TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on genetically modified maize MON 87411 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-124)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-NL-2015-124 for the placing on the market of genetically modified (GM) maize MON 87411 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-NL-2015-124 is for food and feed uses, import and processing of maize MON 87411 in the European Union. Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on maize MON 87411, 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 maize MON 87411, and declared fit for regulatory purpose. The certified reference materials of maize MON 87411 can be accessed at the American Oil Chemists' Society (AOCS)[2]. The GMO Panel is of the opinion that the post-market environmental monitoring (PMEM) plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2015-124. 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: maize, MON 87411, EFSA-GMO-NL-2015-124, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: Competent Authority of the Netherlands

Question number: EFSA-Q-2015-00101

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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.
[2] https://www.aocs.org/store/shop-aocs

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Table of contents

Summary 1
1. Introduction 4
1.1. Terms of Reference 4
2. Considerations 5
2.1. Name and address of the Applicant 5
2.2. Designation and specification of the product 5
2.3. Scientific opinion of the GMO Panel 5
2.4. Cartagena Protocol 6
2.5. Labelling 6
2.6. Methods for detection 6
2.7. Certified reference materials 6
2.8. Post-market environmental monitoring (PMEM) 6
2.9. Member States Comments 6
3. Conclusions 7
List of Annexes 8

1. Introduction

On 10 March 2015, EFSA received from the Competent Authority of the Netherlands application EFSA-GMO-NL-2015-124, submitted by Monsanto Europe S.A./N.V under Articles 5 and 17 of Regulation (EC) No 1829/2003[3]. The scope of application EFSA-GMO-BE-2015-124 is for import, processing, and food and feed uses of maize MON 87411 within the European Union (EU). The unique identifier of maize MON 87411 is MON-87411-9.

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 27 January 2015, 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[4].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-NL-2015-124 valid on 17 August 2015.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-NL-2015-124. 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[5], 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-NL-2015-124 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-NL-2015-124 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.

[3]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.
[4]http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00101
[5]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

Application EFSA-GMO-NL-2015-124 was submitted by

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

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

2.2. Designation and specification of the product

Maize MON 87411 was developed to confer resistance to corn rootworms (*Diabrotica* spp.) by the expression of a modified version of the *Bacillus thuringiensis cry3Bb1* gene and a DvSnf7 dsRNA expression cassette, and tolerance to glyphosate-containing herbicides by the expression of a CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 *epsps*) gene.

The scope of application EFSA-GMO-BE-2015-124 is for import, processing, and food and feed uses of maize MON 87411 within the EU.

2.3. Scientific opinion of the GMO Panel

On 31 May 2018, the GMO Panel adopted a scientific opinion on maize MON 87411 (application EFSA-GMO-NL-2015-124). 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 (Annex A).

The molecular characterisation data establish that maize MON 87411 contains a single insert consisting of one copy of the CP4 epsps and the cry3Bb1 expression cassettes and one copy of the DvSnf7 dsRNA expression cassette. Bioinformatics analyses of the sequences encoding the newly expressed proteins and other open reading frames within the insert, or spanning the junctions between the insert and genomic DNA, do not indicate significant similarities to toxins and allergens. The in planta RNAi off-target search, performed with the sequence of the DvSnf7 dsRNA, does not provide indication for an off-target effect that would need further safety assessment. The stability of the inserted DNA and of the introduced trait is confirmed over several generations. The methodology used to quantify the levels of the CP4 EPSPS and Cry3Bb1 proteins is considered adequate. The protein characterisation data comparing the structural and biochemical properties of plant and microbial derived CP4 EPSPS and Cry3Bb1 proteins indicate that these proteins are equivalent and the microbial produced proteins can be used in the safety studies.

No statistically significant differences in the agronomic, phenotypic and physiological characteristics between maize MON 87411 and its conventional counterpart are identified. None of the differences identified in forage and grain composition between maize MON 87411, its conventional counterpart and the non-GM commercial reference varieties needs further assessment regarding food and feed safety, except for palmitic acid levels in grains from not treated maize MON 87411, which were further assessed.

The GMO Panel did not identify safety concerns regarding the toxicity and allergenicity of the CP4 EPSPS and Cry3Bb1 proteins, as expressed in maize MON 87411 and found no evidence that the genetic modification might significantly change the overall allergenicity of maize MON 87411. The nutritional impact of maize MON 87411-derived food and feed is expected to be the same as those derived from the conventional counterpart and non-GM commercial reference varieties. The GMO Panel concludes that maize MON 87411, as described in this application, is nutritionally equivalent to and as safe as the conventional counterpart and the non-GM maize reference varieties tested, and no post-market monitoring of food/feed is considered necessary.

Considering the introduced traits, the outcome of the comparative analysis, the routes and levels of exposure, the GMO Panel concludes that maize MON 87411 would not raise safety concerns in the

case of accidental release of viable GM maize grains into the environment. The PMEM plan and reporting intervals are in line with the intended uses of maize MON 87411.

Based on the relevant publication identified through the literature searches, the GMO Panel did not identify any safety issues pertaining to the intended uses of maize MON 87411. In the context of PMEM, the applicant should improve future literature searches according to the GMO Panel recommendations.

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-NL-2015-124, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The GMO Panel concludes that maize MON 87411, as described in this application, is as safe as its conventional counterpart and the tested non-GM maize reference varieties with respect to potential effects on human and animal health and the environment.

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 maize MON 87411 transformation event in crop DNA. The reports were issued on 13 October 2008, 23 June 2016 and 1 March 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[6] (Annexes D1, D2, D3).

2.7. Certified reference materials

The certified reference materials of maize MON 87411 can be accessed at the America Oil Chemists' Society (AOCS) (Annex E).

2.8. Post-market environmental monitoring (PMEM)

The GMO Panel is of the opinion that the PMEM plan proposed by the applicant is in line with the scope of application EFSA-GMO-NL-2015-124 (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).

[6]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.

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-NL-2015-124 for food and feed uses, import and processing of maize MON 87411 in the EU.

List of Annexes[7]

Annex A:	Scientific opinion of the GMO Panel on maize MON 87411
Annex B:	Cartagena Protocol
Annex C:	Labelling proposal
Annex D1:	Validation report by EURL-GMFF of the event-specific method for the quantification of maize MON 87411
Annex D2:	Validated detection method for maize MON 87411
Annex D3:	Sampling / DNA extraction
Annex E:	Certified reference materials
Annex F:	Post-market environmental monitoring plan
Annex G:	Member States' comments and GMO Panel responses

[7]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-2018-00468