SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 25 September 2019

doi: 10.2903/j.efsa.2019.5845

Assessment of genetically modified maize MON 89034 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-015)

EFSA Panel on Genetically Modified Organisms (GMO),
Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst,
Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko,
Francisco Javier Moreno, Ewen Mullins, Fabien Nogué, Nils Rostoks,
Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann, Fabio Veronesi,
Fernando Álvarez, Michele Ardizzone and Tommaso Raffaello

Abstract

Following the submission of application EFSA-GMO-RX-015 under Regulation (EC) No 1829/2003 from Bayer Agriculture BVBA, the EFSA Panel on Genetically Modified Organisms (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 genetically modified maize MON 89034, for food and feed uses, excluding cultivation within the EU. The data received in the context of this renewal application contained post-market environmental monitoring reports, 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. Under the assumption that the DNA sequence of the event in maize MON 89034 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-015 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034.

© 2019 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: Maize, MON 89034, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2018-00673

Correspondence: GMO_secretariat_applications@efsa.europa.eu

Panel members: Hanspeter Naegeli, Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins, Fabien Nogué, Nils Rostoks, Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi.

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 Antonio Fernandez Dumont, Andrea Gennaro, Irene Muñoz-Guajardo, Konstantinos Paraskevopoulos and Nikoletta Papadopoulou for the support provided to this scientific opinion.

Suggested citation: EFSA Panel on Genetically Modified Organisms (GMO), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Álvarez F, Ardizzone M and Raffaello T, 2019. Assessment of genetically modified maize MON 89034 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-015). EFSA Journal 2019;17 (11):5845, 10 pp. https://doi.org/10.2903/j.efsa.2019.5845

ISSN: 1831-4732

© 2019 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

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-015 under Regulation (EC) No 1829/2003[1] from Bayer Agriculture BVBA, the EFSA Panel on Genetically Modified Organisms (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 genetically modified (GM) maize MON 89034. The scope of the renewal application EFSA-GMO-RX-015 is for the renewal of the placing on the market of products containing, consisting of, or produced from maize MON 89034, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-015, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-015 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.

Under the assumption that the DNA sequence of the event in maize MON 89034 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-015 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034 (EFSA, 2008).

[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

Abstract 1
Summary 2
1. Introduction 5
1.1. Background 5
1.2. Terms of Reference as provided by the requestor 5
2. Data and methodologies 6
2.1. Data 6
2.1.1. Post-market monitoring reports 6
2.1.2. Systematic search and evaluation of literature 6
2.1.3. Updated bioinformatic data 6
2.1.4. Additional documents or studies provided by the applicant 7
2.1.5. Overall assessment as provided by the applicant 7
2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation 7
2.2. Methodologies 7
3. Assessment 7
3.1. Evaluation of the post-market monitoring reports 7
3.2. Evaluation of the systematic search and evaluation of literature 7
3.3. Evaluation of the updated bioinformatic data 7
3.4. Evaluation of the additional documents or studies provided by the applicant 8
3.5. Evaluation of the overall assessment as provided by the applicant 8
3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation 8
4. Conclusions 8
Documentation as provided to EFSA 8
References 9
Abbreviations 9
Appendix A – List of relevant publications identified by the applicant through the systematic literature search (January 2008 – June 2018) 10

1. Introduction

1.1. Background

On 29 August 2018, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-015 for the renewal of the authorisation of maize MON 89034 (Unique Identifier MON-89Ø34-3), submitted by Bayer Agriculture BVBA (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[2]

Following receipt of application EFSA-GMO-RX-015, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.[3]

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013[4] and, when needed, asked the applicant to supplement the initial application. On 4 December 2018, EFSA declared the application valid and made the valid application available to the MS and the European Commission.

Following the submission of application EFSA-GMO-NL-2007-37 and the publication of the EFSA scientific opinion (EFSA, 2008), the placing on the market of maize MON 89034 for products containing, consisting of, or produced from this genetically modified (GM) maize, excluding cultivation in the EU, was authorised by Commission Decision 2009/813/EC.[5] A copy of this authorisation was provided by the applicant.[6]

From the validity date, EFSA and its scientific Panel on Genetically Modified Organisms (hereafter referred to as 'the GMO Panel') endeavoured to respect a time limit of 6 months to issue a scientific opinion on application EFSA-GMO-RX-015. Such time limit was extended whenever EFSA and/or its GMO Panel requested supplementary information to the applicant. According to Regulation (EC) No 1829/2003, any supplementary information provided by the applicant during the risk assessment was made available to the MS and European Commission (for further details, see the section 'Documentation', below).

In accordance with Regulation (EC) No 1829/2003, EFSA consulted the nominated risk assessment bodies of the MS, including national Competent Authorities within the meaning of Directive 2001/18/EC.[7] The MS had three months to make their opinion known on application EFSA-GMO-RX-015 as of date of validity.

1.2. Terms of Reference as provided by the requestor

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA and its GMO Panel were requested to carry out a scientific risk assessment of maize MON 89034 for the renewal of authorization for placing on the market of products containing, consisting of, or produced from GM maize MON 89034 in the context of its scope as defined in application EFSA-GMO-RX-015.

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 including the opinions of the nominated risk assessment bodies of the MS.[8]

In addition to the present scientific opinion on maize MON 89034, EFSA and its GMO Panel were also asked to report on the particulars listed under Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003. The relevant information is made available in the EFSA Register of Questions,[9] including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a Post-Market Environmental Monitoring plan as provided by the applicant; the method(s), validated by the Community reference

[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] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00673
[4] Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L157, 8.6.2013, p. 1–48.
[5] Commission Decision of 30 November 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 314/102, 30.11.2009.
[6] Dossier: Maize MON 89034 – Annex 1.
[7] 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.
[8] Opinions of the nominated risk assessment bodies of EU Member States can be found at the EFSA Register of Questions,
[9] http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00673

laboratory, for detection, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it and the appropriate reference materials.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-015 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, no new sequencing study was submitted among the additional documents or studies performed by or on behalf of the applicant. 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 MON 89034 renewal application under the assumption that the MON 89034 event sequence is identical to the sequence of the originally assessed event (EFSA, 2008).

2.1.1. Post-market monitoring reports[10]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food and 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 MON 89034, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize MON 89034 (EFSA, 2008), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from July 2009 till July 2018. The annual PMEM plans submitted by the applicant included (1) commodity crop (GM and non-GM) imports into the EU by country of origin and destination; (2) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in maize grains import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of maize possibly containing maize MON 89034; (3) the reports of the surveillance activities conducted by such operators; and (4) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

2.1.2. Systematic search and evaluation of literature[11]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed a systematic literature search covering the period from January 2008 till June 2018, in accordance with the recommendations on literature search outlined in EFSA (2010, 2017a).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether, 285 publications were identified (after removal of duplicates).[12] After applying the eligibility/inclusion criteria defined a priori by the applicant, five publications were identified as relevant for food and feed safety assessment or molecular characterisation. The list of relevant publications is provided in Appendix A.

2.1.3. Updated bioinformatic data[13]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for maize MON 89034 event 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, an analysis of possible horizontal gene transfer (HGT) (EFSA, 2017b), and a safety assessment of the newly expressed proteins Cry1A.105 and Cry2Ab2 regarding their capacity to trigger celiac disease (EFSA GMO Panel, 2017a). Upon EFSA request, the applicant provided additional information followed by

[10] Dossier: Maize MON 89034 – Annex 2; additional information: 21/2/2019.
[11] Dossier: Maize MON 89034 – Annex 3.1; additional information: 21/2/2019.
[12] One hundred seventy-eight publications were identified in Web of Science™ Core Collection database and 107 publications were identified in CAB Abstracts® database.
[13] Dossier: Maize MON 89034 – Annex 3.2; additional information: 22/5/2019 and 19/6/2019.

further clarifications on the celiac disease analysis for Cry1A.105 protein. The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4. Additional documents or studies provided by the applicant[14]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize MON 89034 and searched for any available full reports of studies performed by or on behalf of the applicant over the course of the authorisation period and not previously submitted to the EU.

2.1.5. Overall assessment as provided by the applicant[15]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize MON 89034 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA, 2008).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[15]

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

2.2. Methodologies

The GMO Panel assessed the application for renewal of the authorisation of maize MON 89034 for food and feed uses 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 the nominated risk assessment bodies of EU MS were taken into consideration during the scientific risk assessment.[9]

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of maize MON 89034, 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 search on maize MON 89034 and the newly expressed proteins Cry1A.105 and Cry2Ab2. The overall quality of the performed literature search is acceptable; however, the GMO Panel considers that future searches could be improved. The GMO Panel recommends the applicant for future searches 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);
- adapt the search to the size of the retrieved publications (and thus not combine search sets when one of the search sets already yields only a small number of publications)

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 MON 89034 (EFSA, 2008) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses of maize MON 89034 confirm that no known endogenous genes were disrupted by the insert. Analyses of the amino acid sequence of the newly

[14] Dossier: Maize MON 89034 – Annex 3.3.
[15] Dossier: Maize MON 89034 – Annex 4.

expressed Cry1A.105 and Cry2Ab2 proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. In addition, bioinformatic analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA confirm the previous conclusions indicating that the expression of an ORF showing significant similarities to toxins or allergens for the event MON 89034 is highly unlikely (EFSA, 2008; EFSA GMO Panel, 2017b,c, 2019a,b).

The updated bioinformatic analysis for maize event MON 89034 do not reveal any new DNA sequence that could provide sufficient length and identity which could facilitate HGT by double homologous recombination (HR) confirming the previous conclusions (EFSA GMO Panel, 2017b,c, 2019a,b). Given the results of this analysis and that the recombinant DNA in maize MON 89034 does not confer selective advantages or increased fitness to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible HGT.

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

Taking into account (i) the relevance for molecular characterisation, human and animal safety and the environment; and (ii) the scope of this renewal application, there are no unpublished studies available performed by the applicant and not previously submitted to the EU since MON 89034 was authorised.

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 renewal application EFSA-GMO-RX-015 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize MON 89034.

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 plant material, including maize MON 89034. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in maize grains import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of application EFSA-GMO-RX-015, 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 event in maize MON 89034 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-015 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034.

Documentation as provided to EFSA

1) Letter from the European Commission to EFSA received on 29 August 2018 for the continued marketing of genetically modified maize MON 89034 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture BVBA (EFSA-GMO-RX–015).
2) Application EFSA-GMO-RX-015 validated by EFSA, 4 December 2018.
3) Receipt of spontaneous information from the applicant, 12 December 2018.
4) Request for supplementary information to the applicant, 19 December 2018.
5) Request for supplementary information to the applicant, 29 January 2019.
6) Receipt of supplementary information from the applicant, 21 February 2019.
7) Request for supplementary information to the applicant, 11 March 2019.
8) Receipt of supplementary information from the applicant, 22 May 2019.
9) Request of clarifications to the applicant, 6 June 2019.
10) Receipt of clarifications requested to the applicant, 19 June 2019.

References

EFSA (European Food Safety Authority), 2008. Scientific Opinion – Application (Reference EFSA-GMO-NL-2007-37) for the placing on the market of insect-resistant genetically modified maize MON 89034, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2008;6 (12):909, 30 pp. https://doi.org/10.2903/j.efsa.2009.909

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

EFSA (European Food Safety Authority), Gennaro A, Gomes A, Herman L, Nogue F, Papadopoulou N and Tebbe C, 2017b. Technical report on the explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA supporting publication 2017:EN-1273, 11 pp. https://doi.org/10.2903/sp.efsa.2017.en-1273

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, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Eigenmann P, Epstein M, Hoffmann-Sommergruber K, Koning F, Lovik M, Mills C, Moreno FJ, van Loveren H, Selb R and Fernandez Dumont A, 2017a. Guidance on allergenicity assessment of genetically modified plants. EFSA Journal 2017;15(5):4862, 49 pp. https://doi.org/10.2903/j.efsa.2017.4862

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, Lanzoni A and Paraskevopoulos K, 2017b. Scientific Opinion on application EFSA-GMO-BE-2013-118 for authorisation of genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 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):4921, 32 pp. https://doi.org/10.2903/j.efsa.2017.4921

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, 2017c. Scientific Opinion on application EFSA-GMO-BE-2013-117 for authorisation of genetically modified maize MON 87427 × MON 89034 × 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, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Álvarez F, Ardizzone M, De Sanctis G, Fernandez Dumont A, Gennaro A, Gómez Ruiz JÁ, Lanzoni A, Papadopoulou N and Paraskevopoulos K, 2019a. Scientific Opinion on the assessment of genetically modified maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-134). EFSA Journal 2019;17(8):5774, 36 pp. https://doi.org/10.2903/j.efsa.2019.577

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Álvarez F, Ardizzone M, De Sanctis G, Fernandez Dumont A, Gennaro A, Gómez Ruiz JÁ, Lanzoni A, Neri FM, Paraskevopoulos K and Raffaello T, 2019b. Scientific Opinion on the assessment of genetically modified maize MON87427 x MON 89034 x MIR162 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-131). EFSA Journal 2019;17(7):5734, 33 pp. https://doi.org/10.2903/j.efsa.2019.5734

Abbreviations

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

Appendix A – List of relevant publications identified by the applicant through the systematic literature search (January 2008 – June 2018)

Reference
Castillo-Lopez E, Clark KJ, Paz HA, Ramirez HAR, Klusmeyer TH, Hartnell GF and Kononoff PJ, 2014. Performance of dairy cows fed silage and grain produced from second-generation insect-protected (*Bacillus thuringiensis*) corn (MON 89034), compared with parental line corn or reference corn. Journal of Dairy Sciences, 97, 3832–3837.
Curran KL, Festa AR, Goddard SC, George GH and Taylor ML, 2015. Kernel compositions of glyphosate-tolerant and corn rootworm-protected MON 88017 sweet corn and insect-protected MON 89034 sweet corn are equivalent to that of conventional sweet corn *(Zea mays)*. Agricultural and Food Chemistry, 63, 3046–3052.
Drury SM, Reynolds TL, Ridley WP, Bogdanova N, Riordan S, Nemeth MA, Sorbet R, Trujillo WA and Breeze ML, 2008. Composition of forage and grain from second generation insect-protected corn MON 89034 is equivalent to that of conventional corn (*Zea mays* L.). Journal of Agricultural and Food Chemistry, 56, 4623–4630.
Gampala SS, Fast BJ, Richey KA, Gao Z, Hill R, Wulfkuhle B, Shan G, Bradfisch GA and Herman RA, 2017. Single-event transgene product levels predict levels in genetically modified breeding stacks. Journal of Agricultural and Food Chemistry, 65, 7885–7892.
Venkatesh TV, Cook K, Liu B, Perez T and Willse A, 2014. Compositional differences between near-isogenic GM and conventional maize hybrids are associated with backcrossing practices in conventional breeding. Plant Biotechnology Journal, 1–11.