Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-017 from Bayer Agriculture BVBA under Regulation (EC) No. 1829/2003

16 March 2021
Ref. SC/1510/BAC/2021_0253

Context

Application EFSA-GMO-RX-017 was submitted by Bayer Agriculture BVBA for the renewal of authorisation for the marketing of genetically modified (GM) maize MON 88017 x MON 810 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 insect-resistant and herbicide-tolerant maize MON 88017 x MON 810 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (EFSA Journal 2009;7(7))[2].

The renewal application was validated by EFSA on 24 October 2019 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 29 January 2021 (EFSA Journal 2021;19(1):6375)[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 maize MON 88017 x MON 810 (BAC_2009_01491)[4], and the published opinion of the EFSA GMO Panel form the basis of the advice of the BAC on application EFSA-GMO-RX-017.

[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.2009.1192
[3] https://doi.org/10.2903/j.efsa.2021.6375
[4] http://www.bio-council.be/Advices/BAC_2009_01491.pdf

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Scientific evaluation

The data for application EFSA-GMO-RX-017 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 (1) an analysis of the potential similarity of the newly expressed proteins and newly created open reading frames within the insert or spanning the junctions with genomic DNA to known toxins or allergens, (2) a safety assessment of the newly expressed proteins Cry3Bb1, Cry1Ab and CP4 EPSPS regarding their capacity to trigger celiac disease, and (3) updated information on the location of the insert within the maize genome, revealing that in the reference genome the maize sequences that are part of the flanking regions of the insert are ~12.5 Mbp apart; and
- reports of additional studies performed by the applicant over the course of the authorisation period.

In order to assess the uncertainties on the safety of the event resulting from the potential deletion of a ~12.5 Mbp region of the maize genome at the site of insertion, EFSA requested additional information, in particular molecular data, and a further assessment by the applicant. These data, including proteomic and transcriptomic data, showed no significant differences in the expression of almost all of the genes located in the ~12.5 Mbp region compared to non-GM maize comparators, suggesting that they are present and normally expressed in MON 810.

Taking the above information into account, as well as the fact that the previous assessments did not reveal any safety issue on the basis of phenotypic, agronomic, composition and toxicology data, and the experience with the crop over several decades, the BAC considers there is no (novel) safety concern for human or animal health.

Further, the BAC did not identify any risk that the import and processing of this GM maize could pose to the European environment.

Conclusion

The BAC is of the opinion that the data on maize MON 88017 x MON 810 provided by the applicant, and the opinion of EFSA, confirm its latest opinion on maize MON 88017 x MON 810 that in the context of its proposed uses, maize MON 88017 x MON 810 is unlikely to pose any risk to human and animal health and the European environment.

The BAC wants to note that, while the omics data presented by the applicant can provide insight in unintended molecular changes, the previous assessments done on the basis of phenotypic, agronomic, composition and toxicology data, are sufficiently robust to provide a strong weight of evidence on safety.

In addition, the BAC recommends following up any unanticipated allergenicity aspects of the GM maize in the existing allergenicity monitoring systems.

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