Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2023-21253 (genetically modified soybean MON 87769) from Bayer under Regulation (EC) No. 1829/2003

3 February 2026
Ref. SC/1510/BAC/2026_0127

Context

Application GMFF-2023-21253 was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) soybean MON 87769 (Unique Identifier MON 87769-7) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

Soybean MON 87769 expresses the *pjΔ6d* and *ncΔ15d* genes which results in an altered fatty acid composition. The most important change is the production of stearidonic acid production. The placing on the market of soybean MON 87769 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2014;12(5):3644)[2].

The renewal application was validated by EFSA on 25 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 19 January 2026 (EFSA Journal 2026;24:e9845)[3].

The advice of the BAC on application GMFF-2023-21253 is based on the contents of the renewal application, the BAC's previous positive advice on soybean MON 87769 (BAC_2014_0427)[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.2014.3644
[3] https://doi.org/10.2903/j.efsa.2026.9845
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2014_0427.pdf

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Scientific evaluation

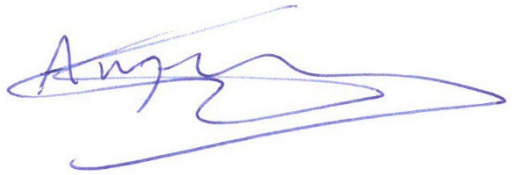
The data for application GMFF-2023-21253 provided by the applicant included:

- the annual post-market monitoring (PMM) and post-market environmental monitoring (PMEM) reports covering the years of import,
- a systematic literature search covering the complete duration of the event's authorisation, and
- an updated bioinformatic package including (1) 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, and (2) a safety assessment of the newly expressed proteins PjΔ6D and NcΔ15D regarding their capacity to trigger celiac disease.

The members of the Biosafety Advisory Council did not identify any information elements in the renewal application GMFF-2023-21253 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 87769 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, soybean MON 87769, 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

Annex : Outcome of the assessment of the application

Annex: Outcome of the assessment of renewal application EFSA-GMFF-2023-21253 by the Biosafety Advisory Council during the formal consultation of the Member States (3-month commenting period in accordance with Articles 6.4 and 18.4 of Regulation (EC) No 1829/2003)

Coordinator: René Custers
SBB: Adinda De Schrijver

Application for renewal: **EFSA-GMFF-2023-21253**
Applicant: **Bayer CropScience**
GMO: **soybean MON 87769**
Validation of dossier by EFSA: **25 July 2024**

Scope of the application:
☒ GM plants for food use
☒ Food containing or consisting of GM plants
☒ Food produced from GM plants or containing ingredients produced from GM plants
☒ GM plants for feed use
☒ Feed produced from GM plants
☒ Import and processing (Part C of Directive 2001/18/EC)
☐ Seeds and plant propagating material for cultivation in European Union (Part C of Directive 2001/18/EC)

The coordinator decided that an evaluation by external experts was not necessary for this dossier, since no adverse effects are reported since the commercialisation of soybean MON 87769, the information in the current application for renewal does not point to new hazards, and the previous application for this event had received a positive advice from the Biosafety Advisory Council.

The following comment was sent to EFSA: “We neither have comments, nor requests for additional information”.