

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2023-21251 (RX-039) (genetically modified maize MON 87460) from Bayer CropScience under Regulation (EC) No. 1829/2003

3 February 2026
Ref. SC/1510/BAC/2026_0130

Context

Application EFSA-GMFF-2023-21251 (RX-039) was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) maize MON 87460 (Unique Identifier MON-87460-4) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Maize MON 87460 expresses the cold shock protein B (CspB) from *Bacillus subtilis* and the marker NPTII from Tn5 of *Escherichia coli*. Maize MON 87460 was developed to provide reduced yield loss under conditions in which water is limited compared with conventional maize. The placing on the market of maize MON 87460 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2012;10(11):2936)².

The renewal application was validated by EFSA on 10 July 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 since no adverse effects are reported since the commercialisation of maize MON 87460, the information in the current application for renewal does not point to new hazards or modified use of the GMO, and the previous application for this event had received a positive advice from the Biosafety Advisory Council.

The scientific opinion of EFSA's GMO Panel, including the responses from the Panel to comments submitted by the Member States during the three-month consultation period, was published on 8 December 2025 (EFSA Journal 2025;23:e9744)³.

The advice of the BAC on application EFSA-GMFF-2023-21251 (RX-039) is based on the contents of the renewal application, the BAC's previous positive advice on maize MON 87460 (BAC_2013_0194)⁴, and the published opinion of the EFSA GMO Panel.

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.2012.2936>

³ <https://doi.org/10.2903/j.efsa.2025.9744>

⁴ https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2013_0194.pdf

Scientific evaluation

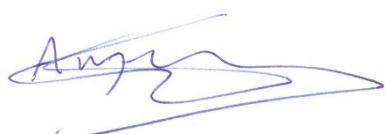
The data for application EFSA-GMFF-2023-21251 (RX-039) provided by the applicant included:

- the annual post-market environmental monitoring (PMEM) reports covering a reporting period from April 2015 to June 2024,
- scoping reviews of the literature covering the period from January 2014 to September 2024,
- an updated bioinformatic package including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer, and a safety assessment of the newly expressed proteins CspB and NPTII regarding their capacity to trigger celiac disease symptoms; and
- reports of additional studies performed by the applicant over the course of the authorisation period.

The members of the Biosafety Advisory Council did not identify any information elements in renewal application EFSA-GMFF-2023-21251 (RX-039) that would raise safety concerns for human or animal health or the environment.

Conclusion

The Biosafety Advisory Council is of the opinion that the data on maize MON 87460 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, maize MON 87460 is unlikely to pose any risk to human and animal health and the European environment.



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