Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

# Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-020 from BASF under Regulation (EC) No. 1829/2003

13 September 2022
*Ref. SC/1510/BAC/2022_1045*

## Context

Application EFSA-GMO-RX-020 was submitted by BASF Agricultural Solutions Seed US LLC for the renewal of authorisation for the marketing of genetically modified (GM) soybean A5547-127 (Unique Identifier ACS-GMØØ6-4) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

The placing on the market of the herbicide-tolerant soybean A5547-127 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (EFSA Journal 2011;9(5):2147)[2].

The renewal application was validated by EFSA on 7 May 2022 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 to consult external experts to take a closer look at the updated bioinformatic data provided in the application for renewal with the aim to assess whether these data could modify the previous conclusions.

The opinion of the EFSA Scientific Panel on GMOs was published on 20 June 2022 (EFSA Journal 2022;20(6):7340)[3], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The previous advice of the BAC on soybean A5547-127 (BAC_2011_0553)[4], and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-020.

[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.2011.2147
[3] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7340
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2011_0553.pdf

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## Scientific evaluation

The data for application EFSA-GMO-RX-020 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 an updated analysis of the potential similarity of the newly expressed protein and newly created open reading frames within the insert or spanning the junctions with genomic DNA to known toxins or allergens and a safety assessment of the newly expressed proteins PAT regarding their capacity to trigger celiac disease, and reports of additional studies performed by the applicant over the course of the authorisation period.

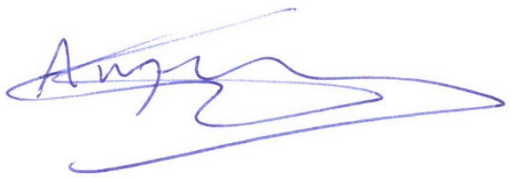
A closer look was taken at the updated bioinformatic data provided in the application for renewal, as these revealed new information on the insertion locus. The data confirm the previous results indicating that no endogenous gene has been interrupted by the event.

The BAC is of the opinion that no new information is available in the renewal application EFSA-GMO-RX-020 that would raise a safety concern for human or animal health.

Further, the BAC did not identify any information indicating to a potential risk that the import and processing of this GM soybean could pose to the European environment.

## Conclusion

The BAC is of the opinion that the data on soybean A5547-127 provided by the applicant, and the opinion of EFSA, confirm its latest opinion on soybean A5547-127 that in the context of its proposed uses, soybean A5547-127 is unlikely to pose any risk to human and animal health and the European environment.



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