Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-016 from Syngenta under Regulation (EC) No. 1829/2003

22 January 2021
Ref. SC/1510/BAC/2021_0063

Context

Application EFSA-GMO-RX-016 was submitted by Syngenta for the renewal of authorisation for the marketing of genetically modified (GM) maize Bt11 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 and herbicide-tolerant maize Bt11 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (EFSA Journal 2009;7(2))[2].

The renewal application was validated by EFSA on 26 November 2018 and a formal three-month consultation period of the Member States was started 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 (GMOs) 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 application for the event had received a positive advice from the BAC, 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 13 January 2021 (EFSA Journal 2021;19(1):6347)[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 Bt11 (BAC_2009_904)[4], and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-016.

[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] https://doi.org/10.2903/j.efsa.2009.977
[3] https://doi.org/10.2903/j.efsa.2021.6347
[4] http://www.bio-council.be/Advices/BAC_2009_00904.pdf

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Scientific evaluation

The data for application EFSA-GMO-RX-016 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports covering the years of import, a systematic literature search covering the complete duration of the event's authorisation, an updated bioinformatic package including an analysis of the potential similarity of the newly expressed proteins and newly created open reading frames within the insert or spanning the junctions with genomic DNA to known toxins or allergens and a safety assessment of the newly expressed proteins Cry1Ab and PAT regarding their capacity to trigger celiac disease, and reports of additional studies performed by the applicant over the course of the authorisation period.

The BAC did not identify any information in the renewal application EFSA-GMO-RX-016 that would raise a safety concern for human or animal health.

Further, the BAC did not identify any risk that the import and processing of this GM maize could pose to the European environment.

Conclusion

The BAC is of the opinion that the data on maize Bt11 provided by the applicant, and the opinion of EFSA, confirm its latest opinion on maize Bt11 that in the context of its proposed uses, maize Bt11 is unlikely to pose any risk to human and animal health and the European environment.

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

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