

# Procedure file

Basic information			
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation		Awaiting Council's 1st reading position	
Possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory  Amending Regulation (EC) No 1829/2003 <a href="#">2001/0173(COD)</a>			
Subject 3.10.08.01 Feedingstuffs, animal nutrition 3.10.09.06 Agro-genetics, GMOs 3.10.10 Foodstuffs, foodstuffs legislation 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety			
Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 ENVI Environment, Public Health and Food Safety	 <a href="#">LA VIA Giovanni</a>	09/06/2015
		Shadow rapporteur  <a href="#">BALAS Guillaume</a>	
		 <a href="#">GIRLING Julie</a>	
		 <a href="#">MEISSNER Gesine</a>	
		 <a href="#">STAES Bart</a>	
		 <a href="#">EVI Eleonora</a>	
		 <a href="#">D'ORNANO Mireille</a>	
	Committee for opinion  AGRI Agriculture and Rural Development	Rapporteur for opinion  <a href="#">DESS Albert</a>	Appointed 20/05/2015
	 IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	 ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	<a href="#">Agriculture and Fisheries</a>	<a href="#">3402</a>	13/07/2015
European Commission	Commission DG	Commissioner	
	<a href="#">Health and Food Safety</a>	ANDRIUKAITIS Vytenis Povilas	
European Economic and Social Committee			

Key events			
22/04/2015	Legislative proposal published	<a href="#">COM(2015)0177</a>	Summary
30/04/2015	Committee referral announced in Parliament, 1st reading		
13/07/2015	Debate in Council	<a href="#">3402</a>	
13/10/2015	Vote in committee, 1st reading		
19/10/2015	Committee report tabled for plenary, 1st reading	<a href="#">A8-0305/2015</a>	Summary
28/10/2015	Results of vote in Parliament		
28/10/2015	Debate in Parliament		
28/10/2015	Decision by Parliament, 1st reading	<a href="#">T8-0379/2015</a>	Summary

Technical information	
Procedure reference	2015/0093(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 1829/2003 <a href="#">2001/0173(COD)</a>
Legal basis	Treaty on the Functioning of the EU TFEU 114
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a>
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	ENVI/8/03379

Documentation gateway					
Legislative proposal		<a href="#">COM(2015)0177</a>	22/04/2015	EC	Summary
Document attached to the procedure		<a href="#">COM(2015)0176</a>	22/04/2015	EC	Summary
Committee draft report		<a href="#">PE560.784</a>	25/06/2015	EP	
Committee opinion	<b>AGRI</b>	<a href="#">PE560.772</a>	03/09/2015	EP	
Economic and Social Committee: opinion, report		<a href="#">CES2913/2015</a>	16/09/2015	ESC	
Amendments tabled in committee		<a href="#">PE567.727</a>	18/09/2015	EP	
Committee of the Regions: opinion		<a href="#">CDR3636/2015</a>	13/10/2015	CofR	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A8-0305/2015</a>	19/10/2015	EP	Summary
Text adopted by Parliament, 1st reading/single reading		<a href="#">T8-0379/2015</a>	28/10/2015	EP	Summary

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

---

**PURPOSE:** to amend existing legislation in order to give Member States the possibility to restrict or prohibit the use of genetically modified food and feed on their territory.

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

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** Regulation (EC) No 1829/2003 allows Member States to adopt measures restricting or prohibiting the use of authorised GMOs and GM food and feed only if they are able to demonstrate that the product in question is likely to pose risks to health and to the environment. The Regulation requires the Commission as risk manager to take a decision on an application for authorisation in a reasonable period of time (to grant an authorisation or refuse an authorisation).

Since the entry into force of Regulation (EC) No 1829/2003, there has never been a qualified majority amongst Member States in favour of or against a draft Commission Decision authorising Genetically Modified Organisms (GMOs) and Genetically Modified (GM) food and feed. The result has always been a no opinion for all stages of the procedure. As a result, the authorisation decisions have been adopted by the Commission, in accordance with applicable legislation, without the support of the Member States committee opinion.

Regarding cultivation of GMOs, [Directive \(EU\) 2015/412](#) grants Member States more flexibility to decide whether or not they wish to cultivate GMOs on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs. However, that Directive does not cover GMOs and GM food and feed authorised under Regulation (EC) No 1829/2003.

In its [Communication](#) on the reviewing the decision-making process on genetically modified organisms (GMOs), the Communication concluded that the current legal framework should be amended, by extending the approach agreed in Directive (EU) 2015/412 to other products covered by the Regulation (EC) No 1829/2003.

**CONTENT:** the Commission proposal amends Regulation (EC) No 1829/2003 to introduce new provisions allowing Member States to restrict or prohibit the use of GMOs and GM food and feed covered by the GMO legal framework, in part or all of their territory, in complement to the possibilities already offered to Member States with respect to GMOs for cultivation by Directive (EU) 2015/412. The proposal does not affect the Union procedure of authorisation based on risks which should remain harmonised at Union level in order to maintain a same level of safety throughout the EU.

According to the proposed Regulation, Member States may adopt measures restricting or prohibiting the use GMOs or GM food and feed products provided that such measures are:

- 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;
- proportional and non-discriminatory.

Where a Member State intends to adopt measures restricting or prohibiting the use of products, it shall first submit to the Commission a draft of those measures, and the corresponding justification. The Commission shall immediately notify to the other Member States the draft measures and the corresponding justification.

During a period of 3 months from the date of submission to the Commission of the draft measures and various information:

- the Member State shall refrain from adopting and implementing those measures;
- the Commission and the Member States may make any comments they consider appropriate to the Member State which has submitted the draft measures.

The proposal does not allow Member States to restrict or prohibit the use of products which do not have to be labelled under the GMO legal framework, even if they may contain a small proportion of GMOs or GM food and feed below the thresholds set out therein.

Provisions are also established to protect the rights of economic operators which lawfully placed on the market a GMO or a GM food and feed before the Member State adopt measures pursuant to the proposal. Sufficient time should be given to operators to allow the phasing out of the product from the market.

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

---

This Communication from the Commission reports on the results of the Commissions review of the decision-making process for authorising genetically modified organisms (GMOs).

It sets out the rationale that has led to the legislative proposal adopted by the Commission aiming to review the decision-making process for authorising GMOs.

The decision-making process in the field of GMOs is governed by both a specific legal framework and common institutional rules. This Communication summarises the context of such decisions, discusses the way the authorisation process has worked in practice, and describes changes introduced recently.

**The legal framework:** the European Union has a comprehensive legal framework in place for the authorisation, traceability and labelling of GMOs.

- [Regulation \(EC\) No 1829/2003](#) on genetically modified food and feed (the 2003 Regulation) covers food, food ingredients, and feed containing, consisting of or produced from GMOs;

- The other piece of legislation in this area is [Directive 2001/18/EC](#) on the deliberate release into the environment of genetically modified organisms. This covers GMOs for uses other than food and feed (notably for cultivation).

Both legislative acts set out authorisation procedures the aim of which is to ensure that the placing on the market of the products concerned will not pose a risk to human or animal health or to the environment.

Decision-making process: the Political Guidelines presented by the Commission to the European Parliament explained the problem faced in the specific GMO context namely that the system did not allow the individual concerns of democratically elected governments to be taken into account.

From a legal point of view, decisions to authorise GMOs take the form of implementing acts adopted by the Commission (comitology). Whilst the Commission therefore plays a decisive role in the authorisation process, Member States are also very much involved. However, since the entry into force of the 2003 Regulation, Member States have never obtained a qualified majority in favour of or against a draft Commission decision authorising GMOs, whether for cultivation or for GM food and feed. The result has always been no opinion.

It has become the norm for decision on GMO authorisations that the dossier is returned to the Commission for the final decision, making decisions in this area very much the exception to the usual functioning of the EU comitology procedure as a whole. This implies de facto that the Commission is systematically put in a situation where it has to take a decision on authorisations without support of Member States in relevant committees.

Recent reform of the rules for GMOs authorised for cultivation: in 2010, the Commission submitted a proposal to amend the GMO legislation to extend the grounds on which Member States could restrict or prohibit the cultivation of EU authorised GMOs on their territory ("opt-outs").

The proposed amendment has now been adopted into EU law as [Directive \(EU\) 2015/412](#) (The 2015 Directive). It enables Member States to restrict or prohibit GMO cultivation on their territory (or part of it) provided that such measures are justified on the basis of compelling reasons other than the risk to human or animal health and the environment that is, criteria other than those assessed by EFSA in its risk assessment.

The 2015 Directive therefore gives Member States more flexibility to decide whether or not they wish to cultivate GMOs on their territory, whilst still maintaining the system of EU authorisation based on risk assessment.

Commissions proposal: the Commission proposes to amend the 2003 Regulation in such a way as to allow Member States to restrict or prohibit the use, on part or all of their territory, of GM food and feed authorised at EU level for compelling reasons other than the risk to human or animal health or to the environment. This will enable Member States to address at national level considerations which are not covered by the EU decision-making process.

Any Member State wishing to make use of this "opt-out" will need to provide justification for that specific case, taking into account the GMO in question, the type of measure envisaged, and the specific circumstances present at national or regional level that constitute the grounds for such an opt-out.

This proposal would mirror and complement the rights already given to Member States in respect of GMOs for cultivation by the 2015 Directive and cover the much greater number of authorisations granted, which are those for food and feed.

According to the Commissions opinion, the EU should have a consistent set of rules for GM authorisations for cultivation and for food and feed.

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

---

The Committee on the Environment, Public Health and Food Safety adopted the report by Giovanni LA VIA (EPP, IT) on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory.

The committee recommended that Parliament reject the Commission proposal and called on the Commission to withdraw its position.

In its proposal, the Commission suggests to mirror, as regards genetically modified food and feed, the recent amendment of Directive 2001/18/EC in respect of GMOs intended for cultivation ([Directive \(EU\) 2015/412](#) which entered into force in early April 2015). Accordingly, it proposed to allow Member States to restrict or prohibit - under certain conditions - the use of genetically modified food and feed on their territory after these products have been authorised ("opt-out").

Members considered, in particular, that - as its adoption was not preceded by an assessment of all possible impacts and alternative options available - the proposal conflicts with the "Better Regulation" and "Transparency" pledges made by the new Commission.

As the EU remains highly dependent on the supply of proteins from GM sources and considering that the proposal is likely to have negative indirect effect on imports, Members are of the view that the proposal may seriously endanger livestock production and also negatively affect agriculture in the EU.

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

---

The European Parliament adopted by 577 votes to 75, with 38 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory.

In line with the recommendation by the Committee on the Environment, Public Health and Food Safety, Parliament rejected the Commission proposal by 619 votes to 58, with 13 abstentions. It called on the Commission to withdraw its position.

In its resolution, Parliament recalled that the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Belgian Chamber of Representatives, the Spanish Parliament, the Netherlands House of Representatives and the Austrian Federal Council, asserted that the draft legislative act does not comply with the principle of subsidiarity.