EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Held in Brussels on 22 July 2009

(Section Genetically Modified Food & Feed and Environmental Risk)

Chair: Dorothée André for points 1, 2, 3
Sebastien Goux for the other points

All the Member States were present except Cyprus.

SECTION A Draft presented for an opinion

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 59122xNK603 (DAS-59122-7xMON-ØØ6Ø3-6) 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))

A draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122xNK603 maize pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

Vote: no opinion (152 votes in favour, 112 votes against, 77 abstentions, 4 votes not represented)

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

- the application contains insufficiencies on the hybrid scheme however not compromising the safety of the product;
- the need for further internal consultations;
- the lack of time for the national environmental assessment;

- the European Food Safety Authority (EFSA) opinion is not considered as fully satisfactory;

- the difficulties to apply the labelling threshold for GM food and feed and stacked events;

- the approach followed for the evaluation of stacked events;

- 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.

One delegation 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 DAS-59122-7xMON-00603-6 due to the following reasons:

(a) The risk assessment which has been carried out lacks a lot of data and is not suitable to give a scientific proof for the safety for human and animal health as well as the environment. This concerns particularly molecular characterisation, expression-level of GM proteins, compositional analysis (e.g. vitamin B1), toxicology (e.g. 90day-toxicity study with the stack is lacking as well as whole food testing), allergenicity assessment of the stacked event, environmental risk assessment and the intended monitoring plan.

In general the carried out safety assessment is mainly based on assumptions and not on empirical data, which can not be regarded as state of the art.

(b) As long as no official (guidance) document on the interpretation of detection results of the described methods for stacked events are available, no approval for placing on the market of this product should be given.

(c) From the Austrian point of view, products others than food and feed containing or consisting of DAS-59122-7xMON-00603-6, are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

2. 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 MON89034 (MON-89Ø34-3) 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))

A draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 maize pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was submitted to the Committee for an opinion.

Vote: no opinion (167 votes in favour, 109 votes against, 65 abstentions, 4 votes not represented)

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

- the need for further internal consultations;
- the need for toxicological long term studies;
- 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.

One delegation 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 MON-89034-3 due to the following reasons:

(a) The risk assessment which has been carried out lacks a lot of data and is not suitable to give a scientific proof for the safety for human and animal health as well as the environment.

This concerns particularly agronomic parameters, environmental risk assessment (e.g. target specifity of cry-proteins) and the intended monitoring plan.

(b) From the Austrian point of view, products others than food and feed containing or consisting of MON-89034-3, are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

3. 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 MON88017 (MON-88Ø17-3) 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))

The comments made by the public on the EFSA opinion related to MON88017 maize were first presented to Member States followed by the presentation of the draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON88017 maize. This was followed by a discussion on these documents and the vote on the draft Decision.

Vote: no opinion (167 votes in favour, 80 votes against, 94 abstentions, 4 votes not represented)

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

- the need for further internal consultations;
- the need for toxicological long term studies;
- 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.

One delegation 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 MON-88017-3 due to the following reasons:

(a) The risk assessment which has been carried out lacks a lot of data and is not suitable to give a scientific proof for the safety for human and animal health as well as the environment. This concerns particularly compositional analysis and the intended monitoring plan.

(b) From the Austrian point of view, products others than food and feed containing or consisting of MON-88017-3, are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

SECTION B Information and/or discussion

4. EFSA Opinion on an application for the placing on the market of insect resistant and glyphosate tolerant genetically modified maize MON88017 for food and feed uses from Monsanto

A presentation of the opinion adopted by EFSA on MON88017 maize was made by a representative of EFSA and was followed by a discussion with Member States on certain specific aspects of the opinion.

It was specified that Member States have still the opportunity to send their comments to EFSA concerning an opinion even after the expiration of 3-month period foreseen in the Regulation for the consultation.

5. EFSA Opinion on an application for the placing on the market of glyphosate tolerant genetically modified cotton GHB 614 for food and feed uses from Bayer

A presentation of the opinion adopted by EFSA on GHB614 cotton was made by a representative of EFSA and was followed by a discussion with Member States on certain specific aspects of the opinion.

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

A Commission representative introduced the evaluation exercise, referring to the two information sessions already provided to the Committee in February and April. He clarified that the presence of the evaluators was aimed at facilitating contacts between the evaluators and the competent authorities in the follow up of the evaluation exercise.

Two members of the evaluation team provided the Committee with a presentation describing timeline, methodological approach and preliminary understanding of the exercise.

Nine delegations expressed their satisfaction with the work proposed by the evaluators. Two delegations stated that they will provide the evaluators with relevant studies already performed at national level.

On the content of the evaluation one delegation underlined the challenges of getting consumers' view, while another stressed the need to cover in the evaluation also the issue of benefits arising from GMOs. Clarifications on the future questionnaire were asked by two delegations which also stressed the need to have sufficient time for the reply.

7. WTO: State-of-play with respect to the dispute between the EC, US, Canada and Argentina on the measures affecting the approval and the marketing of biotech products

A Commission representative explained the recent development in the case.

In particular a mutually agreed solution has been reached by Canada and the EC and signed on 15 July 2009. This agreement provides for the establishment of a regular dialogue on issues of mutual interest on Agriculture Biotechnology.

Technical discussions are still taking place with Argentina, which, as a sign of satisfaction with this dialogue, has extended the Reasonable Period of Time for Implementation of the WTO panel report until 31 December 2009. The Commission hopes to strike with Argentina a solution similar to the one agreed with Canada.

The last technical discussions hold between EC and US officials took place in October 2008 and new US administration has still to decide the way forward on this case.

8. Miscellaneous

Traces of non EU authorised GM maize in US Soy

Three Member States indicated that they had been approached by the food and feed industry and relayed the industry's concerns due to the presence of non EU authorised GM maize in US soy. The industry reported high risks of shortage of soybean as of mid of September. They enquired about the Commission position and the announced legislative proposal of the Commission with respect to the "technical solution" that was announced after the College debate in May 2008.

The chair indicated that the Commission had also been recently informed by the food and feed industry and was currently considering the situation. She also indicated that the situation was applying for both US soybean. The appropriate EU policy in this context is primarily to maintain the effective functioning of the system of authorisations that relies on the safety assessments carried out by EFSA. For example, MON88017 maize for which a draft Decision is submitted to the committee today is the GM maize that is, according to the industry, currently the most present unauthorised GM maize in US soybean. A support of Member States with qualified majority in the Committee would allow a faster approval process.

With respect to the legislative proposal that was announced by the Commission on 2008, the Committee was reminded that it would aim at reducing the current level of uncertainty in GMO testing in order to create a level playing field for the operators and to minimise the risks of disruptions of import of raw materials. Intensive consultations have been initiated both amongst Commission services as well as with stakeholders and Member States. Further discussions are still needed in order to ensure that such a proposal would receive the necessary support of the Council and the European Parliament that will both be involved in its adoption.

She noted that today only three Member States intervened in the debate and that the involvement of all parties was needed to ensure an appropriate implementation of the EU legislation on GMOs and to avoid as much as possible negative impacts on the EU food and feed chain

Safety assessment: contribution of Member States

The chair outlined the different opportunities that Member States had to contribute to the safety assessment for applications submitted under Regulation (EC) No 1829/2003 on GM Food and Feed.

EFSA is carrying a three-month Member State consultation on all the applications as soon as they are considered as complete. In addition, as a follow-up of the Environmental Council of 4th December 2008, it was clarified that Member States could submit later in the process written comments to be considered by EFSA and its GMO Panel. This is in particular useful for comments related to additional information submitted to the applicant.

The annex G of each EFSA opinion on GM applications explains how Member States comments have been taken into account by the GMO Panel. If, despite this annex, Member States would still consider that further clarification is needed, they should indicate this to EFSA. Under these circumstances, it could be useful to re-formulate the comment in the light of the first answer provided by EFSA.

The Commission invites EFSA representatives to present the opinions to SCFCAH and provide opportunities to Member States to request further clarifications. In order to increase the efficiency of this discussion, it would be useful if Member States could submit their questions in advance of the meeting to the Commission who will inform EFSA.

Member States were thus called to make full use of these different opportunities. The whole process aims to ensure that all scientific questions have been raised in advance of the SCFCAH meeting where a draft decision is considered.