

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2024-23010 (RX-044, genetically modified cotton T304-40) from BASF under Regulation (EC) No. 1829/2003

9 October 2025
Ref. SC/1510/BAC/2025_1206

Context

Application EFSA-GMFF-2024-23010 (RX-044) was submitted by BASF for the renewal of authorisation for the marketing of genetically modified (GM) cotton T304-40 (Unique Identifier BCS-GHØØ4-7) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Cotton T304-40 produces the Cry1Ab and PAT proteins for protection against certain pests and tolerance to glufosinate-ammonium herbicides, respectively. The placing on the market of cotton T304-40 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2013;11(6):3251)².

The renewal application was validated by EFSA on 30 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 22 July 2025 (EFSA Journal 2025; 23:e9580)³.

The contents of the renewal application, the previous positive advice of the BAC on cotton T304-40 (BAC_2014_0141)⁴, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMFF-2024-23010 (RX-044).

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.2013.3251>

³ <https://www.efsa.europa.eu/en/efsajournal/pub/9580>

⁴ https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2014_0141.pdf

Scientific evaluation

The data for application EFSA-GMFF-2024-23010 (RX-044) provided by the applicant included:

- the annual post-market environmental monitoring (PMEM) reports covering a reporting period from April 2015 to June 2023,
- a systematic literature search covering the period from April 2015 to February 2025,
- an updated bioinformatic package including (1) an analysis of the insert and flanking sequence, 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, and (2) a safety assessment of the newly expressed proteins Cry1Ab and PAT regarding their capacity to trigger celiac disease symptoms; and
- reports of additional studies performed by or on behalf of 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-2024-23010 (RX-044) 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 cotton T304-40 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, cotton T304-40 is unlikely to pose any risk to human and animal health and the European environment.



Dr. ir. Geert Angenon
President of the Belgian Biosafety Advisory Council