Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2022-9450 (genetically modified maize MON810) from Bayer under Regulation (EC) No. 1829/2003

12 March 2024
Ref. SC/1510/BAC/2024_0351

Context

Application GMFF-2022-9450 (RX-028) was submitted by Bayer for the renewal of authorisation for the marketing of genetically modified (GM) maize MON 810 (Unique Identifier MON-ØØ81Ø-6) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

Maize MON 810 expresses a modified *cry1Ab* gene which provides protection to certain lepidopteran pests. The placing on the market of the insect-resistant maize MON 810 for food and feed uses is currently authorised following the positive opinions of EFSA (EFSA 2009, 2012)[2,3]

The renewal application was validated by EFSA on 10 March 2023 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.

The scientific opinion of the EFSA Scientific Panel on GMOs was published on 19 January 2024 (EFSA Journal 2024;22(1):e8489)[4], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The previous advices of the BAC on maize MON810 (BAC_2009_01510; BAC_2013_0023)[5,6], and the published scientific opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-028.

[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.2009.1149
[3] https://doi.org/10.2903/j.efsa.2012.3022
[4] https://doi.org/10.2903/j.efsa.2024.8489
[5] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2009_01510.pdf
[6] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2013_0023.pdf

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Scientific evaluation

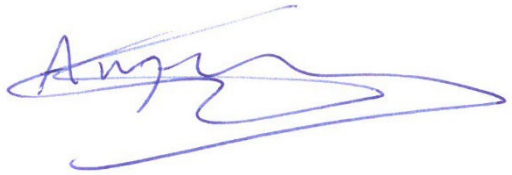
The data for application EFSA-GMO-RX-028 provided by the applicant included:

- 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 (1) 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 (2) a safety assessment of the newly expressed protein Cry1Ab regarding its capacity to trigger celiac disease;
- reports of additional studies performed by the applicant.

The Belgian experts and the members of the Biosafety Advisory Council did not identify any information elements in the renewal application EFSA-GMO-RX-028 that would raise a safety concern for human or animal health or the environment.

Conclusion

The BAC is of the opinion that the data on maize MON 810 provided by the applicant, and the opinion of EFSA, confirm its latest opinion on maize MON 810 that in the context of its proposed uses, maize MON 810 is unlikely to pose any risk to human and animal health and the European environment.



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