STANDING COMMITTEE
ON THE FOOD CHAIN AND ANIMAL HEALTH

SECTION ON GENETICALLY MODIFIED FOOD AND FEED AND ENVIRONMENTAL RISK

SUMMARY RECORD OF THE 2nd MEETING – 23 June 2004

Chairman – Mr. Patrick Deboyser

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

The order of points for discussion under this agenda item was slightly modified; point 1(b) was taken first, followed by 1(a) and 1(c). Two more points were added for discussion under this agenda item, i.e. the question of GM labelling requirements for mass caterers and for honey.

a) Fermentation products

Member States and operators had raised questions about the scope of Regulation (EC) N° 1829/2003 in respect to food and feed produced by fermentation using genetically modified micro-organisms (GMMs).

This matter had already been discussed at the 10th meeting of the Section on General Food Law of the Committee when the Commission had put forward an initial interpretation of Regulation (EC) N° 1829/2003 that would have resulted in all substances such as additives, flavourings or vitamins produced by GMMs falling within the scope of the legislation, as well as foods such as alcoholic beverages or dairy products when the GMM was still present in the product.

At the meeting, two Member States presented an alternative approach based on the discussions that were held in prior to the adoption of the political agreement during the legislative procedure which led to a common Council / Commission declaration "that the status of food produced by fermentation using genetically modified micro-organisms not present in the final product needs 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 approach would have resulted in all fermentation products produced by GMMs falling outside of the scope of the Regulation until further clarification, provided that the GMM was not present in the final product.

The Chairman indicated that the Commission was willing to review its position and follow the approach proposed by these 2 Member States, since it was essential that the Commission and all Member States develop a common approach to the legislation in this matter.

There was a general discussion. Several Member States indicated that, in the interest of developing a common approach to the Regulation on this question, they might accept the approach put forward by the two Member States. Three Member States had serious doubts about this interpretation referring to recital 16 of the Regulation in this respect.

No agreement could be reached. It was concluded that the Commission would circulate a statement on the matter. If necessary, the matter would be discussed again at the earliest possible opportunity.

b) Self-cloning

The Chairman explained that contrary to transgenic micro-organisms that contain genetic material from a foreign species, self-cloned micro-organisms only contain genetic material from organisms of the same or a closely related species. An exchange of genetic material between these micro-organisms can also occur by natural means. The legislator did not consider it necessary to subject these micro-organisms to the common containment measures for genetically modified micro-organism laid down in Directive 90/219/EEC since self cloned micro-organisms as defined in Annex II Part A of that Directive are excluded from its scope. However, if these micro-organisms are released in the environment, the requirements of Directive 2001/18/EC on the deliberate release into the environment of GMOs apply.

The Chairman suggested that the application of Regulation (EC) N° 1829/2003 on genetically modified food and feed should be aligned to the approach followed in the environmental legislation. Accordingly, the requirements of the Regulation would not apply to food and feed produced from self-cloned micro-organisms that are kept under contained conditions; however, if food or feed consisting of or containing these micro-organisms is placed on the market, the full requirements of the Regulation would apply.

An initial discussion took place. Three Member States had reservations on the approach proposed by the Chairman. It was concluded that this matter was subject to the conclusion to be reached under point 1 (a) of the agenda.

c) Operation of the 0.9 labelling threshold

A letter and a note were sent by the Belgian authorities regarding the interpretation of Article 24(2) of the Regulation.

A consensus was reached on the following approach, which should apply both for food and feed: When the food/feed is composed of one food/feed (e.g. a feed material or an ingredient), the threshold must be calculated on the basis of such a food/feed. In compound feedingstuffs or foods composed of more than one ingredient, the adventitious or technically unavoidable presence of material consisting of, containing or produced from GMOs (hereinafter referred to as GM material) might be detected. In that case, it is necessary to examine each of the different ingredients/feeds of which the

food/compound feed is composed to determine where such adventitious pr technically unavoidable presence came from. The calculation of the threshold should be done on the basis of each of the components of the food/feed where the GM material is present. If the threshold is exceeded in one of those components of the food/feed, then the food/compound feed should indicate on the label the presence of the GM material in relation to that specific food/feed component.

GM labelling requirements for mass caterers:

As a follow up of the discussion on 30 April in the Section on General Food Law, the Chairman confirmed, at the request of a Member State that, whilst it was regrettable that there was divergent views between the Commission and some Member States on the interpretation of an important provision of Community law, this divergence had little practical consequences since it was not questioned that, under the Commission interpretation, Member States were allowed to extend the labelling provisions of Regulation (EC) N° 1829/2003 to cover supplies by mass caterers. The labelling provisions for mass caterers were a matter of subsidiarity falling in the competences of MS and having little if any impact on the common market.

GM labelling of honey:

The regulatory status of honey with respect to the Novel Food Regulation (EC) N° 258/97 had already been discussed at the Standing Committee on the Food Chain and Animal Health on 13 of June 2002. In this meeting, it was agreed that honey does not fall under the scope of the Novel Food Regulation (EC) N° 258/97 and that the possible presence of GM pollen in honey should be considered as an adventitious and unavoidable contamination.

At the request of a Member State the Committee confirmed this view with respect to Regulation (EC) N° 1829/2003 on GM food and feed: Honey is considered as an animal product according to Directive 2001/110/EEC relating to honey and does hence not fall under the scope of the Regulation if produced by non genetically modified bees. Pollen is considered as a constituent particular to honey. Bees forage over several kilometres visiting both wild and cultivated plants, this process is beyond the control of the bee keeper. Therefore, the possible presence of GM pollen in honey should be considered as an adventitious and unavoidable contamination that does not need to be labelled provided that the proportion of GM pollen in the honey is no higher than 0.9 per cent.

2. Guidance on sampling and testing under Regulation (EC) N° 1830/2003

The document ENV/04/04/4 entitled draft Commission Recommendation on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) N° 1830/2003 was shortly introduced by the Chairman. Two Member States raised concerns about the implementation of the Commission Recommendation. It was clarified that the document was tabled for information purposes only, and that an

extensive discussion had already taken place in other bodies. The Chairman indicated that the text of the draft Recommendation had been agreed, awaiting linguistic comments from the MS and adoption by the Commission.

3. New and transformed applications for authorisation of GM food under Regulation (EC) N° 1829/2003

a) New applications under Regulation (EC) N° 1829/2003

The UK informed that a new application under Reg. 1829/2003 has been submitted to EFSA. This application refers to the hybrid of NK603 x MON810 and its scope covers food and feed use, but no cultivation. The application has received the code EFSA/GMO/UK/2004/01 and is currently checked for completeness by EFSA.

EFSA informed that a second application has been submitted to EFSA under Regulation (EC) 1829/2003. The application, received 10 June 2004, is a transformation of the application on maize 1507 maize previously submitted under Article 4 of Regulation (EC) No 258/97 to a GM food application under Regulation (EC) 1829/2003 (Art. 46(1)). Its scope covers food use but no cultivation. This application has received the file no. EFSA-GMO-NL-2004-02 and is currently checked for completeness by EFSA.

b) Transformed applications in accordance with Article 46(1) of the Regulation

A table was distributed to MS summarizing the applications under the Novel Food Regulation (EC) N° 97/258 that will be converted to applications under Reg. 1829/2003 in application of Article 46(1). An updated version of this table can be consulted on the Web pages of DG SANCO.

4. Transformed applications for authorisation of GM feed under Regulation (EC) N° 1829/2003

a) Transformed applications in accordance with Article 46(3) of the Regulation

A document was distributed to the delegations in application of Article 46(3) of Regulation (EC) 1829/2003.The document includes a list of requests that were submitted following the procedure of Directive 2001/18/EC. Some of them, for which the assessment report provided for in Article 14 of Directive 20011/18/EC has not been sent, must be transformed into applications of Chapter III, Section 1 of Regulation (EC) N° 1829/2003.

According to Article 6 of Regulation (EC) N° 641/2004, the national competent authorities within the meaning of Directive 2001/18/EC of the Member State in which the notification was submitted are responsible for asking the notifier to submit the complete

dossier. DG ENVIRONMENT has already informed of this obligation to the competent authorities within the meaning of Directive 2001/18/EC.

b) Transformed applications in accordance with Article 46(4) of the Regulation

A document was distributed to the delegations. The document includes the product notification details of a feed falling within the scope of Directive 82/471/EEC. This application must be transformed into application under Chapter III, Section 1 of Regulation (EC) N° 1829/2003.

Following the procedure laid down in Article 7 of Regulation (EC) N° 641/2004, the Commission has already asked the applicant to submit the complete dossier. Nevertheless, this obligation is subject to the clarification of the scope of Regulation (EC) N° 1829/2003 as regard fermentation products.

c) Supplementation of applications in accordance with Article 46(5) of the Regulation

A list of applications under Directive 70/524/EEC that need to be supplemented by an application under Regulation (EC) N° 1829/2003 was distributed to the delegations. According to Article 8 of Regulation (EC) N° 641/2004, the Member State rapporteur must ask the applicant to submit the application. This obligation is subject to the clarification of the scope of Regulation (EC) N° 1829/2003 as regard fermentation products because all the applications listed for feed additives belong to this category of products.

5. Exchange of views on the contribution of companies to the costs for validation of detection methods

The Commission representative presented a discussion document on the structure and amount of contributions from the notifier towards variable costs for method validations by the CRL pursuant to Article 32. This document had already been tabled in the meeting of 30 April. Member States were asked for comments, to be submitted also in written form. For the contribution of companies, a tentative figure of 150.000 € was proposed, that is however still subject to discussion.

The Chairman stressed in its conclusion that there is need for solid legal rules in order to charge companies. The JRC should organise an expert meeting to further discuss and agree on the appropriate level of these contributions. This meeting is tentatively scheduled to take place in September in Brussels.

6. Debriefing on the first oral hearing of the WTO panel held in Geneva

The Commission representative updated the members of the Committee on the state of play of the WTO dispute on GMOS. In particularly he informed them about the subject

matter of the dispute and the line of argumentation developed by the parties to the dispute during the first Oral Hearing that was held in Geneva on 2-3 and 4 June. Some Member States requested clarifications concerning the type of information to become available to the Panel and information to be considered as confidential. The Commission representative informed the Committee that the EC submission is available on the WEB page of DG Trade.

7. Miscellaneous

GM free labelling scheme:

At the request of a Member State, the opportunity of a GM free labelling scheme was discussed. While some Member States reported that they have adopted rules for such a labelling scheme at national level, other Member States voiced fears that such a labelling scheme would confuse consumers by introducing a third category of products next to the conventional and the GM products foreseen by the legislation. Most of the Member States that have such national rules stipulate that the threshold for adventitious and technically unavoidable presence of GM material in GM free products should be below the detection level.

The Chairman indicated that whilst a GM free labelling scheme was originally foreseen in the White Paper on Food Safety, this approach was subsequently abandoned by the Commission. In his view, three categories of products can be distinguished:

1) Organic food products: Genetically modified organisms and/or any product derived from such organisms must not be used in organic farming (with the exception of veterinary medicinal products). Under current legislation the possibility is not excluded that organic products may contain GM material above the labelling threshold even though no GM material has been directly used in the organic production process. The Commission is currently considering a proposal to amend the relevant legislation (Regulation (EEC) N° 2092/91) in order to prevent products labelled as containing GMOs from being sold as organic.

2) Food categories that have not been genetically modified hitherto: labelling these foods as GM free is suggesting that they possess a special characteristic when in fact all similar food possess the same characteristic, and this is misleading within the meaning of Article 2(1)(a) of Directive 2000/13/EC.

3) Food products that can be genetically modified or not: Such food can be placed on the market without a GM label provided that they contain less than 0,9 % of GM material and that the presence of GM material is unintentional and technically unavoidable. For these food a GM free labelling scheme could be developed, but the Commission has currently no intention of proposing such a scheme at Community level, not is it advising Member States to develop such schemes at national level.

Diverging scientific opinions:

On request of a Member State, the Chairman clarified that if diverging scientific opinions between EFSA and the national food safety assessment bodies exist, Article 30 of Regulation (EC) N° 178/2002 should be applied.

Labelling of carriers:

On request of a Member State, the Chairman clarified that carriers for food additives that are exempted from labelling should also be exempted from labelling when produced from a GMO: The reason is that according to Article 13(1) of Regulation (EC) N° 1829/2003, the labelling requirements of this Regulation apply without prejudice to other requirements of Community law concerning the labelling of foodstuffs. If the requirements of Article 6.4(c)ii of the General Labelling Directive 2000/13/EC are met, the labelling of the carriers not compulsory, even if they are produced from a GMO.

Carriers used in premixtures of feed additives however are considered as feed materials and GM labelling is mandatory if they are produced from a GMO.

Presentation GMO EFSAnet and GMO EFSA public web page

The EFSA representative presented the GMO EFSAnet, an electronic system whereby complete applications (including confidential information) submitted to EFSA under Regulation (EC) No 1829/2003 are made available to all Member States, the European Commission and the members of the GMO Panel.

The EFSA representative informed that when an application is submitted to EFSA, it is first checked for completeness. Only valid applications are made accessible to members of the GMO EFSAnet. From the date of receipt of a valid application by EFSA, EFSA starts to carry out the safety assessment and Member States have the possibility to comment on the application dossier during the 3 months consultation period.

EFSA has created a new GMO EFSA public web page where information related to the applications submitted to EFSA under Regulation (EC) 1829/2003 can be found http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html.

Next meeting:

The next meeting of the Section GM food and feed is tentatively scheduled for the 14 October. A meeting of the Working Group GM food and feed is tentatively scheduled for the 21 of September.