Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-023 (genetically modified soybean 40-3-2) from Bayer under Regulation (EC) No. 1829/2003

30 January 2023
Ref. SC/1510/BAC/2023_0104

Context

Application EFSA-GMO-RX-023 was submitted by Bayer Agriculture BV for the renewal of authorisation for the marketing of genetically modified (GM) soybean 40-3-2 (Unique Identifier MON-Ø4Ø32-6) for food and feed uses, import and processing (excluding cultivation) within the European Union within the framework of Regulation (EC) No. 1829/2003[1].

Soybean 40-3-2 expresses the *cp4 epsps* gene providing tolerance to glyphosate-based herbicides. The placing on the market of the herbicide-tolerant soybean 40-3-2 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (EFSA Journal 2010;8(12):1908)[2].

The renewal application was validated by EFSA on 17 May 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 (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 not to request external experts to assess this dossier.

The opinion of the EFSA Scientific Panel on GMOs was published on 19 December 2022 (EFSA Journal 2022;20(12):7685)[3], together with the responses from the EFSA GMO Panel to comments submitted by the Member States during the three-month consultation period.

The contents of the renewal application, the previous positive advice of the BAC on soybean 40-3-2 (BAC_2011_0745)[4], and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-023.

[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] doi: 10.2903/j.efsa.2010.1908
[3] doi: 10.2903/j.efsa.2022.7685
[4] https://www.bio-council.be/sites/biocouncil.be/files/advices/BAC_2011_0745.pdf

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Scientific evaluation

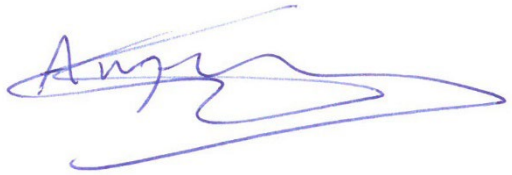
The data for application EFSA-GMO-RX-023 provided by the applicant at the time of submission included:

- the annual post-market environmental monitoring (PMEM) reports covering the last 10 years of import;
- a systematic literature search covering the complete duration of the event's latest authorisation;
- an updated bioinformatic package including (1) an analysis of the potential similarity of the newly produced protein and newly created open reading frames within the insert or spanning the junctions with genomic DNA to known toxins or allergens, and (2) a safety assessment of the newly produced CP4 EPSPS protein regarding their capacity to trigger celiac disease;
- reports of additional studies performed by the applicant over the course of the authorisation period.

The Biosafety Advisory Council did not identify any information in the renewal application EFSA-GMO-RX-023 that would raise a safety concern for human or animal health or the environment.

Conclusion

The BAC is of the opinion that the data on soybean 40-3-2 provided by the applicant and the opinion of EFSA confirm its latest opinion that in the context of its proposed uses, soybean 40-3-2 is unlikely to pose any risk to human and animal health and the European environment.



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