State concerned may for the whole duration of the consent/authorisation and as from the date of entry into force of the Union authorisation, adopt the measures either in the form originally proposed, or as amended to take account of any non-binding comments received from the Commission. Those measures shall be communicated to the Commission, the other Member States and the authorisation holder without delay.

Member States shall make publicly available any such measure to all operators concerned, including growers.

Independent research: the Commission and the Member States should ensure that the necessary resources for independent research on the potential risks arising from the deliberate release or the placing on the market of GMOs are secured, and that independent researchers should be given access to all relevant material, while respecting intellectual property rights.

Labelling: to guarantee a high level of consumer protection, the Member States and operators should also take effective labelling and information measures pursuant to Regulation (EC) Nº 1830/2003 to guarantee transparency about the presence of GMOs in products.

Reporting: no later than four years after the date of entry into force of the Directive, the Commission shall also report on the actual remediation of environmental damages that might occur due to the cultivation of GMOs.

## 2010/0208(COD) - 25/02/2015 Commission opinion on Parliament's position at 2nd reading

The Commission expressed its opinion on the European Parliament's amendments to the Council's position regarding the proposal for 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 GMOs in their territory.

With a view of combining an EU authorisation system for GMOs, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory, the Commission adopted this legislative proposal in July 2010.

This proposal provides a legal base in the EU legal framework on GMOs for Member States to restrict or prohibit in all or part of their territory the cultivation of GMOs that have been authorised at EU level. Those prohibitions or restrictions shall be based on grounds other than those covered by the environmental and health risk assessment under the EU authorisation system.

The European Parliament voted in second reading a consolidated text which contains a number of amendments to the text of the Council's position at first reading. The text is the result of negotiations between the European Parliament, the Council and the Commission. The Commission accepted all the amendments voted by the European Parliament.

## 2010/0208(COD) - 11/03/2015 Final act

PURPOSE: to adopt new rules authorising the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

LEGISLATIVE ACT:

CONTENT: the Directive amends Directive 2001/18/EC by introducing a new Article which allows Member States to restrict or prohibit the cultivation of authorised GMOs in part or all of their territories on grounds other than those covered by the environmental risk assessment under the EU authorisation system and those related to avoiding the unintended presence of GMOs in other products.

The main amendments introduced are as follows:

Cultivation of GMOs:

(1) During the authorisation procedure of a given GMO: a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation. That demand shall be communicated to the Commission at the latest 45 days from the date of circulation of the assessment report. The Commission shall make the demand publicly available by electronic means. Within 30 days from the presentation by the Commission of that demand, the notifier/applicant may adjust or confirm the geographical scope of its initial notification/application. In the absence of confirmation, the adjustment of the geographical scope of the notification/application shall be implemented in the written consent issued under this Directive.

(2) After authorisation of a GMO: whilst it is expected that most restrictions or prohibitions adopted pursuant to this Directive will be implemented at the stage of consent/authorisation or renewal thereof, there should, in addition, also be the possibility for Member States to adopt reasoned measures restricting or prohibiting the cultivation in all or part of their territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised, on the basis of grounds related to environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy. A Member State which intends to adopt these type of measures shall first communicate a draft and the corresponding grounds invoked to the Commission. During a period of 75 days starting from the date of such communication, the Member State concerned shall refrain from adopting and implementing those measure and ensure that operators refrain from planting the GMO or GMOs concerned. The Commission may make any comments it considers appropriate. Where a Member State wishes all or part of its territory to be reintegrated into the geographical scope of the consent/authorisation from which it was previously excluded, it may make a request to that effect to the competent authority.

Avoid cross-border contamination: as from 3 April 2017, Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in the light of particular geographical conditions.

Report: no later than 3 April 2019, the Commission shall present: (i) a report regarding the use made by Member States of this Directive, accompanied by any legislative proposals if appropriate; (ii) a report on the actual remediation of environmental damages that might occur due to the cultivation of GMOs.

Updating the annexes: no later than 3 April 2017, the Commission shall update the Annexes to Directive 2001/18/EC as regards the environmental risk assessment, with a view to incorporating and building upon the strengthened 2010 Authority guidance on the environmental risk assessment of genetically modified plants.

ENTRY INTO FORCE: 2.4.2015.