

1.



Brussels, 22.4.2015
COM(2015) 176 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

Reviewing the decision-making process on genetically modified organisms (GMOs)

1. INTRODUCTION

The European Commission was appointed on the basis of the set of Political Guidelines it presented to the European Parliament. In these Guidelines, the Commission made a commitment to review the current legislation on the authorisation of genetically modified organisms (GMOs).

This Communication reports on the results of the Commission's review of the decision-making process for authorising GMOs and sets out the rationale that has led to the legislative proposal adopted by the Commission¹.

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.

It explains the conclusion reached by the Commission and the considerations taken into account in drawing this conclusion: the exceptional circumstances specific to GMOs which underlie the commitment in the Political Guidelines, in particular the democratic and legal issues.

2. THE DECISION-MAKING PROCESS IN THE FIELD OF GMOs

2.1. 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 feed² ("the 2003 Regulation") covers food, food ingredients, and feed containing, consisting of or produced from GMOs. It also covers GMOs for other uses such as cultivation, if they are to be used as source material for the production of food and feed. All above, as covered by the 2003 Regulation, are hereafter referred to as "GM food and feed".

The other piece of legislation in this area is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms³ ("the 2001 Directive"). 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. In view of this, a scientific risk assessment is at the centre of the procedure: every authorisation for placing a product on the market must be duly justified, and the main ground on which such a justification can rely is scientific

¹ 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 (COM 2015/177).

² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

³ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

assessment⁴. The legislation gives responsibility for scientific risk assessments to the European Food Safety Authority (EFSA), in cooperation with the Member States' scientific bodies.

From a legal point of view, decisions to authorise GMOs take the form of implementing acts adopted by the Commission⁵. Whilst the Commission therefore plays a decisive role in the authorisation process, Member States are also very much involved.

Member States' involvement at the authorisation stage

Member States are involved at two stages: they vote on draft decisions tabled by the Commission in the Standing Committee, and, if no decision can be reached at that level, they then vote in the Appeal Committee.⁶ As in all other committees set up under EU legislation, Member States vote in these committees under the rule of the qualified majority, as defined in the Treaty⁷.

Where there is no qualified majority in favour of or against the draft decision in the Appeal Committee, the result is “no opinion”.

Final adoption by the Commission

The rules governing this procedure (Regulation (EU) No 182/2011⁸) provide that where “no opinion” is issued by the Appeal Committee, “*the Commission may adopt the draft implementing act*”⁹. This wording implies that the Commission can exercise a certain amount of discretion¹⁰. In the case of decisions relating to GMOs, however, the 2003 Regulation and the 2001 Directive significantly reduce its margin for manoeuvre. 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 Justice¹¹, requires the Commission to adopt a decision (authorising or prohibiting placing the product on the EU market)

⁴ Articles 7 and 19 of Regulation (EC) No 1829/2003 provide that the Commission may, take into account “*other legitimate factors relevant to the matter into consideration*”, in addition to the opinion issued by EFSA.

⁵ In accordance with the examination procedure set out in Regulation (EU) No 182/2011.

⁶ Where the Standing Committee issues a negative opinion (a qualified majority against) or “no opinion”, the Commission may decide to refer the matter to the Appeal Committee.

⁷ Article 16(4) and (5) of the Treaty on European Union. As of 1 November 2014, a qualified majority is defined as votes representing at least 55% of the 28 Member States, and at least 65% of the EU population.

⁸ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

⁹ Article 6(3) of Regulation (EU) No 182/2011.

¹⁰ This differs from the previous procedure set out in Council Decision 1999/468/EC. Under that procedure, the Commission had no margin of manoeuvre in case where the Council was unable to issue an opinion in favour or against the proposed measures. Where the Council issued a “no opinion” (or where the Council did not arrive to any opinion within three months), the Commission was obliged to adopt the proposal submitted to the Council.

¹¹ See in particular CJEU, C-390/99, Canal Satélite Digital SL, according to which prior authorisation procedures, such as the system of authorisation for GMOs and GM food and feed, prevent a product from being placed on the market without authorisation and are therefore compatible with the Treaty on the Functioning of the European Union (TFEU) only to the extent that: 1) they are justified by legitimate reasons (e.g. assessment of the potential effects on health and the environment), and 2) they are not, with respect to their duration, the amount of costs to which they give rise, or any ambiguity as to the conditions to be fulfilled, such as to deter the operators concerned from pursuing their business plans.

within a reasonable period of time. This means that where the legislation prohibits the placing of a product (in this case, a GMO) on the market unless it is authorised, it is not possible for the authorising body (in this case, the Commission) to simply abstain for an unlimited period of time from taking any decision (be it authorising or prohibiting the product) assuming that a valid request for authorisation had been submitted. Where a vote results in “no opinion”, the Commission cannot therefore simply abstain from taking a decision.

Possible emergency measures at EU or Member State level

The 2003 Regulation contains provisions allowing the Commission or Member States to adopt emergency measures to prevent the placing on the market or use of an authorised GMO. Recourse can only be made to such measures if there is scientific evidence demonstrating that the product is likely to pose a serious risk to health or to the environment.

2.2. The reality of decision-making for the authorisation of GMOs

Since the entry into force of Regulation (EC) 1829/2003, 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 feed¹². The result has always been “no opinion”. This has consistently been the case at all stages of the procedure (both in the Standing Committee and in the Appeal Committee, under the current rules, and in the Council in the past) (see Tables 1 to 3 and Graph 1 of the Annex).

GMOs for cultivation

The cultivation of GMOs in the EU is limited. Since 1990, only three GMOs have been authorised for cultivation, and only one product (MON810 maize) is currently authorised. It is cultivated in five Member States and the areas on which it is grown represent only 1.5% of the total area of land devoted to maize production in the EU¹³.

The low number of authorisations for cultivation granted to date, as well as the safeguard clauses adopted by a number of Member States to prevent the use of GMOs authorised by EU legislation¹⁴, both illustrate the position of many Member States on this issue. The resistance to GMOs in cultivation has increased in recent years, with many Member States opposing the authorisation of maize 1507 in the Council in February 2014¹⁵ (see Table 1 of the Annex).

¹² Only two GMOs are authorised in the Union for uses other than cultivation and food and feed. They are types of carnation flowers authorised for placing on the market for ornamental use. The voting pattern on such GMOs is similar to that seen for food and feed authorisations. The result of the votes was always “no opinion”, with more Member States voting in favour than against. Voting patterns appears to be consistent, irrespective of whether the GMO is authorised for cultivation, food and feed or for other purposes.

¹³ 148 660 ha in 2013, primarily in Spain (136 962 ha), with smaller areas in Portugal, the Czech Republic, Romania and Slovakia.

¹⁴ Nine Member States have introduced safeguard clauses preventing the placing on the market and use on their territory of the only GMO currently authorised for cultivation in the EU.

¹⁵ When the Standing Committee was asked to vote on an authorisation for MON810 maize in 1998, there was a qualified majority in favour (and the Council was therefore not required to vote): 10 Member States in favour, 1 Member State against, 4 Member States abstained. When the decision on the Amflora potato was submitted to the Council vote in 2007, there was no opinion: 10 Member States in favour, 11 against and 6 abstained. When 1507 maize and Bt 11 maize were submitted to the vote of the

GM food and feed

The number of GM food products available for purchase is small (even though the joint authorisation with feed means that a larger number are authorised). Evidence from opinion surveys confirms the general impression that EU citizens are opposed to GM food¹⁶. Many food retailers have chosen not to place GM food on shelves. This may be as a result of the labelling requirements¹⁷ for GM food, and also the availability of non-GM alternatives.

Some consumers want to be sure that there are no GMOs involved at any stage of the production of the food they buy. A number of livestock producers, traders and retailers, in various Member States, have therefore tried to make their avoidance of GMOs a selling point. This has led to the use of labels such as “fed with GM-free feed”¹⁸ or organic.

In contrast to the situation observed for GM food, there is a substantial market in the EU for GM feed. This is particularly true for compound feed, a mixture of feed materials for farm animals used for its high energy and high protein content. Most of the feed used in the EU is imported (over 60% of the EU’s plant protein needs being met with imports in 2013 – essentially soybean and soya meal), and imports come mainly from countries where cultivation is dominated by GMOs – 90% of imports originate from countries where around 90% of the land used for soybeans is planted with GM soybean¹⁹. The main reasons for the widespread use of GM soymeal appear to be availability, price²⁰ and competitiveness²¹.

The fact that GM feed is widely used has not, however, affected voting patterns. Votes on GM food and feed continue to systematically lead to “no opinion” (see Tables 2 and 3 and Graph 1 of the Annex). While voting positions have broadly stabilised over time, there is typically more Member States supporting the draft decision than opposing to it.

Whilst Member States have been keen to introduce safeguards clauses to prevent the use of GMOs for cultivation, they have not been widely used for GM food and feed (with only one Member State currently having measures in place, relating to three products).

Standing Committee in 2009, there was no opinion: 6 Member States were in favour, 12 Member States against and 7 abstained. When maize 1507 was submitted to a vote in the Council in 2014, there was no opinion: 5 Member States in favour, 19 Member States against and 4 Member States abstained (informal vote).

¹⁶ A Special Eurobarometer survey on biotechnology published, in October 2010, indicated that EU citizens do not see genetically modified food as offering benefits, consider genetically modified foods as likely to be unsafe or even harmful, and are not in favour of the development of genetically modified food.

¹⁷ According to Regulation (EC) No 1829/2003, the labelling of food products containing or consisting in GMOs as well as all food and feed derived from GMOs must indicate the presence of the genetic modification. The legislation allows food and feed not to be labelled as genetically modified if genetically modified material is present in not more than 0.9 per cent of the food and feed ingredients considered individually or of the food and feed consisting of one single ingredient, provided that this presence is adventitious or technically unavoidable.

¹⁸ In practice, the market remains small, with only a relatively limited range of such products available.

¹⁹ In 2013, 43.8% of the EU feed imports originated from Brazil where 89% of soybean cultivation was GM; 22.4% originated from Argentina where 100% of soybean cultivation was GM; 15.9% originated from the United States where 93% of soybean cultivation was GM; 7.3% originated from Paraguay where 95% of soybean cultivation was GM. Source: Eurostat and International Grains Council.

²⁰ Industry figures suggest that a price premium of around 40 EUR per tonne is paid for long term contractual agreements, raising to up to 100 EUR per tonne on the spot market for non-GM feed.

²¹ The purchase of compound feed represents over 32% of the value of EU livestock production.

Nevertheless, the number of Member States voting against the authorisation of GM food and feed shows that Member States do not feel that the process allows them to fully address their individual concerns.

Conclusion on the decision-making process

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 whole²². The issues raised by Member States who have opposed authorisations are most often not based on scientific considerations, but reflect national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment.

Whilst the current legislation allows the Commission to take into consideration “other legitimate factors”, in addition to the risk assessment carried out by EFSA, it has not been in a position to justify an EU-wide ban on products considered safe by EFSA on the grounds of these factors²³.

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. This situation is specific to the granting of GMOs authorisations.

3. THE 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”). In the explanatory memorandum of the proposal, the Commission explained that “*national, regional or local levels of decision-making are considered to be the most appropriate frameworks to address the particularities linked to GMO cultivation*”. The proposed amendment has now been adopted into EU law as Directive (EU) 2015/412²⁴ (“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. This is a major development, as it allows Member States to take into account their national context, where there might be legitimate grounds for restricting or prohibiting GMO cultivation, other than those related to risks to

²² In 2012, 1946 votes took place under the EU comitology procedure in Standing Committee. Of these, only 82 votes resulted in “no opinion”. Nine of these procedures were referred to the Appeal Committee. (The corresponding figures for 2013 and 2014 are respectively as follows: 1959/53/28; and 1908/46/21).

²³ The use by the Commission of the “other legitimate factors” mentioned in Regulation (EC) No 1829/2003, as grounds to refuse to grant the authorisation could only be legally defensible if justified by overriding reasons of public interest of the same nature as those mentioned in Article 36 TFEU and in the related case-law of the Court of Justice (see, for example, CJEU, 20.02.1979, Case 120/78 Rewe-Zentral (Cassis de Dijon), [1979] ECR 649) and by objectives of general interest as referred to in Article 52(1) of the Charter of Fundamental Rights and in the relevant case law of the Court of Justice (see for example CJEU, 12.07.2012, Case C-59/11, Association Kokopelli, ECLI:EU:C:2012:447).

²⁴ Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 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 (OJ L 68, 13.3.2015, p. 1).

health and the environment. Member States can therefore take account of considerations beyond those covered by the EU system of authorisation, which is focussed on scientific assessment and operates within the limits imposed by EU law. The provision applies to both future authorisations and to GMO that have already been authorised at EU level.

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. The Directive thus addresses one of the main concerns voiced over years in relation to the authorisation procedure, and is fully in line with the approach set out in the Political Guidelines presented by the Commission to the European Parliament.

The 2015 Directive only applies, however, to GMOs for cultivation and not to GM food and feed, which represent the majority of the authorisations granted in the EU.

4. THE COMMISSION PROPOSAL

In view of the above considerations, 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 – that is, criteria other than those assessed by EFSA in its risk assessment²⁵.

The measures adopted by Member States must be compatible with the rules on the internal market, and in particular with Article 34 TFEU, which prohibits measures that would have an effect equivalent to a quantitative restrictions on the free movement of goods. Member States making use of this proposal will therefore need to justify the measures introduced on grounds in accordance with Article 36 TFEU and the case-law of the Court of Justice on overriding reasons of public interest²⁶. 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. When exercising this new competence, Member States remain fully bound by their international obligations, including WTO rules.

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. The EU would have a consistent set of rules for GM authorisations for cultivation and for food and feed. As in the case of the 2015 Directive, the practical effect of the proposal will depend on the extent to which Member States make use of its provisions.

The Commission believes this to be the right way of addressing the challenges in relation to the decision-making process at EU level.

In making this proposal, the Commission has taken into consideration the following key parameters:

²⁵ 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 (COM 2015/177).

²⁶ CJEU, 20.02.1979, Case 120/78 Rewe-Zentral (Cassis de Dijon), [1979] ECR 649.

- First, the Commission considers that it is important to maintain a single risk-management system, based on independent risk assessment in preference to a system involving national authorisations with mutual recognition. A single risk management system is the most effective way of ensuring the same level of protection throughout the EU, as well as the functioning of the internal market.
- Second, Article 41 of the Charter and the case-law of the Court on prior authorisation regimes oblige the Commission as risk manager to take decisions on applications for authorisation. The Commission is not permitted to put decisions indefinitely on hold, i.e. to effectively impose moratoria on authorisations.
- Third, the EU's existing legal and institutional framework must be respected. The relative voting weight of Member States in the Council is set out in the Treaties and the Regulation governing the adoption of implementing acts is based on these voting rules. The same Regulation also set out the rules to be applied in situations where there is no qualified majority supporting or opposing a draft implementing measure. These rules apply to all policy areas. The Commission does not consider it justified to depart from the horizontal procedural rules agreed to implement the EU *acquis*.

5. CONCLUSION

The Commission considers that it is appropriate to adapt the legal framework for decision-making on GM food and feed. 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. The Commission proposes to allow Member States to use legitimate factors to restrict or prohibit the use of GMOs on their territory, whilst ensuring that the measures are in line with the rules on the internal market and with the institutional framework of the EU. This will enable Member States to address at national level considerations which are not covered by the EU decision-making process.

As equally indicated in the Political Guidelines, the Commission is committed to deepen the internal market. The conclusions drawn in this Communication concern the problems that have arisen in the context of the decision-making process for implementing acts on GMOs, and cannot be extrapolated beyond this particular context.

The Commission therefore proposes to the European Parliament and to the Council an amendment to the GM food and feed legal framework to extend the solution agreed at the beginning of this year by the European Parliament and by the Council on GMO cultivation to GM food and feed.