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SCIENTIFIC OPINION

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Assessment of genetically modified maize MON 810 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2022-9450)

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Abstract

Following the submission of dossier GMFF-2022-9450 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV, 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 protected genetically modified maize MON 810, for food and feed uses (including pollen), excluding cultivation within the European Union. The data received in the context of this renewal application contained post-market environmental monitoring reports, an evaluation of the literature retrieved by a scoping review, 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. Under the assumption that the DNA sequence of the event in maize MON 810 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in dossier GMFF-2022-9450 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 810.

KEYWORDS

Articles 11 and 23, maize, MON 810, Regulation (EC) No 1829/2003, renewal

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SUMMARY

Following the submission of dossier GMFF-2022-9450 under Regulation (EC) No 1829/2003 from Bayer Agriculture BV, 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 protected genetically modified maize MON 810. The scope of the renewal dossier GMFF-2022-9450 is for the renewal of the placing on the market of maize MON 810 for food and feed uses (including pollen), excluding cultivation, within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account dossier GMFF-2022-9450, 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 GMFF-2022-9450 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a scoping review, 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. Under the assumption that the DNA sequence of the event in maize MON 810 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in dossier GMFF-2022-9450 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 810 (EFSA GMO Panel, 2009, 2012).

1 | INTRODUCTION

1.1 | Background

On 14 December 2022, the European Food Safety Authority (EFSA) received from the European Commission (EC) dossier GMFF-2022-9450 for the renewal of the authorisation of maize MON 810 (Unique Identifier MON-ØØ81Ø-6), submitted by Bayer Agriculture BV (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[1]

Following receipt of dossier GMFF-2022-9450, EFSA informed the Member States (MS) and made the summary of the application available to the public on the Open EFSA portal.[2]

EFSA checked the dossier 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 complete the initial renewal dossier. On 10 March 2023, EFSA declared the application valid and made the valid application available to the MS and the European Commission (EC).

Following the submission of applications EFSA-GMO-RX-MON810 and EFSA-GMO-NL-2012-107, and the publication of the EFSA scientific opinions (EFSA GMO Panel, 2009, 2012), the placing on the market in EU of maize MON 810 was authorised by Commission Implementing Decision 2017/1207/EU for (i) foods and food ingredients produced from MON 810 maize, with the exception of pollen, (ii) feed containing, consisting of or produced from MON 810, and (iii) MON 810 maize in products containing it or consisting of it for any other use than food or feed, with the exception of cultivation, and by Commission Implementing Decision 2013/649/EU for pollen produced from MON 810 maize, as or in foods and food ingredients.[4] A copy of these authorisations were provided by the applicant.[5]

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 dossier GMFF-2022-9450. This 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 5).

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.[6] The MS had three months to make their opinion known on dossier GMFF-2022-9450 as of date of validity.

1.2 | Terms of Reference as provided by the requestor

EFSA and its GMO Panel were requested to carry out a scientific risk assessment of maize MON 810 for the renewal of authorization, according to Articles 11 and 23 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 including the opinions of the nominated risk assessment bodies of the MS.[7]

In addition to the present scientific opinion on maize MON 810, 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 OpenEFSA portal,[8] 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.

[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.

[2]Available online: https://open.efsa.europa.eu/questions/EFSA-Q-2022-00867

[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 L157, 8.6.2013, p. 1–48.

[4]Commission Implementing Decision 2013/649/EU of 6 November 2013 authorising the placing on the market of pollen produced from genetically modified maize MON 810 (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.
Commission Implementing Decision 2017/1207/EU of 4 July 2017renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

[5]Dossier number: GMFF-2022-9450. Technical dossier - Information to support the risk assessment – The authorisation for the placing of the GM food and/or feed onto the market in the EU.

[6]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.

[7]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.

[8]https://open.efsa.europa.eu/questions/EFSA-Q-2022-00867

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of the dossier GMFF-2022-9450 following the EFSA requirements as detailed in EFSA GMO Panel (2015) and EFSA, (2021).

In accordance with Art. 38 of the Regulation (EC) No 178/2002 and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, the non-confidential version of the dossier has been published on OpenEFSA.[9] According to Art. 32c (2) of Regulation (EC) No 178/2002[10] and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[11] EFSA carried out a public consultation on the non-confidential version of the dossier from 19 July to 9 August 2023 for which no comments were received.

The GMO Panel based its scientific assessment of maize MON 810 on the valid dossier GMFF-2022-9450, additional information provided by the applicant during the risk assessment, scientific comments submitted by EU MS and peer-reviewed scientific publications.

In the frame of the contracts OC/EFSA/GMO/2021/06 and OC/EFSA/GMO/2018/04, the contractor performed preparatory work and delivered reports on the methods applied by the applicant in performing updated bioinformatic analyses and literature search, respectively.

2.1.1 | Post-market monitoring and post-market environmental monitoring reports[12]

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 MON 810, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize MON 810 (EFSA GMO Panel, 2009, 2012), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided five annual PMEM reports covering a reporting period from July 2016 until 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 established by EuropaBio[13] for the collection of information recorded by various operators (federations involved in maize import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of maize possibly containing maize MON 810; (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[14]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed scoping reviews covering the period from January 2012 until July 2022, in accordance with the recommendations on literature search outlined in EFSA (2010, 2019).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 1784 publications (including the updated search) were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, 80 publications were identified as relevant for food and feed safety assessment. The relevant publications are listed in Appendix A.

[9] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00867

[10] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[11] Decision available at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

[12] Dossier number: GMFF-2022-9450. Technical dossier – Information to support the risk assessment – Post-market monitoring and post-market environmental monitoring reports; additional information: 26 July 2023. PMEM plan was requested only in Commission Implementing Decision 2017/1207/EU authorising food and feed produced from maize MON 810 [Annex, point (h)]. PMEM plan was not requested in Commission Implementing Decision 2013/649/EU authorising pollen produced from maize MON 810 [Annex, point (h)].

[13] 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.

[14] Dossier number: GMFF-2022-9450. Technical dossier – Information to support the risk assessment – New information-Systematic search and evaluation of the literature; additional information: 26/7/2023.

2.1.3 | Updated bioinformatic[15]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for maize MON 810 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 (EFSA, 2017) and a safety assessment of the newly expressed protein Cry1Ab regarding their capacity to trigger celiac disease (EFSA GMO Panel, 2017). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4 | Additional documents or studies performed by or on behalf of the applicant[16]

In line with the renewal guidance requirements (EFSA, 2021; EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize MON 810 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.

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[17]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize MON 810 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2009, 2012).

2.1.6 | Monitoring plan and proposal for improving the conditions of the original authorisation[18]

The applicant indicated in the dossier that the post-market environmental 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 810 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 opinions 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 and post-market environmental monitoring reports

During the general surveillance activities covering the authorisation period of maize MON 810, no adverse effects were reported by the applicant. Therefore, no further evaluation is needed by the GMO Panel.

3.2 | Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on maize MON 810 and the newly expressed protein Cry1Ab. The overall quality of the performed literature searches is acceptable.

[15]Dossier number: GMFF-2022-9450. Technical dossier – Information to support the risk assessment – New information-Updated bioinformatics; additional information: 26/7/2023, 20/9/2023.

[16]Dossier number: GMFF-2022-9450. Technical dossier – Information to support the risk assessment – New information-Additional documents or studies performed by or on behalf of the applicant.

[17]Dossier number: GMFF-2022-9450. Technical dossier – Information to support the risk assessment – New information-Overall assessment.

[18]Dossier number: GMFF-2022-9450. Technical dossier – Information to support the risk assessment – Post-market environmental monitoring plan.

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 Cry1Ab proteins (EFSA GMO Panel, 2009, 2012) have been identified by the applicant.

3.3 | Evaluation of the updated bioinformatic analyses

The results of the updated bioinformatic analyses to assess the interruption of maize endogenous genes confirmed previous results indicating that a possible genomic deletion or rearrangement happened at the insertion site, and a predicted maize E3 ubiquitin ligase gene was interrupted by event MON 810 (EFSA GMO Panel, 2009, 2012, 2021a, 2021b, 2022).

The analyses of the amino acid sequence of the newly expressed Cry1Ab protein reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. Moreover, the updated bioinformatic analyses of the newly created ORFs within the insert and spanning the junctions between the insert and the flanking regions confirmed previous results indicating that the expression of any ORF showing significant similarities to toxins or allergens in maize MON 810 is unlikely (EFSA GMO Panel, 2009, 2012, 2021a, 2021b, 2022).

The updated bioinformatic analysis for event MON 810 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 GMO Panel, 2021a, 2021b, 2022). Given the results of this analysis and that the recombinant DNA in maize MON 810 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 performed by or on behalf of 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 maize MON 810 was authorised.

3.5 | Evaluation of the overall assessment

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal dossier GMFF-2022-9450 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize MON 810.

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

The PMEM plan[19] covers general surveillance of imported GM plant material, including maize MON 810. This general surveillance is coordinated by 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 dossier GMFF-2022-9450, 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 810 considered for renewal is identical to the sequence of the originally assessed event, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2022-9450 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 810 (EFSA GMO Panel, 2009, 2012).

[19]PMEM plan was requested only in Commission Implementing Decision 2017/1207/EU authorizing food and feed produced from maize MON 810 [Annex, point (h)]. PMEM plan was not requested in Commission Implementing Decision 2013/649/EU authorizing pollen produced from maize MON 810 [Annex, point (h)].

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Letter from the European Commission to EFSA received on 14 December 2022 for the continued marketing of genetically modified maize MON 810 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture BV (GMFF-2022-9450).
- The application was made valid on 10 March 2023.
- Additional Information (Clock 1) was requested on 4 May 2023.
- Additional Information (Clock 1) was received on 26 July 2023.
- Additional Information (Clock 2) was requested on 11 September 2023.
- Additional Information (Clock 2) was received on 20 September 2023.
- Spontaneous information was received on 16 November 2023.

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

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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 Michele Ardizzone, Antonio Fernandez and Aleksandra Lewandowska for the support provided to this scientific opinion.

CONFLICT 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.

REQUESTOR

European Commission (DG SANTE)

QUESTION NUMBER

EFSA-Q-2022-00867

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EFSA (European Food Safety Authority), Devos, Y., Guajardo, I. M., Álvarez, F., & Glanville, J. (2019). 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 - note on literature searching to GMO risk assessment guidance. *EFSA Journal*, EN-1614. https://doi.org/10.2903/sp.efsa.2019.EN-1614

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EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2012). Scientific opinion on an application (EFSA-GMO-NL-2012-107) for the placing on the market of maize MON 810 pollen under regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal*, *10*(12), 3022. https://doi.org/10.2903/j.efsa.2012.3022

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

List of relevant publications identified by the applicant through literature searches (January 2012–July 2022)

Abdo, E. M., Barbary, O. M., & Shaltout, O. E.-S. (2014). Feeding study with *Bt* corn (MON810: Ajeeb YG) on rats: Biochemical analysis and liver histopathology. Food and Nutrition Sciences, 2014.

Agapito-Tenfen, S. Z., Guerra, M. P., Wikmark, O.-G., & Nodari, R. O. (2013). Comparative proteomic analysis of genetically modified maize grown under different agroecosystems conditions in Brazil. Proteome Science, 11, 1–15.

Al-Harbi, A., Lary, S., Edwards, M. G., Qusti, S., Cockburn, A., Poulsen, M., & Gatehouse, A. M. (2019). A proteomic-based approach to study underlying molecular responses of the small intestine of Wistar rats to genetically modified corn (MON810). Transgenic Research, 28, 479–498.

Al-Hmoud, N., Al-Husseini, N., Ibrahim-Alobaide, M. A., Kübler, E., Farfoura, M., Alobydi, H., & Al-Rousan, H. (2014). Unconventional P-35S sequence identified in genetically modified maize. GM Crops & Food, 5, 58–64.

Andreassen, M., Bøhn, T., Wikmark, O.-G., Bodin, J., Traavik, T., Løvik, M., & Nygaard, U. C. (2016). Investigations of immunogenic, allergenic and adjuvant properties of Cry1Ab protein after intragastric exposure in a food allergy model in mice. BMC Immunology, 17, 1–12.

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