

## **Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité**

### **Advice of the Belgian Biosafety Advisory Council on application EFSA-GMFF-2023-21234 (RX-030) (genetically modified cotton MON 88913) from Bayer CropScience under Regulation (EC) No. 1829/2003**

2 July 2025  
Ref. SC/1510/BAC/2025\_0846

#### **Context**

Application EFSA-GMFF-2023-21234 (RX-030) was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) cotton MON 88913 (Unique Identifier MON-88913-8) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003<sup>1</sup>.

Cotton MON 88913 produces the CP4 EPSPS protein, which confers tolerance to glyphosate herbicides. The placing on the market of cotton MON 88913 for food and feed uses, except cultivation, is currently authorised, following the adoption of Commission Implementing Decision (EU) 2015/688 and subsequent updates (EFSA scientific opinions <https://doi.org/10.2903/j.efsa.2013.3311> and complementing statement <https://doi.org/10.2903/j.efsa.2014.3591>).

The renewal application was validated by EFSA on 27 June 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 13 May 2025 (EFSA Journal. 2025;23:e9377)<sup>2</sup>.

The contents of the renewal application, the previous positive advice of the BAC on cotton MON 88913, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMFF-2023-21234 (RX-030).

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<sup>1</sup> 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).

<sup>2</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/9377>

## Scientific evaluation


The data for application EFSA-GMFF-2023-21234 (RX-030) 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 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 CP4 EPSPS protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer and a safety assessment of the newly expressed CP4 EPSPS protein regarding its potential capacity to trigger coeliac disease symptoms,
- 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-2023-21234 (RX-030) 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 MON 88913 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its intended uses, cotton MON 88913 is unlikely to pose any risk to human and animal health and the European environment.



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