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Assessment of genetically modified maize MON 88017 × MON 810 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-017)

EFSA Panel on Genetically Modified Organisms (GMO),
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Abstract

Following the submission of application EFSA-GMO-RX-017 under Regulation (EC) No 1829/2003 from Bayer Agriculture BVBA 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 and herbicide-tolerant genetically modified maize MON 88017 × MON 810, 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, a systematic search and evaluation of literature, and updated bioinformatic analysis. 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 88017 × MON 810 considered for renewal are identical to the sequence of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal application EFSA-GMO-RX-017 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810.

Keywords: Maize, MON 88017 × MON 810, renewal, Articles 11 and 23, Regulation (EC) No 1829/2003

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Summary

Following the submission of application EFSA-GMO-RX-017 under Regulation (EC) No 1829/2003 from Bayer Agriculture BVBA, 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 and herbicide tolerant genetically modified maize MON 88017 × MON 810. The scope of the renewal application EFSA-GMO-RX-017 is for the renewal of the placing on the market of products containing, consisting of, or produced from maize MON 88017 × MON 810, excluding cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-017, 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-017 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search 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 88017 × MON 810 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in the renewal application EFSA-GMO-RX-017 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810 (EFSA, 2009a).

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1. Introduction

1.1. Background

On 21 June 2019, the European Food Safety Authority (EFSA) received from the European Commission (EC) application EFSA-GMO-RX-017 for the renewal of the authorisation of maize MON 88017 × MON 810 (Unique Identifier MON-88Ø17-3 × MON-ØØ81Ø–6), submitted by Bayer Agriculture BVBA (hereafter referred to as 'the applicant') according to Regulation (EC) No 1829/2003[1].

Following receipt of application EFSA-GMO-RX-017, 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 24 October 2019, EFSA declared the application valid and made the valid application available to the MS and the European Commission.

Following the submission of application EFSA-GMO-CZ-2006-33 and the publication of the EFSA scientific opinion (EFSA, 2009a), the placing on the market of maize MON 88017 × MON 810 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the European Union (EU), was authorised by Commission Decision 2010/429/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 six months to issue a scientific opinion on application EFSA-GMO-RX-017. 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 European Commission (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[6]. The MS had 3 months to make their opinion known on application EFSA-GMO-RX-017 as of 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 MON 88017 × MON 810 for the renewal of authorisation for placing on the market of products containing, consisting of, or produced from GM maize MON 88017 × MON 810 in the context of its scope as defined in application EFSA-GMO-RX-017.

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 88017 × 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 EFSA Register of Questions,[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,

[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: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2019-00524
[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 Decision of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 × MON 810 (MON-88Ø17-3 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union L 201/46, 3.8.2010.
[5] Dossier: Maize MON 88017 × MON 810 – Annex 1.
[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 EFSA Register of Questions,
[8] http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2019-00524

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-017 provided by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

In the context of this renewal application, no new sequencing study was submitted among the additional documents or studies performed by or on behalf of the applicant. In accordance with the GMO Panel guidelines for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015), the GMO Panel evaluated the data provided in the context of this maize MON 88017 × MON 810 renewal application under the assumption that the MON 88017 and MON 810 event sequences are identical to the sequences of the originally assessed event (EFSA, 2009a).

2.1.1. Post–market monitoring reports[9]

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 88017 × MON 810, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment of maize MON 88017 × MON 810 (EFSA, 2009a), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided nine annual PMEM reports covering a reporting period from July 2010 until June 2019. 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 for the collection of information recorded by various operators (federations involved in maize grains import and processing) on any observed adverse effect(s) on human health and the environment arising from handling of maize possibly containing maize MON 88017 × 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[10]

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 2009 till September 2020, in accordance with the recommendations on literature search outlined in EFSA (2010, 2017a).

Searches in electronic bibliographic databases and in websites of relevant organisations were performed to identify relevant publications. Altogether 3,162 publications were identified (after removal of duplicates). After applying the eligibility/inclusion criteria defined a priori by the applicant, three publications were identified as relevant for food and feed safety assessment or molecular characterisation. The list of relevant publications is provided in Appendix A.

2.1.3. Updated bioinformatic data[11]

At the time of submission of the renewal dossier, the applicant provided a complete bioinformatic dataset for maize MON 88017 and MON 810 events 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, 2017b), and a safety assessment of the newly expressed proteins Cry3Bb1, Cry1Ab and CP4 EPSPS regarding their capacity to trigger celiac

[9] Dossier: Maize MON 88017 × MON 810 – Annex 2; additional information: 21/1/2020.
[10] Dossier: Maize MON 88017 × MON 810 – Annex 3.1; additional information: 11/11/2019, 26/2/2020 and 20/11/2020.
[11] Dossier: Maize MON 88017 × MON 810 – Annex 3.2; additional information: 26/2/2020, 29/5/2020 and 10/7/2020.

disease (EFSA GMO Panel, 2017a). The outcome of the updated bioinformatic analyses is presented in Section 3.3.

2.1.4. Additional documents or studies provided by the applicant[12]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize MON 88017 × 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.

2.1.5. Overall assessment as provided by the applicant[13]

The applicant provided an overall assessment concluding that information provided in the application for renewal of authorisation of maize MON 88017 × MON 810 for food and feed uses in the EU does not change the outcome of the original risk assessment (EFSA, 2009a).

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[13]

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 MON 88017 × 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 comments raised by the nominated risk assessment bodies of EU Member States were taken into consideration during the scientific risk assessment.

In the context of the contract OC/EFSA/GMO/2018/04, a contractor performed preparatory work and delivered reports on the systematic literature searches performed by the applicant.

3. Assessment

3.1. Evaluation of the post–market monitoring reports

During the general surveillance activities covering the authorisation period of maize MON 88017 × MON 810, 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 MON 88017 × MON 810 and the newly expressed proteins Cry3Bb1, Cry1Ab and CP4 EPSPS. The overall quality of the performed literature searches is acceptable; however, the GMO Panel considers that future searches could be fine-tuned. The GMO Panel therefore recommends the applicant for future searches to:

- ensure that enough search term variation is used (covering possible synonyms, related terms, acronyms, spelling variants, old and new terminology, brand and generic names, lay and scientific terminology, common typos, translation issues);
- adapt the search to the size of the retrieved publications (and thus not combine search sets when one of the search sets already yields only a small number of publications).

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 MON 88017 × MON 810 (EFSA, 2009a) have been identified by the applicant.

[12] Dossier: Maize MON 88017 × MON 810 – Annex 3.3.
[13] Dossier: Maize MON 88017 × MON 810 – Annex 4.

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 the partial deletion of a putative maize purine permease 11 (MON 88017) (EFSA GMO Panel, 2020) and a putative maize E3 ubiquitin ligase (MON 810) (EFSA, 2009b). The analysis on gene interruption provided by the applicant using the MON 810 revealed that the sequences flanking the insert correspond to sequences that in the maize reference genome are located 12.5 million bases apart on chromosome 5. As these could suggest a deletion or rearrangement of this region, EFSA requested the applicant to provide additional information to investigate this further and analyse the safety consequences of the potential genomic deletion or rearrangement. The additional information provided by the applicant, including published proteomic and transcriptomic analyses of MON 810, showed no significant differences in the expression of most of the genes located in this region compared to non-GM maize comparators, suggesting that they are present and normally expressed in MON 810.

Analyses of the amino acid sequence of the newly expressed Cry3Bb1, Cry1Ab and CP4 EPSPS proteins reveal no significant similarities to toxins, allergens or immunogenic gluten-related epitopes. In addition, bioinformatic analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA confirm the previous conclusions indicating that the expression of ORFs showing significant similarities to toxins or allergens in maize MON 88017 × MON 810 is highly unlikely (EFSA, 2009b,c; EFSA GMO Panel, 2019, 2020).

The updated bioinformatic analysis for events MON 88017 and 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, 2009b; EFSA GMO Panel, 2017b, 2019, 2020). Given the results of this analysis and that the recombinant DNA in maize MON 88017 × 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 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 the applicant and not previously submitted to the EU since MON 88017 × MON 810 was 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 application EFSA-GMO-RX-017 indicating new hazards, relevant changes in exposure or scientific uncertainties that would change previous conclusions on maize MON 88017 × MON 810.

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 88017 × MON 810. This general surveillance is coordinated by EuropaBio 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-017, 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 88017 × 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 application EFSA-GMO-RX-017 for new hazards,

modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MON 88017 × MON 810 (EFSA, 2009a).

5. Documentation as provided to EFSA

1) Letter from the European Commission to EFSA received on 21 June 2019 for the continued marketing of genetically modified maize MON 88017 × MON 810 submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Bayer Agriculture BVBA (EFSA-GMO-RX-017).
2) Application EFSA-GMO-RX-017 validated by EFSA, 24 October 2019.
3) Request for supplementary information to the applicant, 07 February 2020.
4) Receipt of supplementary information from the applicant, 26 February 2020.
5) Request for supplementary information to the applicant, 10 March 2020.
6) Receipt of supplementary information from the applicant, 29 May 2020.
7) Request for supplementary information to the applicant, 4 June 2020.
8) Receipt of supplementary information from the applicant, 10 July 2020.
9) Request for supplementary information to the applicant, 8 September 2020.
10) Receipt of supplementary information from the applicant, 20 November 2020.

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EFSA (European Food Safety Authority), 2009b. Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-CZ-2005-27) for the placing on the market of the insect-resistant and herbicide-tolerant genetically modified maize MON 88017, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2009;7(5):1075, 28 pp. https://doi.org/10.2903/j.efsa.2009.1075

EFSA (European Food Safety Authority), 2009c. Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMO-RX-MON810) for the renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2009;7(6):1149, 85 pp. https://doi.org/10.2903/j.efsa.2009.1149

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637

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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

Appendix A – List of relevant publications identified by the applicant through systematic literature searches (January 2009–September 2020)

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Ben Ali E, Madi ZE, Hochegger R, Quist D, Prewein B, Haslberger AG and Brandes C, 2014. Mutation scanning in a single and a stacked genetically modified (GM) event by real-time PCR and high resolution melting (HRM) analysis. International Journal of Molecular Sciences, 15, 19898–19923
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