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 18 NOVEMBER 2015

(Section Genetically Modified Food and Feed and Environmental Risk)

CIRCABC Link: *https://circabc.europa.eu/w/browse/298e20f2-efa0-426a-b309-6ea8b0cfc1ad*

A.01 Scientific statements on the updated sequence information for maize MIR604 and maize GA21- Presentation by EFSA.

The European Food Safety Authority (EFSA) presented the Scientific Statements on the new sequence information for maize MIR604 and maize GA21 and addressed the questions from Member States. EFSA concluded that the original material used in the risk assessment process of single events already contained the differences reported in 2015 and that they do not give rise to safety issues. A discussion was held on possible causes of these reporting errors.

A.02 Notification of the presence of unauthorised GM oilseed rape in conventional oilseed rape – Information by the Commission and Member States.

A recent notification by the UK on the presence of unauthorised GM oilseed rape in conventional oilseed rape was discussed.

The seeds were imported into the UK from FR and sown in small plots for official registration of new plant varieties. The seeds have also been sown in small trial plots in other Member States.

The Competent Authorities of the Member States involved confirmed that all the plants in the affected plots were being destroyed, and seeds that had not been planted recalled.

The Commission informed about actions it had taken and reminded Member States of their legal obligations in such situations, in particular with regard to measures to be taken to terminate the release, to initiate remedial action and to communicate relevant information.

The Commission also made available to Member States a detection method for further official controls. The detection method has been verified by the EU GMO Reference Laboratory.

The origin of the unauthorised GM presence is under investigation.

A.03 Draft Best Practice Document on "Coexistence of genetically modified cotton with conventional and organic farming " - Presentation by the European Coexistence Bureau, JRC.

Joint Research Centre (Sevilla) presented the Draft Best Practice Document on "Coexistence of genetically modified cotton with conventional and organic farming". Member States did not make any comment. Nevertheless, they may provide comments in writing within one month.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision authorising the placing on the market of genetically modified soybean MON 87705 × MON 89788 pursuant to Regulation (EC) No 1829/2003.

The draft Decision authorising the placing on the market of genetically modified soybean MON 87705 × MON 89788 was presented to the Committee for vote. Following a question on the additional nutritional labelling, the Commission clarified that it is not a nutritional claim but is an obligatory labelling for the nutritional traits according to Regulation (EC) 1829/2003.
Upon a question on the EFSA's scientific advice on a recent publication on the formaldehyde, EFSA explained the reasoning for its conclusions. EFSA considers that its previous risk assessment conclusions on the already assessed GMOs remain valid.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Lack of 90-day toxicity study
- Risk assessment deemed not sufficient
- Interactions between single events not sufficiently assessed
- Precautionary principle
- 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 Statement
Although several scientific questions concerning the risk assessment of soybean MON 87705 x MON 89788 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 MON 87705 x MON 89788 due to the following reasons:

a. *The agronomic and phenotypic analyses showed a number of significant differences between GM and non-GM varieties which had not been considered sufficiently. Additionally several important phenotypic key endpoints have not been reported. Both observations are compromising the reliability of the drawn conclusions from the risk assessment.*

b. *From the Austrian point of view, products others than food and feed containing or consisting of soybean MON 87705 x MON 89788 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 genetically modified soybean MON 87708 × MON 89788 pursuant to Regulation (EC) No 1829/2003.

The draft Decision authorising the placing on the market of genetically modified soybean MON 87708 × MON 89788 was presented to the Committee for vote.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Risk assessment deemed not sufficient
- Interactions between single events not sufficiently assessed
- Precautionary principle
- 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 Statement

Although several scientific questions concerning the risk assessment of soybean MON 87708 x MON 89788 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 MON 87708 x MON 89788 due to the following reasons:

a. *Several important parameters concerning the phenotypic assessment have not been provided increasing the uncertainty of the conclusions on environmental and agronomic risk assessment.*
b. *From the Austrian point of view, products others than food and feed containing or consisting of soybean MON 87708 x MON 89788 are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

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 genetically modified soybean FG72 pursuant to Regulation (EC) No 1829/2003.

The draft Decision authorising the placing on the market of genetically modified soybean FG72 was presented to the Committee for a vote.

Reasons for the negative vote or abstention:

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

Although several scientific questions concerning the risk assessment of soybean FG72 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 FG72 due to the following reasons:

a. *The compositional analyses - although already repeated on material from different field trials - showed again significant trends indicative for unintended effects, which have not been followed up.*
b. *From the Austrian point of view, products others than food and feed containing or consisting of soybean FG72 are not within the scope of EU-Regulation 1829/2003 but under Directive 2001/18/EC.*

Vote taken: no opinion

M.01 Update on the New Cultivation Directive.

Upon a request from a Member State, Member States informed about the consultation phase in their respective countries before opting-out under the New Cultivation Directive.

The Commission updated on the state of play of the Member States' demands for exclusion from the geographical scope of GMO applications. It was underlined that all companies agreed with the 19 Member States' demands – 1 company replied in writing, while the others agreed tacitly. Official letters informing Member States about the outcome of their demands are now being prepared by the Commission.

M.02 New Plant Breeding Techniques.

The Commission updated on the state of play of the Commission's legal analysis on New Plant Breeding Techniques. It was underlined that it will be a Commission analysis, so no formal consultation is envisaged. However, before adoption, the

document will be presented to an expert group of the Member States' Competent Authorities.

N.B. The drafts on which the Committee expressed an opinion are subject to a defined procedure in relation to the formal adoption by the Commission.

Dorothée ANDRE

Head of Unit