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Standing Committee on Plants, Animals, Food and Feed

Section *Genetically Modified Food and Feed*

7 March 2019

CIRCABC Link: ***https://circabc.europa.eu/w/browse/d36ff9ae-0fd1-41e0-8ee0-8fec085e3c37***

SUMMARY REPORT

A.01 Assessment of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing, under Regulation (EC) No 1829-2003 (application EFSA-GMO-NL-2013-112) - 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 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations. No questions were raised by Member States.

A.02 Assessment of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2013-113) - 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 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and subcombinations. No questions were raised by Member States.

A.03 Assessment of genetically modified soybean A2704-12 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-009) - Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of products containing, consisting of or produced from genetically modified soybean A2704-12. No questions were raised by Member States.

A.04 Assessment of genetically modified oilseed rape T45 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-012) - Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of products containing or produced from genetically modified oilseed rape T45. No questions were raised by Member States.

A.05 Emergency measure on rice from China (Decision 2011/884/EU): overview of the results of Member States' controls.

The Commission presented an overview of the results of Member States' controls for 2018. Although a decrease of the incompliances was observed comparing to 2017, it was agreed to maintain the emergency measure in place.

B.01 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 soybean MON 87751 (MON-87751-7), 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 soybean MON 87751 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

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 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

Austria made the following declaration:

"Austria objects the renewal application for placing on the market of genetically modified maize 1507 x NK603 (RX-008) for the following reason:
The applicant has not provided up-to-date sequence information for the renewal application, although this information is deemed crucial for the re-evaluation process.
EFSA is referring to the usefulness of accurate sequence information, too ("Mutations occurring in seed lines containing this event(s) and giving rise to varieties imported to the EU close to the time of the renewal applications could be considered for further risk assessment (Section 3). The sequence identity of each event can most easily be ascertained by resequencing of relevant plant material… The applicant should review and assess their relevance for molecular characterisation,

human and animal safety and the environment. Amongst those studies, data on the sequence of the event(s) for renewal, derived from seed lines containing this event(s) and giving rise to varieties imported to the EU close to the time of the renewal application, should be included." EFSA, 2015).
EFSA. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 13, 4129 (2015)."

Written statement issued by Sweden:

"The authorization of placing on the market of products containing, consisting of, or produced from the abovementioned maize is on the agenda for the meeting of the GMFF-Committee on 7 March 2019. The proposed authorizations do not include cultivation. The GM-maize 1507 x NK603 are 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. that the products are safe for human and animal health as well as for the environment. Sweden therefore votes in favor of granting the products authorization in accordance with the Commission's 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."

M.01 Follow-up on the implementation of the ruling of the Court of Justice of the European Union (case C-528/16) on mutagenesis.

The Commission thanked the Member States for further information provided regarding the implementation of the Court ruling at national level. To discuss the matter, the Commission indicated that a joint meeting involving all GMO competent authorities is planned for 25 April 2019.

M.02 International aspects.

The Commission informed the Member States that a bilateral meeting with Canada took place on 4 March and that the minutes will be published online.
The Commission also invited Member States to share possible comments in this Committee in relation with international events taking place in 2019 (including OECD working group meetings at the beginning of April).

M.03 Follow-up discussion of RASFF notification 2018.2755 (rDNA of unauthorised GM bacteria in vitamin B2 80% feed additive).

The Commission informed the Member States about the publication of the "EFSA statement on the risk posed to humans by a vitamin B2 produced by a genetically modified strain of Bacillus subtilis used as a feed additive" 1, relating to RASFF case 2018.2755.

[1] Publicly available in https://www.efsa.europa.eu/sites/default/files/scientific_output/ON-5615.pdf