TECHNICAL REPORT

APPROVED: 28 July 2017 PUBLISHED: 1 August 2017

Overall opinion of the European Food Safety Authority on application (EFSA-GMO-BE-2013-117) by Monsanto Europe S.A./N.V. for placing on the market of genetically modified maize MON 87427 x MON 89034 x NK603 for food and feed uses, import and processing in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-BE-2013-117 for the placing on the market of genetically modified (GM) maize MON 87427 x MON 89034 x NK603 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-BE-2013-117 is for food and feed uses, import and processing of maize MON 87427 x MON 89034 x NK603 and subcombinations, independently of their origin, in the EU. Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on maize MON 87427 x MON 89034 x NK603, 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) validates, and declares fit for purpose, the detection methods for each single event applied for the detection and quantification of the respective events in maize MON 87427 x MON 89034 x NK603.

The certified reference materials of maize MON 87427 x MON 89034 x NK603 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) and at the American Oil Chemists' Society (AOCS-USA). Since the post-market environmental monitoring (PMEM) plan for maize MON 87427 x MON 89034 x NK603 does not include any provisions for the two subcombinations not previously assessed, the GMO Panel recommended the applicant to revise the PMEM plan accordingly. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

EFSA did not consider proposals for e.g. labelling, detection and information under Cartagena protocol since they fall outside its remit.

Key words: maize, MON 87427 x MON 89034 x NK603, EFSA-GMO-BE-2013-117, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: Competent Authority of Belgium

Question number: EFSA-Q-2017-00538

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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 and Feed Risk Assessment and Environment Risk Assessment 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), 2017. Overall opinion of the European Food Safety Authority on application (EFSA-GMO-BE-2013-117) by Monsanto Europe S.A./N.V. for placing on the market of genetically modified maize MON 87427 x MON 89034 x NK603 for food and feed uses, import and processing in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. EFSA supporting publication 2017 EN-1278. 8 pp.

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1. Introduction

On 13 September 2013, EFSA received from the Competent Authority of Belgium an application (reference EFSA-GMO-BE-2013-117), submitted by Monsanto Europe S.A./N.V. under Articles 5 and 17 of Regulation (EC) No 1829/2003[2], to support the placing of genetically modified (GM) maize MON 87427 x MON 89034 x NK603 on the market in the European Union (EU). The unique identifier of maize MON 87427 x MON 89034 x NK603 is MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6. The scope of application EFSA-GMO-BE-2013-117 is for food and feed uses, import and processing of maize MON 87427 x MON 89034 x NK603 and subcombinations, independently of their origin, in the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 5(3) and 17(3) of the above mentioned Regulation. On 22 July 2014, 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-BE-2013-117 valid on 22 January 2014.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-BE-2013-117. 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-BE-2013-117 from 11 June 2015[5] till 11 September 2015.

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-BE-2013-117 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 European Union Reference Laboratory, 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-2013-00765
[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.
[5] The 3-month commenting period on application EFSA-GMO-BE-2013-117 started following the adoption by the EFSA GMO Panel of application EFSA-GMO-BE-2012-110 (on maize MON 87427).

2. Considerations

2.1. Name and address of the Applicant(s)

Application EFSA-GMO-BE-2013-117 was submitted by

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

Monsanto Europe S.A.
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Belgium

2.2. Designation and specification of the product

The three-event stack maize was produced by conventional crossing to combine three single maize events: MON 87427, expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein for tolerance to glyphosate-containing herbicides; MON 89034, expressing the Cry1A.105 and Cry2Ab2 proteins which confer resistance to specific lepidopteran pests; and NK603, expressing the CP4 EPSPS protein and its variant CP4 EPSPS L214P for tolerance to glyphosate-containing herbicides.

The scope of application EFSA-GMO-BE-2013-117 is for food and feed uses, import and processing of maize MON 87427 x MON 89034 x NK603 and subcombinations, independently of their origin, in the EU.

2.3. Scientific opinion of the GMO Panel

On 28 June 2017, the GMO Panel adopted a scientific opinion on maize MON 87427 x MON 89034 x NK603 (application EFSA-GMO-BE-2013-117) (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 GMO Panel has previously assessed the three single events combined to produce this three-event stack maize and did not identify safety concerns. No new data on the single events, leading to modification of the original conclusions on their safety, were identified. Based on the molecular, agronomic, phenotypic and compositional characteristics, the combination of the single maize events and of the newly expressed proteins in the three-event stack maize did not give rise to issues regarding food and feed safety or nutrition. In the case of accidental release of viable grains of maize MON 87427 × MON 89034 × NK603 into the environment, the three-event stack maize would not raise environmental safety concerns. The GMO Panel concludes that the three-event stack maize is as safe and as nutritious as the non-GM comparator and the tested non-GM reference varieties in the context of its scope. The GMO Panel considered that its previous conclusions on the two-event stack maize MON 89034 × NK603 remain valid. For the two maize subcombinations for which no experimental data were provided, the GMO Panel assessed the likelihood of interactions among the single events and concluded that their combination would not raise safety concerns. These two subcombinations are therefore expected to be as safe as the single events, the previously assessed maize MON 89034 × NK603 and maize MON 87427 × MON 89034 × NK603. Since the post-market environmental monitoring plan for the three-event stack maize does not include any provisions for the two subcombinations not previously assessed, the GMO Panel recommended the applicant to revise the plan accordingly.

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 proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management (Annex C).

2.6. Methods for detection

The European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) has previously validated individually, and declared fit for purpose, the detection methods for the single events MON 87427, MON 89034 and NK603 (Annexes D2a-c).

In the context of application EFSA-GMO-BE-2013-117 on three-event stack maize MON 87427 x MON 89034 x NK603, the EURL-GMFF has checked *in-house* the performance of each validated detection method when applied to genomic DNA extracted from maize MON 87427 x MON 89034 x NK603. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from maize MON 87427 x MON 89034 x NK603 is provided in Annexes D1 and D3.

2.7. Certified reference materials

The certified reference materials of MON 87427, MON 89034 and NK603 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) and at the American Oil Chemists' Society (AOCS-USA) (Annexes Ea, Eb, Ec).

2.8. Post-market environmental monitoring (PMEM)

Since the PMEM plan for maize MON 87427 x MON 89034 x NK603 does not include any provisions for the two maize subcombinations not previously assessed, the GMO Panel recommended the applicant to revise the plan accordingly (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-BE-2013-117 for food and feed uses, import and processing of maize MON 87427 x MON 89034 x NK603 and subcombinations, independently of their origin, in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the GMO Panel (maize MON 87427 x MON 89034 x NK603)
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report by EURL-GMFF of the detection methods for the single events applied to maize MON 87427 x MON 89034 x NK603
Annex D2a:	Validated detection method for maize MON 87427
Annex D2b:	Validated detection method for maize MON 89034
Annex D2c:	Validated detection method for maize NK603
Annex D3:	Sampling / DNA extraction
Annex Ea:	Certified reference materials (MON 87427)
Annex Eb:	Certified reference materials (MON 89034)
Annex Ec:	Certified reference materials (NK603)
Annex F:	Post-market environmental monitoring
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-2017-00538