# Briefing

EU Legislation in Progress

1 June 2015

European Parliament

# Imports of GM food and feed

## Right of Member States to opt out


**SUMMARY**

All genetically modified organisms (GMOs) need authorisation before they can be placed on the EU market. However, a qualified majority amongst the Member States has never been reached either in favour of or against any authorisation proposal put forward by the Commission.

The Commission has therefore concluded that the legal framework for decision-making on genetically modified (GM) food and feed needs to be adapted, and proposes to extend to GM food and feed the solution agreed by the European Parliament and the Council on GMO cultivation. The Member States would thus be allowed to restrict or prohibit the use of genetically modified food and feed on their territory, despite it being authorised at EU level.

Stakeholders have been critical of the proposal, claiming that it jeopardises the internal market, would cause serious distortions to competition and leave measures taken by Member States vulnerable to legal challenge.


**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**

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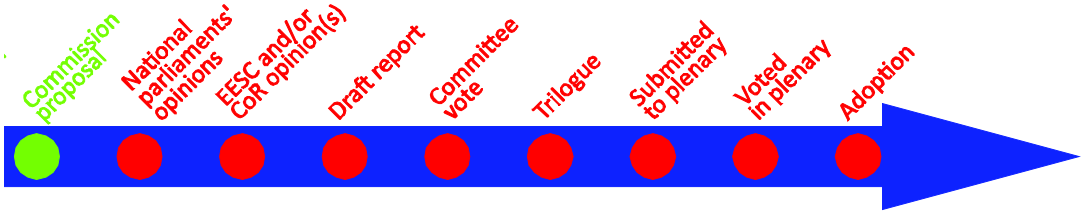
| *Committee responsible*: | Environment, Public Health and Food Safety (ENVI) | COM(2015) 177 *of* 22.4.2015 |
| *Rapporteur*: | (not yet appointed) | *procedure ref.*: 2015/0093(COD) |
| *Next steps expected*: | Exchange of views in ENVI Committee with Commissioner Andriukaitis on 8 June | Ordinary legislative procedure |





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Author: Tarja Laaninen

**Members' Research Service**



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## Introduction

On 22 April 2015, the Commission adopted a proposal for a Regulation on the possibility for Member States to restrict or prohibit the use of genetically modified food and feed on their territory.

All GMOs need an authorisation before they can be placed on EU market. The authorisation is given in the form of an implementing act under the 'examination' procedure, based on a risk assessment conducted by the European Food Safety Authority (EFSA). The Implementing Decision has to be approved by a qualified majority in a standing committee of Member States' representatives. However, a qualified majority amongst the Member States has never been found, either in favour of or against a proposal for decision put forward by the Commission. According to the applicable legislation and case law, the Commission is ultimately obliged to adopt a decision.

The Commission concludes that the legal framework for decision-making on GM food and feed needs to be adapted, and proposes to extend the solution recently agreed by the European Parliament and the Council on GMO cultivation to GM food and feed. The Member States would thus be given the possibility to restrict or prohibit the use of genetically modified food and feed on their own territory, despite it being authorised at EU level.

## Context

Genetically modified organisms are organisms whose genetic material has been modified artificially in order to give them new properties, for example resistance to drought or insects. GMOs may be plants, animals or micro-organisms.

The use of GMOs divides opinion, with pro-GMO campaigners seeing them as a means to increase yields, reduce the use of pesticides and insecticides, improve food quality and reduce prices. Anti-GMO campaigners, on the contrary, worry about possible long-term effects on human and animal health as well as on the environment, warn that they might cause superbugs to emerge that would necessitate the use of even stronger pesticides, are concerned that they could eventually reduce biodiversity by possibly mixing with conventional crops, and claim that the power of the multinational biotech companies would grow too strong.

There are now 68 GMOs authorised for food and feed use in the EU. These organisms, listed in the EU Register of authorised GMOs, include maize, cotton,[1] soybean, oilseed rape and sugar beet. On 24 April 2015, just two days after the Commission published its legislative proposal on the use of GM food and feed, the Commission authorised 10 new varieties for import into the EU and renewed seven existing authorisations. These authorisations had been pending for months (some for over a year), as no new authorisations were granted before the Commission had completed its review of the

decision-making process. Another 58 applications for authorisation are still pending. Of these, 17 have already been assessed by EFSA and given a positive opinion while one has had an inconclusive opinion.

The market situation in the EU differs significantly between food and animal feed. There is hardly any GM food on the market. The Commission considers this may be linked to the labelling obligations, as well as the availability of non-GM alternatives. On the contrary, the livestock sector in the EU is heavily dependent on imports from third countries of vegetable proteins, mainly soya and soymeal fed to cattle. According to Commission figures, in 2013 the EU imported 18.5 million tonnes of soymeal and 13.5 million tonnes of soybean, representing more than 60% of its plant protein needs. Most of the imports come from countries where GM crops are widely cultivated: 90% originate from four countries in which around 90% of cultivated soybeans are genetically modified.[2]

## Existing situation

Three legal acts make up the EU's legislative framework on genetically modified organisms. First, Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms covers *cultivation*. This Directive was recently amended by Directive (EU) 2015/412 of the European Parliament and of the Council, which gave Member States the possibility to ban the cultivation of GMOs within their borders, based on grounds such as agricultural or environmental policy objectives, socioeconomic impacts or other compelling grounds other than risks to human health or the environment. The new Directive entered into force on 2 April 2015.

Second, Regulation (EC) No 1830/2003 sets out the rules for *traceability and labelling* of GMOs. Labelling is compulsory for any food and feed containing GMOs.

Third, Regulation (EC) No 1829/2003 – amendment of which is the object of the current legislative proposal – covers GMOs used in *food or feed*.

All GMOs, whether intended to be cultivated, imported, used in food or feed or for other purposes, need an authorisation before they can be put on the market in the EU. Applications for authorisation are first submitted to a Member State, which sends them to the European Food Safety Authority (EFSA). In collaboration with Member States' scientific bodies[3] the EFSA assesses possible risks of GMOs to human and animal health and the environment.

In recent years there has been criticism from NGOs, the media and the European Parliament about the independence of the risk-assessment procedure of EFSA. It has been suggested that there are conflicts of interests, with members of EFSA's scientific panels having overly close ties to industry.[4] EFSA has responded to the criticism, saying that it has improved its practices. Its risk-assessment methods have also been criticised, as usually only a 90-day feeding trial (mostly with rats) is required to assess long-term risks, while some studies indicate that adverse health impacts only manifest themselves after a longer time period. Critical information contained in the research is also often classified as confidential, while access to research material is restricted, which makes independent research on GMOs difficult.

Within three months of receiving EFSA's opinion, the Commission prepares a draft implementing decision, proposing to grant or refuse authorisation. If its proposal differs from EFSA's scientific opinion, the reasons must be explained. According to Articles 7 and 19 of the current Regulation, the Commission may also take into account 'other

legitimate factors relevant to the matter under consideration'. However, the Commission indicates that it has not been in a position to justify an EU-wide ban on this basis.

The Commission's draft decision is submitted to Member States, who vote on it under qualified majority rules[5] in the Standing Committee consisting of Member States' experts. If no qualified majority is reached, the Commission can refer the matter to the Appeal Committee (or to the Council as has been done in the past).[6] If still no decision is reached, it is up to the Commission to adopt the final decision. The Commission cannot simply abstain from taking a decision. The system of prior authorisation, interpreted in the light of Article 41 of the Charter of Fundamental Rights and the case law of the Court of Justice,[7] requires the Commission to adopt a decision on an application within a reasonable period of time.

Although generally more Member States support than oppose the Commission's draft decision proposing authorisation of GM food and feed, a qualified majority has never been reached.[8] The return of a dossier to the Commission at the end of the procedure for final decision has become the norm instead of the exception – the situation being unique to GMO authorisations compared with other implementing decisions. According to the Commission, the reasons why Member States vote against authorisations of GMOs are often not based on science, but rather on other considerations reflecting national concerns.

After authorisation, Member States can only provisionally ban an authorised GMO, by invoking special safeguard or emergency clauses (article 23 of Directive 2001/18/EC or article 34 of Regulation (EC) No 1829/2003). These measures have to be based on new scientific evidence suggesting that the product poses a risk to health or the environment. Until now, however, EFSA has judged all safeguard measures taken by Member States to be scientifically unfounded. Despite this, the Council has rejected the Commission's proposals to lift national safeguard clauses. Some of these measures have been challenged in national courts or in the European Court of justice.

Member States have used these clauses mainly to prevent the cultivation of GMOs, and to a much lesser extent, to ban GM food and feed. According to the Commission, there is only one Member State which currently has measures concerning food and feed in place, relating to three products.

The European Parliament plays no part in the authorisation process itself. The only option it has is to adopt non-legislative resolutions: in January 2014 it adopted a resolution opposing the Commission proposal for a Council decision authorising the cultivation of the GM 'Maize 1507' and called on the Council to reject the Commission proposal.[9]

## The changes the proposal would bring

According to the review of the GMO decision-making process conducted by the Commission, the problem in the specific context of GMOs is that the system does not allow the individual concerns of democratically elected governments to be taken into account. The review ends up with the conclusion that the current legal framework should be amended, by extending the principles agreed in Directive (EU) 2015/412 on the cultivation of GMOs to products covered by Regulation (EC) No 1829/2003 (GM food and feed).

The Commission proposes to amend Regulation (EC) No 1829/2003 by adding a new Article 34a, allowing Member States to restrict or prohibit the use of GM food and feed in part or all of their territory, complementing the possibilities they already have concerning GMOs for cultivation.

The current authorisation system and the labelling rules would not be amended.

Member States would have to justify the measures they are adopting. They would not be allowed to use justifications related to risks to human and animal health or to the environment, as these are already assessed by the European Food Safety Authority at EU level during the authorisation procedure.

Any opt-out measures must comply with the principles of the internal market (in particular Article 34 TFEU prohibiting quantitative restrictions to free movement of goods) and the EU's international obligations, including those related to the World Trade Organization. The measures have to be based on compelling grounds in accordance with Article 36 TFEU[10] and the notion of overriding reasons of public interest as developed by the case law of the European Court of justice. Moreover, the measures need to respect the principles of proportionality and non-discrimination between national and non-national products.

In addition to newly authorised products, Member States would also be able to restrict or prohibit GM food and feed already on the market, but would have to allow operators a reasonable period of time to enable existing stocks of the product to be used up.

A Member State would have to notify the Commission of its intended measure and its justification at least three months in advance, to give the Commission and other Member States the opportunity to comment, and it should refrain from implementing those measures during this notice period. After the expiry of this three-month 'standstill period' the measures can be adopted as originally proposed, or amended to take into account comments made by the Commission or other Member States.

## Preparation of the proposal

In his political guidelines for the next European Commission, presented to the European Parliament in July 2014, Commission President Jean-Claude Juncker announced that he intended to review the legislation applicable to the authorisation of genetically modified organisms, stating that for him, 'it is simply not right that under the current rules, the Commission is legally forced to authorise new organisms for import and processing even though a clear majority of Member States is against. The Commission should be in a position to give the majority view of democratically elected governments at least the same weight as scientific advice, notably when it comes to the safety of the food we eat and the environment in which we live.'

In his mission letter to Vytenis Andriukaitis, Commissioner for Health and Food Safety, President Juncker tasked him with focussing, within the first six months of his mandate, inter alia on reviewing the existing decision-making process applied to GMOs.

The Commission's 2015 work programme set out 23 new initiatives, one of them being the review of the GMO decision-making process to 'look at how the rules could be changed to better ensure the majority view of Member States is taken into account'.

In its communication accompanying the legislative proposal, the Commission sets out the results of the review and explains the reasons behind the proposal.

There is no impact assessment accompanying the legislative proposal. The Commission only states that the practical effect of the proposal will depend on the extent to which Member States make use of its provisions.

## Parliament's starting position

In its resolution of 16 January 2014 on the authorisation of 'Maize 1507', the Parliament called on the Commission not to propose to authorise any new GMOs for cultivation and not to renew old authorisations until the risk-assessment methods had been significantly improved. The Parliament considered that the proposal for a Council decision to authorise the 'Maize 1507' exceeded the implementing powers conferred under Directive 2001/18/EC, and called on the Council to reject the Commission proposal. In the Council, 19 Member States voted against authorisation, five voted in favour and four abstained.

In its resolution of 13 January 2015 on the possibility for the Member States to restrict or prohibit the cultivation on GMOs in their territory, the Parliament stressed that risk assessments should take into account the direct, indirect, immediate and delayed effects, as well as the cumulative long-term effects on human health and the environment. The rules on risk assessment should be regularly updated to take account of developments in scientific knowledge. The Parliament also asked the Commission and the Member States to ensure there are the necessary resources for independent research on the potential risks arising from the deliberate release or placing on the market of GMOs, and to ensure that independent researchers have access to all relevant material. Parliament had requested that environmental grounds be among the reasons which Member States could use to justify their cultivation bans, but this was not accepted by Council, deeming it to belong to the risk assessment task of the EFSA.

## Stakeholders' views

In a joint press release the EU food and feed chain partners, including among others the European Association of Farmers and Agri-cooperatives – Copa-Cogeca, the European Association of BioIndustries – EuropaBio, the European Association of the Agrosupply Trade – COCERAL, and the European Compound Feed Manufacturers' Federation – FEFAC, urged the Parliament and Council to reject the Commission's proposal, claiming that it attempts to renationalise EU market authorisations. They warned that the proposal would seriously threaten the internal market and have adverse economic and social impacts. It would cause serious distortions of competition and result in substantial job losses and lower investment in the agri-food chain in 'opt-out' countries. Previously, representatives of EU farming and feed industries had often criticised the Commission, warning that delays in GM feed authorisations are jeopardising critical supplies for the sector.

A group of NGOs, including Friends of the Earth Europe, Greenpeace and the European Organisation for Organic Food and Farming – IFOAM, sent an open letter to Commission President Juncker before the proposal was tabled, saying that the attempt to shift the responsibility for GM crops from the EU to the national level would not make the EU any more democratic, as the Commission would still be able to authorise GM crops against the majority view of the Council, the Parliament and European citizens. After the proposal was published, both Friends of the Earth Europe and Greenpeace criticised it further, claiming that it gives empty promises to empower national governments to ban

GM food and feed without giving them the legal grounds to do so, offering EU countries a 'fake right' to opt out that will not stand up in any court.

The proposal could also affect the ongoing Transatlantic Trade and Investment Partnership (TTIP) negotiations between the EU and the US. The United States Trade Representative Michael Froman commented on the proposal saying he was 'disappointed' with it, stating that it appears hard to reconcile with the EU's international obligations. According to Froman, dividing the EU into 28 separate markets for circulation of certain products and proposing this kind of trade-restrictive action is not constructive.

## Advisory committees

The European Economic and Social Committee is expected to adopt its opinion in late September or early October 2015 (rapporteur: José Maria Espuny Moyano, Spain; co-rapporteur: Martin Siecker, The Netherlands).

The Committee of the Regions is likely to adopt its opinion in December 2015 (rapporteur not yet confirmed). In an opinion of January 2011 on the cultivation of genetically modified crops, the Committee of the Regions pointed out that restrictive or prohibitive measures 'must be restricted to the cultivation of GMOs, that they must not hinder the placing on the market or importing of genetically modified products or seeds and that they must be compatible with the EU's international obligations, particularly those pertaining to the World Trade Organization'.

## Council

The timeline for discussion of the proposal in the Council is yet to be made known. There have been very few reactions from Member States. Germany has been reported to be sceptical of national import bans, with a spokesman for the Agriculture Ministry warning that there could be negative effects on the free movement of goods, and the Economic Affairs Ministry's spokesman considering that national bans would raise considerable legal concerns in the WTO.

## National parliaments

Some national parliaments have already started their parliamentary scrutiny of the proposal, examining whether the draft is in compliance with the principle of subsidiarity. The deadline set for them to give Reasoned Opinions is 23 June 2015.

## Parliamentary advice

In October 2014 the EP's Policy Department A published an in-depth analysis on the state-of-play and current and future challenges of food safety. As regards GMOs, the analysis notes that the authorisation process for import and cultivation of GMOs remains controversial, and that the lack of 'public' studies, as well as the fact that most studies are funded by the industry or conducted by the companies applying for authorisation is criticised.

As there was no impact assessment from the Commission, the Ex-Ante Impact Assessment unit of the EPRS cannot carry out any initial appraisal.

## Legislative process

The responsible Committee in the EP is the Environment, Public Health and Food Safety Committee. The Agriculture and Rural Development (AGRI) and Industry, Research and

Energy (ITRE) Committees will give opinions. A first exchange of views with Commissioner Andriukaitis is due to be held on 8 June in the ENVI Committee.

## References

Possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory / European Parliament, Legislative Observatory (OEIL).

Food Safety: State-of-Play, Current and Future Challenges / European Parliament, Policy Department A, 2014.

## Endnotes

1 Cottonseed meal (byproduct remaining after the seeds are crushed and the oil extracted) and cottonseed hulls can be added to animal feed.

2 In 2013, 43.8% of imports originated from Brazil, where 89% of soybean is GM; 22.4% came from Argentina, where 100% of soybean cultivated is GM; 15.9% originated from the US, where 93% of soybean is GM, and 7.3% from Paraguay, where 95% of soybean cultivated is GM.

3 A network of over 100 organisations and authorities across Europe, including over 250 experts.

4 A decision of the European Ombudsman on a complaint against the European Food Safety Authority in May 2013 criticised EFSA for failing to assess the potential conflict of interest arising from the move of a former member of its staff to a biotechnology company.

5 As from 1 November 2014, a qualified majority is defined as at least 55% of the 28 Member States, comprising at least 15 of them and representing at least 65% of the EU population (Article 16(4) of the Treaty on European Union). Former rules on qualified majority (applied before the Lisbon Treaty) can still be applied until 31 March 2017, if any Member State requests it.

6 Examination procedure set out in Regulation (EU) No 182/2011.

7 CJEU, C-390/99, Canal Satélite Digital SL, par.41. In September 2013 the European Court of Justice found that the European Commission had failed to forward the application for cultivation of GM 'Maize 1507' in a timely manner and had failed to put the matter to a vote in the Council without delay.

8 Tables of the voting results are represented in the Annex to the Commission Communication on reviewing the decision-making process on genetically modified organisms (GMOs).

9 The Commission has still not authorised the 'Maize 1507', and EFSA is currently reconsidering its risk management advice on it in the light of new research results suggesting that maize pollen can travel further than previously assumed. EFSA's assessment is due to be completed by the end of May 2015.

10 Article 36 TFEU: 'The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.'

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