EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE JOINT MEETING STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED

Section *Genetically Modified Food and Feed and Environmental Risk*

and

REGULATORY COMMITTEE under DIRECTIVE 2001/18/EC HELD IN BRUSSELS ON 27 JANUARY 2017

CIRCABC Link: *https://circabc.europa.eu/w/browse/7e20f9f4-30d8-4da9-8841-4554877937f2*

A.01 Discussion on comments to the draft Commission Directive, amending Annexes II, III, IIIB and IV of Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms.

The Commission presented a summary of the comments received through TBT and SPS and through the feedback mechanism. The Commission also presented a summary of the technical comments submitted by Member States on Annex II to the Directive, followed by a brief discussion. The Commission indicated that the draft Directive will be revised taking into account the comments received, and will be submitted to the Committee as soon as possible.

A.02 Update from Member States on measures taken according to article 1 (1) of Directive (EU) 2015/412 to avoid possible cross border contamination of GMOs into neighbouring Member States in which cultivation of those GMOs is prohibited.

The Commission asked Member States cultivating maize MON810 and having borders with Member States where cultivation is prohibited, to inform the Committee on the adoption of cross border measures. The adoption of these measures is an obligation under Directive 2001/18/EC and has to be fulfilled by 3 April 2017. The Member States concerned informed the Committee about the progress of updating their national legislation and expressed their intentions to finalize the legislation on time.

A.03 Review of the requirement to perform 90-day feeding studies in rodents with whole genetically modified food/feed under Commission Implementing Regulation (EU) No 503/2013.

As set out in Article 12 of Commission Implementing Regulation (EU) 503/2013, the Commission has conducted a review of the requirement to perform 90-day feeding studies in rodents with whole genetically modified food/feed on the basis of new scientific information.
The Commission presented its conclusions to maintain the requirement for the submission of a 90 day feeding study to Member States as a necessary additional safety layer in the safety assessments of GMO applications. The conclusions will be published on the Health and Food Safety Directorate General internet site.
The Commission explained that developments in scientific knowledge on replacement, reduction and refinement of animal use in scientific procedures are not at present sufficient to allow for the replacement of the 90 day feeding study in rodents by alternatives. In addition, there remain difficulties to define, with the necessary precision, the level of uncertainties in the application safety data package which would trigger the requirement for the 90-day studies on a case by case basis.
In the ensuing discussion, the majority of Member States supported the Commission's conclusion to maintain the 90 day feeding study requirement.

A.04 Scientific opinion on application for placing on the market the genetically modified herbicide-tolerant maize DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 - Presentation by EFSA.

EFSA presented the opinion on the application for the placing on the market of products containing, consisting of, or produced from genetically modified herbicide-tolerant maize DAS-40278-9 under Regulation (EC) No 1829/2003. The presentation was followed by questions from Member States.

A.05 Scientific opinion on application for renewal of authorization for continued marketing of genetically modified insect resistant maize 1507 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 - Presentation by EFSA.

EFSA presented the opinion on the application for the placing on the market of products containing, consisting of, or produced from genetically modified insect resistant maize 1507 under Regulation (EC) No 1829/2003. The presentation was followed by questions from Member States.

A.06 Risk assessment of new sequencing information on GM maize event DAS-59122-7- Presentation by EFSA.

EFSA presented its statement on the new sequencing information on maize DAS-59122-7 which was published on 5 December 2016. EFSA concluded that reported sequence errors do not alter the validity of the previous EFSA opinion/assessment of DAS-59122-7.

B.01 Exchange of views and possible opinion 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.

Common for B.01, B.02 and B.03 : The Commission presented the changes introduced in the three draft legal acts further to the discussion held with Member States in the previous Standing Committee meeting. The changes further enhance the clarity and practicability of the risk management measures proposed.

Reasons for the negative vote or abstention on point B.01:

- No agreed national position
- Negative public opinion
- Political reasons
- Uncertainties in risk assessment
- Safety concerns for the environment

Vote taken: No opinion

B.02 Exchange of views and possible opinion 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.

General summary - please see under B.01

Reasons for the negative vote or abstention on point B.02:

- No agreed national position
- Negative public opinion
- Political reasons
- Uncertainties in risk assessment
- Safety concerns for the environment
- Potential risks for the environment and health due to tolerance of maize 1507 to glufosinate ammonium.

Written statement by Sweden:
Market authorisation for the cultivation of the genetically modified maize 1507
The meeting discussed market authorisation for cultivation of seeds of the genetically modified maize 1507 (DAS-01507-1). The genetically modified maize 1507 has insect resistance and tolerance to the herbicides glyphosate and glufosinate ammonium.
Sweden will vote to reject the application for cultivation of the genetically modified maize 1507 (DAS-01507-1) in view of the dangerous properties of glufosinate ammonium and the potential risks to the environment and health posed by that substance once released into the environment.
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 the environment and for biodiversity and that the objective of a non-toxic environment must be attained by avoiding the use of pesticides as far as possible.

The Swedish Government is of the opinion that a holistic approach is important here and has in this case made the overall political assessment that glufosinate ammonium is a pesticide so dangerous that Sweden must vote NO in order to continue to work towards a non-toxic environment in the EU.

Vote taken: No opinion

B.03 Exchange of views and possible opinion 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.

General summary - please see under B.01

Reasons for the negative vote or abstention on point B.03:

- No agreed national position
- Negative public opinion
- Political reasons
- Uncertainties in risk assessment
- Safety concerns for the environment
- Potential risks for the environment and health due to tolerance of maize 1507 to glufosinate ammonium.

Written statement by Sweden

Market authorisation for the cultivation of the genetically modified maize Bt11
The meeting discussed market authorisation for cultivation of seeds of the genetically modified maize Bt11 (SYN-BT011-1). The genetically modified maize Bt11 has insect resistance and tolerance to the herbicides glyphosate and glufosinate ammonium.
Sweden will vote to reject the application for cultivation of the genetically modified maize Bt11 (SYN-BT011-1) in ent and health posed by that substance once released into the environment.view of the dangerous properties of glufosinate ammonium and the potential risks to the environm
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 the environment and for biodiversity and that the objective of a non-toxic environment must be attained by avoiding the use of pesticides as far as possible.
The Swedish Government is of the opinion that a holistic approach is important here and has in this case made the overall political assessment that glufosinate ammonium is a pesticide so dangerous that Sweden must vote NO in order to continue to work towards a non-toxic environment in the EU.

Written statement by the Czech Republic (aggregated statement for all three abovementioned votes):

Regarding the voting of the Czech Republic at today's meeting - agenda items B.01, B.02 and B.03, let me to explain that the positions differed due to lack of consensus among the Competent Authorities at this stage.

Therefore the Czech Republic voted in favour in the case of MON810 (under Regulation 1829/2003) and abstained as regards GM maizes 1507 and Bt11 (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 maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21.

The draft Decision authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 was presented to the Committee and submitted for a vote.

Reasons for the negative vote or abstention:

- No agreed national position
- Negative public opinion
- Political reasons
- National risk assessment not yet finalised
- National GM-free strategy
- EFSA minority opinion
- Risk assessment deemed not sufficient
- Lack of long-term feeding studies

Written statement by Sweden

The meeting discussed market authorisation for the genetically modified maize Bt11 x 59122 x MIR604 x 1507 x GA21 which contains two, three or four of the parts in Bt11, 59122, MIR604, 1507 and GA21, for use in food and feed and for import and processing of material that contains or consists of that maize. The application for market authorisation does not cover cultivation. The genetic modification of maize Bt11 x 59122 x MIR604 x 1507 x GA21 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 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.

Vote taken: No opinion

M.01 Update on CIRCABC list.

The Commission asked those Member States, who have not yet done so, to send the updated list of their experts who should have access to the respective interest groups in CIRCABC to the Commission.

M.02 By-products of L-threonine production using a genetically modified micro-organism (request by a Member State).

A Member State requested the views of the Committee on the GM status of the fermentation liquor from production of L-threonine using a genetically modified micro-organism. In order to have a more in depth view on the matter, the Committee requested additional information from the Member State delegation on the fermentation and filtration processing. If necessary, further discussions will take place in the Committee.

M.03 The Japanese questionnaire on GM uses (request by a Member State).

A Member State informed the Committee that the Japanese Authorities have requested them to complete a questionnaire on GMOs and to conduct a meeting on this. Other Member States confirmed that they would also meet with the Japanese Authorities. The Commission informed Member States that a meeting with the Japanese Authorities will take place to explain the EU legal framework on labelling in relation to GMOs. Furthermore, the Commission offered to provide assistance to the Member States if needed.

M.04 Request of GM-free certificates by Russia.

A Member State enquired about the follow up of the letter from the Russian Federation Authorities with some Member States and with the Commission regarding the registration of feed produced from GMOs. The Commission informed that an official letter has been sent to the Russian Federation and that the relevant technical questions will be raised in bilateral discussions with Russia. The Committee will be informed of the outcome.