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

2015/0093(COD) - 22/04/2015 - Document attached to the procedure

This Communication from the Commission reports on the results of the Commission's 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.

Commission's 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 Commission's opinion, the EU should have a consistent set of rules for GM authorisations for cultivation and for food and feed.