Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2024-22651 (RX-042, genetically modified maize T25) from BASF under Regulation (EC) No. 1829/2003

9 October 2025
Ref. SC/1510/BAC/2025_1203

Context

Application EFSA-GMFF-2024-22651 (RX042) was submitted by BASF for the renewal of authorisation for the marketing of genetically modified (GM) maize T25 (Unique Identifier ACS-ZMØØ3-2) 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 T25 expresses the PAT protein which confers tolerance to the glufosinate-ammonium herbicide. The placing on the market of maize T25 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2013;11(10):3356)[2].

The renewal application was validated by EFSA on 12 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.

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 August 2025 (EFSA Journal 2025;23:e9570)[3].

The contents of the renewal application, the previous positive advice of the BAC on maize T25 (BAC_2014_329)[4], and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMFF-2024-22651 (RX-042).

[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.2013.3356
[3] https://doi.org/10.2903/j.efsa.2025.9570
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2014_0329.pdf

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Scientific evaluation

The data for application EFSA-GMFF-2024-22651 (RX-042) provided by the applicant included:

- the annual post-market environmental monitoring (PMEM) reports covering a reporting period from April 2015 to June 2023,
- scoping reviews covering the period from January 2013 to January 2025,
- an updated bioinformatic package including (1) 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 (2) a safety assessment of the newly expressed protein PAT regarding its capacity to trigger celiac disease; 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-2024-22651 (RX-042) 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 T25 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, maize T25 is unlikely to pose any risk to human and animal health and the European environment.

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