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SCIENTIFIC OPINION

Assessment of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations for renewal authorisation under Regulation (EC) No 1829/2003 (dossier GMFF-2022-9170)

EFSA Panel on Genetically Modified Organisms (GMO) | Ewen Mullins | Jean-Louis Bresson | Tamas Dalmay | Ian Crawford Dewhurst | Michelle M. Epstein | Leslie George Firbank | Philippe Guerche | Jan Hejatko | Francisco Javier Moreno | Hanspeter Naegeli | Fabien Nogué | Nils Rostoks | Jose Juan Sánchez Serrano | Giovanni Savoini | Eve Veromann | Fabio Veronesi | Ana M. Camargo | Tilemachos Goumperis | Paolo Lenzi | Pietro Piffanelli | Tommaso Raffaello

Correspondence: nif@efsa.europa.eu

Abstract

Following the joint submission of dossier GMFF-2022-9170 under Regulation (EC) No 1829/2003 from Bayer Agriculture B.V. and Corteva Agriscience Belgium B.V., 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 and insect resistant genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations, 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 sequences of the events in maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2022-9170 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations.

KEYWORDS

Articles 11 and 23, maize, MON 89034 × 1507 × MON 88017 × 59122, Regulation (EC) No 1829/2003, renewal

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SUMMARY

Following the joint submission of dossier GMFF-2022-9170 under Regulation (EC) No 1829/2003 from Bayer Agriculture B.V. and Corteva Agriscience Belgium B.V., 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 and insect-resistant genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations. The scope of the renewal dossier GMFF-2022-9170 is for the renewal of the placing on the market of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations 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-2022-9170, 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-2022-9170 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 sequences of the events in maize MON 89034 × 1507 × MON 88017 × 59122 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2022-9170 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations (EFSA GMO Panel, 2010, 2011).

1 | INTRODUCTION

1.1 | Background

On 5 December 2022, the European Food Safety Authority (EFSA) received from the European Commission dossier GMFF-2022-9170 for the renewal of the authorisation of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations (Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7–1 × MON-88Ø17-3 × DAS-59122-7), jointly submitted by Bayer Agriculture B.V. and Corteva Agriscience Belgium B.V. (hereafter referred to as 'the applicants') according to Regulation (EC) No 1829/2003.[1]

Following receipt of dossier GMFF-2022-9170, 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 13 April 2023, EFSA declared the application valid and made the valid application available to the MS and the EC.

Following the submission of application EFSA-GMO-CZ-2008-62 and the publication of the EFSA scientific opinion (EFSA GMO Panel, 2010, 2011), the placing on the market of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations 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), excluding cultivation in the EU, was authorised by Commission Implementing Decision 2013/650/EU.[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 6 months to issue a scientific opinion on dossier GMFF-2022-9170. 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 European Commission (for further details, see 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 3 months to make their opinion known on dossier GMFF-2022-9170 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 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations 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 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations, 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]https://open.efsa.europa.eu/questions/EFSA-Q-2022-00845

[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 of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59,122 (MON-89Ø34-3 × DAS-Ø15Ø7–1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89Ø34-3 × DAS-Ø15Ø7–1 × MON88Ø17–3), MON89034 × 1507 × 59,122 (MON-89Ø34-3 × DAS-Ø15Ø7–1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-Ø15Ø7–1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89Ø34-3 × DASØ15Ø7–1), MON89034 × 59,122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DASØ15Ø7–1 × MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

[5]Dossier number: GMFF-2022-9170. 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-2022-00845

2 | DATA AND METHODOLOGIES

2.1 | Data

The applicant has submitted a confidential and a non-confidential version of the dossier GMFF-2022-9170 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 28 July to 18 August 2023 for which no comments were received.

The GMO Panel based its scientific assessment of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations on the valid dossier GMFF-2022-9170, 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 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 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations (EFSA GMO Panel, 2010, 2011), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided eight annual PMEM reports covering a reporting period from November 2013 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 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 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations; (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 to January 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. Altogether 3338 publications (including the updated search) were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, three peer-reviewed and two non-peer reviewed 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-2022-00845

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

[12] Dossier number: GMFF-2022-9170. Technical dossier - Information to support the risk assessment – Post-market monitoring and post-market environmental monitoring reports; additional information: 7/8/2023, 13/10/2023.

[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 1st January 2021.

[14] Dossier number: GMFF-2022-9170. Technical dossier – Information to support the risk assessment – New information-Systematic search and evaluation of the literature; additional information: 7/8/2023, 5/2/2024.

2.1.3 | Updated bioinformatic data[15]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for maize MON 89034 × 1507 × MON 88017 × 59122 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 PAT, CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 regarding their capacity to trigger coeliac 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 provided by 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 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations, 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 as provided by the applicant[17]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA GMO Panel, 2010).

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 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations 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 reports

During the general surveillance activities covering the authorisation period of maize MON 89034 × 1507 × MON 88017 × 59,122 and 8 out of 10 of its subcombinations, no adverse effects were reported by the applicant. Therefore, no further evaluation is needed by the GMO Panel.

[15]Dossier number: GMFF-2022-9170. Technical dossier – Information to support the risk assessment – New information-Updated bioinformatics; additional information: 7/8/2023, 12/12/2023; spontaneous information: 5/2/2024.

[16]Dossier number: GMFF-2022-9170. Technical dossier – Information to support the risk assessment – New information-Additional documents or studies performed by or on behalf of the applicant; additional information: 7/8/2023.

[17]Dossier number: GMFF-2022-9170. Technical dossier – Information to support the risk assessment – New information-Overall assessment.

[18]Dossier number: GMFF-2022-9170. Technical dossier – Information to support the risk assessment – Post-market environmental monitoring plan.

3.2 | Evaluation of the systematic search and evaluation of literature

The GMO Panel assessed the applicant's literature searches on maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations and the newly expressed proteins PAT, CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1. 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 PAT, CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins (EFSA GMO Panel, 2010) have been identified by the applicant.

3.3 | Evaluation of the updated bioinformatic analyses

The updated bioinformatic analyses to assess the interruption of maize endogenous genes confirm previous results indicating the partial deletion of a putative maize purine permease 11 for event MON 88017 (EFSA GMO Panel, 2010, 2021a), a possible interruption of a predicted pentatricopeptide repeat-containing (PPR-containing) protein by event MON 59122 (EFSA GMO Panel, 2013) and no predicted endogenous genes interruption by events MON 89034, 1507 and 59122 (EFSA GMO Panel, 2010, 2019, 2021a, 2021b, 2022a, 2022b).

The analyses of the amino acid sequence of the newly expressed PAT, CP4 EPSPS, Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. Moreover, updated bioinformatic analyses of the newly created open reading frames (ORFs) within the insert or spanning the junctions between the insert and genomic DNA indicate that the expression of any ORF showing significant similarities to toxins or allergens is unlikely in maize MON 89034 × 1507 × MON 88017 × 59122 confirming previous assessment (EFSA GMO Panel, 2010, 2019, 2021a, 2021b, 2022a, 2022b).

The updated bioinformatic analysis for events MON 89034, 1507, MON 88017 and 59122 confirm the assessments provided in the context of previous Scientific Opinions (EFSA GMO Panel, 2010, 2019, 2021a, 2021b, 2022a, 2022b). Given the results of this analysis and that the recombinant DNA in maize MON 89034 × 1507 × MON 88017 × 59122 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

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 or on behalf of the applicant and not previously submitted to the EU since maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations were authorised.

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

The GMO Panel evaluated the overall assessment provided by the applicant and confirms that there is no evidence in renewal dossier GMFF-2022-9170 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations.

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

The PMEM plan covers general surveillance of imported GM plant material, including maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations. 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-2022-9170, 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 sequences of the events in maize MON 89034 × 1507 × MON 88017 × 59122 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal dossier GMFF-2022-9170 for new hazards, modified exposure or scientific uncertainties that would

change the conclusions of the original risk assessment on maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations (EFSA GMO Panel, 2010, 2011).

5 | DOCUMENTATION AS PROVIDED TO EFSA

- Letter from the European Commission to EFSA received on 5 December 2022 for the continued marketing of genetically modified maize MON 89034 × 1507 × MON 88017 × 59,122 and part of its subcombinations submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture B.V. and Corteva Agriscience Belgium B.V. (dossier GMFF-2022-9170).
- The application was made valid on 13 April 2023.
- Additional Information (Clock 1) was requested on 25 May 2023.
- Additional Information (Clock 1) was received on 7 August 2023.
- Additional Information (Clock 2) was requested on 22 August 2023.
- Additional Information (Clock 2) was received on 13 October 2023.
- Additional Information (Clock 3) was requested on 13 October 2023.
- Additional Information (Clock 3) was received on 12 December 2023.
- Additional Information (Clock 4) was requested on 19 December 2023.
- Additional Information (Clock 4) was received on 5 February 2024.
- Spontaneous information was received on 5 February 2024.

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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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

QUESTION NUMBER

EFSA-Q-2022-00845

PANEL MEMBERS

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

REFERENCES

EFSA (European Food Safety Authority). (2010). Application of systematic review methodology to food and feed safety assessments to support decision making. *EFSA Journal*, *8*(6), 1637. https://doi.org/10.2903/j.efsa.2010.1637

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

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

EFSA (European Food Safety Authority). (2021). Administrative guidance for the preparation of renewal applications on genetically modified food and feed. *EFSA Supporting Publication*, EN-6474. https://doi.org/10.2903/sp.efsa.2021.EN-6474

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2010). Scientific opinion on application (EFSA-GMO-CZ-2008-62) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 and all sub-combinations of the individual events as present in its segregating progeny, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Dow AgroSciences and Monsanto. *EFSA Journal*, *8*, 1781. https://doi.org/10.2903/j.efsa.2010.1781

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2011). Statement complementing the EFSA GMO Panel scientific opinion on maize MON 89034 × 1507 × MON 88017 × 59122 (application EFSA-GMO-CZ-2008-62), to cover all sub-combinations independently of their origin. *EFSA Journal*, *9*(10), 2399. https://doi.org/10.2903/j.efsa.2011.2399

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2013). Scientific opinion on an application from Pioneer Hi-Bred International and Dow AgroSciences LLC (EFSA-GMO-NL-2005-23) for placing on the market of genetically modified maize 59122 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003. *EFSA Journal*, *11*(3), 3135. https://doi.org/10.2903/j.efsa.2013.3135

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). (2015). Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. *EFSA Journal*, *13*(6), 4129. https://doi.org/10.2903/j.efsa.2015.4129

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Birch, A. N., Casacuberta, J., De Schrijver, A., Gralak, M. A., Guerche, P., Jones, H., Manachini, B., Messean, A., Nielsen, E. E., Nogué, F., Robaglia, C., Rostoks, N., Sweet, J., Tebbe, C., Visioli, F., Wal, J.-M., Eigenmann, P., … Fernandez Dumont, A. (2017). Guidance on allergenicity assessment of genetically modified plants. *EFSA Journal*, *15*(5), 4862. https://doi.org/10.2903/j.efsa.2017.4862

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Mullins, E., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., Fernandez Dumont, A., … Ramon, M. (2019). Scientific opinion on the assessment of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2013-113). *EFSA Journal*, *17*(1), 5521. https://doi.org/10.2903/j.efsa.2019.5521

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Mullins, E., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Álvarez, F., Ardizzone, M., & Raffaello, T. (2021a). Scientific opinion on the assessment of genetically modified maize MON 88017 × MON 810 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-017). *EFSA Journal*, *19*(1), 6375. https://doi.org/10.2903/j.efsa.2021.6375

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Mullins, E., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Alvarez, F., Ardizzone, M., … Raffaello, T. (2021b). Scientific opinion on the assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-139). *EFSA Journal*, *19*(1), 6351. https://doi.org/10.2903/j.efsa.2021.6351

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Jan Hejatko, J., Naegeli, H., Moreno, H. J., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., De Sanctis, G., … Streissl, F. (2022a). Scientific opinion on the assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSAGMO-NL-2018-151). *EFSA Journal*, *20*(8), 7451. https://doi.org/10.2903/j.efsa.2022.7451

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Ardizzone, M., Martin Camargo, A., … Streissl, F. (2022b). Scientific opinion on the assessment of genetically modified maize DP4114 × MON 89034 × MON 87411 × DAS-40278-9 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-171). *EFSA Journal*, *20*(11), 7619. https://doi.org/10.2903/j.efsa.2022.7619

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 to January 2024)

References
Herman, R. A., Fast, B. J., Scherer, P. N., Brune, A. M., de Cerqueira, D. T., Schafer, B. W., Ekmay, R. D., Harrigan, G. G., & Bradfisch, G. A. (2017). Stacking transgenic event DAS-Ø15Ø7-1 alters maize composition less than traditional breeding. Plant Biotechnology Journal, 15, 1264–1272.
Comisión Nacional Asesora de Biotecnología Agropecuaria. (2022). *RESOL-2019-59-APN-SAYBI#MPYT*.
Leaf, T., & Ostlie, K. R. (2017). Nitrogen rate effects on Cry3Bb1 and Cry3Bb1+ Cry34/35Ab1 expression in transgenic corn roots, resulting root injury, and corn rootworm beetle emergence. *Journal of Economic Entomology*, *110*, 1243–1251.
Lundry, D. R., Burns, J. A., Nemeth, M. A., & Riordan, S. G. (2013). Composition of grain and forage from insect-protected and herbicide-tolerant corn, MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax), is equivalent to that of conventional corn (*Zea mays L.*). *Journal of Agricultural and Food Chemistry*, *61*, 1991–1998.
National Technical Commission on Biosafety. (2022). *Liberação comercial de Milho resistente a insetos e tolerante ao glifosato e glufosinto de amônio, evento MON89034 × MON88017 × TC1507 × DAS-59122-7*. https://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo