

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-024 (genetically modified oilseed rape MS8, Rf3 and MS8 x Rf3) from BASF under Regulation (EC) No. 1829/2003

27 June 2023

Ref. SC/1510/BAC/2023_0605

Context

Application EFSA-GMO-RX-024 was submitted by BASF for the renewal of authorisation for the marketing of genetically modified (GM) oilseed rape MS8, Rf3 and MS8 x Rf3 (Unique Identifier ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACSBNØØ3-6) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003¹.

Oilseed rape MS8 expresses the PAT protein for tolerance to glufosinate-ammonium herbicides and the Barnase protein for male sterility. Rf3 also expresses the PAT protein, in addition to the Barstar protein for restoration of fertility. MS8 x Rf3 is produced by conventional crossing, is fertile and tolerant to glufosinate herbicides. The placing on the market of oilseed rape MS8, Rf3 and MS8 x Rf3 for products containing, consisting of, or produced from this GM oilseed rape, excluding cultivation in the EU, is currently authorised, following two positive opinions of EFSA (EFSA Journal 2012;10(9):2875 and 2017;15(11):5067)².

The renewal application was validated by EFSA on 22 November 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 coordinator for this dossier, on behalf of the Belgian Biosafety Advisory Council (BAC), decided not to request external experts to assess this dossier, since no adverse effects are reported since the commercialisation of oilseed rape MS8, Rf3 and MS8 x Rf3, the information in the current application for renewal does not point to new hazards or modified use of the GMO, 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 26 April 2023 (EFSA Journal 2023;21(4):7934)³. The contents of the renewal application, the previous positive advice of the BAC on oilseed rape MS8, Rf3 and MS8 x Rf3, and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-024.

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/2875> and <https://www.efsa.europa.eu/en/efsajournal/pub/5067>

³ <https://www.efsa.europa.eu/en/efsajournal/pub/7934>

Scientific evaluation

The data for application EFSA-GMO-RX-024 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports covering the years of import, systematic literature searches on oilseed rape MS8, Rf3 and MS8 x Rf3 and the newly expressed proteins Barnase, Barstar and PAT, 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, allergens or immunogenic gluten-related epitopes, 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-024 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 oilseed rape MS8, Rf3 and MS8 x Rf3 provided by the applicant, and the opinion of EFSA, confirm that in the context of its proposed uses, oilseed rape MS8, Rf3 and MS8 x Rf3, is unlikely to pose any risk to human and animal health and the European environment.



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