STANDING COMMITTEE
ON THE FOOD CHAIN AND ANIMAL HEALTH

SECTION ON GENETICALLY MODIFIED FOOD AND FEED AND ENVIRONMENTAL RISK

SUMMARY RECORD OF THE 4th MEETING – 25 January 2005

Chair – Mr Willem Penning

The agenda of the meeting was amended so that the first point referred to a discussion instead of an opinion.

1. Discussion on a draft Commission Decision authorising the placing on the market of foods and food ingredients produced from genetically modified maize line GA21 as novel foods or novel food ingredients under Regulation (EC) N° 258/97 of the European Parliament and of the Council

A draft Commission Decision authorising the placing on the market of food and food ingredients produced from genetically modified maize line GA21 under Regulation (EC) N° 258/97 on novel food and in accordance with Article 46(1) of Regulation (EC) N° 1829/2003 on genetically modified food and feed was submitted to the Committee for discussion.

Member States raised questions *inter alia* about the scope of the decision; the labelling provisions proposed and that the GM food and feed authorisations are aligned with the notifications for existing products. These matters were clarified by the Commission representatives. Member States were asked to send linguistic corrections as soon as possible to the Commission.

2. Applicability to Regulation (EC) N° 1829/2003 of Commission Recommendation 2004/787/EC on technical guidance for sampling and detection of GMOs and material produced from GMOs as or in products in the context of Regulation (EC) N° 1830/2003

A Commission representative informed the Committee that Recommendation 2004/787/EC on technical guidance for sampling and detection of GMOs and material produced from GMOs as or in products in the context of Regulation (EC) N° 1830/2003 was adopted by the Commission on 4 October 2004. This Recommendation had been

subject to extensive consultation of the Member States in the context of meetings of the Competent Authorities dealing with Directive 2001/18/EC and was also presented in a meeting of the Standing Committee of the Food Chain and Animal Health.

A Member State had sought confirmation that the provisions of this Recommendation, in particular the method to express GM content as DNA copy numbers in relation to the number of haploid genomes, was also applicable to GM food and feed authorised under Regulation (EC) N° 1829/2003.

The Commission representative confirmed that this was the case, since the Recommendation was adopted to facilitate a co-ordinated approach of the inspection and control measures for the provisions of Regulation (EC) N° 1830/2003 on labelling and traceability of GMOs, and GM food and feed authorised under Regulation (EC) N° 1829/2003 are subject to these provisions. Furthermore, the method chosen in the Recommendation to measure GM content was the only one to give a comparable result throughout the food chain.

The Commission further outlined that provided that there was enough support from Member States on this approach, the Commission would envisage mandatory rules on this subject in accordance with Articles 14 and 26 of Regulation (EC) N° 1829/2003.

Several Member States questioned the opportunity of applying the Recommendation on sampling and testing to GM food and feed authorised under Regulation (EC) N° 1829/2003. Particular issues of concern were: the provisions on sampling foreseen by the Recommendation, the opportunity of the DNA copy number method in comparison to a measurement based on weight, the variability of the results depending on the biological diversity of the GMOs analysed and the necessity for conversion factors.

A representative from the Joint Research Centre explained that these issues of technical nature would be considered in a decision tool to be elaborated by the European Network of GMO laboratories, but that the enforcement laboratories of all Member States were committed to the Recommendation in general and to the DNA copy number method in particular.

The Chair concluded that the Commission would consider developing a text based on this decision tool that would in particular address the issue of sampling plans and conversion factors.

3. Consultation of competent authorities by EFSA according to Articles 6.4 and 18.4 of Regulation (EC) N° 1829/2003.

A Member State raised concerns about the working arrangement established by EFSA concerning the consultation of Member States' competent authorities during the risk assessment of applications for authorisation of GM food and feed submitted under Regulation (EC) N° 1829/2003.

In fact, Regulation (EC) N° 1829/2003 requires a consultation by EFSA of the national competent authorities within the meaning of Directive 2001/18/EC on applications for authorisation of food or feed containing or consisting of a GMO.

However, EFSA has included in this consultation not only the national authorities competent for Directive 2001/18/EC, but also those competent for Regulation (EC) N° 1829/2003, which has led to confusion in Member States. At the same time, this consultation is conducted on all applications for authorisation of GM food and feed, i.e. also on those referring to food and feed produced from GMOs.

A Commission representative confirmed that, as required for the "one door one key" principle, the environmental safety requirements referred to in Directive 2001/18/EC are also applied to applications for authorisation of GMOs or food or feed containing or consisting of GMOs submitted under Regulation (EC) N° 1829/2003. To this end and in accordance with Article 12(4) of Directive 2001/18/EC, the Regulation requires in Articles 6.4 and 18.4 a consultation by EFSA of the national competent authorities within the meaning of Directive 2001/18/EC on this type of application.

A consultation of these national authorities is thus only foreseen for applications for which the scope overlaps between Regulation (EC) N° 1829/2003 and Directive 2001/18/EC and for which an environmental risk assessment is required, i.e. applications for authorisation of food or feed containing or consisting of GMOs. The intention of the legislator was to foresee a centralised risk assessment procedure whilst strictly sticking to the requirements of Article 12(4) of Directive 2001/18/EC. Indeed, there is the danger that the centralised risk assessment by EFSA, that involves the authorities competent for Directive 2001/18/EC to cater for the "one door one key" principle, is decentralised by the additional involvement of the national authorities competent for Regulation (EC) N° 1829/2003.

The Chair confirmed that only the consultation of competent authorities within the meaning of Directive 2001/18 on applications for authorisation of food or feed consisting of or containing a GMO is foreseen by the legislation and asked EFSA to adapt the explanatory note to the members of the GMO EFSAnet in that respect. The Chair further stressed that the extension of this consultation by EFSA may not put at stake the centralised risk assessment foreseen by Regulation (EC) N° 1829/2003.

4. Update on notifications of existing products received by the Commission pursuant to Articles 8 and 20 of Regulation (EC) N° 1829/2003.

According to Articles 8 and 20 of Regulation (EC) N° 1829/2003, genetically modified food and feed lawfully placed on the market before the entry into application of the Regulation on 18 April 2004 may continue to be placed on the market, used and processed, provided that they were notified to the Commission before 18 October 2004.

To this end, a specific notification procedure was put in place by the Commission services and 29 GM products were notified to the European Commission before the deadline of 18 October 2004.

The notifications have been scrutinised with respect to their completeness and where necessary notifiers have been asked for complementary information. This information has been received for most notifications and for some of them, the scrutiny is almost finalised.

All notified products, for which the notification has been accepted, will be included together in the register on GM food and feed prior to the deadline of 18 April 2005.

One Member State asked to align the validity of new authorisations of GMOs to the validity of the notifications of the corresponding existing products. The Chair refused this request by pointing out that such an alignment is not foreseen by the legislation.

5. Report on the implementation of Regulation (EC) N° 1829/2003 according to Article 48 of that Regulation

According to Article 48 of Regulation (EC) N° 1829/2003 on GM food and feed the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation before 7 November 2005. In order to prepare this report a questionnaire was distributed to Member States on 21 January 2005. To be able to take account of views and information provided by Members States, the questionnaire should be returned by 4 March 2005. Two responses per Member State are expected: one for GM food and one for GM feed. In reply to a question from a Member State, the Commission confirmed that it is drafting a similar questionnaire to be circulated to stakeholders.

6. GM labelling of contaminated compound feed

The question was discussed how to calculate the labelling threshold of 0,9% in a compound feed with unintended contents of GM feed materials either resulting from direct contamination during the preparation process (i.e. not via an ingredient *per se)* or in cases where the feed materials are not available but documentation shows that the feed material was not contaminated.

For some Member States the current legal basis only allows the calculation of the threshold on the basis of the ingredient/feed material that is contaminated. Other delegations presented some possible alternatives.

A representative of the Commission indicated that for the time being, the calculation of thresholds in terms of DNA copy numbers referred to haploid genomes as indicated in the Commission Recommendation 2004/787/EC is only possible for the same botanical species (i.e. soya contaminated with GM soya).

The Chair concluded that this issue needed further examination.

7. Miscellaneous

The subject of illegal import of GM papaya from Hawaii into the Community was raised by a Member State:

The food inspection authorities of this Member State repeatedly detected the marketing of genetically modified papaya although no authorisation for genetically modified papaya has been granted in the Community. The national authorities notified the Commission and other Member States of the Community of such cases under the rapid alert system in accordance with Regulation (EC) N 178/2002.

From this Member State, the fruits were transferred to other Member States of the Community.

The genetic modification was detected using a method developed and evaluated in the Member State. The authorities have this method at their disposal and are prepared to support other Member States in detecting such modification.

The Member State has now taken steps to ensure that papaya imports from Hawaii presented at its border control posts are tested for genetic modification. In addition, the customs administrations of the other EU Member States were informed of the measures taken through the customs information system.

However, in view of the Community's internal market, this national measure was not considered sufficient by the Member State concerned. Experience had shown that traders quickly move to other Member States. For reasons of preventive consumer protection, the Member State therefore considers it necessary that other Member States also take appropriate measures to control papaya imports from Hawaii.

To ensure that such measures be taken, the Member State asked the Commission to impose appropriate special conditions in accordance with Article 53 of Regulation (EC) N°178/2002.

The issue was debated. One other Member State confirmed that the GM papayas had been imported in their territory, adequate measures were taken. Other Member States asked for details on the detection method to be provided. The representative of the Joint Research Centre informed the Committee that a GM methods database including a method for ring spot virus resistant papaya was available at the following URL: http://biotech.jrc.it

The Chair concluded that an emergency measure according to Article 53 of Regulation (EC) N° 178/2002 can only be taken on the condition that it is evident that the food or feed in question is likely to constitute a serious risk to human health, animal health or the environment. However, in the present case this condition is not met. Furthermore, the two Member States concerned have shown that by means of the measures taken, the illegal import of GM papayas can be contained and that the other Member States have been put in a position to take adequate measures by the RASFF notifications and by the present discussion.

For these reasons, the Commission does not consider such an emergency measure as justified.