

# Genetically modified food and feed

2001/0173(COD) - 25/10/2006 - Follow-up document

**PURPOSE:** to report on the implementation of Regulation 1829/2003/EC.

**CONTENT:** article 48 of Regulation 1829/2003/EC obliges the Commission to prepare a report on the implementation of the Regulation (and the transitional measures in particular) and what impact the Regulation has had on human and animal health; on consumer protection; on consumer information and on the functioning of the internal market.

To help prepare the report, the Commission compiled a questionnaire, which all of the Member States' authorities and relevant stakeholders were asked to complete. Having carefully analysed the answers the Commission makes the following findings:

## **On the implementation of the Regulation:**

- By 1 July 2006 the Commission had received 34 applications for authorisation.
- Only one authorisation for a product has been approved in accordance with the procedure set down in the Regulation. It is for food containing, consisting or produced from 1507 maize. It has now been entered on the Community register of GM food and feed.
- By 1 July 2006 the Community Reference Laboratory or CRL, which was set up by the Regulation, had validated 16 methods for the detection and identification of GM food and feed.
- The European Food Safety Authority or EFSA has issued six opinions in relation to the GM authorisation procedure.
- By May 2006, the EFSA had received 26 individual public requests on access to 73 separate applications submitted to the EFSA.
- Of the 26 requests, 18 came from five different NGO's (mainly environmental). Two accounted for the majority of requests.
- Members from national Parliaments and the European Parliament submitted three requests; national authorities submitted two requests and stakeholders have submitted three requests, for information.

Within the framework of the existing Regulation the Commission will be seeking to create greater transparency and consensus during the authorisation procedure. The Commission, is therefore proposing that the following practices be implemented:

In the scientific evaluation phase: to invite the EFSA to liaise more with national scientific bodies; to request more detailed justifications from the EFSA on its opinions regarding individual applications; and to invite the EFSA to clarify specific protocols on scientific studies.

In the decision making phase: the Commission will address the risk assessment phase by introducing a case by case additional proportionate risk management measure in draft decisions and potentially suspending a procedure if a Member State raises important new scientific questions.

## **On transitional measures and products legally placed on the market pre-2003:**

The Regulation provides transitional measures to allow advanced applications pending at the time of the Regulation's adoption, to continue under the then existing legislation. The report finds that:

- By 1 July 2006, eight decisions authorising the placing on the market of GM food were adopted in accordance with old legislation (four under Regulation 258/97/EC and four under Directive 18/2001/EC).
- Twenty-six GM products, that were approved prior to the adoption of the 2003 Regulation, have been put on a special Community list and have been approved for use.

### **On the labelling of GM food and feed:**

Currently few "food" products on the EU market are labelled as genetically modified. As such it can be concluded that the Regulation has not had a large impact on the sale of food labelled as genetically modified. According to the results of the sample analysis reported by the Member States, the frequency of non-compliance to the food labelling requirements may be less than 2% - or 113 out of 7 129 samples analysed.

By contrast "compound feed" labelled as genetically modified is much more present on the Community market. This can largely be explained by the predominance of GM soy in the production of soy at world-scale level and the difference of costs between non-GM soy and GM soy. The results of non compliance to the feed labelling requirement across the EU may be around 6% - or 153 out of the 2 478 samples analysed.

### **On unauthorised products:**

A number of unauthorised GM products have entered the EU. They are:

- GM Papaya from Hawaii. These were detected in one Member State on seven occasions. Since July 2005 no further discovery of unauthorised GM papaya has been notified.
- GM Maize Bt10. The US Mission informed the authorities of an accidental release in the US of the unauthorised GM maize Bt10 (erroneously commercialised as Bt11). Between April and September 2005, 1 600 analytical tests were carried out in the US on corn gluten feed intended for export to the EU. The EU Member States carried out a further 1400 controls at the import stage. No positive results were recorded.
- GM rice LL601. The US Mission informed the EU authorities of the accidental release in the US of the unauthorised GM rice LL601. The EFSA concluded that the consumption of imported US long grain rice containing trace levels of LL601 posed an unlikely imminent safety concern to humans or animals.

Information on the unauthorised products was transmitted to the other Member States via the Rapid Alert System for Food and Feed or RASFF. The Commission finds that the RASFF worked as an effective communication tool allowing for timely action.

### **On the outcome of inspections:**

The Food and Veterinary Office of DG SANCO carried out thirteen inspections in the EU Member States. The inspection teams made the following findings:

- all of the Member States inspected have GMO controls on both food and feed;

- all had adequate controls on BT10;
- the majority of infringements related to the mislabelling of food and feed;
- six Member States did not perform sampling controls at the point of entry;
- three Member States performed no sampling controls on seed consignments for the adventitious presence of GMO;
- official GMO laboratories were mostly accredited to ISO standards;
- four Member States had limited or no capabilities regarding the quantification of GMO's in food or feed; and
- six Member States did not take action in all cases when trace amounts in seed consignments were discovered.

**Conclusions:**

The Commission notes that the Regulation has been operational for short period of time only. Experience, therefore, is limited. This report can only be viewed as preliminary. It is too early to propose any changes to the existing Regulation. A second report will be prepared following a sufficient period of time, which will allow for greater insight into the different aspects of the Regulation's implementation.