



sante.ddg2.g.5(2018)7202626

To: Permanent Representations of all 28 Member States
Missions of Iceland and Norway

Copy to: Contacts Standing Committee on Plants, Animals, Food and Feed
of all 28 Member States - preset
Contacts DG Health and Food Safety and other - preset

Summary Report

Health and Food Safety Directorate General / Unit E3

Meeting: Standing Committee on Plants, Animals, Food and Feed
Section: Genetically Modified Food and Feed
Date: 03 December 2018
Summary Report: Attached in Annex 1

Please find attached the Summary Report of the PAFF Committee Meeting on Genetically Modified Food and Feed, held on 03 December 2018.

N.B. The drafts on which the Committee expressed an opinion are subject to a defined procedure in relation to the formal adoption by the Commission.

Marta PONGHELLINI
Deputy Head of Unit
Animal Nutrition, veterinary medicines
(for Point M.01)

Chantal BRUETSCHY
Head of Unit
Biotechnology

Annex 1 – Summary Report

COPY TO:

CABINET ANDRIUKAITIS: Ms. N. Chaze (by e-mail)
Mr. J. Gurstis (by e-mail)

SG: Ms. A.-L. Barreau (by e-mail)

DG HEALTH AND FOOD SAFETY:

Ms. A. BUCHER (by e-mail)
Mr. R. REIG RODRIGO/Ms. L. CARROUEE (by e-mail)
Ms. D. VAN BUXHOEVEDEN (by e-mail)
Mr. M. HUDSON – Dir. A (by e-mail)
Mr. A. RYS – Dir. B (by e-mail)
Mr. P. BOKOR – D.1 (by e-mail)
Mr. D. LANGE – D.2 (by e-mail)
Mr. K. VANDYCK – D.3 (by e-mail)
Mr. A. DI GIULIO – D.4 (by e-mail)
Ms. S. JÜLICHER – Dir. E (by e-mail)
Ms. A. NIKOLAKOPOULOU – E.1 (by e-mail)
Mr. B. GAUTRAIS – E.2 (by e-mail)
Ms. C. BRUETSCHY – E.3 (by e-mail)
Mr. K. BEREND – E.4 (by e-mail)
Mr. C. SIEBERT – E.5 (by e-mail)
Mr. B. VAN GOETHEM – Dir. G (by e-mail)
Ms. D. ANDRE – G.1 (by e-mail)
Ms. E. ZAMORA ESCRIBANO – G.2 (by e-mail)
Mr. A. GAVINELLI – G.3 (by e-mail)
Mr. E. THEVENARD – G.4 (by e-mail)
Mr. P. LOOPUYT – G.5 (by e-mail)

EFSA: - Mr. D. DETKEN
- Ms. V. VILLAMAR (by e-mail)

NEAR: - Ms. T. BORBAS (by e-mail)



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)7202626

Standing Committee on Plants, Animals, Food and Feed
Section *Genetically Modified Food and Feed*
3 December 2018

CIRCABC Link: <https://circabc.europa.eu/w/browse/0a959f6f-88ba-4b4c-b8cc-a9e467c7bd48>

SUMMARY REPORT

A.01 Assessment of genetically modified soybean MON 87751 for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-121) - Presentation by EFSA.

EFSA presented the opinion on the application for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87751. No questions were raised by Member States.

A.02 Assessment of genetically modified maize 4114 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123) - Presentation by EFSA.

EFSA presented the opinion on the application for the placing on the market of products containing, consisting of or produced from genetically modified maize 4114. No questions were raised by Member States.

A.03 Assessment of genetically modified maize MON 87411 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-124) – Presentation by EFSA.

EFSA presented the opinion on the application for the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411. No questions were raised by Member States.

A.04 Assessment of genetically modified maize 1507 × NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008) – Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of products containing, consisting of, or produced from genetically modified maize 1507 × NK603. No questions were raised by Member States.

A.05 State of play on the European Network of GMO laboratories report on detection methods for new mutagenesis techniques.

The Commission (JRC) explained that the work on the report was ongoing. The European Union Reference laboratory on GM food and feed (EURL GMFF) prepared a first draft, which was circulated to the European Network of GMO Laboratories (ENGL) and discussed in a meeting held on 26 November. The aim is to discuss the draft report in the ENGL Steering Committee meeting (February 2019) and to finalise and adopt it by March 2019.

The Commission invited competent authorities to liaise with their national laboratories to provide timely input to the EURL GMFF/ENGL in view of finalising the report without undue delay.

Regarding the implementation of the ruling of the Court of Justice of the European Union (Case C-528/16) at national level, the Commission thanked for the information already provided by the Member States and encouraged them to complement, where appropriate, their replies, in order to get a comprehensive view of the Member States' actions and to allow constructive discussion with the Member States in 2019.

It was, therefore, agreed to continue the discussion in upcoming PAFF GMFF meetings based on the input from the Member States. The Commission indicated that a joint Committee meeting of all GMO competent authorities could also be organised in 2019 if Member States considered this necessary.

A.06 Follow-up information from the Commission on the notion of placing on the market in relation to the circulation and processing of unauthorised GMOs intended exclusively for export to non-EU countries.

As requested by a number of Member States, and further to the discussion held on 11 September 2018, the Commission provided legal clarification on the notion of "placing on the market" for non-authorised GMOs intended for export to third countries (as provided for under of Article 12 of General Food Law). Any activity involving a transfer of ownership of unauthorised GMOs on the EU territory constitutes a placing on the EU market and is prohibited; such transfer may imply or not a physical movement of the goods in question. In addition, when there is no transfer of ownership and if the GMOs are non-living organisms, there is no need to obtain a pre-market authorisation under the GMO legislation. However, when there is no transfer of ownership and if the GMOs are living organisms, a pre-market authorisation is required under the GMO legislation unless the activities are carried out under contained use conditions. No Member States asked additional questions.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision amending Decision 2009/866/EC, Decision 2010/419/EU, Implementing Decision 2012/651/EU and Implementing Decision (EU) No 2016/1685 as regards the representative of the authorisation holder.

The draft Decision amending Decision 2009/866/EC, Decision 2010/419/EU, Implementing Decision 2012/651/EU and Implementing Decision (EU) No 2016/1685 as regards the representative of the authorisation holder was presented to the Committee and submitted for a vote.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision amending Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision amending Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 was presented to the Committee and submitted for a vote.

Vote taken: No opinion.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient

Written statement issued by Sweden:

“Decision 2007/232/EG gives an authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 x Rf3 for which Bayer CropScience had made an application. It covered feed and products of this particular oilseed rape for other purposes than feed and food. It did not cover cultivation. This oilseed rape is tolerant to herbicides based on glufosinate-ammonium and contains proteins for male sterility and/or recovery of the fertility.

In 2013 authorisation was given to also place food on the market of the oilseed rape mentioned above and food and feed produced of the same oilseed rape (Decision 2013/327/EU). In May 2016 the company made another application for products covered by Decision 2007/232/EG. On 30 November the applicant asked the Commission’s permission to merge the use of oilseed rape in the application of a renewed authorisation of the Decision from 2007 with the use of oilseed rape that is covered by Decision 2013/327/EU. The Commission thinks that the application is justified as a means of simplification and that Decision 2013/327/EU is to be changed to cover also those products at the moment covered by Decision 2007/232/EG and that the latter Decisions is to be repealed.

On 28 November 2017 the GMO Panel of EFSA came to the conclusion that the application for a renewed authorisation did not contain any new evidence which change the conclusions in EFSA’s original risk assessment of 2005.

This does not preclude the Swedish vote on a possible future granting of authorization of cultivation of seeds that are tolerant to glufosinate-ammonium.

Glufosinate-ammonium is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009.

In our view, potential use and cultivation of genetically modified organisms in Sweden should not have a negative effect on biodiversity and, as far as possible, not lead to an increased use of pesticides.”

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

B.03 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 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified genetically modified maize 5307 was presented to the Committee and submitted for a vote.

Vote taken: No opinion.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

B.04 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 MON 87403 (MON-874Ø3-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified genetically modified maize MON 87403 was presented to the Committee and submitted for a vote.

Vote taken: No opinion.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

B.05 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 cotton GHB614 × LLCotton25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified genetically modified cotton GHB614 × LLCotton25 × MON 15985 was presented to the Committee and submitted for a vote.

Vote taken: No opinion.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient

Written statement issued by Sweden:

"The Swedish Board of Agriculture and the National Food Agency make the same conclusion as stated by Efsa i.e. this product is safe for human and animal health as well as for the environment. Sweden therefore votes in favour of granting the product authorization according to the Commission proposal. The application covers food and feed as well as import and production. The authorization does not include cultivation. This particular cotton is resistant to some plant pests of Lepidoptera and is tolerant to herbicides containing glyphosate and glufosinate-ammonium.

This does not preclude the Swedish vote on a possible future granting of authorization of cultivation of seeds that are tolerant to glufosinate-ammonium.

Glufosinate-ammonium is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009.

In our view, potential use and cultivation of genetically modified organisms in Sweden should not have a negative effect on biodiversity and, as far as possible, not lead to an increased use of pesticides."

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

M.01 Discussion on RASFF 2018.2755 (rDNA of unauthorised GM *Bacillus subtilis* in vitamin B2 feed additive).

The Commission clarified that the RASFF notification refers to a vitamin B2 feed additive for use in the EU that is contaminated with a non-authorized GMO. Therefore, the general rules of Regulation (EC) No 1829/2003 apply for contaminated feed additives, premixtures and feed produced with this feed additive; moreover the rules on traceability also apply. Thus Member States must ensure that the feed additive contaminated with a non-authorized GMO and related premixtures and final feed are traced and withdrawn from the market. Representatives of EFSA clarified the relevant aspects of the assessment of microorganisms used for feed additive production and explained that the assessment addresses the possible impact of the presence of the microorganisms on the existing natural level of antimicrobial resistance in the environment. A Member State queried the possible impact of this contamination on food, and it was confirmed that this aspect will be clarified with EFSA.

M.02 Unauthorised presence of GM oilseed rape in conventional seeds.

A Member State updated the Committee about a case of detection of GM oilseed rape seeds in conventional seeds, imported from a third country. The Commission reiterated that according to EU legislation, there is zero tolerance of unauthorized GM seed and the Competent Authorities of the Member States have to terminate the unauthorised release. During the discussion, Member States reported different practices for sampling oilseed rape seeds. The Commission repeated that a dedicated working group is going to discuss these implementation issues.