EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2022)3412558

Standing Committee on Plants, Animals, Food and Feed
Section *Genetically Modified Food and Feed*
01 April 2022

CIRCABC Link: *https://circabc.europa.eu/w/browse/56f62146-8c5a-47ea-9d55-45eb42024c74*

SUMMARY REPORT

A.01 Assessment of genetically modified maize DP4114 × MON 810 × MIR604 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-150) – 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 DP4114 × MON 810 × MIR604 × NK603 and its sub-combinations.

No questions were raised by the Member States.

A.02 Statement complementing the EFSA Scientific Opinion on the assessment of genetically modified oilseed rape MS11 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2016-138)– Presentation by EFSA.

EFSA presented the statement complementing EFSA opinion published on 11 March 2022.

The statement confirms the initial conclusions of EFSA risk assessment, which remain inconclusive because of data gaps in the comparative analysis.

Some Member States indicated that this GM oilseed rape is not meant for commercialization, but that the product that would be commercialized is GM oilseed rape stack Ms11 x Rf3.

The Commission recalled that the requirement to assess single events that are part of a stack is a requirement of the GMO legislation based on the scientific requirements for the assessment of GM stacked events.

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 NK603 × T25 × DAS-40278-9 and its sub-combination T25 × DAS-40278-9, 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 NK603 × T25 × DAS-40278-9 and its sub-combination T25 × DAS-40278-9 was presented to the Committee.

Vote taken: no opinion.

Reasons for negative vote or abstention:

- No agreed national position
- Negative public opinion
- Precautionary principle
- Scientific reasons
- Political reasons

Declaration provided by Sweden:

"The authorization of placing on the market of products containing, consisting of, or produced from genetically modified maize is on the agenda on the meeting mentioned above. The authorization does not include cultivation. GM-maize NK603 × T25 × DAS-40278-9 and maize combining the modifications T25 × DAS-40278-9 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 has very serious properties and 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."

Statement provide by Austria:

Austria is of the opinion that the risk assessment, which has been carried out, is affected by uncertainties unsuitable to give a scientific proof for the safety of this product and, therefore, objects the placing on the market of genetically modified maize NK603xT25xDAS-40278-9 and its sub-combination T25xDAS-40278-9 for the following reason:

a. The genetically modified maize NK603xT25xDAS-40278-93 and its subcombination T25xDAS-40278-9 are carriers of an antibiotic resistance marker gene fragment of an ampicillin beta-lactamase, which may facilitate the dissemination of antimicrobial resistance via mosaic gene formation in soil and gut bacteria. Considering the current crisis in antibiotic resistance, we cannot

support a deliberate fueling of the environmental antibiotic resistance gene pool by this product.

b. By not removing this resistance gene fragment from the commercialized product the applicant is violating Commission Implementing Regulation 503/13, Annex II.2 (Specific Considerations), on the "insertion of marker genes and other nucleic acid(s) sequences not essential to achieve the desired trait".

Consequently, 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 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape, Ms1xRf2 (ACS-BNØØ4-7xACS-BNØØ2-5) hybrid oilseed rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape, as well as their derived products.

The draft Decision amending three transitional measures as regards of three discontinued genetically modified oilseed rape, at the request of the notifier, in order to prolong them until 31 December 2025 was presented to the Committee.

No comments were made by the Member States.

The Committee agreed to vote in written procedure in accordance with Article 3(5) of Regulation (EU) No 182/2011.

Vote taken: Favourable opinion.

M.01 Situation resulting from the Russian war of aggression against Ukraine.

The Commission invited Member States to inform the Committee of any impact of the Russian war of aggression against Ukraine on the feed supply in their territories, and whether on-going authorisation procedures could be relevant in this context.

Several Member States expressed concerns about imminent shortages. They indicated that, at this moment, the shortage is limited to maize and that the major candidates for substituting the no-longer available supply from Ukraine are the Americas. They supported the swift processing of relevant applications after EFSA has delivered a favourable scientific opinion. A Member State suggested relying on the minimum required performance limit set out in Regulation (EU) No 619/2011 for feed imports, and another enquired whether other thresholds for the adventitious presence of non-authorised GMOs could be established.

Other Member States raised the question whether authorisations would actually help relieving the shortage, and indicated that all the applicable safety requirements should be met.

The Commission explained that, while it was ready to complete ongoing procedures as soon as possible when this could help to address shortages in feed supply, all safety requirements and procedural rules applicable to authorisations will be complied with. It recalled the conditions for the application of Regulation (EU) No 619/2011 to pending applications or expired authorisations in the EU. It indicated that the GMO legislation does not contain other provisions to allow the adventitious presence of events that are authorised in third countries but not authorised in the EU.