



HAL
open science

Assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005)

Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda de Schrijver, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Ebbesen Nielsen, et al.

► To cite this version:

Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda de Schrijver, Mikolaj Antoni Gralak, et al.. Assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005). EFSA Journal, 2017, 15 (10), 10.2903/j.efsa.2017.5006 . hal-01741288

HAL Id: hal-01741288

<https://hal.science/hal-01741288>

Submitted on 22 Mar 2018

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution - NoDerivatives 4.0 International License

ADOPTED: 21 September 2017

doi: 10.2903/j.efsa.2017.5006

Assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005)

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 and
Nikoletta Papadopoulou

Abstract

Following the submission of application EFSA-GMO-RX-005 under Regulation (EC) No 1829/2003 from Syngenta Crop Protection NV/SA, 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 of the herbicide-tolerant genetically modified maize GA21. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatics 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 GA21 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-005 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize GA21.

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: maize, GA21, renewal, articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2016-00714

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.

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 and Papadopoulou N, 2017. Scientific opinion on the assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005). *EFSA Journal* 2017;15(10):5006, 11 pp. <https://doi.org/10.2903/j.efsa.2017.5006>

ISSN: 1831-4732

© 2017 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](https://creativecommons.org/licenses/by-nd/4.0/) 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-005 under Regulation (EC) No 1829/2003¹ from Syngenta Crop Protection NV/SA, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific opinion on the data submitted in the context of the renewal of authorisation application of the herbicide-tolerant genetically modified (GM) maize GA21. The scope of the renewal application EFSA-GMO-RX-005 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-005, 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-005 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics 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 event in maize GA21 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-005 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize GA21.

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.....	3
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 environmental 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 provided to EFSA.....	8
References.....	9
Abbreviations.....	9
Appendix A – List of relevant studies identified by the applicant in the systematic literature search.....	10
Appendix B – 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 GA21.....	11

1. Introduction

1.1. Background

On 10 November 2016, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) the application EFSA-GMO-RX-005 by Syngenta Crop Protection NV/SA for the renewal of authorisation of genetically modified (GM) maize GA21 (maize MON-ØØØ21-9) for food and feed uses, import and processing within the framework of Regulation (EC) No 1829/2003. Before sending the application to EFSA, the European Commission (DG SANTE) 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 the application EFSA-GMO-RX-005, 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 7 April 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 August 2017) to make their opinion known.

Following the submission of applications EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21 and the publication of the EFSA scientific opinion (EFSA, 2007), the placing on the market of maize GA21 for food/feed uses, except cultivation, was authorised by Commission Decision 2008/280/EC³. A copy of this authorisation was provided by the applicant.⁴

EFSA requested additional information on 30 June 2017, and the applicant submitted it on 6 July 2017.

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 maize GA21 for food and feed uses, import and processing 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 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 Available online: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2016-00714>

³ Commission Decision of 28 March 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21(MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. (2008/280/EC); OJ L 87, pp 19–22.

⁴ Dossier: Part II – Section 2.1.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-005 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. The applicant clarified that the maize GA21 sequence considered in the context of this renewal application is the sequence originally submitted (EFSA, 2007), corrected for sequencing errors consisting of one-base pair addition, a three-base pair deletion and a difference in the number of complete mepsps cassettes present within the insert which were already assessed by the GMO Panel (EFSA GMO Panel, 2015a).

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, 2015b), the GMO Panel evaluated the data provided in the context of this maize GA21 renewal application under the assumption that the event sequence is identical to the corrected sequence of the event (EFSA GMO Panel, 2015a).

2.1.1. Post-market monitoring reports⁵

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 authorising 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 GA21, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of maize GA21 (EFSA, 2007), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from March 2008 to July 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 GA21; (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.

The applicant provided an overall assessment of the general surveillance activities in the renewal dossier.

2.1.2. Systematic search and evaluation of literature⁶

As part of the annual PMEM reports, nine separate literature searches were provided covering a reporting period from March 2008 till July 2016. Search terms and databases were not consistently used throughout the reports. Therefore, the applicant performed a systematic search of studies published between 1 June 2005 and 30 June 2016, relevant to the food/feed and environmental safety assessments of event maize GA21 and mutated 5-enol-pyruvyl-shikimate-3-phosphate-synthase (mEPSPS) protein, covering the authorisation period, and following the principles outlined in the EFSA guidance on the application of systematic review methodology for food and feed safety assessment (EFSA, 2010).

The applicant searched several general and subject-specific databases to identify relevant studies. The search was limited to primary research peer-reviewed studies that were published in English. Altogether 859 studies were retrieved. After applying the eligibility/inclusion criteria defined a priori by the applicant, 16 relevant primary research studies were identified. Ten studies were identified by the applicant as relevant for the food and feed risk assessment and six for the ERA risk assessment (Appendix A).

2.1.3. Updated bioinformatic data⁷

At the time of submission of the renewal dossier, the applicant provided a bioinformatics package for maize GA21 including an analysis of the insert and flanking sequences and an analysis of the

⁵ Dossier: Part II – Section 2.2 and Appendices 2.2-01 to 2.2-09.

⁶ Dossier: Part II – Section 2.3.1 and Appendix 2.3.1-01.

⁷ Dossier: Part II – Section 2.3.2 and Appendices 2.3.2-01 to 2.3.2-10.

potential similarity to allergens or toxins of the newly expressed proteins and of all possible open reading frames (ORFs) within the insert and spanning the junction sites. The bioinformatics package was based on the original sequence corrected for sequencing errors (EFSA GMO Panel, 2015a). The bioinformatics package also included an analysis of possible horizontal gene transfer (HGT).

2.1.4. Additional documents or studies provided by the applicant⁸

In line with the renewal guidance requirements (EFSA GMO Panel, 2015b), the applicant provided an overview on the worldwide approvals of maize GA21 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 European Union (EU) (Appendix B).

The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed by the applicant. The GMO Panel requested to the applicant on 30 June 2017 the full study reports of five of these studies considered potentially relevant for safety assessment. The applicant submitted the requested information on 6 July 2017.

2.1.5. Overall assessment as provided by the applicant⁹

In line with the requirements listed in the renewal guidance (EFSA GMO Panel, 2015b), the applicant provided an overall assessment concluding that information provided in the application for renewal of the authorisation of maize GA21 for food and feed use and processing in the EU, do not change the outcome of the original risk assessment (EFSA, 2007).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation¹⁰

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 GA21 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, 2015b).

The comments raised by Member States are addressed in Annex G of EFSA's overall opinion¹¹ and were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market environmental monitoring reports

During the general surveillance activities covering the authorisation period of maize GA21, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the 16 published studies listed in Appendix A and considered that none of them gave rise to any safety concern for human and animal health and the environment which would change the original risk assessment conclusions on maize GA21 (EFSA, 2007).

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatics analyses on the corrected GA21 event sequence confirmed previous assessments (EFSA, 2007; EFSA GMO Panel, 2010a,b, 2011, 2015a) that no known endogenous genes were disrupted by the insert. Analyses of the amino acid sequence of the newly

⁸ Dossier: Part II – Section 2.3.1, Appendix 2.3.1-01 and additional information: 6/7/2017.

⁹ Dossier: Part II – Section 3.

¹⁰ Dossier: Part II – Section 4.

¹¹ Available online: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00675>

expressed mEPSPS protein revealed no significant similarities to toxins and allergens. In addition, bioinformatics 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 sequence identity analysis of the regions of bacterial origin in maize GA21 did not identify elements with sufficient length and identity to support homologous recombination (EFSA GMO Panel, 2015a). There is no information that would change the previous conclusion of the GMO Panel that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from maize GA21 to bacteria does 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 the full study reports of the additional studies provided and listed in Appendix B. This new information did not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on maize GA21.

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

The GMO Panel evaluated the overall assessment provided by the applicant and confirmed that there is no evidence in the renewal application RX-005 indicating new hazards, relevant changes in exposure or scientific uncertainties.

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

The PMEM plan followed by the applicant consists mainly of general surveillance of imported GM maize plant material, including maize GA21. 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 this 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 GA21 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 GA21 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-005 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize GA21 (EFSA, 2007; EFSA GMO Panel, 2010a,b, 2011, 2015a).

Documentation provided to EFSA

- 1) Letter from the European Commission to EFSA received on 10 November 2016 for the continued marketing of genetically modified maize GA 21 in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Syngenta Crop Protection NV/SA (EFSA-GMO-RX-005).
- 2) Acknowledgement letter dated 16 November 2016 from EFSA to European Commission.
- 3) Letter from EFSA to applicant dated 22 December 2016 requesting additional information under completeness check.
- 4) Letter from applicant to EFSA received on 17 March 2017 providing additional information under completeness check.
- 5) Letter from EFSA to applicant dated 7 April 2017 delivering the 'Statement of Validity' for application EFSA-GMO-RX-005.
- 6) Letter from EFSA to applicant dated 30 June 2017 requesting additional information and stopping the clock.
- 7) Letter from applicant to EFSA received on 6 July 2017 providing additional information.
- 8) Email from EFSA to applicant dated 7 July 2017 re-starting the clock on 6 July 2017.

References

- EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) for the placing on the market of glyphosate-tolerant genetically modified maize GA21, for food and feed uses, import and processing and for renewal of the authorisation of maize GA21 as existing product, both under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG. EFSA Journal 2007;5(10):541, 25 pp. <https://doi.org/10.2903/j.efsa.2007.541>
- 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), 2010a. Scientific Opinion on application (EFSA-GMO-UK-2007-48) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MIR604 × GA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds. EFSA Journal 2010;8(5):1611, 30 pp. <https://doi.org/10.2903/j.efsa.2010.1611>. Available online: www.efsa.europa.eu/en/scdocs/doc/1611.pdf
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2010b. Scientific Opinion on application (Reference EFSA-GMO-UK-2008-56) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize Bt11 × MIR604 × GA21 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds. EFSA Journal 2010;8(5):1616, 30 pp. <https://doi.org/10.2903/j.efsa.2010.1616>. Available online: www.efsa.europa.eu/en/scdocs/doc/1616.pdf
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2011. Scientific Opinion on application (EFSA-GMO-UK-2008-60) for placing on the market of genetically modified herbicide tolerant maize GA21 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003 from Syngenta Seeds. EFSA Journal 2011;9(12):2480, 94 pp. <https://doi.org/10.2903/j.efsa.2011.2480>
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015a. Statement on the risk assessment of new sequencing data on GM maize event GA21. EFSA Journal 2015;13(11):4296, 6 pp. <https://doi.org/10.2903/j.efsa.2015.4296>
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015b. 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>

Abbreviations

ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organisms
HGT	horizontal gene transfer
mEPSPS	mutated 5-enol-pyruvyl-shikimate-3-phosphate-synthase
ORFs	open reading frames
PMEM	post-market environmental monitoring report

Appendix A – List of relevant studies identified by the applicant in the systematic literature search

References	Area of relevance
Batista R, Nunes B, Carmo M, Cardoso C, José HS, de Almeida AB, Manique A, Bento L, Ricardo CP and Oliveira MM, 2005. Lack of detectable allergenicity of transgenic maize and soya samples. <i>The Journal of Allergy and Clinical Immunology</i> , 116, 403–410.	Food and feed risk assessment
Delaney B, Astwood JD, Cunny H, Conn RE, Herouet-Guicheney C, MacIntosh S, Meyer LS, Privalle L, Gao Y, Mattsson J and Levine M, 2008. Evaluation of protein safety in the context of agricultural biotechnology. <i>Food and Chemical Toxicology</i> , 46, S71–S97.	
Fard NA, Minucmehr Z and Mousavi A, 2013. Allergenicity study of genetically modified herbicide resistant crops (bioinformatics assessment). <i>Bulletin of Environment, Pharmacology and Life Sciences</i> , 2, 24–32.	
Green BJ, Cummings KJ, Rittenour WR, Hettick JM, Bledsoe TA, Blachere FM, Siegel PD, Gaughan DM, Kullman GJ, Kreiss K, Cox-Ganser J and Beezhold DH, 2011. Occupational sensitization to soy allergens in workers at a processing facility. <i>Clinical and Experimental Allergy Journal of the British Society for Allergy and Clinical Immunology</i> , 41, 1022–1030, https://doi.org/10.1111/j.1365-2222.2011.03756.x	
Herouet-Guicheney C, Rouqué D, Freyssinet M, Currier T, Martone A, Zhou J, Bates EE, Ferullo JM, Hendrickx K and Rouan D, 2009. Safety evaluation of the double mutant 5-enol pyruvylshikimate-3-phosphate synthase (2mEPSPS) from maize that confers tolerance to glyphosate herbicide in transgenic plants. <i>Regulatory Toxicology and Pharmacology</i> , 54, 143–153.	
Hoff M, Son DY, Gubesch M, Ahn K, Lee SI, Vieths S, Goodman RE, BallmerWeber BK and Bannon GA, 2007. Serum testing of genetically modified soybeans with special emphasis on potential allergenicity of the heterologous protein CP4 EPSPS. <i>Molecular Nutrition and Food Research</i> , 51, 946–955.	
Kim SH, Kim HM, Ye YM, Kim SH, Nahm DH, Park HS, Ryu SR and Lee BO, 2006a. Evaluating the allergic risk of genetically modified soybean. <i>Yonsei Medical Journal</i> , 47, 505–512.	
Kim JH, Lieu HY, Kim TW, Kim DO, Shon DH, Ahn KM, Lee SI and Kim HY, 2006b. Assessment of the potential allergenicity of genetically modified soybeans and soy-based products. <i>Food Science Biotechnology</i> , 15, 954–958.	
Kramer C, Brune P, McDonald J, Nesbitt M, Sauve A and Storck-Weyhermueller S, 2016. Evolution of risk assessment strategies for food and feed uses of stacked GM events. <i>Plant Biotechnology Journal</i> , 14, 1899–1913, https://doi.org/10.1111/pbi.12551	
Takagi K, Teshima R, Nakajima O, Okunuki H and Sawada JI, 2006. Improved ELISA method for screening human antigen-specific IgE and its application for monitoring specific IgE for novel proteins in genetically modified foods. <i>Regulatory Toxicology and Pharmacology</i> , 44, 182–188.	
Wang W, Xia H, Yang Z, Xu T, Si HJ, Cai XX, Wang F, Su J, Snow AA and Lu BR, 2014. A novel 5-enolpyruvylshikimate-3-phosphate (EPSP) synthase transgene for glyphosate resistance stimulates growth and fecundity in weedy rice (<i>Oryza sativa</i>) without herbicide. <i>The New Phytologist</i> , 202, 679–688.	ERA risk assessment
Zonetti P da C, Suzuki LS, Bonini EA, Ferrarese M de LL and Ferrarese-Filho O, 2011. Growth and root lignification of susceptible and glyphosate-resistant soybean. <i>Acta Scientiarum Agronomy</i> , 33, 291–295.	
Gulden RH, Lerat S, Hart MM, Powell JR, Trevors JT, Pauls KP, Klironomos JN and Swanton CJ, 2005. Quantitation of transgenic plant DNA in leachate water: realtime polymerase chain reaction analysis. <i>The Journal of Agricultural and Food Chemistry</i> , 27;53, 5858–5865.	
Han SM, Oh TK, Uddin MR, Shinogi Y, Lee B, Kim CG and Park KW, 2015. Monitoring the occurrence of genetically modified maize in Korea: A 3-year observations. <i>Journal of the Faculty of Agriculture Kyushu University</i> , 60, 285–290.	
Hart MM, Powell JR, Gulden RH, Levy-Booth DJ, Dunfield KE, Pauls KP, Swanton CJ, Klironomos JN and Trevors JT, 2009. Detection of transgenic cp4 epsps genes in the soil food web. <i>Agronomy for Sustainable Development</i> , 29, 497–501.	
ILSI Research Foundation, 2011. A review of the environmental safety of the CP4 EPSPS protein. <i>Environmental Biosafety Research</i> , 10, 5–25.	

Appendix B – 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 GA21

Study identification	Title
Report No: SSB-201-09 ^(a)	Agronomic assessment of maize event GA21 expressing a double mutated maize 5-enol pyruvylshikimate-3- phosphate synthase (mEPSPS) under South African growing conditions
Report No: SSB-200-09 A1 ^(a)	Analysis of the transgenic DNA insertion site in the genome of event GA21 maize
Report No: SSB-152-07 A1 ^(a)	Chromosomal location of the transgenic locus in event GA21 maize
Report No: SSB-172-13 A1 ^(a)	GA21 maize -Southern Blot analysis of NP2673, NP2660, and NP904 generations
Report No: TK0179518 ^(a)	<i>In vitro</i> digestibility of double mutated maize 5- enolpyruvylshikimat e-3-phosphate synthase (mEPSPS) protein under simulated mammalian intestinal conditions
Report No: TK0178932	Effect of pH on the enzymatic activity of double mutated maize 5-enolpyruvylshikimat e-3-phosphate synthase protein
Report No: TK0167134	GA21 - identity confirmation of individual plants of material identification 11GD002605 - assessment
Report No: SSB-021-07	Effect of temperature on the immunoreactivity of the double-mutated maize 5- enolpyruvylshikimat e-3-phosphate synthase (mEPSPS) enzyme
Report No: TK0058213 A1	Re-characterization of microbially produced test substance containing 5- enolpyruvylshikimat e-3-phosphate synthase (mEPSPS) protein and certificate of analysis - amendment 1

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