TECHNICAL REPORT

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Overall opinion of the European Food Safety Authority on genetically modified maize 1507 × NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008)

European Food Safety Authority

Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-RX-008 for the continued placing on the market of genetically modified (GM) maize 1507 × NK603 according to Articles 11 and 23 of Regulation (EC) No 1829/2003.[1]

The scope of application EFSA-GMO-RX-008 is for placing on the market of products containing, consisting of, or produced from maize 1507 × NK603 for import and processing in the European Union (EU). Alongside with the scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel), 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 1507 × NK603. The certified reference materials of maize 1507 × 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-RX-008. 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, 1507, NK603, EFSA-GMO-RX-008, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2018-00509

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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.

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1. Introduction

On 22 December 2016, EFSA received from the European Commission an application (reference EFSA-GMO-RX-008), submitted by Dow AgroSciences LLC and Pioneer Overseas Corporation under Articles 11 and 23 of Regulation (EC) No 1829/2003[2], to support the continued placing on the market of GM maize 1507 × NK603 in the EU. The unique identifier of maize 1507 × NK603 is DAS-Ø15Ø7-1×MON-ØØ6Ø3-6.

The scope of application EFSA-GMO-RX-008 is for placing on the market of products containing, consisting of, or produced from maize 1507 × NK603 for import and processing 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. 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-008 valid on 12 May 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-008. 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-008 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-008 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/questionDocumentsLoader?question=EFSA-Q-2017-00029
[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-RX-008 was submitted by

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

And

Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, Indiana 46268-1054 U.S.A.	*as represented by*	Dow AgroSciences Europe European Development Center, 3B Park Square, Milton Park, Abingdon Oxon OX14 4RN United Kingdom

2.2. Designation and specification of the product

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

The scope of application EFSA-GMO-RX-008 is for placing on the market of products containing, consisting of, or produced from maize 1507 × NK603 for import and processing, excluding cultivation within the EU.

2.3. Scientific opinion of the GMO Panel

On 20 June 2018, the GMO Panel adopted its scientific opinion on maize 1507 × NK603. 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 data received in the context of this renewal application contained a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

In conclusion, under the assumption that the DNA sequence of the events in maize 1507 × NK603 considered for renewal are identical to the newly reported 1507 sequence and the NK603 sequence of the originally assessed two-event stack maize, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-008 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize 1507 × NK603 (EFSA, 2006).

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 1507 and NK603 (Annexes D2a, D2b).

In the context of application EFSA-GMO-RX-008 on two-event stack maize 1507 × NK603, the EURL-GMFF has checked in-house the performance of each validated detection method when applied to genomic DNA extracted from maize 1507 and NK603. The final validation report by the EURL-GMFF of the individual detection methods applied to DNA extracted from maize 1507 × NK603 is provided in Annexes D1.

2.7. Certified reference materials

The certified reference materials of maize 1507 and NK603 can be accessed at Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) (Annexes E1, 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-008 (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-008 for food and feed uses, import and processing of maize 1507 × NK603 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 1507 × NK603
Annex D2a:	Validated detection method for maize 1507
Annex D2b:	Validated detection method for maize NK603
Annex E1:	Certified reference materials (maize 1507)
Annex E2:	Certified reference materials (maize NK603)
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/questionDocumentsLoader?question=EFSA-Q-2018-00509