

Imports of GM food and feed Right of Member States to opt out

SUMMARY

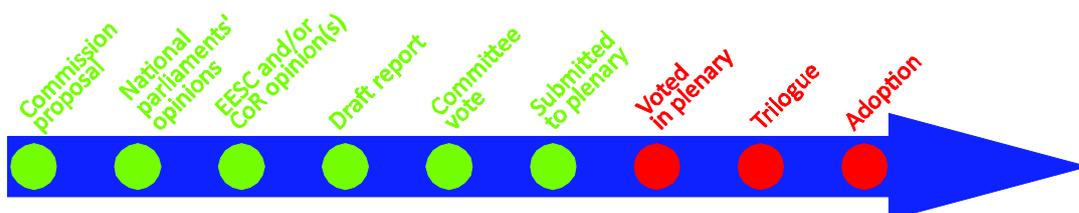
All genetically modified organisms (GMOs) need authorisation before they can be placed on the EU market. However, a qualified majority among the Member States has never been reached either in favour of or against any authorisation proposal put forward by the Commission.

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

<i>Committee responsible:</i>	Environment, Public Health and Food Safety (ENVI)	COM(2015) 177 of 22.4.2015
<i>Rapporteur:</i>	Giovanni La Via (EPP, Italy)	<i>procedure ref.:</i> 2015/0093(COD)
<i>Next steps expected:</i>	Vote in plenary at October III session (26-29 October 2015)	Ordinary legislative procedure



This briefing updates an earlier edition, of 3 July 2015: [PE 564.394](#).

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Introduction

On 22 April 2015, the Commission [proposed a Regulation](#) enabling 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 the EU market. This 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 among 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 Parliament and 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.

According to the [EU Register of authorised GMOs](#), there are 67 GMOs authorised for food and feed use in the EU. These include maize, cotton,¹ soybean, oilseed rape and sugar beet. On 24 April 2015, just two days after publishing 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. In October 2015 there were 43 applications for authorisation pending. Of these, six have already been given a positive opinion by EFSA, while three 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, to feed cattle, pigs and poultry. 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 not linked to risks to human health or the environment. The new Directive entered into force on 2 April 2015.³

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

Third, 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.

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 cooperation with Member States' scientific bodies,⁴ 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 EFSA risk-assessment procedure. It has been suggested that there are conflicts of interest, with members of EFSA's scientific panels having overly close ties to industry.⁵ EFSA has responded to this criticism by suggesting 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 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 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 rules⁶ 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).⁷ If still no agreement 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,⁸ requires the Commission to adopt a decision on an application within a reasonable period of time.

Although in general more Member States support than oppose draft Commission decisions proposing authorisation of GM food and feed, a qualified majority has never been reached.⁹ The return of a dossier to the Commission for final decision has become the norm rather than the exception – this 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 Parliament plays no part in the authorisation process itself. The only option it has to act 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 GM 'Maize 1507' and called on the Council to reject the Commission proposal.¹⁰

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 concludes 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 of the Treaty on the Functioning of the European Union (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 TFEU¹¹ 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 notification 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 focusing, within the first six months of his mandate, 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 '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 Member States to restrict or prohibit the cultivation of 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 Member States to ensure the necessary resources are available 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, which deemed it to belong to the risk assessment tasks of 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 agrifood chain of 'opt-out' countries. In its [position paper](#), EuropaBio warns that if the proposal is adopted, the image of the EU as an unreliable export market will limit the European farmers' access to essential raw materials.¹² 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 United States. The US Trade Representative, Michael Froman [commented](#) on the proposal saying he was

'disappointed' with it, stating that it appears difficult 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.

In April 2015, the Organisation for Economic Co-operation and Development (OECD) published two [consensus documents](#) from its Task Force on Safety Assessment of Foods and Feeds derived from Transgenic Crops. These concluded that the scientific evidence to date is that GM varieties are compositionally equivalent to conventional varieties, and therefore there is no difference between GM crops and conventional crops.

At a July 2015 meeting of the World Trade Organization's Sanitary and Phytosanitary Measures (SPS) Committee, Argentina, Paraguay, USA, Uruguay, Brazil and Canada reportedly [contested](#) the proposed new EU legislation allowing individual EU Member States to ban products without a risk assessment.

Advisory committees

The European Economic and Social Committee (EESC) adopted its [opinion](#) on 16 September 2015 (rapporteur José María Espuny Moyano, Spain; co-rapporteur Martin Siecker, the Netherlands). The EESC welcomes the fact that the Commission is taking action to find solutions to an approval system which has proved inadequate in practice. The Committee regrets, however, that the proposal did not provide a socio-economic impact study of the proposals, and has reservations about the possibility of implementing the rules in the single market and about certain legal aspects. The EESC advises the Commission to withdraw the proposal, as currently worded, and to draw up an improved proposal that addresses the shortcomings identified in the EESC opinion and in recommendations made by the European Parliament.

The Committee of the Regions (CoR) adopted its [opinion](#) on 13 October 2015 (rapporteur Mark Weinmeister, EPP, Germany). In its opinion, the CoR recommends that the proposal for a regulation be rejected. The CoR is surprised that the promise of a review has yielded only a proposal on the use of genetically modified food and feed, as opposed to a radical revision of the authorisation procedure as earlier indicated by the Commission. The CoR remarks that Member States may be motivated to abstain or to vote against authorisation because of concerns relating not only to the scientific assessment but also to issues outside the scope of the EFSA risk assessments, and states that it is imperative that there be a way of taking concerns, including non-scientific concerns, into account in the decision-making process.

The CoR notes that Member States should be granted the right to adopt decisions at national level to restrict or to ban the use of GMOs in food and feed that are authorised at EU level, and regrets the failure to provide a list of examples of legally watertight grounds on which a national prohibition could be justified.

Council

The Agriculture and Fisheries Council discussed the proposal in its meeting on 13 July 2015. The Member States were [reported](#) to be highly sceptical of the proposal, urging the Commission to provide an impact assessment and asking the Council legal service to conduct an analysis of the proposal before they could continue work on it.

At this meeting, delegations from Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Lithuania, Romania, Slovakia, Slovenia, Spain

and the United Kingdom considered that the proposal would be contrary to the single market. Hungary, Malta and Sweden wanted more information from the Council legal service before taking a position.

Council deliberations at technical level have not started yet, but are expected to start soon after the plenary vote in the EP.

National parliaments

By 15 October 2015, parliaments in 19 Member States were in the process of [examining](#) the proposal. In eight countries the scrutiny process has been completed. Two Reasoned Opinions have been received, from the Dutch House of Representatives and the Spanish Cortes Generales, and a third Reasoned Opinion was being drafted by the Romanian Chamber of Deputies.

The [Dutch Parliament](#) considers that the proposal does not comply with subsidiarity and doubts whether the opt-out offered to the Member States is compatible with the operation of the European internal market from a legal point of view. It rejects the proposal to assign the power to restrict or prohibit GMOs to the Member States, because ensuring a level playing field between the Member States is one of the most important tasks of the European Commission.

The [Spanish Parliament](#) considers the proposal to be in breach of the principle of subsidiarity, stating that the proposal would lead to legal uncertainty, unforeseen costs and would break the internal market. The prohibition of 'use' could be extended by some Member States for operations such as transit through, storage or processing in their territory, endangering the free movement of goods. In addition, although products derived from animals fed with genetically modified feed do not need to be labelled as such, the re-nationalisation of GM authorisations could trigger a demand for national labelling requirements to protect farmers of Member States which have decided to ban the use of products derived from GMOs. This would constitute a barrier to imports for animal products from countries with no such prohibition in place.

The Romanian Senate judged the proposal to be in compliance with the principle of subsidiarity and considered that each Member State must have its own policy regarding the use of GMOs in food and feed. The [Romanian Chamber of Deputies](#), however, found the proposal to be in breach of subsidiarity and was drafting a Reasoned Opinion, noting that the proposal is ambiguous and does not provide sufficient legal and technical elements to allow Member States to formulate a well-reasoned opinion.

The [Croatian Parliament](#) and the [Czech Senate](#) supported the initiative of the European Commission to introduce a legal framework allowing Member States to decide on the use of GM food and feed. The Czech Senate stressed that any prohibition or restriction must not pose limitations on the transport of these goods. The Croatian Parliament indicated, nevertheless, that it could not at present endorse in full the submitted text of the Regulation due to a number of open issues, in particular that the Regulation should clearly define legally defensible factors allowing Member States to restrict or prohibit the use of GM food and feed in order to safeguard their own national interests. It also expressed the view that Member States should be allowed to decide on the restriction or prohibition without indicating the reasons.

Parliamentary analysis

In October 2014, the EP's Policy Department for Economic and Scientific Policy 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 criticises the fact that most studies are funded by industry or conducted by companies applying for authorisation and are not publicly available.

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 committee responsible in the EP is the Environment, Public Health and Food Safety (ENVI) Committee. A first exchange of views with Commissioner Andriukaitis was held on 8 June 2015 in the ENVI Committee. On 9 June 2015 the coordinators agreed that the ENVI Chair, Giovanni La Via, would draft a report proposing the rejection of the Commission proposal.

The Agriculture and Rural Development (AGRI) Committee adopted its opinion on 3 September 2015, calling for the ENVI Committee to propose rejection of the Commission proposal.

The ENVI Committee adopted its draft report on 13 October 2015. The [report](#) (rapporteur: Giovanni La Via, EPP, Italy) rejects the Commission proposal and calls on the Commission to withdraw it.

In the explanatory statement the rapporteur refers to concerns expressed by Members of the ENVI Committee in the exchange of views with Commissioner Andriukaitis, including the lack of an impact assessment, the compatibility of measures taken by Member States with Internal Market and WTO rules, the practicability of the proposal as well as discontent that the decision-making process itself (i.e. the authorisation procedure for GMOs) was not reviewed. The rapporteur considers that the proposal may seriously endanger livestock production, which remains dependent on proteins from GM sources, and harm EU agriculture. In addition, he considers that it would be almost impossible to implement, as border controls no longer exist within the EU's agricultural sector. Also, the proposal contains no definition of the term 'use'. According to the rapporteur, the proposal fails to ensure the necessary legal certainty and adequate tools for Member States wishing to ban the use of GM food and feed.

As noted above, the Council has yet to take a position on the proposal.

The plenary vote at first reading is scheduled for the October III session

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 By 4 October 2015, 19 Member States had [demanded](#) a restriction of the geographical scope for a GMO application or authorisation for cultivation to exclude parts or all of their territory.
- ⁴ A network of over 100 organisations and authorities across Europe, including over 250 experts.
- ⁵ 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.
- ⁶ 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, on Member State request.
- ⁷ Examination procedure set out in Regulation (EU) No 182/2011.
- ⁸ 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.
- ⁹ 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).
- ¹⁰ The Commission has still not authorised 'Maize 1507'. EFSA recently [reassessed](#) its risk management advice in the light of research suggesting that maize pollen can travel further than previously assumed. The [conclusion](#) of the reassessment was, however, that the initial recommendations remain valid and that an isolation distance of 30 metres between protected habitats and the nearest field of 'Maize 1507' remains valid.
- ¹¹ 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.'
- ¹² EuropaBio has also drafted an [infographic](#) comparing the voting behaviour of different Member States in the GM approval process to their annual per-capita soya imports.

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