SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 20 June 2018

doi: 10.2903/j.efsa.2018.5347

Assessment of genetically modified maize 1507 × NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008)

EFSA Panel on Genetically Modified Organisms (GMO), Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikołaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Ebbesen Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal, Fernando Álvarez, Michele Ardizzone, Giacomo De Sanctis, Antonio Fernandez Dumont, José Ángel Ruiz Gómez, Anna Lanzoni, Nikoletta Papadopoulou and Konstantinos Paraskevopoulos

Abstract

Following the submission of application EFSA-GMO-RX-008 under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc. and Dow AgroSciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant, herbicide-tolerant genetically modified maize 1507 × NK603, for food and feed uses, import and processing, excluding cultivation within the EU. 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).

Keywords: Maize, 1507 × NK603, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2017-00029

Correspondence: GMO@efsa.europa.eu

Panel members: Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikołaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Ebbesen Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli and Jean-Michel Wal.

Acknowledgements: The Panel wishes to thank the members of its standing Working Groups on Molecular Characterisation, Food/Feed and Environmental Risk Assessment for the preparatory work on this scientific opinion, and the EFSA staff members Claudia Paoletti and Irene Munoz Guajardo for the support provided to this scientific opinion.

Suggested citation: EFSA GMO Panel (EFSA Panel on genetically modified organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Álvarez F, Ardizzone M, De Sanctis G, Fernandez Dumont A, Ruiz Gómez JÁ, Lanzoni A, Papadopoulou N and Paraskevopoulos K, 2018. Scientific Opinion on the assessment of genetically modified maize 1507 × NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008). EFSA Journal 2018;16(7):5347, 11 pp. https://doi.org/10.2903/j.efsa.2018.5347

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Following the submission of application EFSA-GMO-RX-008 under Regulation (EC) No 1829/2003[1] from Pioneer Hi-Bred International, Inc. and Dow AgroSciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application for the insect-resistant, herbicide-tolerant genetically modified (GM) maize 1507 × NK603. The scope of the renewal 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 European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-008, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-008 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses, and additional 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).

[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.

Table of contents

1. Introduction

1.1. Background

On 22 December 2016, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) application EFSA-GMO-RX-008 by Pioneer Hi-Bred International, Inc. and Dow AgroSciences LLC for the renewal of authorisation of genetically modified (GM) maize 1507 × NK603 for the placing on the market of products containing, consisting of, or produced from this GM maize for import and processing submitted within the framework of Regulation (EC) No 1829/2003. Before sending the application to EFSA, the European Commission confirmed whether the data submitted in the context of this renewal application were in line with the legal requirements laid down in Articles 11 and 23 of Regulation (EC) No 1829/2003.

After receiving application EFSA-GMO-RX-008, and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and made the summary of the application available to the public on the EFSA website.[2]

On 12 May 2017, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003. EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had 3 months after the opening of the Member State commenting period (until 1 September 2017) to make their opinion known.

Following the submission of application EFSA-GMO-UK-2004-05 and the publication of the EFSA scientific opinion (EFSA, 2006), the placing on the market of maize 1507 × NK603 for products containing, consisting of, or produced from this GM maize for import and processing, excluding cultivation in the European Union, was authorised by Commission Decision 2007/703/EC.[3] A copy of this authorisation was provided by the applicant.[4]

EFSA requested additional information on 18 May 2017, 7 December 2017, 21 December 2017, 18 January 2018, 20 March 2018 and 15 May 2018. The applicant submitted their reply on 3 November 2017, 8 February 2018, 30 January 2018, 5 March 2018, 3 April 2018 and 23 May 2018, respectively.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of 6 months from the acknowledgement of the valid application. As additional information was requested by the GMO Panel, the time limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1), and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

1.2. Terms of Reference as provided by the requestor

The GMO Panel was requested to carry out a scientific risk assessment on the data submitted in the context of a renewal of authorisation application for the placing on the market of products containing, consisting of, or produced from GM maize 1507 × NK603, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and

[2] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2017-00029

[3] COMMISSION DECISION of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 285/47, 31.10.2007.

[4] Dossier: 1507 × NK603 renewal – Annex 1.

methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-008 provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the context of this renewal application, following requests from EFSA, new sequencing studies were submitted for event 1507 in maize 1507 × NK603 which indicated that a single nucleotide change occurred in the coding region of the Cry1F protein as compared to the original 1507 sequence, corrected in 2017 (EFSA GMO Panel, 2017a).[5] This single nucleotide change did not lead to a change in the amino acid sequence of the Cry1F protein. With regard to NK603, the applicant has stated that the NK603 sequence in 1507 × NK603 is identical to that of the original event (EFSA, 2006).[6]

Taking into account the above described sequence information and in accordance with the GMO Panel guidelines for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015), the GMO Panel evaluated the data provided in the context of this maize 1507 × NK603 renewal application under the assumption that the event sequences in 1507 × NK603 currently on the market are identical to the newly reported 1507 event sequence, and to the NK603 event sequence submitted in the originally assessed stack.

2.1.1. Post-market monitoring reports[7]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food/feed was not required by the authorisation decision. The implementation of a post-market environmental monitoring (PMEM) plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from maize 1507 × NK603, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of maize 1507 × NK603 (EFSA, 2006), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from October 2007 to June 2016. The annual PMEM plans submitted by the applicant included (1) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in maize (or bulk grain) import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of maize possibly containing maize 1507 × NK603; (2) the reports of the surveillance activities conducted by such operators; and (3) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature[8]

In addition to the nine separate literature searches provided as part of the annual PMEM reports, the applicant performed two systematic literature searches covering a period from 1 January 2007 to 17 May 2018, in accordance with the recommendations on literature searching outlined in EFSA (2010, 2017).

Searches against electronic bibliographic databases, citation searching, screening of reference lists, and internet searches to specialist databases were performed to identify relevant publications. Altogether, 120 publications were retrieved. After applying the eligibility/inclusion criteria defined a priori by the applicant, one publication, which was an EFSA GMO Panel opinion (EFSA GMO Panel, 2011) was identified as relevant for food/feed safety assessment, molecular characterisation and environmental safety assessment. The applicant assessed this publication, and concluded that it does not raise any concern for human and animal health of maize 1507 × NK603.

[5] Additional information: 3/11/2017 and 5/3/2018.
[6] Additional information: 8/2/2018.
[7] Dossier: 1507 × NK603 renewal – Annex 2.
[8] Dossier: 1507 × NK603 renewal – Annex 3.1; additional information: 22/5/2017.

2.1.3. Updated bioinformatic data

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic package for single maize events 1507 and NK603 used to produce 1507 × NK603 including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, and an analysis of possible horizontal gene transfer (HGT).[9] On 18 May 2017, EFSA requested a nucleotide sequence alignment of the full maize 1507 event sequence (insert and flanking regions) present in the two-event stack maize 1507 × NK603 with the corrected maize 1507 event sequence previously submitted to EFSA (EFSA GMO Panel, 2017a). On 3 November 2017, the applicant provided the supplementary information which included a complete bioinformatic analysis on the newly reported 1507 event sequence determined using material from maize 1507 × NK603 (Section 2.1).[5] On 20 March 2018, EFSA requested an updated bioinformatic analysis for event NK603 present in the two-stack maize 1507 × NK603. On 3 April 2018, the applicant provided the requested information which included a complete bioinformatic analysis using the original NK603 event sequence.[10] The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4. Additional documents or studies provided by the applicant[11]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize 1507 × NK603 and a list containing the summaries of all studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU (Appendix A).

The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed by the applicant.

On 21 December 2017, the GMO Panel requested the applicant to provide the full study reports of three of these studies considered potentially relevant for safety assessment. The applicant submitted the requested information on 30 January 2018.

2.1.5. Overall assessment as provided by the applicant[12]

In line with the requirements listed in the renewal guidance (EFSA GMO Panel, 2015), the applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize 1507 × NK603 for food and feed use and processing in the EU, does not change the outcome of the original risk assessment (EFSA, 2006).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation

The applicant indicated in the dossier that the environmental monitoring plan is appropriate and does not need any changes.

2.2. Methodologies

The GMO Panel assessed the application for the renewal of the authorisation of maize 1507 × NK603 for food and feed uses, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015).

The comments raised by Member States are addressed in Annex G of EFSA's overall opinion[13] and were taken into consideration during the scientific risk assessment.

[9] Dossier: 1507 × NK603 renewal – Section 3.2.2.
[10] Additional information: 3/4/2018.
[11] Dossier: 1507 × NK603 renewal – Section 3.2.3 and Annex 23.
[12] Dossier: 1507 × NK603 renewal – Section 3.3.
[13] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00714

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of maize 1507 × NK603, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on maize 1507 × NK603. Although the overall quality of the performed literature searches is acceptable, the GMO Panel considers that future searches could be improved. The GMO Panel therefore recommends the applicant to:

- ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues) and that terms are used consistently across databases where appropriate;
- use truncation consistently;
- adapt the syntax (e.g. proximity operators) to each electronic bibliographic database used;
- include controlled vocabulary (subject indexing) in the searches when available (in addition to/combination with text words);
- report the number of publications identified for each single search set performed (or search lines).

The GMO Panel acknowledges that no publications raising a safety concern for human and animal health and the environment which would change the original risk assessment conclusions on maize 1507 × NK603 (EFSA, 2006) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses of maize events 1507 (using the newly reported 1507 event sequence) and NK603 confirmed that no known endogenous genes were disrupted by the inserts. Analyses of the amino acid sequence of the newly expressed CP4 EPSPS, CP4 EPSPS L214P, Cry1F and PAT proteins revealed no significant similarities to toxins or allergens. In addition, bioinformatic analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA revealed no significant similarities to toxins and allergens.

The updated bioinformatic analyses confirmed the previous conclusions on the likelihood of occurrence of HGT for these events (e.g. EFSA GMO Panel, 2017b, 2018). It was concluded that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from maize 1507 × NK603 to bacteria did not raise any environmental safety concern.

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel evaluated the summary and/or full study reports of the additional studies provided and listed in Appendix A. This new information does not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on maize 1507 × NK603.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in the renewal application EFSA-GMO-RX-008 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan covers general surveillance of imported GM maize plant material, including maize 1507 × NK603. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in maize import and processing). In addition, the applicant reviews

relevant scientific publications retrieved from literature searches on an annual basis. As mentioned in Section 2.1.6, the applicant considers that the PMEM plan does not need any changes. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of maize 1507 × NK603 but reminds that monitoring is related to risk management, and thus the final adoption and implementation of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

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).

Documentation provided to EFSA

- Letter from the European Commission to EFSA received on 22 December 2016 for the continued marketing of genetically modified maize 1507 x NK603 in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation (EFSA-GMO-RX-008).
- Acknowledgement letter dated 9 January 2017 from EFSA to European Commission.
- Letter from EFSA to applicant dated 10 February 2017 requesting additional information under completeness check.
- Letter from applicant to EFSA received on 19 April 2017 providing additional information under completeness check.
- Letter from EFSA to applicant dated 12 May 2017 delivering the 'Statement of Validity' for application EFSA-GMO-RX-008.
- Letter from EFSA to applicant dated 18 May 2017 requesting additional information and stopping the clock.
- Letter from applicant to EFSA received on 3 November 2017 providing additional information.
- Letter from EFSA to applicant dated 6 November 2017 re-starting the clock from 3 November 2017.
- Letter from EFSA to applicant dated 7 December 2017 requesting additional information and stopping the clock.
- Letter from EFSA to applicant dated 21 December 2017 requesting additional information and maintaining the clock stopped.
- Letter from EFSA to applicant dated 18 January 2018 requesting additional information and maintaining the clock stopped.
- Letter from applicant to EFSA received on 30 January 2018 providing additional information.
- Letter from applicant to EFSA received on 8 February 2018 providing additional information.
- Letter from applicant to EFSA received on 5 March 2018 providing additional information.
- Letter from EFSA to applicant dated 7 March 2018 re-starting the clock from 5 March 2018.
- Letter from EFSA to applicant dated 20 March 2018 requesting additional information and stopping the clock.
- Letter from applicant to EFSA received on 3 April 2018 providing additional information.
- Letter from EFSA to applicant dated 4 April 2018 re-starting the clock from 3 April 2018.
- Letter from EFSA to applicant dated 15 May 2018 requesting additional information and stopping the clock.
- Letter from applicant to EFSA received on 23 May 2018 providing additional information.
- Letter from EFSA to applicant dated 24 May 2018 re-starting the clock from 23 May 2018.

References

EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified maize 1507 × NK603, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds. The EFSA Journal 2006;4(5):355, 23 pp. https://doi.org/10.2903/j.efsa.2006.355

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011. Statement complementing the EFSA GMO Panel scientific opinion on maize MON 89034 ×1507 × NK603 (application EFSAGMO- NL-2009-65), to cover all subcombinations independently of their origin. EFSA Journal 2011;9(9):2377, 8 pp. https://doi.org/10.2903/j.efsa.2011.2377

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(6):4129, 8 pp. https://doi.org/10.2903/j.efsa.2015.4129

EFSA GMO Panel (EFSA Panel on genetically modified organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Álvarez F, Ardizzone M, Mestdagh S and Ramon M, 2017a. Scientific opinion on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. EFSA Journal 2017;15(1):4659, 11 pp. https://doi.org/10.2903/j.efsa.2017.4659

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Gennaro A, Neri FM and Paraskevopoulos K, 2017b. Scientific Opinion on application EFSA-GMO-BE-2013-117 for authorisation of genetically modified maize MON 87427 x MON 89034 x NK603 and subcombinations independently of their origin, for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Company. EFSA Journal 2017;15(8):4922, 26 pp. https://doi.org/10.2903/j.efsa.2017.4922

EFSA GMO Panel (EFSA Panel on genetically modified organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Broll H, Fernandez Dumont A and Olaru I, 2018. Scientific Opinion on assessment of genetically modified maize NK603 x MON810 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-007). EFSA Journal 2018;16(2):5163, 10 pp. https://doi.org/10.2903/j.efsa.2018.5163

EFSA (European Food Safety Authority), Devos Y, Guajardo IM, Glanville J and Waigmann E, 2017. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publications 2017;14(4):EN-1207, 48 pp. https://doi.org/10.2903/sp.efsa.2017.en-1207

Abbreviations

ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organisms
GMO	Panel EFSA Panel on Genetically Modified Organisms
HGT	horizontal gene transfer
ORFs	open reading frames
PMEM	post-market environmental monitoring report

Appendix A – List of additional studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU with regard to the evaluation of the safety of the food/feed for humans, animal or the environment from maize 1507 × NK603

Study identification	Title
PHI-2015-058	Quantitation of Cry1F,Cry1Ab and CP4 EPSPS Proteins by ELISA in Double (TC1507 X NK603) and Triple Stack (TC1507 X MON810 X NK603) Maize Growing in Net House
PHI-2004-094	Evaluation of Cold Tolerance of 1507xNK603 Maize Seedlings
PHI-2012-287[(a)]	Six Week Poultry Feeding Study with Grains from Maize Hybrid Containing the Combined Trait Product TC1507xNK603
PHI-2013-162[(a)]	Thirteen Week Rat Feeding Study with Maize Grain Containing the Combined Trait Products TC1507xNK603 and TC1507xMON810xNK603
PHI-2013-167[(a)]	Rodent Diet Formulation Study Using Maize Grains Containing The Combined Trait Product TC1507xNK603, TC1507xMON810xNK603 and Non-transgenic Maize Grains

(a): Studies for which the full report was requested by the GMO Panel.