TECHNICAL REPORT

APPROVED: 14 November 2018 PUBLISHED: 16 November 2018

Overall opinion of the European Food Safety Authority on genetically modified soybean MON 89788 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-011 for the continued placing on the market of genetically modified (GM) soybean MON 89788 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-RX-011 is for food and feed uses, import and processing of soybean MON 89788 in the European Union (EU). Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on soybean MON 89788, EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003.

Overall, the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) already validated the detection method of soybean MON 89788, and declared fit for regulatory purpose. The certified reference materials of soybean MON 89788 can be accessed at the American Oil Chemists' Society (AOCS-USA). The GMO Panel is of the opinion that the post-market environmental monitoring (PMEM) plan proposed by the applicant and reporting intervals are in line with the intended uses of soybean MON 89788. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

The particulars regarding e.g. labelling, detection, Cartagena protocol are not considered by EFSA since they fall outside its remit.

Key words: Soybean, MON 89788, EFSA-GMO-RX-011, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2018-00812

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[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. 1–23.

Acknowledgements: EFSA wishes to thank the members of the scientific Panel on genetically modified organisms and of its Working Groups on Molecular Characterisation, Food/Feed and CompERA for the preparatory work on the scientific opinion and EFSA staff for the support provided to the scientific opinion.

Suggested citation: EFSA (European Food Safety Authority), 2018. Overall opinion of the European Food Safety Authority on genetically modified soybean MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011). EFSA supporting publication 2018:EN-1518. 8 pp.

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1. Introduction

On 7 December 2017, EFSA received from the European Commission an application (reference EFSA-GMO-RX-011), submitted by Monsanto Europe N.V. under Articles 11 and 23 of Regulation (EC) No 1829/2003[2], to support the continued placing of genetically modified (GM) soybean MON 89788 on the market in the EU. The unique identifier of soybean MON 89788 is MON-89788-1.

The scope of application EFSA-GMO-RX-011 is for placing on the market of products of products containing, consisting of, or produced from soybean MON 89788 in the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 11(2) and 23(2) of the above mentioned Regulation. On 19 October 2006, EURL–GMFF received samples and control samples in accordance with the same Articles.

According to Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission of the application and made the summary of the application publicly available[3].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-RX-011 valid on 9 April 2018.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-RX-011. Such time limit was extended whenever EFSA requested supplementary information to the applicant.

According to Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consults the risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC[4], of all EU Member States on each request for placing on the market of products consisting of or containing GMOs.

The Member States were therefore given three months to comment the valid application EFSA-GMO-RX-011 from the date of its receipt.

1.1. Terms of Reference

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA is requested to issue an overall opinion on application EFSA-GMO-RX-011 including : i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the scientific opinion of the GMO Panel, iv) the information required under Annex II to the Cartagena Protocol, v) the labelling proposal, vi) the method for detection, validated by the EURL-GMFF, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vii) an indication of where appropriate reference materials can be accessed, viii) the post-market environmental monitoring (PMEM) plan and ix) the Member States' comments submitted during the three-month consultation period.

[2] 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. 1–23.
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00826
[4] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 12.3.2001, p. 1–38.

2. Considerations

2.1. Name and address of the Applicant(s)

Application EFSA-GMO-RX-011 was submitted by

Monsanto Company *represented by*
800 N. Lindbergh Boulevard
St Louis, Missouri, 63167
United States

Monsanto Europe NV
Haven 627, Scheldelaan 460
2040 Antwerp
Belgium

2.2. Designation and specification of the product

Soybean MON 89788 (unique identifier: MON-89788-1) was developed to provide tolerance to glyphosate based herbicides.
The scope of application EFSA-GMO-RX-011 is for placing on the market of products containing, consisting of, or produced from soybean MON 89788 in the EU.

2.3. Scientific opinion of the GMO Panel

On 17 October 2018, the GMO Panel adopted a scientific opinion on soybean MON 89788 (Annex A). During its safety evaluation, the GMO Panel considered the valid application as submitted by the applicant, any additional data provided by the applicant, the scientific comments submitted by the Member States and the relevant scientific literature.

The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatics analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequence of the event in soybean MON 89788 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-011 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788.

2.4. Cartagena Protocol

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol (Annex B).

2.5. Labelling

The GMO Panel did not consider the proposal for labelling which is matter related to risk management (Annex C).

2.6. Methods for detection

The EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify MON 89788 transformation event in crop DNA. The reports were issued on 18 February 2018. The EURL-GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004[5] (Annexes D1, D2, D3).

[5]Regulation (EC) No 641/2004 of the Commission on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. OJ L 102/14, 7.4.2004, p. 1–12.

2.7. Certified reference materials

The certified reference materials of soybean MON 89788 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

2.8. Post-market environmental monitoring (PMEM)

The applicant indicated in the dossier that the PMEM plan is appropriate and does not need any changes (Annex F).

2.9. Member States Comments

The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period (Annex G).

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-RX-011 for food and feed uses, import and processing of soybean MON 89788 in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling proposal
Annex D1:	Validation report by EURL-GMFF of the event-specific detection method for the quantification of soybean MON 89788
Annex D2:	Validated detection method for soybean MON 89788
Annex D3:	Sampling / DNA extraction
Annex E:	Certified reference materials (soybean MON 89788)
Annex F:	Post-market environmental monitoring plan
Annex G:	Member States' comments and GMO Panel responses

[6]The annexes of the EFSA Overall opinion can be found in the Register of Questions (tab "Question documents") on the EFSA website under the following link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00812