EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 16 MARCH 2015

(Section Genetically Modified Food and Feed and Environmental Risk)

CIRCABC Link: *https://circabc.europa.eu/w/browse/f2086088-58a4-4d07-982e-379bc4dac86c*

Chair: Dorothee Andre

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision renewing the authorisation for marketing of genetically modified cotton MON 531 products pursuant to Regulation (EC) No 1829/2003

The draft Decision renewing the authorisation for the placing on the market of genetically modified cotton MON 531 was presented to the Committee. Several Member States commented on the presence of the antibiotic resistance marker genes (ARMGs).
The Commission reminded that the presence of ARMGs was thoroughly assessed by EFSA who considered that the analysis of a possible gene transfer of these genes to bacteria did not indicate a risk to human or animal health or to the environment in the context of its intended uses. The Commission explained that Article 4(2) of Directive 2001/18/EC on the deliberate release of GMOs allows the use of GMOs with ARMGs, on a case-by-case basis, provided no adverse effects on human health or the environment have been identified, which is the case of this GMO. In its horizontal 2009 opinion on ARMG, EFSA concluded that all ARMGs used in GM crops are safe, including *npt*II and *aad*A. The Commission is limiting as much as possible the submission for vote of applications for GMOs containing ARGMs based on the possibility of using alternatives without ARMGs by the applicants.
This is also the case for the GM products under points B.02, B.03 and B.4 of the Agenda which contain ARMGs as well .

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Presence of ARMGs
- No opinion of the Member States' Scientific Council
- Scope of Article 2(a) should be more detailed

AT written statement
Although several scientific questions concerning the risk assessment of cotton MON 531 (MON-ØØ531-6) have been clarified between EFSA scientists and national experts from the Austrian competent authority some important concerns relating to the safety of the product remained.
Austria therefore objects the placing on the market of genetically modified cotton MON 531 (MON-ØØ531-6) due to the following reason:
The event contains two antibiotic resistance marker genes superfluous and without any function in the adult plant. One of these antibiotic resistance marker genes has been classified by EFSA as to be applied only in field trial experiments but not in plants for food and feed use. According to Article 4 (2) of Directive 2001/18/EC, which requires a step-by-step phasing out of antibiotic resistance marker genes in GMOs which may have adverse effects on human health and the environment by the end of 2004 (concerning GMOs released for marketing according to part C) and by the end 2008 (concerning the deliberate release of GMOs into the environment according to part B of the directive) both ARM genes should have been eliminated from the transgenic plant before placing the product on the market.

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

Vote taken: No opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision renewing the authorisation for marketing of genetically modified cotton MON 1445 products pursuant to Regulation (EC) No 1829/2003

The draft Decision renewing the authorisation for the placing on the market of genetically modified cotton MON 1445 was presented to the Committee. Several Member States commented on the presence of the antibiotic resistance marker genes (ARMGs).

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Presence of ARMGs
- Negative opinion of the Member States' Scientific Council
- Scope of Article 2(a) should be more detailed

AT written statement
Although several scientific questions concerning the risk assessment of cotton MON 1445 (MON-Ø1445-2) have been clarified between EFSA scientists and national experts from the Austrian competent authority some important concerns relating to the safety of the product remained.
Austria therefore objects the placing on the market of genetically modified cotton MON 1445 (MON-01445-2) due to the following reason:

The event contains two antibiotic resistance marker genes superfluous and without any function in the adult plant. One of these antibiotic resistance marker genes has been classified by EFSA as to be applied only in field trial experiments but not in plants for food and feed use. According to Article 4 (2) of Directive 2001/18/EC, which requires a step-by-step phasing out of antibiotic resistance marker genes in GMOs which may have adverse effects on human health and the environment by the end of 2004 (concerning GMOs released for marketing according to part C) and by the end 2008 (concerning the deliberate release of GMOs into the environment according to part ? of the directive) both ARM genes should have been eliminated from the transgenic plant before placing the product on the market.

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

Vote taken: No opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision renewing the authorisation of existing genetically modified cotton MON 531 x MON 1445 products and authorising food and feed cottonseed oil produced from MON 531 x MON 1445 pursuant to Regulation (EC) No 1829/2003

The draft Decision renewing the authorisation of existing genetically modified cotton MON 531 x MON 1445 products and authorising food and feed cottonseed oil produced from MON 531 x MON 1445 was presented to the Committee. Several Member States commented on the presence of the antibiotic resistance marker genes (ARMGs).

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Presence of ARMGs
- Negative opinion of the Member States' Scientific Council
- Scope of Article 2(a) should be more detailed

AT written statement

Although several scientific questions concerning the risk assessment of cotton MON 531 (MON-ØØ531-6) x MON 1445 (MON-Ø1445-2) have been clarified between EFSA scientists and national experts from the Austrian competent authority some important concerns relating to the safety of the product remained.

Austria therefore objects the placing on the market of genetically modified cotton MON 531 (MON-ØØ531-6) x MON 1445 (MON-Ø1445-2) due to the following reason:

The stacked event contains two antibiotic resistance marker genes superfluous and without any function in the adult plant. One of these antibiotic resistance marker genes has been classified by EFSA as to be applied only in field trial experiments but not in plants for food and feed use. According to Article 4 (2) of Directive

2001/18/EC, which requires a step-by-step phasing out of antibiotic resistance marker genes in GMOs which may have adverse effects on human health and the environment by the end of 2004 (concerning GMOs released for marketing according to part C) and by the end 2008 (concerning the deliberate release of GMOs into the environment according to part ? of the directive) both ARM genes should have been eliminated from the transgenic plant before placing the product on the market.

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

Vote taken: No opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of genetically modified cotton MON 15985 and renewing the authorisation of MON 15985 products pursuant to Regulation (EC) No 1829/2003

The draft Decision authorising the placing on the market of genetically modified cotton MON 15985 and renewing the authorisation of MON 15985 products was presented to the Committee. Several Member States commented on the presence of the antibiotic resistance marker genes (ARMGs).

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Presence of ARMGs
- The Regulation on GM Food and Feed is not considered as the right legal basis to authorise products other than food and feed containing and consisting of GMOs

AT written statement

Although several scientific questions concerning the risk assessment of cotton MON 15985 (MON-15985-7) have been clarified between EFSA scientists and national experts from the Austrian competent authority some important concerns relating to the safety of the product remained.

Austria therefore objects the placing on the market of genetically modified cotton MON 15985 (MON-15985-7) due to the following reasons:

a. *The event contains two antibiotic resistance marker genes superfluous and without any function in the adult plant. One of these antibiotic resistance marker genes has been classified by EFSA as to be applied only in field trial experiments but not in plants for food and feed use. According to Article 4 (2) of Directive 2001/18/EC, which requires a step-by-step phasing out of antibiotic resistance marker genes in GMOs which may have adverse effects on human health and the environment by the end of 2004 (concerning GMOs released for marketing according to part C) and by the end 2008 (concerning the deliberate release of GMOs into the environment according to part ? of*

the directive) both ARM genes should have been eliminated from the transgenic plant before placing the product on the market.

b. *From the Austrian point of view, products others than food and feed containing or consisting of cotton MON 15985 (MON-15985-7) are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

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

Vote taken: No opinion.

M.01 Exports of enzymes to Turkey: non-GM certificate

The Commission gave an update on the GM-free official declaration that the Turkish authorities are requesting for microorganisms and enzymes imported into their country. The Commission sent a letter to the Turkish authorities on 8 January 2015, proposing an alternative declaration for EU exports. The Turkish authorities replied on 4 February 2015 maintaining their request for the official declaration and specifying that it is justified by the requirements set out in the Regulation on Genetically Modified Organisms and Products in place in Turkey.
The Commission is currently preparing a reply, clarifying the principles of Regulation (EC) 1829/2003 as regards enzymes obtained from non-GM microorganisms, reminding Turkey about its obligation to align its legislation to existing EU legislation on GMOs. The matter will be discussed in the forthcoming SPS Working Group on 27 March 2015. In view of this Working Group the Commission invited the Member States to provide any relevant information.

M.02 Review of GMOs; Food/feed files pending adoption by the Commission

The Commission explained that a review of the decision-making process for GMOs is currently ongoing for which the results will be communicated before the end of April as announced by President Juncker in his political guidelines. The review will be accompanied by a proposal to be discussed in appropriate fora.
It was also clarified that the question of the 13 pending files is being also examined by the Commission.
Finally it was clarified that in case a no opinion is obtained in the Standing Committee on the vote of a GM food and feed file, the matter is referred to the Appeal Committee and not to the Council.

M.03 Implementation of Regulation (EU) 619/2011: request from Italy

The Italian delegation requested a clarification on the procedure to be used to estimate measurement uncertainty within the framework of Regulation (EU) 619/2011, taking into consideration the "Technical guidance document from the EURL GMFF on the implementation of Regulation (EU) No 619/2011" and the JRC-IRMM "Guidance document on measurement uncertainty for GMO testing laboratories", the latter being

referred to in Annex II of the Regulation. The Commission clarified that the approaches described in the two documents are both acceptable.

Directive (EU) 2015/412 amending Directive 2001/18/EC as regard the possibility for the Member States to restrict or prohibit the cultivation of GMOS in their territory.

Directive (EU) 2015/412 was published in the official journal on 13 March 2015 and will enter into force on 2 April 2015. The 6-month transitional period will end on 3 October 2015. A list of the GMO files concerned by this transitional period will be provided to Member States.

M.04 Information on the Study on methods of sampling and analysis for GM material in food

The Commission informed Member States on the state of play of the study on methods of sampling and analysis for GM material in food and in particular about the tools to be used by the contractor to gather data from national competent authorities, i.e. a survey addressed to all Member States and interviews with experts in some of them. Some Member States stressed that they will be ready for an interview only after having received the questionnaire for the survey. The survey will be launched in the coming days with a one month deadline. A dedicated website has been developed by the contractor including, inter alia, the study terms of reference of www.gm-sampling-and-analysis.eu.

The Commission informed that a consolidated document has been prepared with the notifications received from Member States under Article 6(2) of Regulation (EU) 619/2011 which is available on CIRCAB.

M.05 Conference in Hungary on GM-free agriculture on 16 and 17 April 2015

Hungary reported that its Ministry of Agriculture will organise an international conference focused on GM-free labelling, in Budapest on 16 and 17 April. Hungary is currently drafting a new regulation on this issue. Other related topics will be raised during the conference, such as the new Directive on cultivation or Socioeconomic considerations.