

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2023-21254 (RX-041) (genetically modified maize MON 87427) from Bayer under Regulation (EC) No. 1829/2003

02 July 2025
Ref. SC/1510/BAC/2025_0848

Context

Application GMFF-2023-21254 (RX-041) was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) maize MON 87427 (Unique Identifier MON-87427-7) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

The placing on the market of the herbicide-tolerant MON 87427 maize for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 13(6), 4130)².

The renewal application was validated by EFSA on 14 June 2024 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 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 13 May 2025 (EFSA Journal 2025;23:e9380)³, together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The contents of the renewal application, the previous positive advice of the BAC on maize MON 87427 (BAC_2015_00585)⁴, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application GMFF-2023-21254 (RX-041).

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.2015.4130>

³ <https://doi.org/10.2903/j.efsa.2025.9380>

⁴ https://www.bio-council.be/sites/biocouncil.be/files/advice/BAC_2015_0585.pdf

Scientific evaluation

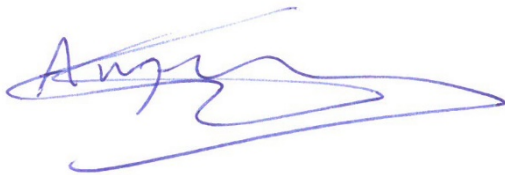
The data for application GMFF-2023-21254 (RX-041) provided by the applicant included:

- 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, and
- an updated bioinformatic package including (1) an analysis of the potential similarity of the newly produced 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 CP4 EPSPS regarding its capacity to trigger celiac disease.

The members of the Biosafety Advisory Council did not identify any information elements in the renewal application GMFF-2023-21254 (RX-041) that would raise a safety concern for human or animal health or the environment.

Conclusion

The Biosafety Advisory Council is of the opinion that the data on maize MON 87427 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, maize MON 87427, is unlikely to pose any risk to human and animal health and the European environment.



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