TECHNICAL REPORT

APPROVED: 19 February 2018 PUBLISHED: 26 February 2018

Overall opinion of the European Food Safety Authority on genetically modified maize NK603 × MON810 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-007)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-007 for the continued placing on the market of genetically modified (GM) maize NK603 × MON810 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1] The scope of application EFSA-GMO-RX-007 is for food and feed uses, import and processing in the European Union (EU). Alongside with the Scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel) on maize NK603 × MON810, 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) validated, and declared fit for purpose, the detection methods for each single event applied for the detection and quantification of the respective events in maize NK603 × MON810. The certified reference materials of maize NK603 × MON810 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-RX-007. 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, NK603 × MON810, EFSA-GMO-RX-007, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2018-00063

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 NK603 × MON810 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-007). EFSA supporting publication 2018:EN-1388. 7 pp.

Table of contents

European Food Safety Authority 1
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 5
2.5. Labelling 5
2.6. Methods for detection 5
2.7. Certified reference materials 5
2.8. Post-market environmental monitoring (PMEM) 6
2.9. Member States Comments 6
3. Conclusions 6
List of Annexes 7

1. Introduction

On 22 December 2016, EFSA received from the European Commission an application (reference EFSA-GMO-RX-007), submitted by Monsanto S.A./N.V. under Articles 11 and 23 of Regulation (EC) No 1829/2003[2], to support the continued placing on the market of genetically modified (GM) maize NK603 × MON810 in the EU. The unique identifier of maize NK603 × MON810 is MON-ØØ6Ø3-6 × MON-ØØ81Ø-6. The scope of application EFSA-GMO-RX-007 is for food and feed uses, import and processing of maize NK603 × MON810 in the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 11(2) and 23(2) of the above mentioned Regulation. On 15 December 2004 and on 19 January 2005, 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-RX-007 valid on 18 April 2017.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-RX-007. 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-RX-007 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-RX-007 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-2017-00028
[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-RX-007 was submitted by

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

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

2.2. Designation and specification of the product

Maize NK603 × MON810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) was developed to be herbicide-tolerant and insect-resistant.

The scope of application EFSA-GMO-RX-007 is for food and feed uses, import and processing of maize NK603 × MON810 in the EU.

2.3. Scientific opinion of the GMO Panel

On 24 January 2018, the GMO Panel adopted a Scientific opinion on maize NK603 × MON810 (application EFSA-GMO-RX-007). 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.

Under the assumption that the DNA sequence of the two events in maize NK603 × MON810 considered for renewal is identical to the sequence of the originally assessed events, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-007 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize NK603 × MON810 (EFSA, 2005) (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 previously validated individually, and declared fit for purpose, the detection methods for the single events NK603 and MON810 (Annexes D2a and D2b).

In the context of application EFSA-GMO-RX-007 on two-event stack maize NK603 and MON810, the EURL-GMFF has checked in-house the performance of each validated detection method when applied to genomic DNA extracted from maize NK603 and maize MON810. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from maize NK603 and maize MON810 is provided in Annexes D1 and D3.

2.7. Certified reference materials

The certified reference materials of maize NK603 and maize MON810 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annexes E1 and E2).

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-RX-007 (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-RX-007 for food and feed uses, import and processing of maize NK603 × MON810 in the EU.

List of Annexes[5]

Annex A:	Scientific opinion of the GMO Panel
Annex B:	Cartagena Protocol
Annex C:	Labelling proposal
Annex D1:	Validation report by EURL-GMFF of the event-specific detection methods for the quantification of maize NK603 × MON810
Annex D2a:	Validated detection method for maize NK603
Annex D2b:	Validated detection method for maize MON810
Annex D3:	Sampling / DNA extraction
Annex E1:	Certified reference materials (maize NK603)
Annex E2:	Certified reference materials (maize MON810)
Annex F:	Post-market environmental monitoring plan
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-2018-00063