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SCIENTIFIC OPINION

Assessment of genetically modified maize NK603 for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2023-21250)

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

Following the submission of dossier GMFF-2023-21250 under Regulation (EC) No 1829/2003 from Bayer CropScience LP, 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 herbicide-tolerant genetically modified maize NK603, for food and feed uses, 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, a search for 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 NK603 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 GMFF-2023-21250 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize NK603.

KEYWORDS

Articles 11 and 23, maize, NK603, Regulation (EC) No 1829/2003, renewal

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SUMMARY

Following the submission of dossier GMFF-2023-21250 under Regulation (EC) No 1829/2003 from Bayer Crop Science LP, 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 herbicide-tolerant genetically modified maize NK603. The scope of the renewal application GMFF-2023-21250 is for the renewal of the placing on the market of maize NK603 for food and feed uses, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account dossier GMFF-2023-21250, 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 dossier GMFF-2023-21250 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a scoping review, a search for 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 NK603 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-2023-21250 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize NK603 (EFSA GMO Panel, 2009).

1 | INTRODUCTION

1.1 | Background

On 12 March 2024, the European Food Safety Authority (EFSA) received from the European Commission (EC) dossier GMFF-2023-21250 for the renewal of the authorisation of maize NK603 (Unique Identifier MON-ØØ6Ø3–6), submitted by Bayer Crop Science LP (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003.[1]

Following receipt of dossier GMFF-2023-21250, 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 supplement the initial application. On 14 June 2024, 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-NL-2005-22 and EFSA-GMO-RX-NK603 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2009), the placing on the market of maize NK603 was authorised by Commission Implementing Decision 2015/684 for (a) foods and food ingredients containing, consisting of, or produced from these GM maize lines, (b) feed containing, consisting of, or produced from these GM maize lines, and c) these GM maize lines in products containing them or consisting of them for any other use than (a) and (b), with the exception of cultivation.[4] A copy of this authorisation was 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 six months to issue a scientific opinion on dossier GMFF-2023-21250. 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-2023-21250 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 NK603 for the renewal of authorisation, 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 NK603, 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.

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of the dossier GMFF-2023-21250 following the EFSA requirements as detailed in EFSA GMO Panel (2015) and EFSA (2021).

[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-2024-00166.

[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 (EU) 2015/684 of 24 April 2015 authorising the placing on the market of genetically modified maize NK603 (MON-ØØ6Ø3–6) and renewing the existing maize NK603 (MON-ØØ6Ø3–6) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2015) 2753).

[5]Dossier: maize NK603 – Technical dossier – Information to support the risk assessment – The authorization for the placing of the GM food and/or feed onto the market in 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-2024-00166.

In accordance with Art. 38 of the Regulation (EC) No 178/2002[9] 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.[10] According to Art. 32c(2) of Regulation (EC) No 178/2002[11] and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations,[12] EFSA carried out a public consultation on the non-confidential version of the dossier from 6 December 2024 to 27 December 2024 for which no comments were received.

The GMO Panel based its scientific assessment of maize NK603 on the valid dossier GMFF-2023-21250, 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 contract OC/EFSA/MESE/2022/03-01-SC17, the contractor performed preparatory work and delivered report on the method applied by the applicant in performing literature search.

2.1.1 | Post-market monitoring and post-market environmental monitoring reports[13]

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 NK603, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize NK603 (EFSA GMO Panel, 2009), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from July 2014 to June 2023. 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[14] 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 NK603; (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[15]

In addition to the separate searches provided as part of the annual PMEM reports, the applicant performed scoping reviews covering the period from January 2014 to September 2024, 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. After applying the eligibility/inclusion criteria defined a priori by the applicant, 23 publications were identified as relevant for food and feed safety assessment. The relevant publications are listed in Appendix A.

2.1.3 | Updated bioinformatics analyses[16]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatics dataset for maize NK603 including an analysis of the insert and flanking sequences, an analysis of the potential similarity to allergens and toxins of the newly expressed proteins and of all possible open reading frames (ORFs) within the insert and spanning the junction sites, an analysis of possible horizontal gene transfer (EFSA, 2017), and a safety assessment of the newly expressed proteins CP4 EPSPS and CP4 EPSPS L214P, regarding their potential capacity to trigger celiac disease symptoms (EFSA GMO Panel, 2017a). The outcome of the updated bioinformatics analyses is presented in Section 3.3.

[9]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.

[10]https://open.efsa.europa.eu/questions/EFSA-Q-2024-00166.

[11]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.

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

[13]Dossier number: GMFF-2023-21250. Technical dossier – Information to support the risk assessment – Post-market monitoring and post-market environmental monitoring reports.

[14]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.

[15]Dossier number: GMFF-2023-21250. Technical dossier – Information to support the risk assessment – New information-Systematic search and evaluation of the literature; additional information: 31/10/2024, 3/2/2025, 21/2/2025.

[16]Dossier number: GMFF-2023-21250. Technical dossier – Information to support the risk assessment – New information- Updated bioinformatics; additional information: 31/10/2024, 3/2/2025, 21/2/2025, 25/4/2025.

2.1.4 | Additional documents or studies performed by or on behalf of the applicant[17]

In line with the renewal guidance requirements (EFSA, 2021; EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize NK603 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[18]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize NK603 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2009).

2.1.6 | Monitoring plan and proposal for improving the conditions of the original authorisation[19]

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 NK603 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

The GMO Panel assessed the nine PMEM reports submitted by the applicant. During the general surveillance activities covering the authorisation period of maize NK603, no adverse effects were reported by the applicant. This was confirmed by the evaluation of the results of the annual literature searches and the annual communications by the operators collating reports of adverse effects from their member organisations and companies. No safety concerns were identified 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 NK603 and the newly expressed proteins CP4 EPSPS and CP4 EPSPS L214P. The overall quality of the performed literature searches is acceptable.

The GMO Panel reviewed the publications identified as relevant by the applicant. No new information raising safety concerns for human and animal health and the environment which would change the original risk assessment conclusions on maize NK603 was identified (EFSA GMO Panel, 2009).

3.3 | Evaluation of the updated bioinformatics analyses

The results of the updated bioinformatics analyses to assess the interruption of maize endogenous genes confirm previous results indicating that no endogenous genes were interrupted (EFSA GMO Panel, 2009, 2021a, 2022a, 2022b).

[17]Dossier number: GMFF-2023-21250. Technical dossier – Information to support the risk assessment – New information-Additional documents or studies performed by or on behalf of the applicant; additional information: 21/2/2025.

[18]Dossier number: GMFF-2023-21250. Technical dossier – Information to support the risk assessment – New information- Overall assessment.

[19]Dossier number: GMFF-2023-21250. Technical dossier – Information to support the risk assessment – Post-market environmental monitoring plan.

The updated analyses of the amino acid sequence of the newly expressed CP4 EPSPS and CP4 EPSPS L412P proteins confirm no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. Moreover, the updated bioinformatics analyses of the newly created ORFs within the insert and spanning the junctions between the insert and genomic DNA confirm previous results which indicate that the production of a new peptide showing significant similarities to toxins or allergens for event NK603 is highly unlikely (EFSA GMO Panel, 2009, 2021a, 2022a, 2022b).

The updated bioinformatics analyses for events NK603 reveal one element of bacterial origin with sufficient length and sequence identity to facilitate homologous recombination with native bacterial genes. However, no pairs of sequences which would facilitate transfer of inserts by double homologous recombination were identified. These results confirm previous conclusions that there is no indication for facilitated double homologous recombination from NK603 (EFSA GMO Panel, 2017b, 2021b). Given the results of this analysis and that the recombinant DNA in maize NK603 does not confer selective advantages to microorganisms, the GMO Panel identified no safety concern linked to an unlikely but theoretically possible horizontal gene transfer (HGT).

3.4 | Evaluation of the additional documents or studies provided 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, the applicant declared that there were no unpublished studies produced, controlled or sponsored by the applicant or provided to the applicant by a third party and not previously submitted to the EU since maize NK603 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-2023-21250 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize NK603.

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 NK603. 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 dossier GMFF-2023-21250 but reminds that 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 NK603 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-2023-21250 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize NK603 (EFSA GMO Panel, 2009).

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Letter from the European Commission to EFSA received on 12 March 2024 for the continued marketing of genetically modified maize NK603 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer CropScience LP (GMFF-2023-21250).
- The application was made valid on 14 June 2024.
- Additional Information (Clock 1) was requested on 2 August 2024.
- Additional Information (Clock 1) was received on 31 October 2024.
- Additional Information (Clock 2) was requested on 4 December 2024.
- Additional Information (Clock 2) was received on 3 February 2025.
- Additional Information (Clock 3) was requested on 5 February 2025.
- Additional Information (Clock 3) was received on 21 February 2025.
- Additional Information (Clock 4) was requested on 10 April 2025.
- Additional Information (Clock 4) was received on 25 April 2025.

ABBREVIATIONS

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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REQUESTOR

European Commission (DG SANTE)

QUESTION NUMBER

EFSA-Q-2024-00166

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and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-150). *EFSA Journal*, *20*(3), 7134. https://doi.org/10.2903/j.efsa.2022.7134

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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 2014 to September 2024)

Abbas, H. K., Bellaloui, N., & Bruns, H. A. (2016). Investigating transgenic corn hybrids as a method for mycotoxin control. *Food and Nutrition Sciences*, *7*, 44–54.

Agapito-Tenfen, S. Z., Vilperte, V., Benevenuto, R. F., Rover, C. M., Traavik, T. I., & Nodari, R. O. (2014). Effect of stacking insecticidal cry and herbicide tolerance epsps transgenes on transgenic maize proteome. *BMC Plant Biology*, *14*, 346.

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