Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

# Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-021 (Soybean MON 87701) from Bayer under Regulation (EC) No. 1829/2003

2 February 2023
*Ref. SC/1510/BAC/2023_0108*

## Context

Application EFSA-GMO-RX-021 was submitted by Bayer for the renewal of authorisation for the marketing of genetically modified (GM) soybean MON 87701 (Unique Identifier MON-88701-3) 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 87701 expresses the *cry1Ac* gene for protection against certain lepidopteran pests. The placing on the market of soybean MON 87701 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2011;9(7):2309)[2].

The renewal application was validated by EFSA on 7 May 2021 and a formal three-month consultation period of the Member States was started, lasting until 7 August 2021, 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 Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, contacted two experts to evaluate the molecular data provided in the dossier, chosen from the common list of experts drawn up by the BAC and the Service Biosafety and Biotechnology (SBB). The experts answered positively to this request, and did not have any comment on the application. No comments were sent to EFSA.

The opinion of the EFSA Scientific Panel on GMOs was published on 19 December 2022 (EFSA Journal 2022;20(12):7683)[3]. This opinion, as well as the previous advice of the BAC on soybean MON 87701 (BAC_2011_0898)[4] which was negative due to animal health concerns, form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-021 given below.

[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] http://www.efsa.europa.eu/en/efsajournal/pub/2309
[3] https://www.efsa.europa.eu/en/efsajournal/pub/7683
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2011_0898.pdf

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## Scientific evaluation

The data for application EFSA-GMO-RX-021 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports covering the years of import, two systematic literature searches covering the complete duration of the event's authorisation, 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 and of all possible open reading frames within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer and a safety assessment of the newly expressed protein Cry1Ac regarding its capacity to trigger celiac disease, and reports of additional studies performed by the applicant over the course of the authorisation period.

The Belgian experts and the members of the Biosafety Advisory Council did not identify any information elements in the renewal application EFSA-GMO-RX-021 that would raise a safety concern for human or animal health or the environment.

## Conclusion

The Biosafety Advisory Council is of the opinion that on the basis of the data on soybean MON 87701 provided by the applicant and the opinion of EFSA, in the context of its proposed uses, the continued authorisation of soybean MON 87701 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

**Minority declaration of P. Baret and W. Vanhove**

Previous BAC advice on soybean MON 87701 (BAC_2011_0898) was negative due to animal health concerns. We believe that the feeding experiment which gave rise to these concerns should be repeated to exclude animal health risks in the current application. To date, no such experiment has been performed. As the required scientific evidence is not provided, we believe the safety of soybean MON 87701 is uncertain.