EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 24 OCTOBER 2014

(Section Genetically Modified Food and Feed and Environmental Risk)

CIRCABC Link: *https://circabc.europa.eu/w/browse/8c66fdb4-8c85-4b43-9261-4ecf69dc4998*

Chair: Dorothee Andre

24 Member States were present, Portugal was represented by the Netherlands, Latvia was represented by Lithuania, Malta was absent and not represented for sections B.02 and B.03 and represented by Ireland for section B.04.

A.01 Rapid Alert System for Food and Feed (RASFF) notifications on Bt63 rice in choline chloride feed additive

The Commission informed that no further RASFF notifications have been submitted on Bt63 rice in choline chloride feed additive since May 2014. Member States have been invited to continue providing information on the controls performed.

A.02 Rapid Alert System for Food and Feed (RASFF) notification(s) on GM Bacillus subtilis in Vitamin B2 feed additive

The Commission presented two recent RASFF notifications on GM Bacillus subtilis in vitamin B2 feed additive and the notifying Member State provided additional information. A Member State informed about controls performed on fermentation products and stressed that it is not always possible to find information on the strain used. The Commission clarified that the authorisations for a number of fermentation products are currently under re-evaluation and the strain will be indicated in the EFSA opinion and in the decision.

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 soybean MON87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003

The draft Decision authorising the placing on the market of genetically modified soybean MON87769 was presented to the Committee. Discussion took place on the wording of the specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation 1829/2003 which is a legal obligation for this nutritionally modified soybean (contains stearidonic acid).
The Commission will discuss further the matter and will propose an amended wording at the next PAFF meeting.

Vote postponed

B.02 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 cotton LLcotton25xGHB614 (BCS-GHØØ2-5xACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003

The draft Decision authorising the placing on the market of genetically modified cotton LLcotton25xGHB614 was presented to the Committee. A Member State made a comment on the elevated levels of gossypol and also suggested to align the post-market monitoring environmental plan with the one for the single event cotton GHB614.

The Commission reminded EFSA analysis as regards gossypol and the conclusion that the elevated levels did not pose safety concerns for humans and animals. It was agreed that the post-market monitoring environmental plan should be aligned with the one for the single event cotton GHB614.

Reasons for the negative vote or abstention:

- Not agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Scientific doubts on the impact of glyphosate residues on animal health
- 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

Vote taken: No opinion.

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 oilseed rape MON88302 (MON-883Ø2-9) pursuant to Regulation (EC) No 1829/2003

The draft Decision authorising the placing on the market of genetically modified oilseed rape MON 88302 was presented to the Committee. Discussions took place on the proposed post-market environmental monitoring plan containing reinforced measures to avoid spillage.

A Member State presented the findings of its inspection on the accidental dissemination of GM oilseed rape grains and a discussion was held on the management and surveillance of zones where loading/unloading is performed.

The Commission underlined that loading/unloading zones are already covered by the obligations in the post-market environmental monitoring plan. It was stressed that competent authorities also have a role to play in the control of operators' obligations.

A Member State suggested including farmers' associations in the post-market environmental monitoring plan for food/feed applications. The Commission will reflect on this proposal.

Reasons for the negative vote or abstention:

- Not agreed national position
- National risk assessment not completed
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Scientific doubts on the impact of glyphosate residues on animal health
- 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
- Post market environmental plan deemed not detailed enough

Austria made a written statement.
Although several scientific questions concerning the risk assessment of oilseed rape MON 88302 (MON-88302-9) 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 is of the opinion that the risk assessment which has been carried out is not suitable to give a scientific proof for the safety of this product and, therefore, objects the placing on the market of genetically modified MON 88302 (MON-88302-9) due to the following reasons:

a. *Absence of any toxicological data from animal feeding studies using MON 88302 as test item.*
b. *Insufficient environmental monitoring plan.*
c. *From the Austrian point of view, products others than food and feed containing or consisting of oilseed rape MON 88302 are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

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 products containing, consisting of, or produced from genetically modified cotton MON89913 (MON-88913-8) pursuant to Regulation (EC) No 1829/2003

The draft Decision authorising the placing on the market of genetically modified cotton MON 89913 was presented to the Committee and then submitted for opinion.

Following a suggestion by a Member State the post-market environmental monitoring plan for cotton MON 89913 was aligned with the one for the cotton LLcotton25xGHB614.

Reasons for the negative vote or abstention:

- Not agreed national position
- National environmental risk assessment not completed
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Scientific doubts on the impact of glyphosate residues on animal health
- 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
- Post market environmental plan deemed not detailed enough

Vote taken: No opinion.

M.01 New Council voting rules as of 1 November 2014

The Commission informed Member States on the new voting rules.

As of 1 November 2014, Quality Majority Vote (QMV) requires at least 55% of the Member States (i.e. 16 Member States) representing at least 65% of the EU population. A blocking minority is constituted either by at least 13 Member States regardless of their population OR by Member States representing more than 35% of the EU population (provided that they are at least 4).

However, until 31 March 2017, any MS may request to vote under the previous QMV rules. These rules automatically apply if such a request is made.

M.02 Renewal of NK603 authorisation

Commission informed that NK603 uses currently authorised are under renewal following a letter from the applicant from 17 October 2013. The draft authorising

decision covering full food/feed scope (renewal and new scope) was voted by the Appeal Committee on 10 July 2014.

M.03 Mandate to EFSA concerning evaluation of risk assessment of GM-products at low levels not intended for EU market

The Commission addressed some questions by a Member State on the new Mandate to EFSA concerning the risk assessment of GM-products not intended for EU market but present at low levels. It was explained that this will potentially cover products that are clearly not intended for the EU market but some third countries might have particular needs for these types of products, e.g. Golden rice.

It was explained that the risk assessment would not be less stringent than for the products falling under Regulation (EC) 619/2011 because for products present at low levels, an application would be submitted, a risk assessment would be performed and authorisation would be granted before low levels of this products can be placed on the EU market.

Regarding the level, 0.9% is the legally defined threshold for adventitious or technically unavoidable presence of GMO in food and feed in the context of labelling. Therefore, for reasons of consistency, the same level has been proposed.

M.04 GM Wheat

The Commission informed the delegations about a USDA APHIS News release of 26 September 2014 announcing the closing of the investigation into the detection of GM wheat in Oregon in 2013 and the opening of a new investigation into separate detection of GM wheat in Montana in 2014.

A summary of the 10 month-investigation in Oregon was provided: the main conclusions indicate that the GM wheat occurrence was an isolated incident, whose cause couldn't be identified, and that no evidence of GM wheat was found on the market.

M.05 Rice alcohol products falling under the scope of Decision 2013/287/EU

A Member State requested to consider that rice alcohol products, falling under the scope of Decision 2013/287/EU, cannot be tested because they do not contain enough DNA to perform the analysis. The Committee agreed that a Member State Competent Authority may decide to perform only documentary checks on specific products, when previous experience demonstrated that these products do not contain sufficient DNA amount to perform a GMO analysis.

M.06 RASFF Standard Operating Procedures (SOPs)

A Member State requested the Commission to provide some clarifications on the application of RASFF SOPs to cases of unauthorised GMO detection. The Commission clarified that:

- In cases where a serious risk requires rapid action, an "alert notification" shall be submitted. In addition to cases where a risk requires or might require rapid action, the RASFF system enables Member States to transmit "information notifications" in cases involving a risk which does not require a rapid action in another member country.
- When there is a favourable EFSA opinion about the safe use of the GM food and feed, this should not be subject of a RASFF notification, even if the product is not authorised in the EU. However, in the framework of Regulation (EC) 619/2011, non-compliant products must always be notified through the RASFF. In case a favourable EFSA opinion is available, the notification should be submitted as "News".