TECHNICAL REPORT

APPROVED: 23 November 2017 PUBLISHED: 28 November 2017

Overall opinion of the European Food Safety Authority on application EFSA-GMO-NL-2011-92 by Pioneer for placing on the market of genetically modified maize 1507 × 59122 × MON 810 × NK603 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-NL-2011-92 for the placing on the market of genetically modified (GM) maize 1507 × 59122 × MON 810 × NK603 according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1]

The scope of application EFSA-GMO-NL-2011-92 is for food and feed uses, import and processing of maize 1507 × 59122 × MON 810 × 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 1507 × 59122 × MON 810 × 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 1507 × 59122 × MON 810 × NK603. The certified reference materials of maize 1507 × 59122 × MON 810 × NK603 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-2011-92. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

The particulars regarding e.g. labelling proposal, detection, Cartagena protocol are not considered by EFSA since they fall outside its remit.

Key words: maize (Zea mays), 1507 × 59122 × MON810 × NK603, EFSA-GMO-NL-2011-92, 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-2017-00672

Correspondence: GMO@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.

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1. Introduction

On 3 February 2011, EFSA received from the Competent Authority of the Netherlands an application (reference EFSA-GMO-NL-2011-92), 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 1507 × 59122 × MON 810 × NK603 on the market in the European Union (EU). The unique identifier of maize 1507 × 59122 × MON 810 × NK603 is DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6xMON-ØØ6Ø3-6. The scope of application EFSA-GMO-NL-2011-92 is for food and feed uses, import and processing of maize 1507 × 59122 × MON 810 × 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 17 and 18 January 2011, 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-2011-92 valid on 30 January 2012.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-NL-2011-92. 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-2011-92 from 30 January 2012 till 30 April 2012.

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-2011-92 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-2011-00116
[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(s)

Application EFSA-GMO-NL-2011-92 was submitted by

Pioneer Hi-Bred International, Inc. 7100 NW 62nd Avenue P.O. Box 1014 Johnston, IA 50131-1014 (U.S.A.)	*Represented by*	Pioneer Overseas Corporation Avenue des Arts, 44 B-1040 Brussels Belgium

2.2. Designation and specification of the product

Maize 1507 × 59122 × MON 810 × NK603 (unique identifier: DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6xMON-ØØ6Ø3-6) was developed to be herbicide-tolerant and insect-resistant.

The scope of application EFSA-GMO-NL-2011-92 is for food and feed uses, import and processing of maize 1507 × 59122 × MON 810 × NK603 and subcombinations, independently of their origin, in the EU.

2.3. Scientific opinion of the GMO Panel

On 14 November 2017, the GMO Panel adopted a scientific opinion on maize 1507 × 59122 × MON 810 × NK603 (application EFSA-GMO-NL-2011-92). 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.

In this opinion, the GMO Panel assessed the four-event stack maize 1507 × 59122 × MON 810 × NK603 and its ten subcombinations, independently of their origin. The GMO Panel previously assessed the four single events combined in this four-event stack maize and five of their combinations and did not identify safety concerns. No new data on the single events or their previously assessed combinations leading to modification of the original conclusions 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 four-event stack maize did not give rise to food and feed safety or nutritional issues. The GMO Panel concludes that the four-event stack maize is as safe and as nutritious as its non-GM comparator. In the case of accidental release of viable grains of maize 1507 × 59122 × MON 810 × NK603 into the environment; this would not raise environmental safety concerns. For four of the subcombinations not previously assessed, protein expression data were provided and did not indicate an interaction affecting the levels of the newly expressed proteins in these subcombinations. The five subcombinations not previously assessed are expected to be as safe as the single maize events, the previously assessed subcombinations and the four-event stack maize. The GMO Panel considers that post-market monitoring of maize 1507 × 59122 × MON 810 × NK603 and its subcombinations is not necessary. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of maize 1507 × 59122 × MON 810 × NK603 and its subcombinations. (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 proposals for labelling 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 1507, 59122, MON810 and NK603 (Annexes D2a-d).

In the context of application EFSA-GMO-NL-2011-92 on the four-event stack maize 1507 × 59122 × MON810 × NK603, the EURL-GMFF has checked in-house the performance of each validated detection method when applied to genomic DNA extracted from maize 1507 × 59122 × MON810 × NK603. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from maize 1507 × 59122 × MON810 × NK603 is provided in Annexes D1 and D3.

2.7. Certified reference materials

The certified reference materials of maize 1507, 59122, MON810 and NK603 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annex E1-4).

2.8. Post-market environmental monitoring (PMEM)

The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of maize 1507 × 59122 × MON810 × NK603 and its subcombinations (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-NL-2011-92 for food and feed uses, import and processing of maize 1507 × 59122 × MON810 × NK603 and its subcombinations in the EU.

List of Annexes[5]

Annex A:	Scientific opinion of the GMO Panel (maize 1507 × 59122 × MON810 × NK603)
Annex B:	Cartagena Protocol
Annex C:	Labelling proposal
Annex D1:	Validation report by EURL-GMFF of the detection methods for the single events applied to maize 1507 × 59122 × MON810 × NK603
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Annex D3:	Sampling / DNA extraction
Annex E1:	Certified reference materials (maize 1507)
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Annex E4:	Certified reference materials (maize NK603)
Annex F:	Post-market environmental monitoring
Annex G:	Member States' comments and GMO Panel responses

[5]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-2017-00672