MEMO/10/325

Brussels, 13 July 2010

Questions and Answers on the EU's new approach to the cultivation of GMOs

Why is the Commission adopting this package today and what does it include?

In March 2010, the European Commission announced that it would come back before the summer break with a proposal on how to combine the EU science-based authorisation system with freedom for Member States to decide on the cultivation of Genetically Modified Organisms (GMOs). The package adopted today delivers on this commitment and complies fully with the position set out by President Barroso in the political guidelines he presented in September 2009.

What are co-existence measures and what does the new Recommendation on co-existence change?

The objective of co-existence measures, in areas where GMOs are cultivated, is to avoid the unintended presence of GMOs in other products, preventing the potential economic loss and the impact of traces of GM crops in non-GM crops, such as conventional and organic crops.

Experience gained over the last years shows that Member States need more flexibility to take into consideration their particular local, regional and national conditions when defining measures to organise the cultivation of GM, conventional and organic crops.

The new Recommendation on co-existence recognises that Member States may adopt measures to avoid the unintended presence of GMOs in other products below the labelling threshold of 0.9%. When co-existence measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops, Member States may restrict GMO cultivation in large areas of their territory. Such restriction measures need to be proportionate to the objective pursued (i.e. protection of particular needs of conventional or organic farming).

The Commission published in 2009 the second report on national strategies for coexistence of GM crops with conventional and organic farming. The report shows that 15 Member States adopted legislation on coexistence while three more notified draft legislation.

The European Coexistence Bureau (ECoB) develops together with Member States best practices for co-existence, which take into consideration that Member States need flexibility to take account of their local and regional conditions.

For more information on ECoB: http://ecob.jrc.ec.europa.eu/

What is the current procedure for authorising the cultivation of GMOs?

GMOs are authorised at EU level on a case-by-case basis on the basis of the particular uses defined by the application of the company, after a positive assessment of health and environmental risks. Applications for cultivation of GMOs can be submitted under Regulation (EC) No 1829/2003 for GM food and feed if those GMOs are to be used as source material in food and feed production. GMOs can also be authorised under the Directive for the deliberate release of GMOs into the environment (Directive 2001/18/EC) for uses other than food/feed. In both cases, the Member States play a significant role, carrying out the initial risk assessment of the GMO for cultivation.

For more information on the authorisation procedures: MEMO/10/58

What are the amendments to the current legislation proposed by the Commission?

The proposed amendment provides for the addition of one article to Directive 2001/18/EC, which explicitly allows Member States to restrict or prohibit cultivation of GMOs on their territories. Member States may use any grounds to do so, other than those covered by the health and environmental risk assessment of the EU authorisation process. Therefore, the proposal gives competence to Member States to decide on cultivation.

When the legal amendment enters into force, Member States will be free to restrict or prohibit the cultivation of all or particular GMOs, in parts of or in their entire territory. This amendment will be applicable to all GMOs that have been authorised for cultivation in the EU, being under Directive 2001/18/EC or under Regulation (EC) No 1829/2003. According to this proposal Member States are only allowed to adopt measures against the cultivation of GMOs. They are not allowed to adopt measures prohibiting the import and/or the marketing in the EU of authorised GM seeds.

Are any GMOs already cultivated in the EU?

Yes. There is **one GM maize –MON 810**– that is commercially cultivated in the EU. This product's genetic modification aims to protect the crop against a harmful pest – the European corn borer. It was authorised in 1998.

A **GM starch potato**, known as "Amflora" potato, was authorised for cultivation and industrial processing on 2 March 2010. This starch potato has increased amylopectin starch content. The starch is intended for industrial uses, such as production of paper.

What are the GM plants that are authorised in the EU for feed and/or food uses?

Besides cultivation, the placing on the EU market of GMOs and the use of their derived products in the food and feed chain is subject to an EU authorisation.

As of today, the list of authorised GMOs includes also: **one sugar beet, three soybean, three oilseed-rape, six cotton and 17 maize products**.

One of the most recently authorised GMO is the "Amflora" starch potato. As it is the case for conventional starch potatoes, "Amflora" is not intended to be used as food. The by-product of the starch potato (pulp) is authorised as feed. The adventitious or technically unavoidable presence of this potato in food and animal feed is authorised up to a level of 0.9%

The list of authorised GM plants and the precise scope of their authorisation is available in the EU register of GM food and feed, which can be found here: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

Have Member States already prohibited GMO cultivation?

Six Member States (Austria, Hungary, France, Greece, Germany and Luxembourg) adopted safeguard measures and prohibited the cultivation of the GM maize MON810 on their territories. Moreover, Austria, Luxembourg and Hungary have notified to the Commission the prohibition of the cultivation of the "Amflora" potato. Poland has legislation in place forbidding the marketing of all GM seeds.

Member States could now reconsider their safeguard measures on GMO cultivation, when there is no scientific justification, and rather use the more flexible Recommendation on co-existence adopted today to avoid unintended GMO presence in other crops.

Once the addition proposed today of the relevant article to Directive 2001/18/EC is applicable, Member States will be able to restrict or prohibit GMO cultivation without resorting to the safeguard clause when no new scientific risk is identified.

Are there any other GMOs for cultivation on which the EU could take decision before the legal change is applicable?

There are more than ten requests for authorisation of GMOs for cultivation (or for their renewal), at different stages of the procedure.

Four GMOs are at an advanced stage. They have received a favourable European Food Safety Authority (EFSA) opinion and their authorisation procedure (or renewal of authorisation procedure) is ongoing. The favourable EFSA opinion concerning the **renewal of the authorisation of MON810 maize**, conferring protection to the plant against certain insects, was adopted in June 2009. There are two other GM maize products - **Bt Maize 1507** (**filed by Pioneer**) and **Bt maize Bt 11** (**filed by Syngenta**) -, which also confer protection to the plant against certain insects. The favourable EFSA opinions were respectively adopted in January 2005 and April 2005 and draft decisions to authorise these two GMOs were voted on 25 February 2009 in the framework of the Regulatory Committee under Directive 2001/18/EC. No qualified majority was obtained. The fourth one is maize **NK 603 (filed by Monsanto),** which is tolerant to the herbicide RoundUp. EFSA adopted a favourable opinion on this product in June 2009.

From a procedural point of view, the next step for MON810 and NK603 would be the submission of a draft decision to the Standing Committee for Food Chain and Animal Health (SCoFCAH) (first step of the comitology procedure). Bt 11 and Bt 1507 are in the middle of the Comitology procedure, the next procedural step being the submission of decisions to the Council.

What improvements have been made to the environmental risk assessment of GMOs since the Council's request in December 2008?

The Commission and EFSA, together with the Member States, are working on the particular areas for improvement of the implementation of the GMO legislation, identified by the 2008 Environment Council conclusions.

The update of the EFSA guidelines for the environmental risk assessment is ongoing and covers the specific areas requested by the Council. Given the complexity of the topic, the need to ensure a broad consultation process and the large number of public comments (approximately 500), EFSA is expected to finish the guidelines in November 2010. The Commission will then discuss these guidelines with Member States to give them normative value with the Member States' endorsement.

Furthermore, EFSA is engaged in dialogue with Member States and stakeholders, enabling them to contribute to its scientific work. EFSA has created a network of Member State experts to exchange scientific knowledge and experience. EFSA is also considering all Member States' comments during the entire risk assessment process.

In addition, EFSA has a comprehensive set of internal mechanisms and working processes to safeguard the independence of the scientific work of its Scientific Committee and Panels, including a comprehensive policy on declarations of interest for its scientific experts. EFSA keeps this policy under regular review, and as encouraged by the Commission, will continue to strengthen the examination of the independence of its experts.

The Commission is analysing how to further reinforce the post-market environmental monitoring of GMO crops, in line with the provisions of the current legislation and the 2008 Environment Council conclusions.

When will the Commission finalise the report on the socio-economic implications of GMOs?

In December 2008, the Council requested the Commission to provide a report on the socio-economic implications of GMOs by June 2010.

This report should be based on information provided by Member States, which have made an important effort to compile information on the socio-economic implications of GMOs and, notably, of their cultivation. But **given that Member States' contributions arrived later than expected**, the Commission will finalize its **report by the end of 2010**. This report will then be submitted to the European Parliament and to the Council for consideration and further discussion.

Can we anticipate a speeding-up of the authorization process of GMOs and a rising of surface of GM cultivated areas in the EU?

There is no speeding up of authorisations or weakening of the rigorous environmental risk assessment requirements of the legislation. The proposal the Commission adopts today does not change these requirements. To the contrary, work on the implementation of the 2008 Council conclusions is since ongoing. Moreover, ensuring a safety assessment following the highest scientific standards and a reinforcement of the monitoring function were and remain priorities for the Commission as concerns GMO cultivation.

For more information please see:

http://ec.europa.eu/food/food/biotechnology/index_en.htm