Adviesraad voor Bioveiligheid
Conseil consultatif de Biosécurité

Advice of the Belgian Biosafety Advisory Council on application EFSA-GMO-RX-011 (soybean MON 89788) from Monsanto under Regulation (EC) No. 1829/2003

11 December 2018
Ref. SC/1510/BAC/2018_1090

Context

Application EFSA-GMO-RX-011 was submitted by Monsanto for the renewal of authorisation for the marketing of genetically modified (GM) soybean MON 89788 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 glyphosate herbicide-tolerant soybean MON 89788 for food/feed uses, except cultivation, is currently authorised following a positive opinion of EFSA (The EFSA Journal (2008) 758, 1-23)[2].

The renewal application was validated by EFSA on 13 April 2018 and a formal three-month consultation period of the Member States was started, lasting until 13 July 2018, 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, since the previous application for this event had received a positive advice from the Biosafety Advisory Council, and no new relevant information was provided in the current application for renewal, which could modify the previous conclusions.

The opinion of the EFSA Scientific Panel on GMOs was published on 16 November 2018 (EFSA Journal 2018;16(11):5468)[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 MON 89788 (BAC_2008_813)[4] and the published opinion of the EFSA GMO Panel form the basis of the advice of the Biosafety Advisory Council on application EFSA-GMO-RX-011 given below.

Scientific evaluation

The data for application EFSA-GMO-RX-011 provided by the applicant at the time of submission included the annual post-market environmental monitoring (PMEM) reports from December 2008 to July 2017, two systematic literature searches covering the complete duration of the event's authorisation, an updated bioinformatic package including an analysis of the potential interruption of

[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] http://www.efsa.europa.eu/en/efsajournal/pub/758
[3] http://www.efsa.europa.eu/en/efsajournal/pub/5468
[4] http://www.bio-council.be/Advices/BAC_2008_813.pdf

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plant genes by the insert, potential similarity of the newly expressed protein with known toxic or allergenic proteins, potential of newly created open reading frames within the insert or spanning the junctions with genomic DNA encoding peptides with sequence similar to known toxins or allergens, potential for horizontal gene transfer to micro-organisms, and reports of additional studies performed by the applicant over the course of the authorisation period.

The Biosafety Advisory Council did not identify any information element in the renewal application EFSA-GMO-RX-011 that would raise a safety concern for human or animal health.

The Biosafety Advisory Council did not identify any risk that the import and processing of this GM soybean could pose to the European environment.

Conclusion

The Biosafety Advisory Council is of the opinion that the data on soybean MON 89788 provided by the applicant, and the opinion of EFSA, confirm its original opinion on soybean MON 89788 that in the context of its proposed uses, soybean MON 89788 is unlikely to pose any risk to human and animal health and the environment.

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