



EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Held in Brussels on 19 October 2009

(Section Genetically Modified Food & Feed and Environmental Risk)

Chair: Dorothee André for point 3.1, Sébastien Goux (all other points)

All Member States were represented with the exception of Cyprus. However, Cyprus mandated the representative of Greece for the vote under point 1 of the agenda.

SECTION A Draft presented for an opinion - Projet présenté pour un avis - Zur Stellungnahme vorgestellter Entwurf

- 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 MIR604 (SYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Right of scrutiny of the European Parliament - Regulation (EC) No 1829/2003, Articles 7(3) and 19(3))**

An EFSA representative presented the opinion related to MIR604 maize. One Member State reported that its scientific assessment body considers that further tests were required regarding the risks of allergenicity of the protein “PMI” that is produced by the genetic modification MIR604. A member of the GMO Panel indicated that the likelihood of allergic reactions to this protein had been thoroughly considered by the GMO Panel and detailed three mutually supportive elements that led the Panel to a favourable conclusion. The chair enquired whether this Member State was satisfied with these explanations. The Member State thanked EFSA and indicated that it would provide this information for due consideration by its national committee.

A Commission representative presented the draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed. Member States did not either question or comment on the draft decision. The draft decision was then submitted to the Committee for an opinion.

Vote: no opinion (141 votes in favour, 96 votes against, 108 abstentions)

The following considerations were mentioned by Member States as reasons for not supporting the draft Decision:

- the need for further internal consultations;
- the European Food Safety Authority (EFSA) opinion is not considered as fully satisfactory;

- Regulation on GM food and feed is not considered as the right legal basis to authorise products other than food and feed containing and consisting of GMOs;
- the negative public opinion with respect to GMO;
- other political reasons.

The delegation of Austria provided a written declaration (see hereunder).

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Declaration of the Austrian delegation

Austria objects the placing on the market of genetically modified maize MIR 604 (SYN-IR6Ø4-5) due to the following reasons:

- a. The risk assessment which has been carried out - in particular concerning the environmental risk assessment - is not suitable to give a scientific proof for the safety of this product. Also the intended monitoring plan is not regarded as state of the art.*
- b. From the Austrian point of view, products others than food and feed containing or consisting of MIR 604 (SYN-IR6Ø4-5), are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

SECTION B Information and/or discussion - Information et/ou discussion - Zur Information und/oder Diskussion

2. EFSA Opinion on an application for renewal of the authorisation of existing products produced from insect resistant genetically modified maize Bt11 from Syngenta

The EFSA opinion was presented to Member States by an EFSA representative. Member States did not raise questions or comments on the opinion.

3. Review of the situation regarding the detection of non EU authorised GM food and feed

3.1 Linseed "Triffid" FP967

The Commission provided an overview of the current RASFF notifications from Member States concerning the presence of CDC Triffid FP967 in linseed originating from Canada and the exchanges which had taken place since the original alert on the 8th of September.

A presentation was made by the Canadian Grain Commission (CGC) who represent the official services of Canada responsible for linseed exports to the EU. This presentation outlined the grain handling systems in Canada, and a proposal for a sampling and testing protocol for future exports of linseed to the EU. The system would consist of two stages of sampling and testing with additional samples taken from each farm delivery should trace back be necessary.

The first stage would take place during transfer to railcars following which samples would be taken by private grain companies and tested in laboratories meeting the requirements of ISO 17025. The second stage would be undertaken by the CGC at the point of final loading of ships destined for the EU. Sampling would be performed according to Commission Recommendation 787/2004/EC, and samples tested

according to the construct specific method developed by Genetic ID and verified by the Community Reference Laboratory.

The CGC provided an overview of the initial investigation which they and the Canadian Food Inspection Agency had begun concerning the source of the contamination. CGC indicated that this GMO had been authorised in Canada for food and feed but had not been commercialised.

The Chair of the meeting indicated that the objective of this discussion was to assess whether the draft protocol submitted by the Canadian authorities was considered as appropriate to prevent the import of Linseed Triffid FP967 in the EU. If this would appear to be the case, the protocol would be adopted officially by the Commission and same protocol should be used by Member States for the control on imported products, in order to avoid discrepancy of results, with no need for adopting emergency measures.

All Member States supported the approach outlined by the Chair of the meeting. Some modifications were discussed. It was also highlighted that in addition to the protocol, the development of the investigation of Canadian authorities on the source of the contamination and on possible additional measures that would be taken to prevent this contamination should be closely monitored.

Some Member States also requested the Commission to provide more detailed guidance on measures to be taken on products that were already on the EU market. The Chair of the meeting reiterated the message that was sent in the context of the RASFF system where the Commission reminded Member States to take appropriate action to ensure that any product containing non authorised GMOs is not placed on the market.

The Chair of the meeting concluded that there was a common understanding within the Committee that, subject to the amendments discussed, the application of the protocol outlined by the Canadian authorities was the appropriate measure to deal with this issue. Member States will be consulted during the next coming days on a final version of the protocol. In addition, Canadian authorities will be requested in writing to maintain their efforts so as to identify and circumvent the source of the contamination.

In order to assess the evolution of the situation, the matter will be on the agenda of the next meeting of the Committee.

3.2 Other non EU authorised GM food and feed notified through the RASFF

In addition to the alerts for linseed FP967, a Commission representative outlined the continuing alerts regarding Emergency Decision 2008/289/EC regarding the unauthorised genetically modified organism 'BT63' in rice products from China. Other notifications were also highlighted, in particular border rejections of consignments of soya products from the USA containing unauthorised maize events.

4. Draft Commission Regulation on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006.

A Commission representative indicated that a new draft of the Commission Regulation is currently in preparation. It should be made available to Member States before the end of the year. This new draft will be notified under the SPS and TBT agreements and will accordingly be subject to a commenting period of 60 days.

5. Application of the GM labelling rules in case of botanical impurities.

A working paper prepared by DG SANCO was considered by the Committee. The implementation of Regulation (EC) No 1829/2003 in case of botanical impurities (e.g. presence of Maize in soy) had already been discussed during the SCFCAH meeting on 23 June 2004. This working paper is providing additional considerations on how Regulation 1829/2003 and Directive 96/25/EC on botanical impurities do apply jointly. It provides a series of concrete examples.

Several Member States thanked the Commission for this working paper that was considered as bringing useful clarifications. During the following discussion, several Member States indicated that there were confronted with difficulties to implement these requirements due to limitations in the currently available analytical methods. It was also indicated that the working document was focussed on feed but that there would be some merits to expand these considerations to food aspects.

The chair concluded that the working document would be reviewed with a view to have further discussion in one of the next meetings of this Committee.

6. Evaluation of Regulation (EC) No 1829/2003 on GM food and feed

A state-of-play of the evaluation was provided to the Committee. All the information regarding this evaluation is available on the website of DG SANCO at the following address: http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm.

The attention of the Committee was in particular drawn to a library of documents related to this Regulation that contains more than 200 documents and that has already been recognised as a valuable source of information by different stakeholders.

Miscellaneous

Long-term reproduction studies on mice

The delegation of Austria informed the Committee about the last developments regarding a study entitled "Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies on mice" that was financed by the Austrian Federal Ministry of Health, Family and Youth and the Ministry of Agriculture, Forestry, Environment and Water Management with a view to examine effects of the stacked GM crop NK603xMON810 in different models (MGS, RACB) of long-term feeding studies. This study was already discussed in the Committee on 16 December 2008 and it was considered that it did not allow to draw conclusions on the investigated GM maize.

The delegation of Austria indicated that the contracted researchers still failed to deliver a satisfactory report on this study, especially with respect to the statistical analysis of the data, and that the Austrian Ministries do not expect anymore to receive such a report.

For the sake of transparency, raw data that were provided by the researchers were made available to EFSA and Member States.

Despite the difficulties encountered with this specific research project, the Austrian delegation reiterated its interest in establishing an adequate model for long-term feeding studies.

Greek law on controls of GM imports

A Commission representative provided a brief update of the actions taken as regards the Greek law on GM imports for third countries, including Bulgaria and Romania. Accordingly, in September 2008 the question of compliance of the Greek law with Regulation 882/2004 on food and feed official controls came up. In December 2008, the Commission sent a letter of formal notice to Greece and a reasoned opinion in April 2009. Given that there was no response from Greece, the Commission representative indicated that the next steps of the procedure would be to refer the case to the European Court of Justice.

(signed)

Dorothee André

Head of Unit