EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2019)533479

Standing Committee on Plants, Animals, Food and Feed
Section *Genetically Modified Food and Feed*
14 January 2019

CIRCABC Link: ***https://circabc.europa.eu/w/browse/b4c6cf3a-a5d6-4f0a-b97f-d0201c230354***

SUMMARY REPORT

A.01 Assessment of genetically modified maize MZHG0JG for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2016–133) - 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 MZHG0JG. No questions were raised by Member States.

A.02 Assessment of genetically modified cotton LLcotton25 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-010) – Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of products containing, consisting of or produced from genetically modified cotton LLcotton25. No questions were raised by Member States.

A.03 Assessment of genetically modified soybean MON 89788 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011) – Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of products containing, consisting of or produced from genetically modified soybean MON 89788. No questions were raised by Member States.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder.

The draft Decision amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder was presented to the Committee and submitted for vote.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision amending Decision 2007/703/EC and Implementing Decisions (EU) 2017/2452 and (EU) 2018/1109 as regards the representative of the authorisation holder.

The draft Decision amending Decision 2007/703/EC and Implementing Decisions (EU) 2017/2452 and (EU) 2018/1109 as regards the representative of the authorisation holder was presented to the Committee and submitted for vote.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision amending Implementing Decisions 2013/648/EU and 2013/650/EU as regards the representative of the authorisation holders.

The draft Decision amending Implementing Decisions 2013/648/EU and 2013/650/EU as regards the representative of the authorisation holders was presented to the Committee and submitted for vote.

Vote taken: Favourable opinion.

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 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 was presented to the Committee and submitted for 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 authorization of placing on the market of products containing, consisting of, or produced from genetically modified maize (including other, see ap B.04) is on the agenda on the meeting mentioned above. The authorization does not include cultivation. Maize 4114 (including their progenitors, see ap B.04) is tolerant to glufosinate-ammonium-based herbicides.

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.

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.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 maize MON 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 was presented to the Committee and submitted for 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.06 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 Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and 3 sub-combinations (Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507) was presented to the Committee and submitted for 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 authorization of placing on the market of products containing, consisting of, or produced from genetically modified maize (including other, see ap B.06) is on the agenda on the meeting mentioned above. The authorization does not include cultivation. Maize Bt11xMIR162X1507xGA21 and subcombinations Bt11 x MIR162 x1507, MIR162 x1507 x GA21 och MIR162 x1507 (including their progenitors, see ap B.06) is tolerant to glufosinate-ammonium-based herbicides.

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.
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.

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

M.01 Commission Decision 2011/884/EU – Emergency measure for rice from China: Member States' reports.

The Commission underlined the need for Member States to send quarterly reports of their controls and results pursuant to Commission Decision 2011/884/EU. The Commission therefore invited the Member States to send all missing data for 2018, by the end of January, to the functional mailbox (SANTE-MS-REPORTS-DECISION-2011-884@ec.europa.eu).

M.02 Follow-up discussion of RASFF notification 2018.2755 (rDNA of unauthorised GM bacteria in vitamin B2 feed additive).

The Commission informed the Member States that, on 20 December 2018, it requested EFSA to provide scientific assistance on the risk posed to humans, through consumption of products deriving from animals fed with the feed additive subject to RASFF notification 2018.2755. EFSA is expected to provide a statement at the end of January 2019.
One Member State informed the Committee that, further to an audit at national level, it became aware that the supplier of this feed additive is also producing food additives. The Commission reiterated that non-authorised GMOs cannot be present in any product marketed in the EU and that Member States have to ensure this is the case.

M.03 Information about the EFSA opinion on the application for authorisation of GM cotton GHB119 x GHB614 x T304-40.

One Member State referred to the EFSA opinion on the GM cotton stack GHB119 x GHB614 x T304-40 that is being reviewed by EFSA because of the non-compliance with Good Laboratory Practices (GLP) of one study related to the event GHB119. EFSA clarified that only the opinion on this stack is impacted, since the entry into force of Implementing Regulation (EU) No 503/2013, where GLP compliance is a legal requirement.

M.04 Unauthorised presence of GM oilseed rape in conventional seeds.

Following the discussions at the previous meeting of the Committee on 3 December 2018, the Member State concerned updated the Committee about the controls performed and the measures taken to terminate the unauthorised release.