Genetically modified organisms (GMOs): possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory

2010/0208(COD) - 13/07/2010 - Legislative proposal

PURPOSE: to amend Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

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

BACKGROUND: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and Regulation (EC) No 1829/2003 on genetically modified food and feed establish a comprehensive legal framework for the authorisation of genetically modified organisms (GMOs), which is fully applicable to GMOs to be used for cultivation purposes throughout the EU as seeds or other plant propagating material.

Under this set of legislation, GMOs for cultivation shall undergo an individual risk assessment before being authorised to be placed on the Union market. The aim of this authorisation procedure is to ensure a high level of protection of human life and health, animal health and welfare, the environment and consumer interests, whilst ensuring the effective functioning of the internal market.

Once a GMO is authorised for cultivation purposes in accordance with the EU legislative framework on GMOs and complies, as regards the variety that is to be placed on the market, with the requirements of EU legislation on the marketing of seed and plant propagating material, Member States are not authorised to prohibit, restrict, or impede its free circulation within their territory, except under the conditions defined by EU legislation.

Experience has shown that cultivation of GMOs is an issue which is more thoroughly addressed by Member States, either at central or at regional and local level. Contrary to issues related to the placing on the market and the import of GMOs, which should remain regulated at EU level to preserve the internal market, cultivation has been acknowledged as an **issue with a strong local/regional dimension**. In accordance with Article 2(2) TFEU Member States should therefore be entitled to have a possibility to adopt rules concerning the effective cultivation of GMOs in their territory after the GMO has been legally authorised to be placed on the EU market.

In this context, it appears appropriate to **grant to Member States**, in accordance with the principle of subsidiarity, **more freedom to decide whether or not they wish to cultivate GMO crops on their territory** without changing the system of Union authorisations of GMOs and independently of the measures that Member States are entitled to take by application of Article 26a of Directive 2001/18/EC to avoid the unintended presence of GMOs in other products.

IMPACT ASSESSEMENT: the Commission considers that the **amendment of the legislation is necessary** to get the right balance between maintaining the EU system of authorisations based on the scientific assessment of health and environmental risks and the need to grant freedom to Member States to address specific national or local aspects raised by the cultivation of GMOs.

This approach, while preserving the EU authorisation system of GMOs as well as the free circulation and import of GM food, feed and seeds, is expected to address the demands of several Member States and

receive public support. It is also estimated that the potential economic and social benefits of this proposal are likely to outweigh the potential disadvantages.

Member States may be in a more appropriate position to carry out their own impact assessments to justify their decisions about cultivation of GMOs in their territories at national/regional/local levels.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal amends Directive 2001/18/EC by introducing a new Article which **allows Member States to restrict or prohibit the cultivation of authorised GMOs** in part or all of their territories on **grounds other than those covered by the environmental risk assessment** under the EU authorisation system and those related to avoiding the unintended presence of GMOs in other products.

This amendment will apply to GMOs authorised for cultivation either under Directive 2001/18/EC or Regulation (EC) No 1829/2003 which also covers applications for cultivation if they concern GMOs that are intended as source materials for the further production of food and feed. It will equally apply to cultivation of all varieties of seed and plant propagating material placed on the market in accordance with relevant EU legislation.

The freedom which Member States will obtain will only concern the act of GMO cultivation, but not the placing on the market and import of authorised GM seeds which must continue unimpeded within the framework of the internal market and the respective international obligations of the Union. The proposal sets out two series of conditions under which Member States can take measures:

1. As the assessment of the safety of GMOs for human/animal health and the environment is carried out at EU level, Member States have the possibility under the existing legal framework to invoke the special procedures of the safeguard clause of Directive 2001/18/EC (Article 23) or the emergency measure of Regulation (EC) No 1829/2003 (Article 34) in case they have serious grounds to consider that the authorised product is likely to constitute a serious risk to health and environment. Consequently, the proposal stipulates that Member States cannot invoke protection of health and environment to justify a national ban of cultivation of GMOs outside these special procedures.
2. Member States can thus invoke grounds (other than those covered by the environmental risk assessment under the EU authorisation system) to restrict or prohibit cultivation of GMOs in their territories. The measures taken by the Member States have to be in conformity with the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU), in particular as regards the principle of non-discrimination between national and non-national products and the provisions on quantitative restrictions of trade between Member States (Articles 34 and 36 TFEU). They should finally be consistent with the international obligations of the EU, and in particular with the ones established under the World Trade Organisation (WTO).

BUDGETARY IMPLICATIONS: this proposal has no financial implications for the Union budget. It will have no impact on small or medium-sized undertakings different than the impact of the current situation.