EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Held in Brussels on 9-10 February 2010

(Section Genetically Modified Food & Feed and Environmental Risk)

Chair: Dorothée André (points 1, 2, 3, 6, 8), Sébastien Goux (points 4, 5, 7)

All the Member States were present except Luxemburg; Norway participated as observer.

Adoption of the agenda

The draft agenda was accepted subject to the modifications that are reflected in the report.

SECTION A **Draft presented for an opinion - Projet présenté pour un avis - Zur Stellungnahme vorgestellter Entwurf**

1. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7xMON-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))

An EFSA representative presented the opinion related to MON88017xMON810 maize. There were no comments or questions from Member States on this opinion.
A Commission representative presented the comments received from the public related to the EFSA opinion on 59122x1507xNK603 maize

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122x1507xNK603 maize pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented. A recital of the draft decision was amended to better reflect the opinion of EFSA and in particular that it was concluded that the GM product is as safe as its conventional counterpart. The draft decision was then submitted to the Committee for an opinion.

Vote: no opinion (183 votes in favour, 112 votes against, 46 abstentions, 4 not represented)

The following considerations were mentioned by Member States as reasons for not supporting the draft Decision:
- the EFSA opinion is not considered as fully satisfactory;
- the absence of a scientific opinion on environmental risk by the national scientific assessment body;
- 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;
- the absence of agreement for the quantification of stacked events;
- other political reasons.

The delegations of Austria and Belgium provided a written declaration (see hereunder).

The Chairman took note of the votes and made the following comments regarding the comments that were put forward by Member States to justify that they did not support the proposal:
- the Commission repeatedly indicated that the Regulation on GM food and feed does allow to authorise products other than food and feed containing and consisting of GMOs. This point will again be discussed at the next committee and it is hoped that all delegations will agree on this point;
- the technical limitations with respect to the quantification of stacked events are inherent to this type of GMOs.
- in accordance with the Regulation, the decisions of authorisations are based on EFSA opinions. While it is understood that some Member States also wish to consult their national committees, the absence of opinions of national committee within the timeframe foreseen in the authorisation should not prevent a Member State to vote in favour of an authorisation.

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Written declaration of the Austrian delegation
Austria objects the placing on the market of genetically modified maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7xMON-ØØ6Ø3-6) due to the following reasons:
a. The risk assessment which has been carried out is not suitable to give a scientific proof for the safety of this product: This concerns in particular the poor quality of molecular characterisation, insufficient testing of potential fusion proteins, poor quality of testing agronomic traits and compositional analysis as well as of the environmental risk assessment. No information is provided whether the levels of endocrine disrupting agents like tetrahydrofuran-diol and leukotoxin-diol were altered in the double stack. Also the intended monitoring plan is not regarded as state of the art. Furthermore a post-market-monitoring plan is regarded as essential but not provided by the notifier.
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 maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7xMON-ØØ6Ø3-6), are not within the scope of EU Regulation 1829/2003 but under Directive 2001/18/EC.

Written declaration of the Belgian delegation

Belgium would like to draw the attention of the Commission, the other member states and EFSA to the following recommendations of our Biosafety Advisory Council:

- *Include the analysis of dietary fibre in the compositional analysis of food and adapt the OECD consensus documents accordingly*
- *Evaluate the allergenicity of the whole GM maize crop*
- *General surveillance to follow up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested*

All the advices of the Biosafety Advisory Council are available at www.conseil-biosecurité.be

2. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7) 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 Commission representative presented the comments received from the public following the publication of the EFSA opinion on 1507x59122 maize

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 maize pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented. A recital of the draft decision was amended to better reflect the opinion of EFSA and in particular that it was concluded that the GM product is as safe as its conventional counterpart. The draft decision was then submitted to the Committee for an opinion.

Vote: no opinion (183 votes in favour, 112 votes against, 46 abstentions, 4 not represented)

The following considerations were mentioned by Member States as reasons for not supporting the draft Decision:
- the EFSA opinion is not considered as fully satisfactory;
- the absence of a scientific opinion on environmental risk by the national scientific assessment body;
- 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;
- the absence of agreement for the quantification of stacked events;
- other political reasons.

The delegation of Austria provided a written declaration (see hereunder).

The Chairman took note of the votes and made the following comments regarding the comments that were put forward by Member States to justify that they did not support the proposal:
- the Commission repeatedly indicated that the Regulation on GM food and feed does allow to authorise products other than food and feed containing and consisting of GMOs. This point will again be discussed at the next committee and it is hoped that all delegations will agree on this point;

- the technical limitations with respect to the quantification of stacked events are inherent to this type of GMOs.
- in accordance with the Regulation, the decisions of authorisations are based on EFSA opinions. While it is understood that some Member states also wish to consult their national committees, the absence of opinions of national committee within the timeframe foreseen in the authorisation should not prevent a Member State to vote in favour of an authorisation.

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Written declaration of the Austrian delegation
Austria objects the placing on the market of genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7) due to the following reasons:
a. The risk assessment which has been carried out is not suitable to give a scientific proof for the safety of this product: This concerns in particular the insufficient analysis of molecular characterisation and gene-expression, the poor quality of testing agronomic traits, allergenicity, toxicology and whole food testing as well as of the environmental risk assessment. No information is provided whether the levels of endocrine disrupting agents like tetrahydrofuran-diol and leukotoxin-diol were altered in the double stack. Also the intended monitoring plan is not regarded as state of the art. Further more a post-market-monitoring plan is regarded as essential but not provided by the notifier.
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 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7, are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

Written declaration of the Belgian delegation
Belgium would like to draw the attention of the Commission, the other Member States and EFSA to the following recommendations of our Biosafety Advisory Council:
- *Include the analysis of dietary fibre in the compositional analysis of food and adapt the OECD consensus documents accordingly*
- *Evaluate the allergenicity of the whole GM maize crop*
- *General surveillance to follow up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested*

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3. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON88017xMON810 (MON-88Ø17-3xMON-ØØ81Ø-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 Commission representative presented the comments received from the public following the publication of the EFSA opinion on 1507x59122 maize.

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON88017xMON810 maize pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented. A recital of the draft decision was amended to better reflect the opinion of EFSA and in particular that it was concluded that the GM product is as safe as its conventional counterpart. The draft decision was then submitted to the Committee for an opinion.

Vote: no opinion (183 votes in favour, 112 votes against, 46 abstentions, 4 not represented)

The following considerations were mentioned by Member States as reasons for not supporting the draft Decision:
- the EFSA opinion is not considered as fully satisfactory;
- the absence of a scientific opinion on environmental risk by the national scientific assessment body;
- 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;
- the absence of agreement for the quantification of stacked events;
- other political reasons.
The delegation of Austria provided a written declaration (see hereunder).

The Chairman took note of the votes and made the following comments regarding the comments that were put forward by Member States to justify that they did not support the proposal:
- the Commission repeatedly indicated that the Regulation on GM food and feed does allow to authorise products other than food and feed containing and consisting of GMOs. This point will again be discussed at the next committee and it is hoped that all delegations will agree on this point;
- the technical limitations with respect to the quantification of stacked events are inherent to this type of GMOs.
- in accordance with the Regulation, the decisions of authorisations are based on EFSA opinions. While it is understood that some Member states also wish to consult their national committees, the absence of opinions of national committee within the timeframe foreseen in the authorisation should not prevent a Member State to vote in favour of an authorisation.

The Chairman indicated that the Commission would be invited to submit a proposal to the Council in accordance with the Regulatory procedure.

Written declaration of the Austrian delegation
Austria objects the placing on the market of genetically modified maize MON88017xMON810 (MON-88Ø17-3xMON-ØØ81Ø-6) due to the following reasons:
a. The risk assessment which has been carried out is not suitable to give a scientific proof for the safety of this product: The molecular characterization (insert integrity, identity and copy number, flanking regions) is only demonstrated on a gross level (single restriction enzyme analysis) and cannot provide evidence for sequence integrity of the single events in the double stack. No data concerning the comparison of herbicide exposed and non-exposed double stacked GM plants are presented for comparative assessment. For the toxicological assessment interactions between the introduced proteins are not sufficiently addressed and a 28-day toxicological study in rodents is missing. Evidence for the

absence of negative effects on non-target organisms due to interactions induced by the combined expression of 2 Cry proteins is also not available.
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 maize MON88017xMON810 (MON-88Ø17-3xMON-ØØ81Ø-6), are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

Written declaration of the Belgian delegation
Belgium would like to draw the attention of the Commission, the other Member States and EFSA to the following recommendations of our Biosafety Advisory Council:

- *Include the analysis of dietary fibre in the compositional analysis of food and adapt the OECD consensus documents accordingly*
- *Evaluate the allergenicity of the whole GM maize crop*
- *General surveillance to follow up unanticipated allergenicity aspects since the allergenicity of the whole GM maize has not been tested*

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SECTION B Information and/or discussion - Information et/ou discussion - Zur Information und/oder Diskussion

4. EFSA Opinion on an application for the placing on the market of the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses, import and processing and for renewal of the authorisation of maize NK603 as existing products, both under Regulation (EC) No 1829/2003 (food and feed aspects)

An EFSA representative presented the opinion on NK603 maize related to food and feed risk assessment.

It was explained that the GMO panel has assessed the comments made by Austria and provided to EFSA related to a recent publication highlighting the existence of several homologous nucleotide sequences in NK603 maize. The results of this analysis which have been published on the EFSA website concludes that the elements present in this recent publication do not raise a safety concern. Therefore, the EFSA opinion on NK603 maize does not need to be modified since the conclusions related to safety are still valid.

5. Draft Commission Regulation on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006

The draft Regulation was reviewed in detail. Two Member States who had provided substantial comments thanked the Commission for having considered their comments in the present draft. However, one of these Member States made some declarations related to cultivation and to the fact that they consider that "import and processing" is

not covered by the Regulation on GM food and feed. Two other Member States indicated a negative stance on the draft. A representative of the Commission indicated that the draft would be reviewed in the light of this discussion. MS were requested to start consultation to determine their position. Vote is anticipated to take place after the end of the SPS/TBT 60-day consultation period.

6. Review of the situation regarding the detection of non EU authorised GM food and feed (LLRice601, BT63 rice, Linseed FP967)

a. LLRice601 in rice from US origin

A Commission representative indicated that there was a series of elements that are in favour of lifting the measures on LLRice601. It was in particular underlined that the FVO mission concluded that the application of the emergency measures as well as the other actions taken by the US industry to prevent the presence of LLRice601 in shipments exported to the EU were satisfactory. In addition, no LLRice601 was detected by the US rice industry for this year. The fact that one RASFF was notified on 2 February on rice packed in Italy after more than 1 year should not change the assessment of the overall situation but it would be useful to understand the origin of this contamination. The Italian authorities confirmed that the enquiry was ongoing. One Member State strongly supported the lifting of the emergency measures. A discussion on a draft decision to lift the emergency measures could be considered at the next meeting of this Committee.

b. Bt63 rice in rice from Chinese origin

A Commission representative indicated that the situation was not satisfactory since the non-authorised Bt63 rice was still detected in products imported from China. A strengthening of the emergency measures is thus envisaged.

c. Linseed "Triffid" FP967 in linseed from Canadian origin

A Commission representative reported on the current situation. In particular, he indicated that the Commission services had been approached by Canadian authorities and operators to modify the protocol of sampling and testing so as to allow testing prior loading. Three Member States explicitly supported such a review of the protocol. One Member State also expressed interest in a FVO mission. Discussions will take place with Canadian authorities with a view to agree on the amendments of the protocol at the next SCFCAH. A further harmonisation of the EU controls on these products (e.g. to ensure that the same protocol of sampling and testing is used by all Member States, to communicate information on the lots that have been already tested negative) without adopting emergency measures will also be considered.

7. Information from the Commission on the current Comitology procedures

A Commission representative provided an overview of current comitology procedures with a specific attention to the regulatory procedure with scrutiny (PRAC). It was stressed that the current procedures would apply as long as the ongoing work regarding the implementation of the Lisbon Treaty was not finalised.

8. Any other business

Low-level presence of non authorised GMOs

Upon request of some Member States, the Chairman indicated that this matter was to be considered as a matter of priority by the new Commission.

Codex

A state-of-play of the discussions on detection methods for GM food in the Codex Committee on Methods of Analysis and Sampling (CCMAS) and on labelling of food derived from modern biotechnology in the Codex Committee on food labelling(CCFL) was provided. Council preparatory meeting for CCMAS on 26 February.

EFSA GMO Panel analysis of publication of de Vendomois et al. (2009)

This publication re-analyses the results of three 90-day feeding study of 3 authorised GM maize (MON810, NK603 and MON863) and claimed that their statistical analysis had identified negative effects. It received media attention and is subject to several Parliamentary questions.

Following a request from the Commission services, the GMO Panel reviewed this publication during its last meeting and adopted minutes that dismiss the conclusion of the publication. These minutes are published on the EFSA website and were presented to the committee. A representative from France indicated that its 2 scientific committees (AFSSA and the "Haut Conseil de Biosécurité") have adopted detailed opinions that are in agreement with the conclusions of EFSA.

On the basis of the reviews by EFSA and the French Scientific committees of the publication of de Vendomois et al. (2009), there are thus no reasons to doubt on the safety of these three GM maize and their authorisation will be maintained.

Dorothée André
Head of Unit