

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-027 (EFSA-GMFF-2022-9170 genetically modified Maize MON 89034 x 1507 x MON 88017 x 59122) from Bayer CropScience and Corteva Agriscience under Regulation (EC) No. 1829/2003

13 June 2024

Ref. SC/1510/BAC/2024_0807

Context

Application EFSA-GMO-RX-027 was submitted by Bayer CropScience and Corteva Agriscience for the renewal of authorisation for the marketing of genetically modified (GM) maize MON 89034 x 1507 x MON 88017 x 59122 and its subcombinations (Unique Identifier MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Maize MON 89034 x 1507 x MON 88017 x 59122 produces the Cry1A.105, Cry2Ab2 and Cry1F proteins for protection against certain lepidopteran insect pests, the Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins for protection against certain coleopteran insect pests, the PAT protein for tolerance to glufosinate-based herbicides and the CP4 EPSPS protein for tolerance to glyphosate-based herbicides. The placing on the market of maize MON 89034 x 1507 x MON 88017 x 59122 for food/feed uses, except cultivation, is currently authorised, following a positive opinion of EFSA (EFSA Journal 2010; 8(9):1781)².

The renewal application was validated by EFSA on 13 April 2023 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 the EFSA Panel on GMOs was published on 29 April 2024 (EFSA Journal 2024;22:e8715)³, 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 positive advice of the BAC on maize MON 89034 x 1507 x MON 88017 x 59122 (ref. BAC_2010_1159), and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-027.

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.2010.1781>

³ <https://www.efsa.europa.eu/en/efsajournal/pub/8715>

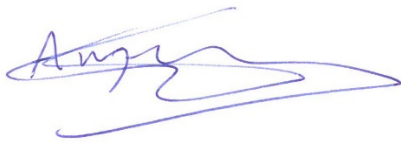
Scientific evaluation

The data for application EFSA-GMO-RX-027 provided by the applicant at the time of submission 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 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. No reports of additional studies performed by the applicant over the course of the authorisation period were included with the application, as the applicant did not identify any that brings new information that might influence the risk assessment of maize MON 89034 x 1507 x MON 88017 x 59122.

The members of the Biosafety Advisory Council did not identify any information elements in the renewal application EFSA-GMO-RX-027 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 maize MON 89034 x 1507 x MON 88017 x 59122 provided by the applicant, and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, maize MON 89034 x 1507 x MON 88017 x 59122, is unlikely to have adverse effects on human and animal health and the environment, in the context of its intended uses.



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