

Adviesraad voor Bioveiligheid

Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2023-21236 (RX-037) (genetically modified soybean MON 87705) from Bayer CropScience under Regulation (EC) No. 1829/2003

3 February 2026
Ref. SC/1510/BAC/2026_0129

Context

Application GMFF-2023-21236 (RX-037) was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) soybean MON 87705 (Unique Identifier MON-87705-6) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Soybean MON 87705 expresses FAD2-1A and FATB1-A dsRNAs, resulting in an altered fatty acid profile, and the CP4 EPSPS protein which confers tolerance to glyphosate herbicides. The soybean has a fatty acid profile that is high in oleic acid. The placing on the market of soybean MON 87705 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2012;10(10):2909)² and a complementing statement (EFSA Journal 2013;11(12):3507)³.

The renewal application was validated by EFSA on 16 December 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 12 January 2026 (EFSA Journal 2026;24:e9846)⁴.

The advice of the BAC on application EFSA-GMFF-2023-21236 (RX-037) is based on the contents of the renewal application, the BAC's previous positive advices on soybean MON 87705 (BAC_2012_1009⁵ and BAC_2014_0366⁶), 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.2012.2909>

³ <https://doi.org/10.2903/j.efsa.2013.3507>

⁴ <https://doi.org/10.2903/j.efsa.2026.9846>

⁵ https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2012_1009.pdf

⁶ https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2014_0366.pdf

Scientific evaluation

The data for application GMFF-2023-21236 (RX-037) 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 February 2025,
- 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 protein CP4 EPSPS and of all possible open reading frames within the insert and spanning the junction sites, a bioinformatics analysis to identify potential off-target genes due to the expression of FAD2-1A and FATB1-A dsRNAs, an analysis of possible horizontal gene transfer, and a safety assessment of the newly expressed protein CP4 EPSPS 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-2023-21236 (RX-037) 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 MON 87705 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, soybean MON 87705, is unlikely to pose any risk to human and animal health and the European environment.



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