



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

## **SUMMARY RECORD OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH**

**Held in Brussels on 29-30 June 2009**

**(Section Genetically Modified Food & Feed and Environmental Risk)**

Chair: Sébastien Goux

All the Member States were present except Czech Republic, Cyprus, and Lithuania.

### Adoption of the agenda

The draft agenda was adopted after the following modifications:

- point 3 (presentation by EFSA of its opinion on MON89034 maize) was withdrawn from the agenda since it had been presented in the previous meeting.
- the points "Update on emergency measures for BT63 rice imports from China" and "confidentiality and access" to documents were added under section Miscellaneous.

**1. Discussion and possible opinion on a draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122xNK603 (DAS-59122-7xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Right of scrutiny of the European Parliament - Articles 7(3) and 19(3) of the Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 )**

The draft Decision on 59122xNK603 maize was presented and discussed. It was clarified that 90-day feeding studies had been carried out for the safety assessment of the single events but not with the hybrid. Two Member States requested the performance of a 90-day feeding study with the hybrid. Two Member States reiterated their opposition to cover "import and processing" under Regulation (EC) 1829/2003.

No Member States requested modifications of the text of the draft Commission Decision as such. The draft Commission Decision should be submitted for an opinion during the next meeting of this Committee.

**2. Discussion and possible opinion on a draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 (MON-89034-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Right of scrutiny of the European Parliament - Articles 7(3) and 19(3) of the Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 )**

The draft Decision on MON89034 maize and the related comments from the public were presented and discussed. One Member State reiterated its opposition to cover "import and processing" under the Regulation.

No Member States requested modifications of the text of the draft Commission Decision as such. The draft Commission Decision should be submitted for an opinion during the next meeting of this Committee.

**3. Rules for applicants for the preparation and presentation of applications to be submitted under Regulation (EC) No 1829/2003 on GM food and feed**

The draft Regulation (recitals and articles) on implementing rules concerning applications for authorisation of genetically modified food and feed was presented and discussed. Comments were made by some Member States and more specifically on Article 8 (amendments to Regulation (EC) No 1981/2006) as regards a missing part in the Article and on Article 9 (transitional provisions) as regards the length of the transitory periods.

The 3 annexes of the draft Regulation were then discussed section by section. Comments were made by some Member States and mainly on the following sections or issues: consideration on marker genes, the risk assessment of GMOs containing stacked events, the information on the inserted sequence, the information on the expression of the insert, the experimental design and statistical analysis of data from field trials for comparative analysis, the definition of "history of safe use" and the need for a 90-day feeding study.

The Chair requested Member States to send their additional comments to the Commission in order for the Commission to be able to prepare a new draft that could be submitted for an opinion of the Committee during one of its following meetings.

## **Miscellaneous**

### **Update on emergency measures for BT63 rice imports from China**

The findings and conclusions of the FVO report 7834-2008 concerning an evaluation of control activities in China regarding emergency measures for rice exports to the EU were presented to the Committee. This report and actions which the Chinese authorities propose concerning the recommendations made can be found through the following web link: [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm).

In addition, an overview of RASFF (Rapid Alert System Food and Feed) alerts for BT63 was presented to the Committee which showed continuing notifications from both border and market controls. Committee members were invited to comment on the report findings and the continuing trends in RASFF alerts. Member States who commented indicated that the current measures were sufficient, while 1 Member State stated that it was their intention to extend the scope of the products which would be targeted for random sampling.

In follow-up to the actions proposed by the Chinese authorities a further FVO mission is planned for early 2010. In the meantime, a new letter will be addressed to the Chinese authorities in order to draw their attention on the most recent RASFF alerts and requesting them to implement all the necessary actions to improve the implementation of the system.

### **Guidelines on RASFF notifications**

In order to harmonise the manner in which the detection of unapproved GMOs is reported by the Member States in the EU RASFF, and to further assist with decision making and follow-up action, a working group chaired by the Community Reference Laboratory (CRL) was convened in June. The aim of this working group was to develop guidelines concerning the information which alerts should contain.

Given the technical nature of the guidelines Member States were invited to consult with their technical experts before the next Standing Committee planned in July. Member States who commented welcomed the initiative indicating the importance of harmonized reporting of information through the RASFF system.

Once the new guidelines are endorsed by Member States it is the intention to put them into effect as soon as possible.

### **1<sup>st</sup> National Reference Laboratory (NRL) workshop 28-29 May 2009**

Under the provisions of Article 32 of the food and feed Regulation (EC) No 882/2004 the CRL is responsible *inter alia* for coordinating within its area of competence the application of new methods of analysis for GMOs, and comparative testing for NRLs in all Member States.

The first NRL workshop took place this May with the objective of agreeing a framework programme for the implementation of the relevant provisions of Regulation (EC) No 882/2004. The plan which was agreed by the NRL members included a proposal to integrate the work of European Network for GMO testing Laboratories (ENGL) with the NRLs in order to foster better dissemination of information. In addition, it was agreed to start a comparative testing scheme in the spring of 2010 with the aim of assisting in the improvement of the quality of analyses. The workshop also identified a need to work more closely with accreditation bodies in view of harmonising the accreditation schemes which are currently in operation in different Member States.

A list of all NRLs which have been nominated by Member States was circulated to the Committee for comment and amendment. Once finalised it is the intention to publish the list of NRLs on the DG SANCO website.

### **Confidentiality and access to documents**

One Member State enquired about practical arrangements for answering to requests of access to documents addressed to Member States for obtaining access to parts of applications under Regulation (EC) No 1829/2003.

The extranet "EFSA-net" allows Member States to have access and to retrieve the information submitted by EFSA. It indicates the parts of the applications for which the applicant has requested confidentiality upon the time of submission of the application. However, any request of access to documents has to be examined in the light of Regulation (EC) No 1049/2001 and possible decisions on confidentiality taken by the Commission in the framework of Regulation (EC) No 1829/2003.

After the summer the Commission will put forward practical arrangements so as to ensure that Member States can easily retrieve the necessary information to answer to requests of access to documents.