

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-019 (genetically modified cotton 281- 24-236 x 3006-210-23) from Corteva under Regulation (EC) No. 1829/2003

30 January 2023
Ref. SC/1510/BAC/2023_0103

Context

Application EFSA-GMO-RX-019 was submitted by Corteva for the renewal of authorisation for the marketing of genetically modified (GM) cotton 281-24-236 x 3006-210-23 (Unique Identifier DAS-24236-5 x DAS-21023-5) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Cotton 281-24-236 x 3006-210-2 expresses the *cry1F* and *cry1Ac* genes providing protection to certain insect pests. The placing on the market of insect-resistant cotton 281-24-236 x 3006-210-2 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (EFSA Journal 2010;8(6):1644)².

The renewal application was validated by EFSA on 21 May 2021 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 (GMOs) 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 opinion of the EFSA Scientific Panel on GMOs was published on 10 November 2022 (EFSA Journal 2022;20(11):7587)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 cotton 281-24-236 x 3006-210-23, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-019.

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 doi: 10.2903/j.efsa.2010.1644

³ doi: 10.2903/j.efsa.2022.7587

Scientific evaluation

The data for application EFSA-GMO-RX-019 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;
- 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 produced proteins Cry1F, Cry1Ac and PAT (as selectable marker) regarding their capacity to trigger celiac disease;
- reports of additional studies performed by the applicant over the course of the authorisation period.

The Biosafety Advisory Council did not identify any information in the renewal application EFSA-GMO-RX-019 that would raise a safety concern for human or animal health or the environment.

Conclusion

The BAC is of the opinion that the data on cotton 281-24-236 x 3006-210-23 provided by the applicant and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, cotton 281-24-236 x 3006-210-23 is unlikely to pose any risk to human and animal health and the European environment.



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