Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Additional advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-BE-2016-138 (oilseed rape MS11) from Bayer CropScience under Regulation (EC) No. 1829/2003

18 June 2026
Ref. SC/1510/BAC/2026_0545

Context

Application EFSA-GMO-BE-2016-138 was submitted by Bayer CropScience for the authorisation for the marketing of genetically modified (GM) oilseed rape MS11 for food and feed uses, import and processing (excluding cultivation) within the European Union, within the framework of Regulation (EC) No. 1829/2003[1].

Oilseed rape MS11 contains a single insert consisting of one copy of the *pat/bar*, *barnase* and *barstar* expression cassettes, conferring male sterility and tolerance to the herbicide glufosinate-ammonium. It is intended to be used only to produce hybrid seed for breeding and thus is not meant to be commercialised as a stand-alone product for food and feed uses, import and processing.

On 1 July 2020, the Belgian Biosafety Advisory Council (BAC) adopted a positive advice[2] on application EFSA-GMO-BE-2016-138. In this advice, the BAC agreed with the conclusions of the EFSA GMO Panel that the accidental release of oilseed rape MS11 into the environment is unlikely to pose a risk to the environment. The BAC also noted that since oilseed rape MS11 is designed to be used only for the production of hybrid seed for breeding and thus is not expected to be commercialised as a stand-alone product for food/feed uses, oilseed rape MS11 is unlikely to pose a risk to human and animal health.

However, in its 2020 scientific opinion[3], the EFSA GMO Panel stated it could not complete the comparative compositional analysis and the food and feed safety assessment because of limitations in the available compositional data set. These limitations were intrinsically linked to the biological characteristics of oilseed rape MS11, in particular the combination of male sterility and herbicide tolerance traits.

Following the 2020 EFSA opinion, additional information and complementary field trials were requested by the European Commission and the EFSA GMO Panel in order to address the limitations identified in the comparative analysis. Upon this request, the applicant performed additional field trials and provided additional data. On 13 April 2026, the EFSA GMO Panel published a statement entitled “Assessment of additional information related to genetically modified oilseed rape MS11 (application EFSA-GMO-BE-2016-138)” (EFSA Journal 2026;24:e10016)[4]. In this additional assessment, the EFSA GMO Panel evaluated the new comparative field trial studies that were specifically designed to address the limitations identified in the original assessment and the compositional data resulting from these studies.

In delivering the present additional advice, the BAC considered in particular its original advice of 1 July 2020 on application EFSA-GMO-BE-2016-138 and the additional EFSA GMO Panel statement published on 13 April 2026.

[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.bio-council.be/sites/biocouncil.be/files/advices/BAC_2020_0616.pdf
[3] https://doi.org/10.2903/j.efsa.2020.6112
[4] https://doi.org/10.2903/j.efsa.2026.10016

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Scientific evaluation

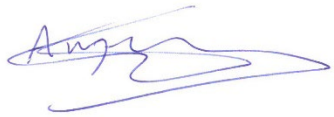
The Biosafety Advisory Council notes that the additional information assessed by EFSA consisted of new comparative field trial studies specifically designed to address the limitations previously identified in the compositional assessment of oilseed rape MS11.

The Biosafety Advisory Council is of the opinion that the additional studies complement the original compositional data set and support its original evaluation of oilseed rape MS11.

The Biosafety Advisory Council notes that the EFSA GMO Panel additionally assessed a 90-day oral toxicity study in rats fed diets containing meal derived from oilseed rape MS11 and concluded that no treatment-related adverse effects were observed.

Conclusion

Following the evaluation of the additional information submitted subsequent to the adoption of the BAC advice of 1 July 2020 concerning application EFSA-GMO-BE-2016-138 (ref. SC/1510/BAC/2020_0616)[2], the Biosafety Advisory Council gives a positive advice for this application.



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