EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)2532794

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 25 APRIL 2016

(Section Genetically Modified Food and Feed and Environmental Risk)

CIRCABC Link: *https://circabc.europa.eu/w/browse/e7073e07-8896-4b83-8f0c-49be81057450*

A.01 JRC/EURL Guideline for the submission of DNA sequences derived from genetically modified plants and associated annotations within the framework of Directive 2001/18/EC and Regulation (EC) No 1829/2003 – presentation by JRC.

JRC presented the Guideline for the submission of DNA sequences derived from genetically modified plants and associated annotations within the framework of Directive 2001/18/EC and Regulation (EC) No 1829/2003. The presentation was followed by questions from Member States.

A.02 Report of the audit carried out in China from 18 to 26 November 2015 by DG SANTE, Directorate for Health and food audits and analysis, to evaluate the controls systems for GMOs – presentation by the Commission.

Directorate for Health and food audits and analysis presented the results of the audit carried out in China in November 2015 to evaluate the controls systems for GMOs. It was reported that there is a comprehensive export control system in place to ensure that food, feed and feed additives exported to the EU are compliant with the EU GMO legislation. GMO field trials are adequately controlled. The Chinese authorities have in place a detailed supervision system, supported by an up-to-the standard laboratory capacity, to ensure compliance with the requirements of Decision 2011/884/EU. Based on the findings, no recommendation was made to the Chinese authorities.

Further to a question on the screening methods applicable for Decision 2011/884/EU, the Commission recalled that the methods were designed to screen several events. Member States also explored the possibility to reduce the frequency of sampling and analysis of rice products from China falling within the scope of Decision 2011/884/EU. In this regard, the Commission reiterated Member States' obligation to report on the results on a quarterly basis all analytical tests carried on products covered by the Decision (Article 6) and asked them to submit the missing reports. A dedicated mailbox for the submission of reports will be created.

A.03 Draft Reference Document "Framework for assessing the socio-economic impacts of Bt maize cultivation" by the European Socio Economic Bureau (ESEB) - Presentation by JRC.

JRC presented the draft Reference Document, which provides a framework for carrying out assessments on the socio-economic impacts of Bt maize cultivation in the EU (at the EU, national or subnational level). The presentation was followed by comments and questions from Member States. They are invited to submit written comments by 1 June 2016.

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 Bt11 × MIR162 × MIR604 × GA21, and genetically modified maizes combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/893/EU, 2011/892/EU and 2011/894/EU.

The draft Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21 and genetically modified maizes combining two or three of all the single events was presented to the Committee and submitted for a vote.

Reasons for the negative vote or abstention:

- Negative public opinion
- Precautionary principle
- No agreed national position
- Political reasons
- Risk assessment deemed not sufficient
- No finalised opinion of the national scientific committee

AT written statement:
Several scientific questions concerning the risk assessment of maize Bt11xMIR162xMIR604xGA21 could be clarified during the SCPAFF Meeting on 14 December 2015, at which EFSA presented its Scientific Opinion.
Important concerns, however, relating to the safety of the product remain unsolved, because, amongst others, prior to that SCPAFF Meeting the time frame for discussing remaining questions with respect to the EFSA Scientific Opinion was too short.

For the following reasons, Austria objects the placing on the market of genetically modified maize Bt11xMIR162xMIR604xGA21:

a. *There is no sufficient knowledge to reach a conclusion on the potential of altered expression of gene products in the notified sub-combinations of the four-event stack and potential interactions between the newly expressed proteins (Cry1Ab, mCry3A, Vip3Aa20, PAT, mEPSPS) which may have an impact on the safety of the product.*
b. *Genetic and phenotypic stability analysis of the four-event stack maize Bt11xMIR162xMIR604xGA21 is mainly based on data derived from experiments with the single events.*
c. *Insufficient comparative assessment: The compositional assessment lacks information on field trials with GM plants not treated with glyphosate- and*

glufosinate-ammonium-based herbicides and is inconclusive. The agronomic assessment lacks statistical power and provides little evidence that the four-event is equivalent to conventional maize.

The Chair informed that the draft Decision will be submitted to the Appeal Committee.

Vote taken: No opinion

M.01 New Plant Breeding Techniques.

Upon a question from a Member State about the New Breeding Techniques, the Commission informed that the work is on-going and the outcome could be expected in the course of 2016.

M.02 Update on the 3 GM soybeans pending final approval.

Upon a request from a Member State, the Commission informed that it is proceeding with the three GM soybeans voted in the Appeal committee on 11 January 2016 which are at the final stage of the authorisation procedure.

M.03 Status of Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory.

Upon a request from a Member State, the Commission confirmed that the proposal was in first reading in Council and that a meeting would be convened by the Dutch Presidency.

M.04 Requests for information from a third country about GMOs specifically authorised, cultivated or used in the respective territories of the Member States.

Several Member States confirmed that they had received such a letter from a third country. Upon a request from a Member State on how to respond, it was agreed that Member States respond bilaterally and inform the Commission of their respective replies.