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Standing Committee on Plants, Animals, Food and Feed
Section *Genetically Modified Food and Feed*
15 September 2020

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SUMMARY REPORT

A.01 Assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA- GMO- DE- 2012- 111) - 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 soybean SYHT0H2. No questions were raised by Member States.

A.02 Assessment of genetically modified maize MON 88017 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA- GMO- RX- 014) - Presentation by EFSA.

EFSA presented the opinion on the application for renewal of products containing, consisting of or produced from genetically modified maize MON 88017. No questions were raised by Member States.

A.03 Assessment of genetically modified oilseed rape MS11 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA- GMO- BE- 2016- 138) - 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 oilseed rape MS11, which is only conclusive for cases of accidental exposure. One Member State raised a question about the approach followed for the risk assessment, to which EFSA explained that the single event MS11 was risk assessed according to its guidance documents and, given the particularities of this product, two scenarios for exposure were considered. The Commission underlined that the risk assessment was in line with the legislation. Further to a Member State's question on the next steps, the Commission clarified that the applicant confirmed that the oilseed rape MS11 was not designed to be commercialized as such (but intended to be used in a stack) and also requested the Commission to put this particular application on hold until EFSA had finalizes the risk assessment of the relevant stack (genetically modified oilseed rape MS11 × RF3). The Commission accepted to put the application on hold as requested.

A.04 Assessment of genetically modified soybean MON 87705 × MON 87708 × MON 89788, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA- GMO- NL- 2015- 126) - 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 soybean MON 87705 × MON 87708 × MON 89788. No questions were raised by Member States. The Commission informed that it had requested the missing information to the applicant.

A.05 Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-UK-2006-34) for authorisation of food and feed containing, consisting of and produced from genetically modified maize 3272 – Discussion.

The Commission recalled the discussion at the Standing Committee of 9 December 2019, and the EFSA positive conclusion regarding the safety of the "distillers' dried grains with solubles" (DDGS) from genetically modified maize 3272. As few Member States were in a position to express their views regarding the implementation of a potential authorisation specific to DDGS from genetically modified maize 3272 for feed uses, it was agreed that all Member States will send their views by email by the end of October 2020.

A.06 Emergency measure on rice from China (Decision 2011/884/EU): overview of the results of Member States' controls - Presentation by the Commission.

The Commission presented an overview of Member States' controls for 2019. In 2019 there was a small increase in the incompliances, comparing to the previous year. The Commission also replied to questions of the Member States on the implementation of this measure under the new regulatory framework of official controls, applicable since 14 December 2019.

A.07 Regulation (EU) 2019/1381 on the transparency and sustainability of EU risk assessment in the food chain (Transparency Regulation) - Presentation by the Commission.

The Commission gave a general presentation on the main new points introduced in the Transparency Regulation and how these affect the application of Regulation 1829/2003. One Member State referred to EFSA's practical arrangements on the notification of studies without entering into detail. The Commission replied that these practical arrangements are still under development and that further consultation with Member States and other stakeholders is planned.

A.08 Food System Common Authorisation Procedure – FSCAP: implementing the new requirements of General Food Law for GMO applications submission - Presentation by the Commission.

The Commission gave a short presentation on the IT system under development for the sector under Regulation 1829/2003 with regard to the implementation of the new Transparency Regulation obligations. No questions were raised by the Member States.

A.09 Brexit preparedness

The Commission recalled that the transition period provided in the EU-UK Withdrawal Agreement will end on 31.12.2020, and reminded Member States of their obligations to prepare for the full implementation of the Agreement on 01.01.2021, when the UK will leave the Internal Market and the EU Customs Union. The Commission indicated that the UK authorities have committed to publish most of their SPS legislation applicable as of next year in October. The Commission stressed it remains available to address any questions arising from Member States on Brexit at future Standing Committee meetings.

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 maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111, was presented to the Committee.

The Committee agreed to vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken by written procedure: no opinion.

Reasons for the negative vote or abstention:

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

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

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 maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON

87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, was presented to the Committee.

The Committee agreed to vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken by written procedure: no opinion.

- Reasons for the negative vote or abstention:
- No agreed national position
- Negative public opinion
- Political reasons
- Precautionary principle
- Risk assessment deemed not sufficient

Written statement issued by Austria:

"Austria is of the opinion that the risk assessment which has been carried out is affected by uncertainties unsuitable to give a scientific proof for the safety of this product and, therefore, objects the placing on the market of genetically modified maize MON87427xMON87460xMON89034xMIR162xNK603 for the following reason:

a. The genetically modified maize MON87427xMON87460xMON89034xMIR162xNK603 is carrier of an antibiotic resistance marker gene (i.e. nptII) which may facilitate the dissemination of antimicrobial resistance in soil and gut bacteria. Considering the current crisis in antibiotic resistance, we cannot support a deliberate fueling of the environmental antibiotic resistance gene pool by this product.

*b. By **not** removing this resistance gene from the commercialized product – although technically possible by the implemented cre-lox system - the applicant is violating Commission Implementing Regulation 503/13 on the "insertion of marker genes and other nucleic acid(s) sequences not essential to achieve the desired trait" and Directive 2001/18/EC on phasing out of antibiotic resistance genes."*

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

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 SYHT0H2 (SYN-ØØØH2-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

The draft Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 was presented to the Committee.

The Committee agreed to vote in written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011.

Vote taken by written procedure: no opinion.

Reasons for the negative vote or abstention:

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

Written statement issued by Sweden:

"The authorization of placing on the market of products containing, consisting of, or produced from genetically modified maize is on the agenda on the meeting mentioned above. The authorization does not include cultivation. Soja bean SYHT0H2 is tolerant to glufosinate-ammonium-based herbicides.

The Swedish Board of Agriculture and the National Food Agency make the same conclusion as stated by Efsa i.e. this product is safe for human and animal health as well as for the environment. Sweden therefore votes in favour of granting the product authorization according to the Commission proposal.

This does not preclude the Swedish vote on a possible future granting of authorization of ***cultivation*** *of seeds that are tolerant to glufosinate-ammonium.*

Glufosinate-ammonium has very serious properties and is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009.

In our view, potential use and cultivation of genetically modified organisms in Sweden should not have a negative effect on biodiversity and, as far as possible, not lead to an increased use of pesticides."

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

M.01 2020 RASFF notifications on alpha amylase

The Commission drew the attention of the Member States to RASFF notifications, regarding the presence of DNA from unauthorized genetically modified microorganism in alpha-amylase food enzymes. The Commission reiterated the zero tolerance of unauthorised GMOs and asked MS to trace and withdraw from the market any products which do not comply with GMO legislation.