TECHNICAL REPORT

APPROVED: 1 September 2017 PUBLISHED: 5 September 2017

Overall opinion of the European Food Safety Authority on application EFSA-GMO-BE-2013-118 by Monsanto Europe S.A./N.V. for placing on the market of genetically modified maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 for food and feed uses, import and processing submitted 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-2013-118 for the placing on the market of genetically modified (GM) maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-BE-2013-118 is for food and feed uses, import and processing of maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 × MON 89034 × 1507 × MON 88017 × 59122, 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 1507 x MON 88017 x 59122.

The certified reference materials of maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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 × MON 89034 × 1507 × MON 88017 × 59122 does not include any provisions for the fourteen maize 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 × MON 89034 × 1507 × MON 88017 × 59122, EFSA-GMO-BE-2013-118, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: Competent Authority of Belgium

[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.

Question number: EFSA-Q-2017-00537

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Table of contents

1. Introduction

On 26 November 2013, EFSA received from the Competent Authority of Belgium an application (reference EFSA-GMO-BE-2013-118), 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 1507 x MON 88017 x 59122 on the market in the European Union (EU). The unique identifier of maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 is MON-87427-7 x MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7. The scope of application EFSA-GMO-BE-2013-118 is for food and feed uses, import and processing of maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 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 21 August 2013, 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-2013-118 valid on 10 March 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-2013-118. 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-2013-118 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-2013-118 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-2013-00926
[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-2013-118 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-2013-118 was submitted by

Monsanto Company 800 N. Lindbergh Boulevard St Louis, Missouri, 63167 United States	*represented by*	Monsanto Europe S.A. Avenue de Tervuren 270-272 B-1150 Brussels Belgium

2.2. Designation and specification of the product

The five-event stack maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 (unique identifier: MON-87427-7 x MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7) was produced by conventional crossing to combine five 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; 1507 expressing the Cry1F protein which confers protection against specific lepidopteran pests and phosphinothricin acetyl transferase (PAT) protein for tolerance to glufosinate-containing herbicides; MON 88017 expressing the Cry3Bb1 protein to confer protection against coleopteran pests belonging to the genus *Diabrotica*, such as the Western corn rootworm (*Diabrotica virgifera virgifera*), and CP4 EPSPS protein for tolerance to glyphosate-containing herbicides; and 59122 expressing the Cry34Ab1 and Cry35Ab1 proteins to confer protection against coleopteran pests belonging to the genus *Diabrotica* and the PAT protein for tolerance to glufosinate-containing herbicides.

The scope of application EFSA-GMO-BE-2013-118 is for food and feed uses, import and processing of maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 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 1507 x MON 88017 x 59122 and its twenty-five subcombinations, independently of their origin (application EFSA-GMO-BE-2013-118) (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 five single events combined to produce this five-event stack maize and eleven subcombinations of these events and did not identify safety concerns. No new data on the single events or their previously assessed subcombinations, leading to modification of the original conclusions were identified. The combination of the single events and of the newly expressed proteins in the five-event stack maize did not give rise to issues – based on the molecular, agronomic/phenotypic or compositional characteristics – regarding food and feed safety and nutrition. Considering the scope of this application, the known biological function of the newly expressed proteins and the data available for the five-event stack maize and its previously assessed maize subcombinations, the GMO Panel considered that different combinations of the single events would not raise environmental concerns. The GMO Panel concludes that the five-event stack maize is as safe and as nutritious as its non-GM comparator and the tested non-GM reference varieties in the context of its scope. For the fourteen 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 combinations would not raise safety concerns. These maize subcombinations are therefore expected to be as safe as the single events, the previously assessed subcombinations and MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. Since the post-market environmental monitoring plan

for the five-event stack maize does not include any provisions for the fourteen maize 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, 1507, MON 88017 and 59122 (Annexes D2a-e).

In the context of application EFSA-GMO-BE-2013-118 on five-event stack maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122, the EURL-GMFF has checked *in-house* the performance of each validated detection method when applied to genomic DNA extracted from maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. The final validation report of the individual detection methods applied to DNA extracted from maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 is provided in Annexes D1 and D3.

2.7. Certified reference materials

The certified reference materials of maize MON 87427, MON 89034 and MON 88017 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annexes E1, E2, E4).

The certified reference materials of maize 1507 and 59122 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annexes E3, E5).

2.8. Post-market environmental monitoring (PMEM)

Since the PMEM plan for maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 does not include any provisions for the fourteen 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-2013-118 for food and feed uses, import and processing of maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and subcombinations, independently of their origin, in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the GMO Panel (maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122)
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 1507 x MON 88017 x 59122
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 1507
Annex D2d:	Validated detection method for maize MON 88017
Annex D2e:	Validated detection method for maize 59122
Annex D3:	Sampling and DNA Extraction
Annex E1:	Certified reference materials (maize MON 87427)
Annex E2:	Certified reference materials (maize MON 89034)
Annex E3:	Certified reference materials (maize 1507)
Annex E4:	Certified reference materials (maize MON 88017)
Annex E5:	Certified reference materials (maize 59122)
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-2017-00537