TECHNICAL REPORT

APPROVED: 17 June 2015 PUBLISHED:19 June 2015

Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-BE-2012-110) for the placing on the market of genetically modified maize MON 87427 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto S.A./N.V.

European Food Safety Authority

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize MON 87427 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of application EFSA-GMO-BE-2012-110 is for import, processing, and food and feed uses of maize MON 87427 within the European Union (EU) in the same way as any non-GM maize, but excludes cultivation in the EU.

The Scientific Panel on Genetically Modified Organisms (EFSA GMO Panel) has carried out the scientific assessment of genetically modified (GM) maize MON 87427 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-BE-2012-110, additional information submitted by the applicant on request of the Panel, the scientific comments submitted by Member States and relevant scientific publications. . In conclusion, the EFSA Panel on Genetically Modified Organisms considers that the information available for maize MON 87427 addresses the scientific comments raised by Member States and that the maize MON 87427, as described in this application, is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses. The European Union Reference Laboratory for GM Food and Feed (EURL-GMFF) considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize MON 87427 can be accessed at the American Oil Chemists' Society (AOCS-USA).

The EFSA GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the EFSA 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; the post-market environmental monitoring plan and reporting intervals are in line with the scope of application EFSA-GMO-BE-2012-110.

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of genetically modified maize MON 87427.

Key words: GMO overall opinion, GMO, maize (Zea mays), MON 87427, tissue-selective, herbicide tolerance, CP4 EPSPS, Regulation (EC) No 1829/2003

Requestor: On request from the Competent Authority of Belgium for an application (EFSA-GMO-BE-2012-110) submitted by Monsanto S.A./N.V

Question number: EFSA-Q-2012-00692

Correspondence: gmo@efsa.europa.eu

Acknowledgements: EFSA wishes to thank the GMO Panel members: Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Hoen-Sorteberg, Huw Jones, József Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Kaare Magne Nielsen, Jaroslava Ovesná, Joe Perry, Nils Rostoks and Christoph Tebbe; the members of the Working Groups on Molecular Characterisation, Food and Feed Risk Assessment and Environment Risk Assessment for the preparatory work on this scientific opinion and EFSA staff members: Hermann Broll, Zoltán Divéki and Andrea Gennaro for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), 2015. Overall opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 on application (reference EFSA-GMO-BE-2012-110) for the placing on the market of tissue-selective herbicide-tolerant genetically modified maize MON 87427 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA supporting publication 2015:EN-827. 10 pp.

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1. Introduction

1.1. Background as provided by the Competent Authority of The Netherlands

On 21 June 2012, the European Food Safety Authority (EFSA) received from the Competent Authority of Belgium an application (reference EFSA-GMO-BE-2012-110) for authorisation of genetically modified maize MON 87427 (Unique Identifier MON-87427-7) submitted by Monsanto Europe S.A./N.V within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The scope of application EFSA-GMO-BE-2012-110 is for import, processing, and food and feed uses of maize MON 87427 within the European Union (EU) in the same way as any non-GM maize, but excludes cultivation in the EU.

In accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the application publicly available on the EFSA website[1] on 20 July 2012. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5 and 17 of Regulation (EC) No 1829/2003. On 30 April 2012 and 26 June 2012, the European Union Reference Laboratory for Genetically modified Food and Feed (EU-RL – GMFF) received samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 3 January 2013 and started the clock in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003.

From that date, EFSA has endeavoured to respect a time limit of six months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (*i.e.*, until 3 April 2013) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 11 April 2013 to 19 November 2014 and from 15 December 2014 to 26 May 2015[2].

The overall opinion on application EFSA-GMO-BE-2012-110 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms together with the particulars required under Articles 6(5)(a-g) and 18(5)(a-g) of Regulation (EC) No 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the information required under Annex II to the Cartagena Protocol, iv) the labelling proposal, v) 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, vi) an indication of where appropriate reference materials can be accessed, vii) the monitoring plan and viii) the Member States' comments submitted during the three-month consultation period.

1.2. Terms of Reference as provided by the Applicant

The European Food Safety Authority (EFSA) received from the Competent Authority of The Netherlands an application for authorisation of genetically modified maize MON 87427 (Unique Identifier MON-87427-7) submitted by Monsanto S.A./N.V.] within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-BE-2012-110). EFSA was

[1] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoade?question=EFSA-Q-2012-00692

[2] Request for supplementary information from the EFSA GMO Panel: Requested(1)on 11/04/2013 – info received on 17/06/2013; requested(2) on 03/06/2013 – info received on 17/06/2013; requested(3) on 13/08/2013 – received on 11/09/2013; requested(4) on 06/06/2014 – info received on 08/07/2014 and clock re-started on 19/11/2014. Requested(5) on 15/12/2014 – info received on 02/03/2015 and on 13/04/2015; requested(6) on 16/03/2015 – info received on 13/04/2015; requested(7) on 07/05/2015 – info received on 08/05/2015 and clock re-started on 26/05/2015.

The applicant provided additional information spontaneously on: 05/12/2103 and on 13/12/2013.

The applicant requested clarifications on: 21/03/2014; EFSA provided clarifications on 08/05/2014.

requested to issue an overall opinion in line with the requirements of the Regulation (EC) No 1829/2003 (Articles 6 and 18).

2. Considerations

2.1. Applicant

The application was submitted by

Monsanto Europe S.A./N.V.
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
USA

2.2. Designation and specification of the product

The scope of application EFSA-GMO-BE-2012-110 is for import, processing, and food and feed uses of maize MON 87427 within the European Union (EU) in the same way as any non-GM maize, but excludes cultivation in the EU.

Maize MON 87427 was developed by *Agrobacterium tumefaciens*-mediated transformation of immature maize embryos. The resulting GM maize expresses 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4, which confers tolerance to the herbicidal active substance glyphosate. However, CP4 EPSPS expression is absent or limited in male reproductive tissues, which eliminates or reduces the need for detasseling when MON 87427 is used as a female parent in hybrid maize seed production.

3. Scientific opinion of the EFSA GMO Panel

The EFSA GMO Panel carried out the scientific assessment of the genetically modified maize MON 87427 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 27 May 2015. In delivering its Scientific Opinion, the EFSA GMO Panel considered application EFSA-GMO-BE-2012-110, additional information submitted by the applicant on request of the Panel, the scientific comments submitted by Member States and relevant scientific publications. In conclusion, the EFSA Panel on Genetically Modified Organisms considers that the information available for maize MON 87427 addresses the scientific comments raised by Member States and that the maize MON 87427, as described in this application, is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses (Annex A).

4. Cartagena Protocol

The information presented in the application and as required under Annex II of the Cartagena Protocol on Biosafety is in line with the scientific opinion of the EFSA GMO Panel (Annex B).

5. Labelling

The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No 1829/2003. On the basis of the scientific opinion of the EFSA GMO Panel, EFSA is of the opinion that there is no need for a specific labelling in accordance with Article 13(2)(a) and 25(2)(c) (Annex C).

6. Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the Genetically Modified Food and Feed has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the maize MON 87427-transformation event in maize DNA. The reports were issued on 13 October 2008 and on 9 June 2015. The European Union Reference Laboratory considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. of the Commission Regulation (EC) No 641/2004 (Annexes D1, D2 and D3).

7. Certified reference materials

The certified reference materials of maize MON 87427 can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

8. Post-market environmental monitoring (PMEM)

The EFSA GMO Panel is of the opinion that the scope of the PMEM plan proposed by the applicant is in line with the intended uses of maize MON 87427, as the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. The EFSA GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan (Annex F).

9. Member States' Comments

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

10. Conclusions

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of genetically modified maize MON 87427.

List of Annexes[3]

Annex A:	Scientific opinion of the EFSA GMO Panel (maize MON 87427)
Annex B:	Cartagena Protocol (maize MON 87427)
Annex C:	Labelling (maize MON 87427)
Annex D1:	Validation report (maize MON 87427)
Annex D2:	Validated method (maize MON 87427)
Annex D3:	Sampling and extraction (maize MON 87427)
Annex E:	Certified reference materials (maize MON 87427)
Annex F:	Post-market environmental monitoring (maize MON 87427)
Annex G:	Member States' comments (maize MON 87427)

[3]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-2015-00349