TECHNICAL REPORT

APPROVED: 18 May 2018 PUBLISHED: 24 May 2018

Overall opinion of the European Food Safety Authority on genetically modified maize 4114 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-NL-2014-123 for the placing on the market of genetically modified (GM) maize 4114 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-NL-2014-123 is for food and feed uses, import and processing of maize 4114. Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on maize 4114, 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 4114, and declared fit for regulatory purpose. The certified reference materials of maize 4114 can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM). 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-2014-123. 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, 4114, EFSA-GMO-NL-2014-123, 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-2018-00311

Correspondence: GMO_secretariat_applications@efsa.europa.eu

[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), 2018. Overall opinion of the European Food Safety Authority on genetically modified maize 4114 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123). EFSA supporting publication 2018:EN-1425. 8 pp.

Table of contents

1. Introduction

On 27 November 2014, EFSA received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2014-123), submitted by Pioneer Overseas Corporation under Articles 5 and 17 of Regulation (EC) No 1829/2003[2], to support the placing of genetically modified (GM) maize 4114 on the market in the European Union (EU). The unique identifier of maize 4114 is DP-ØØ4114-3.

The scope of application EFSA-GMO-NL-2014-123 is for food and feed uses, import and processing of maize 4114.

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 16 June 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-NL-2014-123 valid on 30 March 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-2014-123. 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-NL-2014-123 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-2014-123 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-2014-00850
[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

Application EFSA-GMO-NL-2014-123 was submitted by

Pioneer Hi-Bred International, Inc *represented by*
Alfred-Nobel-Strasse 50
7100 NW 62nd Avenue
P.O. Box 1014
Johnston, IA 50131-1014
U.S.A

Pioneer Overseas Corporation
Avenue des Arts, 44
B-1040 Brussels
Belgium

2.2. Designation and specification of the product

Maize 4114 was developed to confer resistance against specific lepidopteran and coleopteran pests by the expression of the *cry1F, cry34Ab1 and cry35Ab1* genes derived from *Bacillus thuringiensis* and tolerance to the herbicidal active ingredient glufosinate-ammonium by expression of the *PAT* gene derived from *Streptomyces viridochromogenes*.

The scope of application EFSA-GMO-NL-2014-123 is for food and feed uses, import and processing of maize 4114.

2.3. Scientific opinion of the GMO Panel

On 19 April 2018, the GMO Panel adopted a scientific opinion on maize 4114 (application EFSA-GMO-NL-2014-123). 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 molecular characterisation data and bioinformatics analyses did not identify issues requiring further assessment for food/feed safety. The GMO Panel concludes that none of the differences identified in the agronomic, phenotypic and compositional characteristics of maize 4114 required further assessment regarding environmental and food and feed safety. The GMO Panel did not identify safety concerns regarding the toxicity and allergenicity of the proteins Cry1F, Cry34Ab1, Cry35Ab1 and PAT expressed in maize 4114, and found no evidence that the genetic modification might significantly change the overall allergenicity of maize 4114. The nutritional impact of maize 4114-derived food and feed is expected to be similar to that from the non-GM comparator and non-GM commercial reference varieties. The GMO Panel concludes that there is a very low likelihood of environmental effects resulting from the accidental release of viable grains from maize 4114 into the environment. The PMEM plan and reporting intervals are in line with the intended uses of maize 4114. Based on the relevant publications identified through the literature searches, the GMO Panel did not identify any safety issues pertaining to the intended uses of maize 4114. In the context of PMEM, the applicant should improve the literature searches according to the GMO Panel recommendations. In conclusion, the GMO Panel considers that maize 4114, as described in this application, is as safe as the non-GM comparator and other non-GM maize varieties with respect to potential effects on human and animal health and the environment (Annex A).

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 4114 transformation event in crop DNA. The

reports were issued on 10 April 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).

2.7. Certified reference materials

The certified reference materials of maize 4114 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annex E1).

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-2014-123 (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).

[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.

3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-NL-2014-123 for food and feed uses, import and processing of maize 4114 in the EU.

List of Annexes[6]

Annex A:	Scientific opinion of the EFSA GMO Panel (maize 4114)
Annex B:	Cartagena Protocol (maize 4114)
Annex C:	Labelling proposal (maize 4114)
Annex D1:	Validation report by EURL-GMFF of the event-specific method for the quantification of maize 4114
Annex D2:	Validated detection method for maize 4114
Annex D3:	Sampling and DNA extraction (maize 4114)
Annex E:	Certified reference materials (maize 4114)
Annex F:	Post-market environmental monitoring plan (maize 4114)
Annex G:	Member States' comments and GMO Panel responses (maize 4114)

[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-2018-00311