

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on renewal application GMFF-2025-33580 (genetically modified soybean FG72) from Syngenta under Regulation (EC) No. 1829/2003

29 September 2026
Ref. SC/1510/BAC/2026_0825

Context

Application GMFF-2025-33580 (RX-047) was submitted by Syngenta for the renewal of authorisation for the marketing of genetically modified (GM) soybean FG72 (Unique Identifier MST-FGØ72-2) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Soybean FG72 produces the HPPD W336 and 2mEPSPS proteins, for tolerance to isoxaflutole- and glyphosate-based herbicides. The placing on the market of soybean FG72 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2015;13(7):4167)².

The renewal application was validated by EFSA on 2 July 2025 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 3 July 2026 (EFSA Journal 2026;24:e10179)³.

The advice of the BAC on application GMFF-2025-33580 (RX-047) is based on the contents of the renewal application, the BAC's previous positive advice on soybean FG72 (BAC_2015_0597)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.2015.4167>

³ <https://doi.org/10.2903/j.efsa.2026.10179>

⁴ https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2015_0597.pdf

Scientific evaluation

The data for application GMFF-2025-33580 (RX-047) provided by the applicant included:

- the annual post-market environmental monitoring (PMEM) reports covering the period from July 2015 to June 2024,
- scoping literature reviews covering the period from January 2014 to February 2026,
- an updated bioinformatic package including an analysis to identify potential interrupted genes at the insertion site, 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, an analysis of possible horizontal gene transfer, and a safety assessment of the newly expressed protein 2mEPSPS and HPPD W336 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 GMFF-2025-33580 (RX-047) 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 soybean FG72 provided by the applicant, and the opinion of EFSA, confirm its latest opinion that in the context of its proposed uses, soybean FG72 is unlikely to pose any risk to human and animal health and the European environment.



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