EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)5782726

Standing Committee on Plants, Animals, Food and Feed

Section *Genetically Modified Food and Feed*

11 September 2018

CIRCABC Link: ***https://circabc.europa.eu/w/browse/d724f206-1adc-40d2-a110-69c2bbb08939***

SUMMARY REPORT

A.01 Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG taking into consideration an additional toxicological study - Presentation by EFSA.

EFSA presented the statement on the risk assessment of an additional toxicological study submitted by Syngenta Crop Protection AG, in the context of application for the placing on the market of products containing, consisting of or produced from genetically modified maize 5307. No questions were raised by Member States.

A.02 Assessment of genetically modified cotton GHB614 × LLCotton25 × MON15985 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-94) - 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 cotton GHB614 × LLCotton25 × MON15985. One Member State still had comments from its national competent authority for some of the studies performed with the single events.

A.03 Assessment of genetically modified maize MON 87403 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2015-125) - 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 87403. No questions were raised by Member States.

A.04 Assessment of genetically modified Bt11 x MIR162 x 1507 x GA21 and three subcombinations independently of their origin, for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2010-86) - 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 Bt11 x MIR162 x 1507 x GA21 and three subcombinations. No questions were raised by Member States.

A.05 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, the Commission provided an explanation of the notion of "placing on the market" in Regulation (EC) No 1829/2003 in relation to the export of unauthorised GMOs to third countries under Article 12 of General Food Law.

Further to a brief technical discussion with the Member States, this point will be put again on the agenda of a forthcoming Standing Committee meeting.

A.06 Information from the Commission regarding RASFF notifications, reference numbers 2017.BXH and 2017.1199, regarding unauthorised GM cotton seeds.

Upon request of a Member State, the Commission provided clarification regarding the unauthorised GM cotton seeds referred to in RASFF notifications 2017.BXH and 2017.1199. The Commission explained that Member States' competent authorities are responsible for taking the necessary measures to terminate any unauthorised release, in accordance with Article 4(5) of the Directive 2001/18/EC. In this respect, the competent authorities must verify that all the activities necessary to terminate the release, including loading, transport, handling or destruction of the GMOs are subject to specific containment measures, providing a high level of safety for human health and the environment.

A.07 Information and discussion on unauthorised release of GM wheat (MON71200) in Canada.

The Commission updated Member States on the follow-up actions relating to an unauthorized release of GM wheat in Canada. The European Union Reference Laboratory for GM Food and Feed (EURL GMFF) explained that the cooperation with the official Canadian laboratory resulted in swift availability of the detection method and positive control samples, allowing the EURL GMFF to start the production of the positive control plasmid. The EURL GMFF confirmed that the detection method fulfils the necessary performance criteria for qualitative controls and the European Network of GMO Laboratories (ENGL) has been informed accordingly. No questions were raised by Member States.

A.08 Information and discussion on the European Court of Justice ruling (25 July 2018) on new mutagenesis techniques.

The Commission (SANTE) presented briefly the outcome of the European Court of Justice ruling (Case C-528/16). Further to the questions raised, the Commission confirmed that there was no need for a roadmap to implement the ruling and underlined the role of competent authorities in the implementation of the GMO legislation as interpreted by the Court, in particular with regard to field trials and controls.

In the ensuing discussion, most Member States raised the difficulties linked to identification and quantification of the products produced with new mutagenesis techniques and underlined the need to gather information on the potential products likely to enter the EU market.

To help Member States and their national laboratories, the Commission (JRC) explained that it will work with the European Network of GMO Laboratories (ENGL) on the analytical challenges of new mutagenesis techniques and hold a first discussion early October on the occasion of the bi-annual ENGL meeting. JRC also underlined that the detection methods per se have to be developed by applicants.

Member States confirmed their willingness to share with the Commission and other Member States any information relevant to implement properly the court ruling (potential applications, field trials, experience etc.) and to cooperate with the ENGL.
The Commission took note of the comment by a Member State on the need to clarify also the legal status of the techniques other than mutagenesis and said it would come back on this issue at the appropriate moment.

It was agreed to pursue the discussion at the next Regulatory Committee on Directive 2001/18/EC.

B.01 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 Chair informed the Committee that this point was postponed because of a recent change of the applicant's legal entity, which needs to be reflected accordingly in the draft Decision.

Vote Postponed

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 NK603xMON810 (MON-ØØ6Ø3-6xMON-ØØ81Ø-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 NK603xMON810 was presented to the Committee and submitted for a vote.

Vote taken: No opinion.

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

<u>*Reasons for the negative vote or abstention:*</u>

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

Belgium made the following declaration:
"La Belgique souhaite qu'à l'avenir les renouvellements d'autorisation entre Food et Feed soient dissociés. En effet, nous considérons que la portée des questions diffère entre celles liées à la nourriture à destination animale et celles liées à la nourriture à destination humaine et que dès lors ces autorisations ne peuvent être analysées et traitées conjointement."

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 MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU, was presented to the Committee and submitted for a vote.

Further to a comment of a Member State, the Commission clarified that, at the request of the applicant, the sub-combination MON 89034 × MON 88017 is included in the scope of the present Decision and therefore the Decision 2011/366/EU is repealed.

Vote taken: No opinion.

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

<u>*Reasons for the negative vote or abstention:*</u>

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

Belgium made the same declaration as for point B.02:
"La Belgique souhaite qu'à l'avenir les renouvellements d'autorisation entre Food et Feed soient dissociés. En effet, nous considérons que la portée des questions diffère entre celles liées à la nourriture à destination animale et celles liées à la nourriture à destination humaine et que dès lors ces autorisations ne peuvent être analysées et traitées conjointement."

Written statement issued by Sweden:

"The authorization of placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 x MON 89034 x 1507 x MON88017 x 59122 (including other, see ap B.03) is on the agenda on the meeting mentioned above. The authorization does not include cultivation. Maize MON 87427 x MON 89034 x 1507 x MON88017 x 59122 (including their progenitors, see ap B.03) 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."

In relation with points B.02 and B.03, Italy issued the following written declaration to the minutes after the meeting:

"Italian vote against is based firstly on a precautionary attitude regarding the placing on the market of genetically modified food and feed, also taking into account the sensitivity and the concerns of Italian consumers worried for GMO impact on human health and environment, as well as for the loss of their national agricultural products based on biodiversity. This position is however in line with precautionary position already expressed in the past with the abstention, because Italian consumers ask for the Establishment the application of all the possible precautions on this issue.

Furthermore present position comes from a specific strategic choice of Italy aimed to address the European discussion on a new supply system of protein obtained from plants and to reflect on this possibility also at a scientific level. Italy believes that authorizing GM feeds and foods means to strengthen of a non-virtuous cycle that is to introduce such products with the possibility of a more intensive use of herbicides instead to add value with the rotation of crops and the autochthonous ones, which show a better adaptability to unfavourable or aggressive changes and natural or artificial events.

In other words, with this reasoned vote against, we intend to put in the forefront (and hopefully to discuss the political tables with the other Member States) the safeguard of agri-food and biodiversity, the only condition that can truly guarantee sustainability in agriculture and to guarantee better quality levels of crops and food."

M.01 Confidentiality of application for authorisation of genetically modified food and feed.

Further to the request of a Member State who reported that an applicant had claimed confidentiality of the full application dossier for authorisation, the Commission indicated that confidentiality claims submitted under Regulation (EC) No 1829/2003 cannot cover an entire application; such claims must refer to specific parts of the application and be accompanied by verifiable justification.

M.02 90-day feeding study in rodents with whole genetically modified food and feed.

Further to the request of a Member State to discuss the potential follow up to the research projects GRACE and G-TwYST, which was supported by another Member State, the Commission agreed that it would be put on the agenda of a forthcoming Standing Committee meeting.