Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-026/1 (genetically modified oilseed rape GT73) from Bayer under Regulation (EC) No. 1829/2003

2 December 2022
Ref. SC/1510/BAC/2022_1402

Context

Application EFSA-GMO-RX-026/1 was submitted by Bayer for the renewal of authorisation for the marketing of genetically modified (GM) oilseed rape GT73 (Unique Identifier MON-ØØØ73-7) for the placing on the market of foods and food ingredients containing, consisting of, or produced from oilseed rape GT73 with the exception of isolated seed protein, and feed produced from this GM oilseed rape, excluding cultivation within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

Oilseed rape GT73 expresses the CP4 EPSPS and the GOXv247 proteins which confer tolerance to glyphosate herbicides. The placing on the market of oilseed rape GT73 for food/feed uses, except cultivation, is currently authorised by Commission Decision 2015/701/EU of 24 April 2015, amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019, following a positive opinion of EFSA (EFSA Journal 2013;11(2):3079)[2] on 12 February 2013, and a positive advice of the Belgian Biosafety Advisory Council (BAC) on 16 April 2013.

The renewal application was validated by EFSA on 16 July 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 being part of the products).

Within the framework of this consultation, the Belgian Biosafety Advisory Council (BAC) decided that an expertise by external experts was not necessary for this dossier, since the previous application for this event had received a positive advice from the Biosafety Advisory Council, and the current application for renewal does not point to new hazards or modified use of the GMO.

The opinion of the EFSA Scientific Panel on GMOs was published on 6 October 2022 (EFSA Journal 2022;20(10):7563)[3], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The opinion of EFSA, as well as the previous advice of the BAC on oilseed rape GT73 (BAC_2013_0251)[4] form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-026/1 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://doi.org/10.2903/j.efsa.2013.3079
[3] https://www.efsa.europa.eu/en/efsajournal/pub/7563
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2013_0251.pdf

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Scientific evaluation

The data for application EFSA-GMO-RX-026/1 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports covering a reporting period from July 2010 till July 2021, a systematic literature search covering the complete duration of the event's authorisation, an updated bioinformatic package including an analysis of the potential similarity of the newly expressed proteins and newly created open reading frames within the insert or spanning the junctions with genomic DNA to known toxins or allergens, an analysis of possible horizontal gene transfer and a safety assessment of the newly expressed proteins regarding their capacity to trigger celiac disease, 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-026/1 that would raise a safety concern for human or animal health or the environment.

Conclusion

Based on the whole set of data on oilseed rape GT73 provided by the applicant, the opinion of EFSA, and the original advice of the BAC on oilseed rape GT73, the Biosafety Advisory Council is of the opinion that in the context of its proposed uses, oilseed rape GT73 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 oilseed rape could pose to the European environment.

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