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Questions and answers on the evaluation of the European Union's GMO legislation

Why did the Commission carry an evaluation of the GMO legislation?

As part of the continuous process of reviewing the existing legislation and the improvement of its implementation, the Commission carried out an evaluation of the Genetically Modified Organisms' (GMO) legislation between 2009 and early 2011. Two different consultancies addressed GMO cultivation and GM food and feed aspects. The main goal was to collect facts and opinions, particularly from stakeholders and competent authorities. The evaluations assessed the effectiveness and efficiency of the legislative processes and formulated options for the improvement and adjustment.

The evaluation on GM food and feed was finished in July 2010 and the one on cultivation was ready in March 2011. These evaluations were followed by a Commission analysis of policy consequences.

What is the key finding of these evaluations?

The evaluations found that the legislation's objectives for safety on health and environment and the creation of an internal market remain consistent with the needs of society, but are not being fully met as intended by the legislators. The authorisation process could be made more efficient and transparent. There is a risk that trade disruptions could become more frequent and severe and affect more products as more GMOs are approved outside Europe.

What are the reasons behind the "dysfunction" of the GMO legislation?

According to the evaluation, the EU operates an approval system built on a science-based safety assessment for products that many in Europe, including several Member States governments, object to on socio-economic and ethical grounds. This is particularly the case for the cultivation of GMOs. There is a general understanding amongst most Member States and other stakeholders that the use of national safeguard measures, while presented as having a scientific justification, is sometimes an expression of political objections.

What is needed to improve this situation for GMO cultivation?

The consultation revealed support in various Member States for options that would provide Member States with more flexibility and freedom on GMO cultivation. The Commission's package of July 2010, which presents options to allow more choice to Member States in deciding whether to cultivate GMOs are an attempt to meet that challenge. The co-existence recommendation included in that package could provide more flexibility than those introduced under the previous guidelines and more opportunities to define "GMO-free" areas.

The environmental risk assessment has scope for greater harmonisation and more explicit guidelines. The evaluation concludes that asking Member States to formally accept such guidelines could help to align otherwise diverse Member State concerns. On the basis of revised European Food Safety Authority (EFSA) guidance, the Commission has also initiated discussions with Member States and stakeholders to transform the EFSA guidelines into a legal text.

The Commission published in April 2011 a report on socio-economic implications of GM crops, based on contributions from the Member States as requested by the 2008 Environment Council Conclusions. The Commission followed up by launching on 18 October 2011 a process to aid Member States collect and share information.

What is needed to improve the situation for imported products?

The evaluations conclude that there is an expected increase in the number of countries growing GM crops, as well as increases in the type of GM crops. The developments are likely to result in an increasing number of applications for authorisation in the EU, which could lead to an increasing number of issues with asynchronous authorisations, i.e. low level presence (LLP) of unauthorised GMOs in imported products (feed, food and seeds).

The primary answer to these developments is to improve the functioning of the different steps of the authorisation procedure. In addition, while there is generally a simple majority of votes from Member States in favour of authorisations, adjustments are needed if qualified majority votes are to be a realistic prospect.

In the coming weeks, the Commission will present to Member States a draft Regulation that will define more precise requirements for the submission of applications for GM food and feed. This aims to streamline the safety assessment by detailing clearly which type of studies are required and which protocols have to be applied. The adoption of this Regulation should also result in a better support of Member States on decisions of authorisation since they will be based on commonly agreed rules.

The Commission is addressing the problem of LLP of unauthorised GMOs through a step-by-step approach, tackling the affected sectors in order of priority. A regulation addressing LLP in feed imports entered into force on 15 July 2011. The Commission is assessing and monitoring the effects of this first measure.

What other concrete areas for improvement have been identified?

Post-market environmental monitoring raises particular challenges. It requires greater harmonisation and standardisation of data collection and analysis and better guidelines for monitoring and reporting by Member States and by companies.

A harmonised - voluntary - approach to GMO-free labelling would allow fairer competition between EU operators, minimise operational expenses and make it easier to build market share in the GM-free sector.

How is the Commission addressing these findings?

The work of the Commission over the past year and a half is in line with the evaluations and addresses many of its recommendations. There is a full package of ongoing actions in key areas such as

- the need for more flexibility on GMO cultivation,
- the LLP solution ,
- the compilation of technical information on the socio-economic implications of GMO cultivation,
- the assessment of new plant breeding techniques,
- the reinforcement of monitoring activities,
- the review and transformation of the risk assessment guidelines into legal documents approved by Member States,
- and the upgraded communication activities on GMO issues, to name a few.

An important area of work aims at ensuring better use of expertise and for increased Member States' input during the entire risk assessment process. EFSA has put in place a substantial number of initiatives to this end. In particularly, Member States' engagement in EFSA's Scientific Network for the Risk Assessment of GMOs is fundamental for the harmonisation of risk assessment practices.

Before the end of the year, the Commission will launch a study to take detailed stock of existing GMO-free labelling systems and to assess the need for harmonisation in this field.

Is the Commission going to overhaul the GMO legislation?

The evaluation reports confirm that the "dysfunction" of the GMO legislation in practice does not stem from its design or its objectives, which remain pertinent, but rather from the difficult political context in which it is implemented. Better implementation of the existing legislation and carefully designed measures addressing political issues are the best way forward. The evaluation provides a substantive amount of material for fine tuning ongoing adjustments of the system.

What is the present situation concerning the marketing of GM products in the EU?

There are two GMOs that are commercially cultivated in the EU, one GM maize – MON810- and a GM starch potato, known as the "Amflora" potato. In 2010, MON810 was cultivated on almost 89.000 hectares in five Member States and the Amflora potato on 265 hectares in three Member States. The cultivation of MON810 maize concentrates in regions with high levels of corn borer infestations (a pest affecting both the quality and the quantity of the harvest), whilst the potato is cultivated near processing plants.

The availability of GM-labelled food products in the EU is extremely limited. The range of GM-labelled products consists primarily of soybean oil for cooking and some imported products; there are no retailer own-brand labelled GM products.

The vast majority of compound feed (85%-90%) and up to 95% of soybean feed imports are labelled as GM. These figures have been on the rise as planting of GM increases. There is a relatively small niche market of non-GM feed for the “organic” segment and non-GM supply chains.

There are 43 GMOs authorised in the EU for food and feed uses. They can be found in the EU Register for GM food and feed:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

See also IP/11/1285