

Adviesraad voor Bioveiligheid Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-NL-2019-158 (canola *B. juncea* RF3) from BASF under Regulation (EC) No. 1829/2003

1 October 2026
Ref. SC/1510/BAC/2026_0831

Context

Application EFSA-GMO-NL-2019-158 was submitted by BASF for the authorisation for the marketing of genetically modified (GM) canola *Brassica juncea* RF3 (Unique Identifier ACS-BNØØ3-6) for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003¹.

B. juncea RF3 contains a single insert consisting of one copy of each of the PAT/*bar* and Barstar expression cassettes, to confer tolerance to glufosinate-based herbicides, as well as to express Barstar to restore fertility in Barnase-expressing plants by neutralising the Barnase protein. *B. juncea* RF3 was obtained by crossing conventional *B. juncea* with GM RF3 *B. napus*. Event RF3 has been authorised in *B. napus* since 2013² and has been evaluated in several applications for stacked events.

The application EFSA-GMO-NL-2019-158 was validated by EFSA on 14 September 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 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 EFSA's GMO Panel was published on 4 August 2026 (EFSA Journal 2026;24:e10178³). In delivering the present advice, the BAC considered in particular the opinion of EFSA and its previous advices^{4,5} on the application for oilseed rape (*B. napus*) MS8, RF3 and MS8 x RF3, which concluded that the GMO is unlikely to pose any risk to human and animal health, or the environment.

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 Commission Implementing Decision 2013/327/EU of 25 June 2013

³ See <https://doi.org/10.2903/j.efsa.2026.10178>

⁴ Advice on application EFSA-GMO-RX-004: https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2018_0056.pdf

⁵ Advice on application EFSA-GMO-RX-024: https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2023_0605.pdf

Scientific evaluation

1. Molecular characterisation

With regard to the molecular characterisation, the Biosafety Advisory Council is of the opinion that the information provided is sufficient and does not raise safety concerns.

2. Assessment of food/feed safety and nutritional value

2.1. Assessment of compositional analysis

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the compositional data of GM *B. juncea* RF3, in comparison with its conventional counterpart, do not raise safety concerns.

2.2. Assessment of toxicity

The Biosafety Advisory Council evaluated the safety of the newly produced PAT and Barstar proteins in the context of previous applications and no food and feed safety concerns with respect to toxicity were identified. Since no new information on the toxicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.

The Biosafety Advisory Council agrees with the GMO panel of EFSA that the available data on the toxicity of GM *B. juncea* RF3, in comparison with its conventional counterpart, does not raise food and feed safety concerns regarding toxicity.

2.3. Assessment of allergenicity

The Biosafety Advisory Council has evaluated the safety of the newly produced PAT and Barstar proteins in the context of previous applications, and no concerns regarding allergenicity were identified. Since no new information on the allergenicity of these proteins has become available, the Council is of the opinion that its previous conclusions remain valid.

2.4. Nutritional value

The Biosafety Advisory Council is of the opinion that the information provided is sufficient to conclude that the nutritional characteristics of *B. juncea* RF3-derived food and feed are not expected to differ from those of conventional *B. juncea* varieties.

3. Environmental risk assessment

The Biosafety Advisory Council agrees with EFSA's assessment of the environmental risk, and is of the opinion that accidental spillage of *B. juncea* RF3 seeds will not raise a safety concern.

4. Monitoring

With regard to monitoring, the Biosafety Advisory Council is of the opinion that the information provided is sufficient.

Conclusion

The Biosafety Advisory Council is of the opinion that the data on *B. juncea* RF3 provided by the applicant and the opinion of EFSA confirm that in the context of its proposed uses, *B. juncea* RF3 is unlikely to pose any risk to human and animal health and the European environment.



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President of the Belgian Biosafety Advisory Council

Annex: minority declaration

Annex: Minority declaration by P. Baret

This dossier concerns *Brassica juncea*, which can hybridise with species naturally present in Belgium. Given the nature of one of the modifications (herbicide resistance), the risk of survival of hybrids is increased. This risk of gene flow from importation of seeds was identified as early as 2014 but is not taken into account in this dossier. This major environmental risk should lead to a negative opinion.