Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2023-21250 (RX-040, genetically modified maize NK603) from Bayer CropScience under Regulation (EC) No. 1829/2003

9 October 2025
Ref. SC/1510/BAC/2025_1202

Context

Application EFSA-GMFF-2023-21250 (RX-040) was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) maize NK603 (Unique Identifier MON-ØØ6Ø3-6) 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 NK603 expresses the CP4 EPSPS and CP4 EPSPS L214P proteins which confer tolerance to glyphosate herbicides. The placing on the market of maize NK603 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2009;1137, 1-50)[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 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 20 June 2025 (EFSA Journal 2025;23:e9505)[3].

The contents of the renewal application, the previous positive advice of the BAC on maize NK603 (BAC_2009_01367)[4], and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMFF-2023-21250 (RX-040).

[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.2009.1137
[3] https://www.efsa.europa.eu/en/efsajournal/pub/9505
[4] https://www.bio-council. be/sites/biocouncil.be/files/advices/BAC_2009_01367.pdf

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Scientific evaluation

The data for application EFSA-GMFF-2023-21250 (RX-040) provided by the applicant included:

- the annual post-market environmental monitoring (PMEM) reports covering the period from July 2014 to June 2023,
- scoping reviews 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 (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of the newly expressed proteins CP4 EPSPS and CP4 EPSPS L214P, regarding their potential 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 the renewal application EFSA-GMFF-2023-21250 (RX-040) 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 NK603 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, maize NK603 is unlikely to pose any risk to human and animal health and the European environment.

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