

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-018 (cotton GHB614) from BASF under Regulation (EC) No. 1829/2003

15 September 2021
Ref. SC/1510/BAC/2021_0874

Context

Application EFSA-GMO-RX-018 was submitted by BASF for the renewal of authorisation for the marketing of genetically modified (GM) cotton GHB614 for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Cotton GHB614 expresses the 2mEPSPS protein which provides tolerance to glyphosate herbicides. The placing on the market of cotton GHB614 for food/feed uses, except cultivation, is currently authorised by Commission Decision 2011/354/EU of 17 June 2011, amended by Commission Implementing Decision (EU) 2019/1195 of 10 July 2019, following a positive opinion of EFSA (EFSA Journal 2009; 985, 1-24)² on 5 March 2009, and a positive advice of the Belgian Biosafety Advisory Council (BAC) on 21 April 2009.

The renewal application was validated by EFSA on 11 August 2020 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 Belgian Biosafety Advisory Council (BAC), under the supervision of a coordinator and with the assistance of its Secretariat, decided that an evaluation by external experts was not necessary for this dossier, since no adverse effects are reported since the commercialisation of cotton GHB614, 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 opinion of the EFSA Scientific Panel on GMOs was published on 7 July 2021 (EFSA Journal 2021; 19(7):6671)³.

The opinion of EFSA and the previous advice of the BAC on cotton GHB614 (BAC_2009_924)⁴ form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-018 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 <https://www.efsa.europa.eu/en/efsajournal/pub/985>

³ <https://www.efsa.europa.eu/en/efsajournal/pub/6671>

⁴ http://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2009_00924.pdf

Scientific evaluation

The data for application EFSA-GMO-RX-018 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 on cotton GHB614 and the newly expressed protein 2mEPSPS, an updated bioinformatics package including an analysis of the potential similarity of the newly expressed protein and newly created open reading frames within the insert or spanning the junctions with genomic DNA to known toxins or allergens, and 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-GMO-RX-018 that would raise a safety concern for human or animal health or the environment.

Conclusion

Based on the whole set of data on cotton GHB614 provided by the applicant, the opinion of EFSA, and the original advice of the BAC on cotton GHB614, the Biosafety Advisory Council is of the opinion that in the context of its proposed uses, cotton GHB614 is unlikely to pose any risk to human and animal health.

The Biosafety Advisory Council did not identify any risk that the import and processing of this GM cotton could pose to the European environment.



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