



EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Genetically Modified Food and Feed*
16 January 2018

CIRCABC Link: <https://circabc.europa.eu/w/browse/c2bb0aa4-3b2b-4d89-bd32-adc5c7f8fb06>

SUMMARY REPORT

- A.01 Scientific Opinion on application EFSA-GMO-BE-2013-118 for authorisation of genetically modified maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 and sub-combinations independently of their origin, for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Company - Presentation by EFSA.**

EFSA presented the opinion on application for the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 and its subcombinations. No questions were raised by Member States.

- A.02 Scientific opinion: Assessment of genetically modified maize 1507 x 59122 x MON810 x NK603 and sub-combinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-92) - Presentation by EFSA.**

EFSA presented the opinion on application for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 x 59122 x MON810 x NK603 and its subcombinations. One MS asked for clarifications about the application of EFSA guidance documents related to field trials and the testing of commercial varieties. EFSA clarified which guidance was applicable for this specific application, and recalled that guidance documents do not apply retro-actively.

- A.03 Scientific opinion: Assessment of genetically modified oilseed rape MS8, RF3 and MS8 x RF3 for renewal of authorisation under regulation (EC) No 1829/2003 (application EFSA-GMO-RX-004) - Presentation by EFSA.**

EFSA presented the opinion on the application for the renewal of oilseed rape MS8, RF3 and MS8 x RF3. No questions were raised by Member States.

A.04 Scientific opinion: Assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005) - Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of maize GA21. No questions were raised by Member States.

A.05 Scientific opinion: Assessment of genetically modified sugar beet H7-1 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-006) - Presentation by EFSA.

EFSA presented the opinion on the application for the renewal of sugar beet H7-1. One Member State referred to the fact that no new sequencing information had been submitted. EFSA explained that this is not mandatory in the frame of renewal applications and referred also to the obligation for applicants and authorisation holders to submit any new information which may impact the risk assessment.

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 maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and its three possible sub-combinations pursuant to Regulation (EC) 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 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU, 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.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 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

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.

Written statement issued by Sweden

"The authorisation of placing on the market of products containing, consisting of, or produced from genetically modified maize is on the agenda for this meeting. The authorisation does not include cultivation. Maize 59122 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 authorisation according to the Commission proposal.

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

M.01 Presentation of AAC and AAC-FF.

The Commission presented the information system "Administrative Assistance and Cooperation network" (AAC). This is an IT application that can be used, on a voluntary basis, by the competent authorities of the Member States to signal cases of non-compliances or fraud for GM food and feed.

M.02 Emergency decision 2011/884/EU: Member States' reports.

Member States were reminded of the obligation to send quarterly reports of their controls and results to the Commission by the end of January 2018, using the dedicated functional mailbox: SANTE-MS-REPORTS-DECISION-2011-884@ec.europa.eu.

M.03 Sequencing mandate COM to EFSA: Technical note and checking of the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified (GM) event, and generational stability and integrity.

The Commission explained that a mandate was sent to EFSA in October 2017 to develop a document regarding the quality of the methodology, analysis and reporting of sequencing information of the genetically modified (GM) event. This is to harmonise further the submission of data by applicants. The document is to be finalised and published in September 2018 the latest, and will apply from 1 October 2018 onwards.

For all GMO applications submitted from 1 October 2018 onwards, EFSA will check and evaluate the sequencing information related to such application (including the quality check currently performed by DG JRC), based on the newly developed document.

M.04 RASFF - Biomass.

This issue was discussed at the request of a Member State. Two Member States updated the Committee on the measures they implemented regarding the case of an unauthorised feed material produced from genetically modified microorganisms (biomass), which was notified in RASFF in autumn 2017. The Member States concerned confirmed that no further shipments to other Member States of the biomass and compound feed at issue had taken place.

The Commission thanked the two Member States for this information and invited the Member States concerned to keep providing updates in the Rapid Alert System for Food and Feed. The Commission announced that it would continue to follow-up this case in RASFF.