EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

Brussels,
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SUMMARY REPORT OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH HELD IN BRUSSELS ON 10 JUNE 2013 (Section Genetically modified Food & Feed)

Chair: Dorothee Andre

26 Member States were present, Lithuania was represented by Latvia.

A.1 Discussion on the United States Department of Agriculture investigation into the detection of genetically modified glyphosate resistant wheat in the State of Oregon, USA.

The Chair invited the US representatives to present information on their investigation to date, including the magnitude of the problem, and actions which have been taken or will be taken. The Chair also reminded on the EU zero tolerance policy regarding non-authorised Genetically Modified Organism (GMOs). The US representatives provided an overview of their investigations regarding the detection of the glyphosate resistant wheat volunteers in a single farm in the US state of Oregon in spring 2013. It was explained that the detection of MON 71800 wheat followed from the spraying of volunteer wheat in a fallow field (as part of crop rotation) with glyphosate herbicide, and that their investigations so far involved sampling volunteer wheat in the 2nd field of the same farm, adjacent farms, wheat from the previous harvest (up to 2009), and seed from the merchant who originally supplied the farm. The US representatives stated that all samples analysed were negative, and that the evidence to date indicated that this was an isolated incident and that the GM event was not present in the food/feed chain.

Member States asked for information as regards the sampling and testing which had been carried out along the food and feed chain, and details on the protocols which had been used. The US representative provided details on their investigations to date. The Chair thanked the US delegation and requested additional information on the sampling and testing protocols used.

The representative from the Joint Research Centre (JRC) provided an overview of the proposed screening strategy for testing for GM glyphosate resistant wheat as an interim measure while the event specific method supplied by Monsanto is being verified by them. Following an exchange with the Committee Members the JRC representative indicated that an interim protocol would be published on the JRC website in the coming days.

B.1 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034×1507×NK603 (MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034×1507×NK603 (MON-89Ø34-3xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council was presented and submitted to the Committee for an opinion.

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

- •Concerns over the EFSA safety assessment;
- •Political reasons;
- •Negative public opinion;
- •No support of the EFSA assessment of some single events present in this GMO;
- •Concerns over the possible negative long-term effects of NK603;
- •Risk assessment on potential synergistic effects between the single GM events considered insufficient;
- • Concerns over the detection method;
- •The Regulation on genetically modified food and feed is not considered as the right legal basis to authorise products other than food and feed containing and consisting of GMOs (genetically modified organisms);
- •Safety concerns regarding MON89034;
- •No agreed position between different ministries.

Statement of the Austrian delegation:

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 evaluation of gene expression data (no statistical significance analysis of differences)
- insufficient comparative assessment (only 4 test locations for a single season, no statistical comparison with parental lines)
- incompleteness of the environmental monitoring plan

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 MON89034x1507xNK603 are not within the scope of EU-Regulation (EC) No 1829/2003 but under Directive 2001/18/EC.

The Chair indicated that the Commission will submit a proposal to the Appeal Committee in accordance with Regulation (EU) No 182/2011.

Vote taken: no opinion (161 votes in favour, 116 votes against, 68 abstentions).

B.2 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034×1507×MON88017×59122 (MON-89Ø34-3xDAS-Ø15Ø7-1xMON-88Ø17-3xDAS-59122-7), four related GM maizes combining three different single GM events (MON89034×1507×MON88017 (MON-89Ø34-3xDAS-Ø15Ø7-1xMON-88Ø17-3), MON89034×1507×59122 (MON-89Ø34-3xDAS-Ø15Ø7-1xDAS-59122-7), MON89034×MON88017×59122 (MON-89Ø34-3xMON-88Ø17-3xDAS-59122-7), 1507×MON 88017×59122 (DAS-Ø15Ø7-1xMON-88Ø17-3xDAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034x1507 (MON-89Ø34-3xDAS-Ø15Ø7), MON89034x59122 (MON-89Ø34-3xDAS-59122-7), 1507xMON88017 (DAS-Ø15Ø7-1xMON-88Ø17-3), MON 88017x59122 (MON-88Ø17-3xDAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034×1507×MON88017×59122 (MON-89Ø34-3xDAS-Ø15Ø7-1xMON-88Ø17-3xDAS-59122-7), four related GM maizes combining three different single GM events (MON89034×1507×MON88017 (MON-89Ø34-3xDASØ15Ø7-1xMON-88Ø17-3), MON89034×1507×59122 (MON-89Ø34-3xDASØ15Ø7-1xDAS-59122-7), MON89034×MON88017×59122 (MON-89Ø34-3xMON-88Ø17-3xDAS-59122-7), 1507×MON 88017×59122 (DAS-Ø15Ø7-1xMON-88Ø17-3xDAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034x1507 (MON-89Ø34-3xDAS-Ø15Ø7), MON89034x59122 (MON-89Ø34-3xDAS-59122-7), 1507xMON88017 (DASØ15Ø7-1xMON-88Ø17-3), MON 88017x59122 (MON-88Ø17-3xDAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council was presented and submitted to the Committee for an opinion.

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

- •Concerns over the EFSA safety assessment;
- •Political reasons;
- •Negative public opinion;
- •No support of the EFSA assessment of some single events present in this GMO;
- •Concerns over the possible negative long-term effects of NK603;
- •Risk assessment on potential synergistic effects between the single GM events considered insufficient;
- • Concerns over the detection method;
- •The Regulation on genetically modified food and feed is not considered as the right legal basis to authorise products other than food and feed containing and consisting of GMOs (genetically modified organisms);
- •Safety concerns regarding MON89034;
- •No agreed position between different ministries.

Statement of the Austrian delegation:

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 comparative assessment (unavailability of quadruple stack specific comparative data between herbicide-treated and non-treated plants)
- insufficient toxicological assessment of the stacked event for potential interaction between Cry1A.105, Cry2Ab2, CryF1, Cry34Ab1, Cry35Ab1, PAT and CP4 EPSPS
- incompleteness of the environmental monitoring plan

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 MON89034x1507xMON88017x59122 are not within the scope of EU-Regulation (EC) No 1829/2003 but under Directive 2001/18/EC.

The Chair indicated that the Commission will submit a proposal to the Appeal Committee in accordance with Regulation (EU) No 182/2011.

Vote taken: no opinion (161 votes in favour, 116 votes against, 68 abstentions).

B.3 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of genetically modified maize MON 810 pollen (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Commission Implementing Decision authorising the placing on the market of genetically modified maize MON 810 pollen (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council was presented and submitted to the Committee for an opinion.

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

- Concerns over the EFSA safety assessment of MON810 pollen which is considered inconclusive;
- Possible uncertainties over the protection of human health;
- Political reasons;
- Negative public opinion;
- Concerns over a possible negative effect of Cry proteins;
- Existing National bans;
- Legal uncertainties over labelling of pollen in honey;
- No agreed National position.

The Chair indicated that the Commission will submit a proposal to the Appeal Committee in accordance with Regulation (EU) No 182/2011.

Vote taken: no opinion (154 votes in favour, 145 votes against, 46 abstentions) .

M.1 One Member State asked to have access to the reference material and the validation methods for the 3 GM potato applications recently withdrawn by Bayer in order to perform controls. The Commission will clarify whether this could be requested to the applicants given the current status of the files.

The Commission informed Member States about the state-of-play of the DG Research project on a 2-year study with NK863 which was recently voted by written procedure by the Management committee under the FP7 (Committee meeting will take place on 25 June).

Upon a request from a Member State, the Commission clarified the state-of-play of the extension of Regulation (EU) No 619/2011 to food. The Commission is preparing a Road map as a first step of the impact assessment, which will be followed by an external evaluation starting by end of 2013.

The Commission informed that the amended Decision on emergency measures regarding unauthorised genetically modified rice in rice products originating from China was adopted on 13 June 2013 and that the new Implementing Regulation on GM food and feed applications was published on 8 June 2013.