EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Held in Brussels on 8 and 9 February 2011

(Section Genetically Modified Food & Feed and Environmental Risk)

Chair: Dorothée André

All Member States were represented with exception of Estonia represented by Portugal and Slovenia represented by Italy

Adoption of the agenda

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

1. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604 (SYN-BTØ11-1xSYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented and submitted to the Committee for an opinion.

The Commission made the following declaration with reference to a Member State request for clarification related to the potential presence of Cry-proteins residues in GM food:

"The Commission will provide as soon as possible clarification regarding the legal situation of Cry-proteins contained in insect-resistant genetically modified crops in relation to the thresholds for pesticide residues in food and feed according to Regulation (EC) No 396/2005 on pesticide residues and ensure the appropriate follow-up."

Vote: no opinion (180 votes in favour, 99 votes against, 66 abstentions)

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

- toxicological and allergenicity studies are not considered as satisfactory;

- lack of satisfactory environmental assessment;

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

- the 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;

- negative public opinion and perception to GMO;

- political reasons.

One Member State indicated that it voted in favour after due consideration of the above-mentioned declaration from the Commission.

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

Declaration from the Austrian delegation

Austria objects the placing on the market of genetically modified maize MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) 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 testing agronomic performance, phenotypic stability, compositional analysis, toxicity, as well as whole food testing and monitoring.

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 MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

Declaration from the Belgian delegation

Belgium votes against the authorisation of the placing on the market of products containing, consisting of, or produced from GM maize Btl1xMIR604.

Our Biosafety Advisory Council disagrees with the GMO panel of EFSA that it is unlikely that these GMO's have adverse effects on human health in the context of its intended use, because identified potential allergenicity of the trangsene PMI protein has not been tested in vitro on serum of patients allergic to latex nor by appropriate in vivo tests.

Declaration from the Latvian delegation

Latvia votes against taking into account the political aspects and the negative attitude of the public.

2. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604xGA21 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented and submitted to the Committee for an opinion.

The Commission made the following declaration with reference to a Member State request for clarification related to the potential presence of Cry-proteins residues in GM food:

"The Commission will provide as soon as possible clarification regarding the legal situation of Cry-proteins contained in insect-resistant genetically modified crops in relation to the thresholds for pesticide residues in food and feed according to Regulation (EC) No 396/2005 on pesticide residues and ensure the appropriate follow-up."

Vote: no opinion (180 votes in favour, 109 votes against, 56 abstentions)

The following reasons were mentioned by Member States Competent Authorities for not supporting the draft Decision:

- toxicological and allergenicity studies are not considered as satisfactory;
- lack of satisfactory environmental assessment;
- difficulties to apply the labelling threshold for GM food and feed and stacked events;
- the 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;
- negative public opinion and perception to GMO;
- political reasons.

One Member State indicated that it voted in favour after due consideration of the above-mentioned declaration from the Commission.

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

Declaration from the Austrian delegation

Austria objects the placing on the market of genetically modified maize MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) 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 testing agronomic performance, phenotypic stability, compositional analysis, toxicity, as well as whole food testing and monitoring.

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 MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.

Declaration from the Belgian delegation

Belgium votes against the authorisation of the placing on the market of products containing, consisting of, or produced from GM maize MIR604xGA21.

Our Biosafety Advisory Council disagrees with the GMO panel of EFSA that it is unlikely that these GMO's have adverse effects on human health in the context of its intended use, because identified potential allergenicity of the trangsene PMI protein has not been tested in vitro on serum of patients allergic to latex nor by appropriate in vivo tests.

Declaration from the Latvian delegation

Latvia votes against taking into account the political aspects and the negative attitude of the public.

3. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented and submitted to the Committee for an opinion.

The Commission made the following declaration with reference to a Member State request for clarification related to the potential presence of Cry-proteins residues in GM food:

"The Commission will provide as soon as possible clarification regarding the legal situation of Cry-proteins contained in insect-resistant genetically modified crops in relation to the thresholds for pesticide residues in food and feed according to Regulation (EC) No 396/2005 on pesticide residues and ensure the appropriate follow-up."

Vote: no opinion (180 votes in favour, 109 votes against, 56 abstentions)

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

- toxicological and allergenicity studies are not considered as satisfactory;
- lack of satisfactory environmental assessment impact;
- difficulties to apply the labelling threshold for GM food and feed and stacked events;
- the 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;
- negative public opinion and perception to GMO;
- political reasons.

One Member State indicated that it voted in favour after due consideration of the above-mentioned declaration from the Commission.

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

Declaration from the Austrian delegation

Austria objects the placing on the market of genetically modified maize BtllxMIR604xGA21 (SYN-BTØ11-lxSYN-IR6Ø4-5xMON-ØØØ21-9) 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 molecular characterisation, testing agronomic performance, phenotypic stability, compositional analysis, toxicity, as well as whole food testing and monitoring.

b. Moreover this GMO contains a herbicide tolerance-gene (pat-gene), which confers tolerance against glufosinate-ammonium herbicides. These have been classified recently as potentially harmful, respectively with negative impact on reproduction.

c. 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 b egiven.

d. From the Austrian point of view, products others than food and feed containing or consisting of maize BtllxMIR604xGA21 (SYN-BTØ11-lxSYN-IR6Ø4-5xMON-ØØØ21-9) are not within the scope of EU-Regulation (EC) No 1829/2003 but under Directive 2001/18/EC.

Declaration from the Belgian delegation

Belgium votes against the authorisation of the placing on the market of products containing, consisting of, or produced from GM maize Btl1 xMIR604xGA21.

Our Biosafety Advisory Council disagrees with the GMO panel of EFSA that it is unlikely that these GMO's have adverse effects on human health in the context of its intended use, because identified potential allergenicity of the trangsene PMI protein has not been tested in vitro on serum of patients allergic to latex nor by appropriate in vivo tests.

Declaration from the Latvian delegation

Latvia votes against taking into account the political aspects and the negative attitude of the public.

4. Draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed was presented and submitted to the Committee for an opinion.

The Commission made the following declaration with reference to a Member State request for clarification related to the potential presence of Cry-proteins residues in GM food:

"The Commission will provide as soon as possible clarification regarding the legal situation of Cry-proteins contained in insect-resistant genetically modified crops in relation to the thresholds for pesticide residues in food and feed according to Regulation (EC) No 396/2005 on pesticide residues and ensure the appropriate follow-up."

Vote: no opinion (192 votes in favour, 87 votes against, 66 abstentions)

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

- toxicological studies are not considered as satisfactory;

- further studies on possible effects of adjuvants to allergenicity are considered necessary;

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

- lack of information on the monitoring plan;

- lack of satisfactory environmental assessment;

- the 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;

- negative public opinion and perception to GMO;

- political reasons.

One Member State indicated that it voted in favour after due consideration of the above-mentioned declaration from the Commission.

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

Declaration from the Austrian delegation

Austria objects the placing on the market of genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21023-5) due to the following reasons:

a. 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.

b. Moreover this GMO contains a herbicide tolerance-gene (pat-gene), which confers tolerance against glufosinate-ammonium herbicides. These have been classified recently as potentially harmful, respectivelywith negative impact on reproduction.

c. From the Austrian point of view, products others than food and feed containing or consisting of cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21023-5) are not within the scope of EU-Regulation (EC) No 1829/2003 but under Directive 2001/18/EC.

Declaration from the Latvian delegation

Latvia votes against taking into account the political aspects and the negative attitude of the public.

5. Commission Regulation laying down the methods of sampling and analysis for the official control of feed as regards the presence of genetically modified material for which an authorisation procedure is pending or the authorization of which has expired

A Commission representative presented the revised version of the Draft Commission Regulation. In particular, he indicated that the following modifications had been made following the exchange of views that took place during the previous meetings:

- recitals have been added to clarify the context of the measures and in particular that they will in practice apply to GMOs for which safety information will be available within the EU and is expected to be available at international level;

- the measures will only apply to GM material for which the reference material produced and certified in accordance with the relevant ISO guidelines is available;

- one Article and one recital were also added regarding the handling of results obtained below the MRPL which would have to be recorded by Member States and reported to the Commission. Appropriate measures (including emergency measures) should be considered when the provisions of the Regulation are not sufficient to ensure the protection of human and animal health, or the environment;

- sampling procedures were revised to improve their practicability;

- it was clarified that the analysis is related to the presence of GM material in individual feed materials or feed additives. In addition, measures were included to harmonise the expression of the analytical results.

The Committee welcomed this new draft and considered that these modifications improved the draft. Several Member States supported this draft since it puts in place very strict rules for the official control of non authorised GMOs.

Following a further exchange of views, the main modification that was brought to the draft was to clarify that the scope of the draft regulation was, inter alia, covering GM material for which a valid application has been submitted under the Regulation (EC) No 1829/2003 and which is authorised for commercialisation in a third country.

The chair concluded by indicating that there was broad support to the text but that more time was needed for some Member States to be in a position to vote in favour. As a consequence, it is intended to submit a revised draft for vote on 22 February.

Several Member States indicated that they were disappointed that no vote could be taken today. They also indicated that they considered that food should ideally be covered by this draft Regulation and called the Commission to duly consider an extension of the scope of to these products in the future.

6. Update on the actions taken following the detection of non authorised Amadea potato in Amflora potato on 27 August 2010.

A representative of the Commission provided a state-of-play of the actions taken following the detection of non authorised Amadea potato in Amflora potato. All the lots that were found to be contaminated or suspicious have been destroyed. In 2011, the cultivation of Amflora potato is expected to only take place in Sweden and Germany.

7. Presentation of the publication "A Decade of EU-funded GMO research" (2001-2010) published by DG Research and Innovation.

A presentation was given by a Commission representative (DG RTD) on projects related to GMOs funded by the European Commission under the Research Framework Programmes. Booklets presenting the results of more than 50 projects, along a period of 10 years, have been recently published by DG RTD[1] and were distributed during the meeting. The presentation will be uploaded on CIRCA website.

8. Environmental risk assessment guidelines: presentation from the Commission on the step forward.

A Commission representative provided a presentation on the state-of-play of the Environmental Risk Assessment guidelines which were published by EFSA on 12 November 2010. Member States were recalled to send comments by 15 February; these comments will be analysed and discussed at the next meeting in April. One Member State asked for clarification related to the procedure which will be followed and to the legislative act form which will be adopted by the Commission. It was clarified that the development of the ERA guidelines will follow the same process as for GM food and feed guidelines. The presentation will be uploaded on CIRCA website.

9. State-of-play regarding the use of the tool "CIRCA".

A Commission representative provided a presentation on the use of CIRCA tool and recalled Member States to register their name in order to get the password for the access to the documents. COM will help those who are not familiar with the use of CIRCA and will distribute the rules for registration. The presentation will be uploaded on CIRCA website.

---

[1] The publication can be downloaded http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf