SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 1 September 2022

doi: 10.2903/j.efsa.2022.7562

Assessment of genetically modified maize MIR162 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-025)

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Abstract

Following the submission of application EFSA-GMO-RX-025 under Regulation (EC) No 1829/2003 from Syngenta Crop Protection NV/SA, 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 genetically modified maize MIR162, 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. The GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-025 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MIR162.

Keywords: maize, MIR162, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission

Question number: EFSA-Q-2021-00122

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Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The Panel wishes to thank the members of its standing Working Groups on Molecular Characterization, Food/Feed and Environmental Risk Assessment for the preparatory work on this scientific opinion, and the EFSA staff members Michele Ardizzone, Giuseppe Emanuele Condorelli, Antonio Fernandez Dumont and Pietro Piffanelli for the support provided to this scientific opinion.

Suggested citation: EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ, Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Camargo AM, Goumperis T, Kagkli DM, Lenzi P, Lewandowska A, Raffaello T and Streissl F, 2022. Scientific Opinion on the assessment of genetically modified maize MIR162 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-025). EFSA Journal 2022;20(9):7562, 13 pp. https://doi.org/10.2903/j.efsa.2022.7562

ISSN: 1831-4732

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

Summary

Following the submission of application EFSA-GMO-RX-025 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 for the insect-resistant genetically modified maize MIR162. The scope of the renewal application EFSA-GMO-RX-025 is for the renewal of the placing on the market of products containing, consisting of, or produced from maize MIR162, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-025, 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-025 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, additional studies performed by or on behalf of the applicant and updated bioinformatics analyses. 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.

The GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-025 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MIR162 (EFSA, 2012).

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1. Introduction

1.1. Background

On 26 February 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-025 for the renewal of the authorisation of maize MIR162 (Unique Identifier SYN-IR162-4), submitted by Syngenta Crop Protection NV/SA (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003[1].

Following receipt of application EFSA-GMO-RX-025, EFSA informed the Member States (MS) and made the summary of the application available to the public on the EFSA website.[2]

EFSA checked the application for compliance with the relevant requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013[3] and, when needed, asked the applicant to supplement the initial application. On 16 July 2021, EFSA declared the application valid and made the valid application available to the MS and the EC.

Following the submission of application EFSA-GMO-DE-2010-82 and the publication of the EFSA scientific opinion (EFSA, 2012), the placing on the market of maize MIR162 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/651/EU[4] and Commission Implementing Decision (EU) 2019/60 amending Decision 2009/866/EC, Decision 2010/419/EU, Implementing Decision 2012/651/EU and Implementing Decision (EU) 2016/1685[5]. Copies of these authorisations were 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-025. 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 EC (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 3 months to make their opinion known on application EFSA-GMO-RX-025 as of the 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 MIR162 for the renewal of authorization for placing on the market of products containing, consisting of, or produced from GM maize MIR162 in the context of its scope as defined in application EFSA-GMO-RX-025.

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 MIR162, 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.

[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, pp. 1–23.
[2] Available online: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00122
[3] 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 L 157, 8.6.2013, pp. 1–48.
[4] Commission Implementing Decision of 18 October 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 290/14, 20.10.2012.
[5] Commission Implementing Decision (EU) 2019/60 of 11 January 2019 amending Decision 2009/866/EC, Decision 2010/419/EU, Implementing Decision 2012/651/EU and Implementing Decision (EU) 2016/1685 as regards the representative of the authorisation holder. Official Journal of the European Union L 12/31, 15.1.2019.
[6] Dossier: Maize MIR162 – Annex I.
[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, pp. 1–38.
[8] Opinions of the nominated risk assessment bodies of EU Member States can be found at the Open EFSA Portal https://open.efsa.europa.eu/questions, querying the assigned Question Number.

The relevant information is made available in the Open EFSA portal,[9] including the information required under Annex II to the Cartagena Protocol, a labelling proposal, a post-market environmental monitoring (PMEM) plan as provided by the applicant; the method(s), validated by the Community reference 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-025 submitted according to EFSA requirements (EFSA GMO Panel, 2015; EFSA, 2019a) and provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the frame of the contracts OC/EFSA/GMO/2020/01 and OC/EFSA/GMO/2018/04, contractors performed preparatory work and delivered reports on the methods applied by the applicant in performing sequencing and literature search, respectively.

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 PMEM plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from maize MIR162, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize MIR162 (EFSA, 2012), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from October 2012 to June 2021. 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 managed by EuropaBio[11] for the collection of information recorded by various operators (federations involved in maize grains import, storage and processing) on any observed adverse effect(s) on human health and the environment arising from handling of maize possibly containing maize MIR162; (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[12]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed two systematic literature searches covering the period from January 2010 until February 2022, in accordance with the recommendations on literature search outlined in EFSA (2010, 2019b).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 3,411 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, 50 peer-reviewed and non-peer-reviewed publications were identified as relevant for food and feed safety assessment or molecular characterisation. The relevant publications are listed 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 data set for maize MIR162 event including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed protein and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of the newly expressed proteins VIP3Aa20 and PMI regarding their capacity to trigger celiac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

[9] Available online: https://open.efsa.europa.eu/questions/EFSA-Q-2021-00122
[10] Dossier: Maize MIR162 – Annex II; additional information: 28/4/2022.
[11] The responsibilities of EuropaBio in coordinating activities of technology providers on the post-market environmental monitoring of GM crops were taken over by CropLife Europe as of 1 January 2021.
[12] Dossier: Maize MIR162 – Annex III; additional information: 28/4/2022.
[13] Dossier: Maize MIR162 – Annex III; additional information: 11/10/2021, 28/4/2022, 19/7/2022.

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

In line with the renewal guidance requirements (EFSA GMO Panel, 2015; EFSA, 2019a), the applicant provided an overview on the worldwide approvals of maize MIR162 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 (Appendix B).

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

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 MIR162 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA, 2012).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[16]

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 MIR162 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 Member States were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market monitoring reports

During the general surveillance activities covering the authorisation period of maize MIR162, 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 MIR162 and the newly expressed proteins VIP3Aa20 and PMI. The overall quality of the performed literature searches is acceptable.

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 MIR162 (EFSA, 2012) have been identified by the applicant.

3.3. Evaluation of the updated bioinformatic data

The results of the updated bioinformatic analyses to assess the interruption of maize endogenous genes confirm previous results indicating that no endogenous genes have been interrupted by event MIR162 (EFSA, 2012; EFSA GMO Panel, 2019, 2021).

Analyses of the amino acid sequence of the newly expressed proteins VIP3Aa20 and PMI reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. The updated bioinformatic analyses of the newly created ORFs within the insert do not indicate sequence similarities to toxins or allergens in maize MIR162. In addition, the updated bioinformatic analysis of the newly created ORFs spanning the junctions with genomic DNA confirms previous results which did not indicate sequence similarities to toxins or allergens in maize MIR162 (EFSA, 2012; EFSA GMO Panel, 2019, 2021).

[14] Dossier: Maize MIR162 – Annex III; additional information: 11/10/2021, 28/4/2022.
[15] Dossier: Maize MIR162 – Annex III.
[16] Dossier: Maize MIR162 – Part III – Summary.

The updated bioinformatic analyses for event MIR162 did not reveal any DNA sequence that could provide sufficient length and identity which could facilitate horizontal gene transfer (HGT) by double homologous recombination, confirming previous conclusions (EFSA, 2012; EFSA GMO Panel, 2019, 2021). Given the results of this analysis and that the recombinant DNA in maize MIR162 does not confer selective advantages 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

The GMO Panel evaluated the full study reports of the additional studies provided, including a new sequencing study (Appendix B). The sequencing data are compliant with the requirements laid down in the EFSA Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants (EFSA GMO Panel, 2018). The study reports a nucleotide difference in the sequence of the event in recent plant material (year of collection 2018), compared to the sequence of the event in the originally assessed application (EFSA, 2012). The difference is located in a cytosine homopolymer region in the second of the two ZmUbiInt promoters contained in the MIR162 insert (bp 6,770–6,782). The location of the difference suggests that it is due to the technical difficulties with sequencing the homopolymer regions. Bioinformatic analyses identified no risks for human and animal safety related to the nucleotide difference.

Overall, the new additional documents or studies provided by the applicant do not raise any concern for human and animal health and the environment, which would change the original risk assessment conclusions on maize MIR162.

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-025 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize MIR162.

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 MIR162. This general surveillance is coordinated by CropLife Europe 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-025, 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

The GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-025 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MIR162 (EFSA, 2012).

5. Documentation as provided to EFSA

1) Letter from the European Commission to EFSA received on 26 February 2021 for the continued marketing of genetically modified maize MIR162 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Syngenta Crop Protection NV/SA (EFSA-GMO-RX-025).
2) Application EFSA-GMO-RX-025 validated by EFSA, 16 July 2021.
3) Request for supplementary information to the applicant, 11 August 2021.
4) Receipt of supplementary information from the applicant, 10 November 2021.
5) Request for supplementary information to the applicant, 2 February 2022.
6) Receipt of supplementary information from the applicant, 28 April 2022.
7) Request for supplementary information to the applicant, 20 May 2022.
8) Receipt of supplementary information from the applicant, 19 July 2022.

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Abbreviations

GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
HGT	horizontal gene transfer
ORFs	open reading frames
PMEM	post-market environmental monitoring
PMI	phosphomannose isomerase
VIP3Aa20	vegetative insecticidal protein (vip3Aa variant)

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2010–February 2022)

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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 and feed for humans, animal or the environment from maize MIR162

Study identification	Title
TK0060148	Metabolic Profiling of Sugars and Sugar Phosphates in Grain Derived from MIR162 Maize
JY150240-1	Report of oral acute toxicity study of PMI protein
TK0107154	Characterisation of Vegetative Insecticidal Protein (Vip3Aa20) Test Substance and Certificate of Analysis
TK0235588	Characterisation of Microbially Produced Test Substance PMI-0114 Containing Phosphomannose Isomerase (PMI) Protein and Certificate of Analysis
TK0285529	In vitro Digestibility of Phosphomannose Isomerase (PMI) Protein Under Simulated Mammalian Gastric Conditions for China
TK0329350	Effect of Temperature on the Stability of Phosphomannose Isomerase (PMI) Protein
WIL-639227; TK0256516	A Single-Dose Oral Gavage Toxicity Study of PMI-0114 in CD-1 Mice with a 14-Day Recovery Period
TK0428575	Event MIR162: Insert and Flanking Sequence Analysis of Event MIR162 in Material ID 12MG000996
TK0537123	Storage Stability Assessment of Microbially Produced Test Substance VIP3A20–0111 Containing Vip3Aa20 Protein