1. **NK603**

   Opinion on a draft Commission Decision authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97

   A draft Commission Decision to place genetically modified maize line NK603 on the Community market under Regulation (EC) No 258/97 on novel food and in accordance with Article 46(1) of Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

   The Committee did not deliver an opinion on the draft authorisation Decision since there was not a qualified majority. Eight Member States voted in favour of the draft Decision; 5 voted against and 2 abstained.

   The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure. The Council can either adopt the proposal or indicate opposition to the proposal by qualified majority within three months of submission of the proposal. If the Council does not act within that period, the Commission can adopt the measures envisaged.

2. **Interpretation and implementation of Regulation (EC) No 1829/2003 on genetically modified food and feed:**

   a) **Labelling requirements for mass caterers**

   The Commission had been requested to clarify whether the labelling requirements of Regulation 1829/2003, and in particular the requirements of Article 13, apply to establishments serving food to the public (mass caterers).

   The Commission representative indicated that the Commission’s interpretation, as laid down in an answer to Parliament (written question No. 4049/03), is that the labelling requirements of Regulation (EC) No. 1829/2003 are not applicable to food supplied by mass caterers to their customers where such foods have been prepared or processed; they do, however, apply to food which are supplied to mass caterers and which are delivered as such to the final consumer. This interpretation is consistent with the interpretation which has traditionally been given to Article 1(1) of Directive 2000/13/EC, which is written in a similar manner.
Three Member States (France, Germany and Austria) expressed diverging views based on the definition of “final consumer” in Regulation (EC) 178/2002 and on an interpretation given by the Legal Service of the Council. These Member States indicated that they apply Regulation (EC) 1829/2003 on their territory as requiring the labelling by mass caterers of all food containing, consisting of or derived from GMOs.

The representative of the Commission indicated 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) No 1829/2003 to cover supplies by mass caterers. This was indeed already the situation prior to the entry into application of Regulation (EC) 1829/2003 and it had not lead to difficulties for the functioning of the internal market.

There were also diverging views concerning the provisions of Article 14(2), which stipulates that specific rules concerning the information to be given by mass caterers may be adopted in the Regulatory Committee procedure. Some Member States stated that this provision only allows detailing of existing information requirements, whilst other Member States stated that Article 14(2) also allows the introduction of new requirements concerning the information to be given. The Commission representative did not pronounce on this question, indicating that the Commission had no intention to use this provision for the time being.

**b) Labelling of enzymes in cheese**

According to Article 6(2)(b) of the general labelling Directive 2000/13/EC, the labelling of ingredients of cheese, butter, fermented milk and cream is not compulsory provided that no other ingredients than lactic products, enzymes, micro-cultures and salt have been used.

The Commission clarified that this exemption also applies when these ingredients are genetically modified. The reason is that, as detailed above, according to Article 13(1) of Regulation (EC) No 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(2)(b) are met, the labelling of the ingredients of the foodstuffs mentioned above is not compulsory, even if these ingredients are genetically modified.

**c) Labelling of alcoholic beverages**

According to Article 6(3) of the general labelling Directive 2000/13/EC, the Council shall adopt specific rules on the labelling of ingredients of alcoholic beverages containing more than 1.2 % by volume of alcohol. Since these specific rules have never been adopted by Council, the current interpretation is that labelling of ingredients of alcoholic beverages is not compulsory in the Community.
The Commission clarified that this exemption does not apply to genetically modified ingredients of alcoholic beverages. The reason is that for these ingredients it can be considered that the Council and the Parliament have acted by laying down specific labelling rules in Regulation (EC) No. 1829/2003. Genetically modified ingredients of alcoholic beverages have thus to be labelled according to the labelling requirements of this Regulation.

d) Fermentation Products

Member States and operators have raised questions about the scope of Regulation (EC) No. 1829/2003 in respect to foods or food ingredients produced by fermentation using micro-organisms. The Commission representative indicated that the following two situations should be distinguished:

Substances such as food/feed additives or vitamins produced by fermentation

According to the Commission, substances produced by fermentation of micro-organisms:

- do not fall in the scope of the legislation (authorisation and labelling) if produced from a conventional micro-organism, irrespective of whether the substrate used for this fermentation is genetically modified or not;¹
- fall in the scope of the legislation (authorisation and labelling) when produced from a genetically modified micro-organism, irrespective of whether the substrate used for the fermentation is genetically modified or not.

In other words, it is the genetic modification of the micro-organism and not of the substrate that determines whether a substance produced by fermentation falls under the scope of the legislation or not.

Foodstuffs such as alcoholic beverages or dairy products produced by fermentation

According to the Commission, in the case of foodstuffs produced by fermentation, it is the starting materials of the fermentation that fall under the scope of the legislation, and not the metabolites that are produced during the fermentation process. If one or more of these starting materials are GM, these materials should be subject to the authorisation and labelled as GM, unless they are removed during the production process.

If GM microorganisms (e.g. yeasts or lactic bacteria) are used and are still present in the final food or feed, they should be subject to authorisation and labelling. Where they are removed, the resulting food is considered to have been produced with a GMM, but not from a GMM; in such case, the authorisation and labelling provisions of the Regulation are not applicable.

¹ However, if the genetically modified substrate is placed on the marked together with the substance, the substrate falls under the scope of the legislation
Member States expressed initial views on this topic. It was agreed that further discussion was needed within the GM food and feed section of the Standing Committee.

e) **Self cloning**

Due to lack of time this point could not be discussed. It was agreed that it should also be discussed within the GM food and feed section of the Standing Committee.

3. **Phytosterols/phytostanols**

a) **Opinion on a Draft Commission Decision authorising the placing on the market of milk based beverages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97**

This proposal received a favourable opinion by qualified majority. Two Member States voted against, because they disagree with the addition of phytosterols to foods and food ingredients.

b) **Opinion on a draft Commission Decision authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97**

c) **Opinion on a draft Commission Decision authorising the placing on the market of rye bread with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97**

The Committee was a split and did not deliver an opinion on either of the two proposals. Six Member States voted in favour; 3 Member States abstained and 6 Member States voted against. However, all conditions for authorisation provided by Regulation (EC) No 258/97 appear to be fulfilled and the SCF delivered a positive opinion on the safety of these products. Therefore, in accordance with the Regulatory procedure, the Commission will be invited to submit a proposal to Council.

d) **Opinion on a draft Commission Decision on authorising the placing on the market of sausages with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97**

The Committee delivered a negative opinion. Eleven Member States voted against, 3 Member States voted in favour and one abstained. The majority of the Member States expressed doubts on the appropriateness of adding phytosterols to sausages. However, all conditions for authorisation provided by Regulation (EC) No 258/97 appear to be fulfilled and the SCF delivered a positive opinion on the safety of these products. Therefore, in accordance with the Regulatory procedure, the Commission will be invited to submit a proposal to Council.

e) **General discussion on phytosterols (substantial equivalence)**
This matter had already been discussed at the 9th meeting of the Committee, but some Member States had requested to be able to reflect on the matter and others had sought further clarification from the Commission.

There was further discussion and the Chairman concluded that there appeared to be agreement within the Committee that where authorisation to place on the market a specific food or category of food (vector) with specified added phytosterols had been granted to a company, another company should be entitled to place on the market the same food or category of food with the same specified added phytosterols after a notification to the Commission, accompanied by a declaration from the manufacturer of the ingredient that the added phytosterols are the same in the product already authorised and in the product being notified. The Commission would circulate this notification to all Member States in accordance with Article 5 of Regulation (EC) No 258/97.

f) Notification from DANONE under the simplified procedure

The Commission representative informed the Committee that a notification had been received from Danone concerning the placing on the market of a milk based product with added phytosterols (DANACOL®). This was raising some difficulties, as the available and generally recognised scientific evidence supplied in support of the notification was relating to the safety of the food, and not to the substantial equivalence to the existing food or to the food subject to the notification; in addition, the food to which substantial equivalence was being claimed was not clearly identified. The Commission had discussed the matter with Danone, and it had been agreed that the company would seek an opinion from the competent body of a Member State (Finland) in order to establish the substantial equivalence to existing food of the food being the subject of the notification.

4. German notification on mandatory indication of treatment methods for conservation of fruits, vegetables or potatoes

After the presentation by the German delegation of its draft measure, only some delegations reacted, generally supporting the idea of informing consumers, but questioning the consequence for the circulation of products on the market.

Delegations were therefore requested to send their position within ten days, in particular on a possible labelling requirement at EU level, which might be introduced in the proposal on MRL for pesticides.

5. Novel foods and food supplements

A discussion paper on the novel food Regulation and food supplements had been circulated prior to the meeting. Due to the limited time available the Committee agreed that an exchange of views should take place during the meeting of the Working Group on Novel Foods on 14 May.
6. **Information on the situation in Member States regarding the use of ephedrine alkaloids in food supplements or other foods following the relevant ban (on the sale of food supplements containing ephedrine alkaloids) by the FDA in the US**

Delegations were invited to provide information on the situation in their country. The Netherlands indicated that they considered products containing ephedrine alkaloids medicines. As The Netherlands was the only Member State in which ephedrine had been on the market as a food ingredient (in food supplements), the Chairman concluded that there was no need to discuss this matter any further.


The representative of the Commission informed the Committee about the meeting on 19 April with stakeholders and Member States concerning the implementation of Regulation (EC) 178/2002 and in particular Article 18 on traceability. The Commission provided its view that Article 18 does not require internal traceability (i.e. correlation between inputs and outputs) to be established by food and feed business operators. More detailed Community provisions may be adopted for specific sectors under the Regulatory procedure. In the absence of Community legislation Member States may also adopt more detailed traceability requirements.

At least one Member State disagreed with the Commission’s interpretation and considered that Article 18 implicitly requires internal traceability. Some other Member States preferred to reflect on it and confirm their position at a later stage.