EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Brussels,
SANCO G **ARES(2014)1999493**

SUMMARY REPORT OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH HELD IN BRUSSELS ON 23 MAY 2014

(Section Genetically Modified Food and Feed and Environmental Risk)

Chair: Dorothee Andre

27 Member States were present, RO was represented by NL

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

The Commission updated on the alerts on Bt63 rice in choline chloride feed additives: since the last SCFCAH meeting on 24 April 2014, no further notifications have been submitted.
The EURL-GMFF presented a technical note prepared on the basis of experience and testing results obtained on samples from some Member States: no major difficulties were found in the extraction of suitable DNA, whilst low rice DNA yield and inhibition effects were reported for premixtures; in the latter, rice was not detectable or was detected in trace amounts. No Bt63 was found in premixtures, although premixtures derived from Bt63 positively tested choline chloride feed additives.
On the basis of these results, the Commission and Member States agreed to stop testing premixtures and to limit the analytical check to the feed additive.
The Commission confirmed that an FVO audit on feed additives will be carried out in China between 9 and 19 June 2014 and that the choline chloride issue will be addressed. The EURL-GMFF technical note will be shortly provided to the Chinese Authority (AQSIQ).
The Commission reported on the FEFANA FAMI-QS certification instruction which requires the removal of rice from the choline chloride preparation. It was agreed to request to FEFANA the extension of the scope of this protocol to all feed materials containing rice.
The issue will be discussed with AQSIQ at a meeting with DG SANCO on 13 May 2014.

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 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003

The draft Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (altered nutritional profile, herbicide-tolerant) was presented to the Committee and then submitted for opinion.
Member States commented on the specific nutrition labelling provisions in Article 3(2) of the draft decision and a modification was made to clarify that the nutrition labelling shall appear after the name of the organism on the label and, where appropriate, in the documents accompanying the products.
A representative of the Commission gave further clarification on the import data to be provided by the applicant in the context of the post-market monitoring of the oil extracted from soybean 305423.

Reasons for negative votes or abstention:

- No agreed national position;
- National risk assessment not completed;
- Negative public opinion;
- Political reasons;
- Risk assessment deemed not sufficient;
- 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;
- Precautionary principle.

AT declaration:
Although several scientific questions concerning the risk assessment of soybean 305423 (DP-305423-1) 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 soybean 305423 (DP-305423-1) due to the following reasons:

a. *A large number of significant differences of the analytes during comparative assessment may indicate unintended effects.*
b. *The subchronic toxicity analysis was insufficient due to the application of an inadequate comparator.*
c. *From the Austrian point of view, products others than food and feed containing or consisting of soybean 305423 (DP-305423-l)are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

Vote taken: no opinion

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 soybean MON87705 (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003

The draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87705 (altered nutritional profile, herbicide-tolerant) was presented to the Committee and then submitted for opinion.
Same comments on the specific nutrition labelling provisions in Article 3(2) of the draft decision were made as under B.01 and the draft was modified accordingly.

Reasons for negative votes or abstention:

- No agreed national position;
- Risk assessment of additional data not completed;
- Negative public opinion;
- Political reasons;
- Risk assessment deemed not sufficient;
- 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;
- Precautionary principle.

AT declaration:
Several scientific questions concerning the risk assessment of soybean MON87705 (MON-87705-?) have been clarified between EFSA scientists and national experts from the Austrian competent authority.
However, Austria is of the opinion that the post market environmental monitoring measures as described by the applicant are insufficient to detect unintended effects and from the Austrian point of view, products others than food and feed containing or consisting of soybean MON87705 (MON-87705-?) are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.
For these reasons Austria objects the placing on the market of genetically modified soybean IV10N87705 (MON-87705-6).

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 soybean BPS-CV127-9 (BPS-CV127-9) pursuant to Regulation (EC) No 1829/2003 – Discussion and possible vote

The draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean BPS-CV127-9 (herbicide-tolerant) was presented to the Committee and then submitted for opinion.

Reasons for negative votes or abstention:

- No agreed national position;

- National risk assessment not completed;
- Negative public opinion;
- Political reasons;
- Risk assessment deemed not sufficient;
- 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;
- Precautionary principle;
- Partial scope.

AT declaration:
Although several scientific questions concerning the risk assessment of soybean BPS-CV127-9 (BPSCV127-9) 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 soybean BPS-CV127-9 (BPSCV127-9) due to the following reasons:

a. *Inconclusive comparative assessment due to unintended effects and inherent genetic differences between GM line and comparator used for the field trials.*
b. *Absence of evaluable toxicological data from a 90 day subchronic toxicity animal study, which would have been indicated due to the inconclusive comparative assessment.*
c. *From the Austrian point of view, products others than food and feed containing or consisting of soybean BPS-CV127-9 (BPSCV127-9) are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

Vote taken: no opinion

M.01 DG RTD call for a 2-year study on NK603 maize

A representative from the Commission informed the Member States that the contract for the 2-year study on GM NK603 which was launched by Directorate General for Research has not been signed yet.
A short update on the state-of-play of the GRACE project was presented. On 19-20 May 2014 a stakeholder's workshop took place to discuss the results of the 90-day study with MON810 maize and present the state-of-play of the chronic toxicity study with MON810 maize. Member States were invited to send their comments to the consortium until 18 June 2014.

M.02 Withdrawal of cultivation applications

Upon a question from a Member State, a representative of the Commission confirmed that Monsanto has withdrawn 8 cultivation applications in 2013-2014:

1. MON89034 x MON88017 Maize;

2. MON89034 Maize;
3. MON89034 x NK603 Maize;
4. NK603 x MON810 Maize;
5. MON88017 Maize;
6. H7-1 Sugarbeet;
7. 40-3-2 Soybean;
8. NK603 Maize

M.03 Summary report of the FAO Technical Consultation on LLP of GMOs

A Member State asked for information about next steps regarding the draft FAO summary report and made comments on it, in particular as regards the imbalance between the extent of quotes from some specific countries, as well as the absence referring to developing countries' specific needs for detection methods. The Commission will consider them and informed Member States about its own comments, i.e. the correction of some EU quotes, mainly when the EU mentioned asynchronous or obsolete non-authorised GMOs but FAO's summary refer to non-authorised GMOs in general.