Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application GMFF-2023-21237 (genetically modified soybean MON 87708) from Bayer under Regulation (EC) No. 1829/2003

02 July 2025
Ref. SC/1510/BAC/2025_0847

Context

Application GMFF-2023-21237 was submitted by Bayer CropScience for the renewal of authorisation for the marketing of genetically modified (GM) soybean MON 87708 (Unique Identifier MON-877Ø8-9) 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 87708 expresses a *dmo* (dicamba mono-oxygenase) gene which confers tolerance to dicamba herbicides. The placing on the market of soybean MON 87708 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 11(10), 3355)[2].

The renewal application was validated by EFSA on 28 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 to consult an additional expert on toxicology in order to gain better insight in the clinical observations of the 90-day rat study. The absence of a sound explication of certain observed clinical differences in this study, led to an inconclusive opinion of the BAC on MON 87708 in 2014 (BAC_2014_0325)[3]. Further, the coordinator decided not to request external experts to assess the renewal dossier.

The scientific opinion of the EFSA Scientific Panel on GMOs was published on 13 May 2025 (EFSA Journal 2025;23(5):e9379)[4], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The contents of the renewal application, the previous inconclusive advice of the BAC on soybean MON 87708, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application GMFF-2023-21237.

[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.2013.3355
[3] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2014_0325.pdf
[4] https://doi.org/10.2903/j.efsa.2025.9379

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Scientific evaluation

The data for application GMFF-2023-21237 provided by the applicant included:

- the annual 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 DMO protein regarding its capacity to trigger celiac disease.

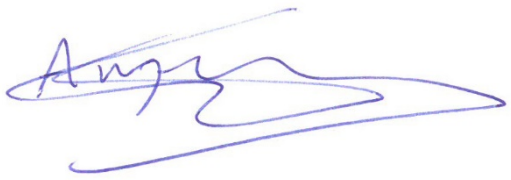
The members of the Biosafety Advisory Council did not identify any information elements in the renewal application GMFF-2023-21237 that would raise a safety concern for human or animal health or the environment.

The Biosafety Advisory Council wishes to note that during the evaluation of the original application in 2011 it had raised questions in relation to the data presented in the 90-day study which remained unresolved. Following a consultation of a current toxicology expert and upon further evaluation, the members of the Biosafety Advisory Council, are of the opinion that:

- the elevated eosinophil count observed for male rats in the 30% feeding group, falls within in the historical range of data and therefore does not pose an issue, and
- the slight, but significant, alanine aminotransferase (ALT) activity observed in the male rats of the 30% feeding group is rather an isolated finding than a true effect, as in case of true liver toxicity the increase in ALT activity would be higher, other clinical parameters would be elevated as well, the observed toxicity would be supported by histopathologic findings, and it is unlikely that such an effect would not be observed in female rats.

Conclusion

The Biosafety Advisory Council is of the opinion that the data on soybean MON 87708 provided by the applicant in the renewal dossier, in particular the absence of any reports on adverse effects since 2015, the scientific opinion of EFSA, and the further insights in the outcomes of the 90-day toxicity study, indicate that soybean MON 87708 is unlikely to pose any risk to human and animal health and the European environment in the context of its proposed uses.



Dr. ir. Geert Angenon
President of the Belgian Biosafety Advisory Council

Minority declaration of P. Baret and V. Fontaine

During the assessment of the application EFSA/GMO/NL/2012/108 from Monsanto under Regulation (EC) No. 1829/2003 on 08-12-2015, inconsistencies in the toxicological tests raised concerns and triggered a minority advice of P. Baret and D. Perreaux. Ten years later, no further information was provided by the notifier during the renewal procedure. To remove the concern, a replication of the contested experiment would have been sufficient.
In consequence, the minority advice is still valid: “Considering that the consulted expert still believes that there is a need for further testing in order to exclude any toxicological effect of soybean MON87708, two members of the Council consider that a negative advice should be issued.”