EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE JOINT MEETING OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED *(Genetically Modified Food and Feed and Environmental Risk)* AND THE REGULATORY COMMITTEE under DIRECTIVE 2001/18/EC 08 JULY 2016

CIRCABC Link: *https://circabc.europa.eu/w/browse/24e41245-73c4-4832-b8c6-777ffe716ea6*

A.01 Scientific opinion on application for the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 under Regulation (EC) No 1829/2003 – Presentation by EFSA.

EFSA presented the opinion on application for the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 under Regulation (EC) No 1829/2003. The presentation was followed by questions from Member States.

A.02 Scientific opinion on application for placing on the market of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MS8 × RF3 × GT73 and subcombinations, which have not been authorised previously (i.e. MS8 × GT73 and RF3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003 – Presentation by EFSA.

EFSA presented the opinion on application for placing on the market of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MS8 × RF3 × GT73 and sub-combinations, which have not been authorised previously (i.e. MS8 × GT73 and RF3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003. The presentation was followed by questions from Member States.

A.03 Technical study to assess the need for harmonisation of sampling and analysis methods for GM material in food – Presentation by the Commission and exchange of views.

The Commission presented the study to Member States, which was distributed to them four weeks before the meeting. Based on the study results and the ensuing

discussion, Member States agreed that the harmonization of sampling and analysis methods for food would not be justified based on the outcome of the study. The Commission encouraged the proper implementation of the existing legislation and, where possible, a higher convergence between Member States' practices.

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 cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5×DAS-21Ø23-5×MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Reasons for the negative vote or abstention:

- No agreed national position
- Absence of opinion of the national scientific committee
- Negative public opinion
- Political reasons
- Lack of long-term feeding study
- Risk assessment deemed not sufficient
- Interactions between single events not sufficiently assessed
- 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

Sweden's written statement is the following :
Market authorisation for the genetically modified cotton 281-24-236x3006-210-23xMON88913 (DAS-24236-5 x DAS-21023-5 x MON-88913-8) for use in food and feed and for import and processing.

The meeting discussed market authorisation for the genetically modified cotton 281-24-236 x 3006-210-23 x MON 88913 for use in food and feed and for import and processing of material that contains or consists of that cotton. The application for market authorisation does not cover cultivation. The genetic modification of cotton 281-24-236 x 3006-210-23 x MON 88913 confers insect resistance and tolerance to the herbicides glyphosate and glufosinate ammonium.
The Swedish Board of Agriculture and the National Food Agency share the European Food Safety Authority's view that the product is safe for human and animal health and for the environment. Sweden will therefore vote in favour of the European Commission's proposed decision.
This position does not affect Sweden's stance on the future decision on the cultivation of GMO crops that are tolerant to the herbicide glufosinate ammonium. Glufosinate ammonium has very dangerous properties and is classified as reprotoxic in category 1B, which means that it does not meet the requirements for authorisation under the EU's new Regulation No 1107/2009 on plant protection products.
Sweden is of the opinion that any potential use and cultivation of genetically modified organisms in Sweden must not have negative consequences for biodiversity and that any increased use of pesticides is to be avoided as far as possible.

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

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 the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Draft Commission Implementing Decision renewing the authorization for placing on the market of genetically modified maize MON 810 products was presented to the Committee and submitted for vote.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- Lack of long-term feeding and toxicity studies
- 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

As a consequence, the Chair informed the Committee that the draft Decision will be submitted to the Appeal Committee.

Vote taken: no opinion.

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 (MON-ØØ81Ø-6) seeds.

The Commission presented the proposals under points C.01, C.02 and C.03, which relate to two draft Decisions for the authorization of maize Bt11 and maize 1507 cultivation and a draft Regulation for the renewal of the authorization of maize MON810 cultivation.
The three proposals are based on regularly updated EFSA opinions, take into account all relevant scientific outputs, and reflect the demands of 19 Member States to exclude all or part of their territory from the cultivation of these three GMOs, pursuant to the provisions of Directive (EU)2015/412.
Further to several Member States' comments on technical and practical aspects of the proposals, clarifications were given by the Commission and by EFSA experts. The proposals will be subject to a second discussion and possible vote in October.

C.02 Exchange of views of the Committee on a draft Commission Implementing Decision concerning the placing on the market for cultivation of genetically modified maize 1507 (DAS-Ø15Ø7-1) seeds – Presentation by the Commission and exchange of views.

Please see under point C.01 above.

C.03 Exchange of views of the Committee on a draft Commission Implementing Decision concerning the placing on the market for cultivation of genetically modified maize Bt11 (SYN-BTØ11-1) seeds.

Please see under point C.01 above.

M.01 Teosintes

The Commission informed Member States about the occurrence of teosintes, a wild relative of maize, in Spanish and French maize fields, and confirmed that a mandate was sent to EFSA to assess any possible impact on GM maize cultivation by September 2016. The French and Spanish delegations provided a short overview of their experience with teosinte to date.

M.02 Unauthorised GM oilseed rape in conventional oilseed rape.

With regard to the finding of unauthorized GM oilseed rape in conventional oilseed rape, the Commission underlined the need for Member States concerned to provide the Commission with the monitoring plans and the respective reports as agreed in May 2016.

M.03 Update of the Annexes 2 and 3 of Directive 2001/18 – state of play.

Further to a question from two Member States, the Commission confirmed that the work on the update date of the annexes of Directive 2001/18/EC on environmental risk assessment of GMOs in accordance with Article 3 of Directive (EU) 2015/412 was ongoing.

M.04 Threshold in seeds.

Further to a question from a Member State, the Commission agreed that some reflection could be carried out, notably in light of the report on seed sampling and testing by the European Network of GMO laboratories.

M.05 Presence of GM Bacillus subtilis in vitamin B2 used as feed additive.

One Member State provided preliminary information on a new finding of GM Bacillus subtilis in vitamin B2 feed additive. Confirmation of the analytical results is awaited before submitting, if justified, the notification through RASFF.

M.06 Joint meeting of Committees 2009/41 and 2001/18 Directives – Gene therapy.

One Member State invited the Commission to organize a joint meeting under Directive 2001/18/EC and Directive 2009/41/EC, in particular to discuss issues such as harmonization of risk assessment in gene therapy and gene drives. The Commission agreed to address this request.

M.07 New Breeding Techniques – state of play.

Upon a question from a Member State about the New Breeding Techniques, the Commission informed that the work is ongoing but timing and outcome cannot be anticipated.