Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-013 (maize MIR604) from Syngenta under Regulation (EC) No. 1829/2003

10 December 2019
Ref. SC/1510/BAC/2019_1084

Context

Application EFSA-GMO-RX-013 was submitted by Syngenta for the renewal of authorisation for the marketing of genetically modified (GM) maize MIR604 for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

The placing on the market of the insect-resistant maize MIR604 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (The EFSA Journal (2009) 1193, 1-26)[2].

The renewal application was validated by EFSA on 5 November 2018 and a formal three-month consultation period of the Member States was started, lasting until 11 February 2019, in accordance with Articles 6.4 and 18.4 of Regulation (EC) No. 1829/2003 (consultation of national Competent Authorities within the meaning of Directive 2001/18/EC designated by each Member State in the case of genetically modified organisms being part of the products).

Within the framework of this consultation, the coordinator for this dossier, on behalf of the Belgian Biosafety Advisory Council (BAC), decided not to request external experts to assess this dossier, since the previous applications for the event (as part of a stack) had received a positive advice from the Biosafety Advisory Council, and no new relevant information was provided in the current application for renewal, which could modify the previous conclusions.

The opinion of the EFSA Scientific Panel on GMOs was published on 7 November 2019 (EFSA Journal 2019;17(11):5846)[3], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The previous advice of the BAC on maize MIR604 (BAC_2009_1365)[4], the subsequent advices on applications involving the event, and the published opinion of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-013 given below.

Scientific evaluation

The data for application EFSA-GMO-RX-013 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports from July 2009 to June 2018, a systematic literature search covering the complete duration of the event's authorisation, an updated bioinformatic package including an analysis of the potential interruption of genes by the insert, potential similarity of the newly expressed protein with known toxic or allergenic proteins, potential of

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1).
[2] http://www.efsa.europa.eu/en/efsajournal/pub/1193
[3] http://www.efsa.europa.eu/en/efsajournal/pub/5846
[4] http://www.bio-council.be/Advices/BAC_2009_01365.pdf

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newly created open reading frames within the insert or spanning the junctions with genomic DNA encoding peptides with sequence similar to known toxins or allergens, potential for horizontal gene transfer to micro-organisms, and an assessment of the capacity of the newly expressed proteins to trigger celiac disease.

The Biosafety Advisory Council did not identify any information element in the renewal application EFSA-GMO-RX-013 that would raise a safety concern for human or animal health or the environment.

The Biosafety Advisory Council did not identify any risk that the import and processing of this GM maize could pose to the European environment.

Conclusion

The Biosafety Advisory Council is of the opinion that the data on maize MIR604 provided by the applicant, and the opinion of EFSA, confirm its latest opinion on maize MIR604 that in the context of its proposed uses, maize MIR604 is unlikely to pose any risk to human and animal health and the European environment.

In addition, the Biosafety Advisory Council recommends following up any unanticipated allergenicity aspects of the GM maize in the existing allergenicity monitoring systems.

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