STANDING COMMITTEE
ON THE FOOD CHAIN AND ANIMAL HEALTH

SECTION ON GENETICALLY MODIFIED FOOD AND FEED AND ENVIRONMENTAL RISK

SUMMARY RECORD OF THE 3rd MEETING – 24 September 2004

Chair – Mrs. Paola Testori Coggi

1. Implementation of Regulation (EC) N° 1829/2003

The Chair explained that the objective of the meeting was to continue the discussion of the last meeting of 23 of June about the scope of Regulation (EC) N° 1829/2003 in respect to food and feed produced by fermentation using genetically modified micro-organisms (GMMs).

The Chair recalled that in the last meeting two Member States had presented an approach which was based on the discussions that were held in Council prior to the adoption of the political agreement of 28 November 2002 which paved the way for the adoption by Parliament and Council of Regulation (EC) No 1829/2003. It was recalled that, during these discussions, a Member State had requested the extension of the scope of the Regulation to cover: "food and food ingredients produced by fermentation using genetically modified micro-organisms from which the genetically modified micro-organisms may have been removed". There had been insufficient support for this proposal but, at the request of this Member State, the Council and the Commission agreed "that the status of food produced by fermentation using genetically modified micro-organisms not present in the final product (would) need to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen in Article 48 of the Regulation".

This clearly suggested that Council did not intend the scope of Regulation No 1829/2003 to include food produced by fermentation using GMMs, because if Council had intended to include these foods in the scope, there would have been no reason for Council to turn down this request, or to record the aforementioned statement. Parliament had been fully informed of the common position agreed upon by Council in first reading and had not sought to amend it with the purpose of including food produced by fermentation using micro-organism not present in the final product.

The Chair indicated that it was essential to develop a pragmatic approach to the legislation in this matter. Furthermore there was merit in proceeding as envisaged in the joint statement of the Council and the Commission and to review this matter in the context of the report to be presented by the Commission in November 2005; this report would examine the opportunity of presenting a proposal to extend the scope of the

Regulation to cover all fermentation products and to lay down appropriate rules for their safety assessment and their labelling, as the current rules for the authorisation and labelling of GM products had clearly not be laid down with fermentation products produced by GMMs in mind.

There was a tour de table. Twenty-three Member States indicated that, in the interest of developing a pragmatic approach to the Regulation on this question, they could accept the approach put forward by the Chair. One Member State could not accept this approach; one Member State reserved its position.

The Chair concluded that, with the exception of one Member State disagreeing and one Member State reserving its position, there was consensus that:

Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No 1829/2003. These food and feed have to be considered as having been produced with the GMM, rather than from the GMM.

Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is present in the final product, totally or partially, whether alive or not, are included in the scope of Regulation (EC) No 1829/2003, in regard of both authorisation and labelling.

Safety evaluation and authorisation of feed produced by fermentation using a genetically modified micro-organism will continue to be covered by the provisions of Regulation (EC) No 1831/2003 and Directive 82/471/EEC.

Safety evaluation of food additives and enzymes produced by GMMs will be considered in the forthcoming legislative proposals for the amendment of the framework Directive 89/107/EEC on food additives and for food enzymes.

The question of the possible extension of the scope of Regulation (EC) No 1829/2003 to some or all food and feed produced by fermentation using a genetically modified micro-organism not present in the final product as regards their safety assessment, authorisation and labelling will be reviewed in the context of the report to be presented by the Commission in 2005, in accordance with Article 48 of the Regulation and the statements dated 28 November 2002 and recorded in the Council minutes.

2. Any other business

The Chair raised three points under any other business for information purposes:

<u>Contribution of companies towards the cost for validation of detection methods</u>

A Commission representative from the Joint Research Centre presented the draft discussion document "Towards an equitable and sustainable cost recovery mechanism for the CRL", prepared with the input of the European Network of GMO Laboratories (ENGL) calculating that the variable costs per validation vary between 85,000 and 100,000. He pointed out that the fixed costs, currently covered by the Commission are very high and that other costs, e.g. the organisations of meetings with ENGL experts are not covered. The Chair indicated that soon a proposal to be submitted for voting will be tabled.

State of applications for authorisation / notifications under the Novel Food Regulation (EC) No 258/97, Directive 2001/18/EC on the deliberate release into the environment of GMOs and Regulation (EC) No 1829/2003 on GM food and feed

Commission representatives updated the Committee on the state of play of applications for authorisation of GMOs and GM food and feed.

There are three applications for authorisation pending under Article 7 of Regulation (EC) No 258/97. Amongst these three applications, the application for authorisation of food and food ingredients derived from NK603 maize is most far advanced in the procedure. After receiving no qualified majority either in the Standing Committee on the Food Chain and Animal Health or in the Council, the proposal was transferred back to the Commission for adoption in accordance with Comitology rules. Two more applications are pending, one for the authorisation of GA21 maize and one for the authorisation of MON 863 maize. The validation of detection methods is on-going for both of these GMOs. However, the validation of GA21 maize has revealed some technical issues that need further clarification with experts from the ENGL before the method may be considered fit for regulatory compliance.

There are four applications for authorisation of GM food and feed pending under Regulation (EC) No. 1829/2003: Two of these applications were originally submitted under Regulation (EC) No 258/97 and have been transformed according to Article 46(1) of the Regulation, two are new applications for authorisation. These applications have been submitted to the competent authorities of a Member State and subsequently transmitted by these authorities to EFSA. EFSA is currently checking their completeness. For further details, please refer to the EFSA web pages at the following URL:
http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

Details of the current state of play for product approvals under Directive 2001/18/EC were added: A number of applications have been transformed to Regulation (EC) No 1829/2003 in accordance with Article 46(3) of that Regulation, whilst twelve applications for the placing on the market of GMOs remain under the Directive. The three most advanced applications have scopes limited to import, processing and feed use. All three were submitted by Monsanto and included two GMO maize products (NK603 and MON863) and a GMO oilseed rape (GT73). The NK603 maize product was approved for import and feed uses, by Commission Decision of 19 July 2004 (but application of this decision is dependent on a corresponding approval for use of the NK603 maize in food).

The GT73 oilseed rape is currently with the Environment Council for decision and it is foreseen that the Regulatory Committee under Directive 2001/18/EC will be formally consulted in November 2004 in terms of an opinion on the MON863 maize. The remaining applications, some of which are limited to uses for import, processing and feed use whereas others include cultivation, are further back in the procedure and are currently being appraised by Member States.

Notification of existing products pursuant to Articles 8 and 20 of Regulation (EC) Nr 1829/2003 on GM food and feed

A Commission representative updated the Committee on the situation concerning the notification of existing products according to Articles 8 and 20 of Regulation (EC) No 1829/2003.

To date, the Commission has received 9 notifications of existing products under Regulation (EC) No 1829/2003. An updated list of the notifications received by the Commission is posted on the web pages of DG Health and Consumer Protection at the following URL:
http://europa.eu.int/comm/food/food/biotechnology/gmfood/notification_en.htm

The Commission has forwarded these notifications to EFSA and the Member States and has initiated the process of examination and verification of their completeness, as foreseen by the Regulation. Subsequently, the products will be entered in the Register of GM food and feed by 18 April 2005.