# Assessment of genetically modified maize MON 88017 x MON 810 for renewal authorisation under Regulation (EC) No 1829/2003.

Maes o ddiddordeb ymchwil: Novel and non-traditional foods, additives and processes
Statws y prosiect: Wedi'i gwblhau
Cod prosiect: RP1179
Awduron: Risk Assessment Unit, FSA and Risk Assessment Team FSS.
Cynhaliwyd gan: Food Standards Agency and Food Standards Scotland
Dyddiad cyhoeddi: 11 Hydref 2022

## 1. Executive Summary

The FSA and FSS have undertaken an assessment of application RP1179 for the renewal of authorisation of genetically modified maize MON 88017 x MON 810 for food and feed uses, import and processing.

A GM application has been received by Great Britain (GB) where the European Food Safety Authority (EFSA), prior to the end of the transition period, evaluated an application for the product. FSA and FSS have reviewed the EFSA opinion (footnote 1) and confirmed that it is sufficient for GB risk analysis and therefore was used this to form the basis of the UK opinion.

The FSA and FSS risk assessors conclude that the EFSA opinion is sufficient and relevant for GB risk analysis and therefore genetically modified maize MON 88017 x MON 810, as described in this application, poses no new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment.

## 2. Background and purpose of review

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**Question number: EFSA-Q-2019-00524**

In accordance with Retained EU Regulation 1829/2003 on genetically modified food and feed, the application RP1179 for the renewal of the authorisation of genetically modified maize MON 88017 x MON 810 has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA and FSS have adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.
Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application is now made to GB, FSA and FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its opinion. Therefore, FSA and FSS risk assessors have reviewed the EFSA opinion1 for the application below in the context of intended

GB use and have concluded that the intended uses are safe.

In reviewing the EFSA risk assessment opinion the reviewers have verified that the standard approach as outlined in the relevant guidance has been followed and the arguments made are consistent with the data summarised in the opinion. Consideration has been given to the processes undertaken to ensure the outcome is robust and whether there are any aspects that would require further review such as specific issues for the countries of the UK. The result of the assessment is that the EFSA scientific opinion is sufficient also for GB risk analysis.

# 3. Details of EFSA assessment

## 3.1 Applicant

**Name**: Bayer Agriculture BVBA
**Address**: Haven 627, Scheldelaan 460, B-2040 Antwerp, Belgium

**Name**: Monsanto Company
**Address**: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, USA

## 3.2 Methodology applied in the EFSA opinion

EFSA Genetically Modified Organisms (GMO) Panel guidance: Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003 (2013) and principles in Regulation (EC) No 1829/2003. The EFSA GMO panel were not asked to review the labelling of this GMO or the requirements under the Cartagena protocol and therefore no consideration was given to these points in the assessment.

## 3.3 Source/organism

Maize (Zea mays L.) modified by combining two single maize events

## 3.4 Genetic modification step

- cp4 epsps (aroA:CP4) (from Agrobacterium tumefaciens) to confer glyphosate tolerance.
- cry3Bb1 and cry1Ab (both from Bacillus thuringiensis) to confer coleopteran resistance particularly corn rootworm, and lepidopteran resistance respectively.

## 3.5 Specification

In accordance with Commission Regulation (EC) No 65/2004, the unique identifier for this event is MON-88Ø17-3 x MON-ØØ81Ø–6.

Information provided on the identity, composition and specifications of the plant does not raise safety concerns. In the context of this renewal application, no new sequencing data were provided by the applicant. Updated bioinformatics analyses were therefore performed using the original sequence data provided, on the basis that the MON 88017 and MON 810 event sequences are the same as the sequences of the originally assessed events (The EFSA Journal (2009) 1192, 1-27).

## 3.6 Exposure assessment

Not relevant.

### 3.7 Toxicological data

Updated bioinformatic analyses did not identify any similarities with known toxins or allergens. No new safety concerns were identified from the literature review.

### 3.8 Analytical method review

FSA and FSS accepted the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) report, showing that the detection methods for the genetically modified maize MON 88017 x MON 810 were previously validated, and declared fit for purpose. The previous assessment of the methodology remains appropriate and valid.

### 3.9 Post market environmental monitoring plan

## 4. EFSA assessment and conclusions

There is no evidence in renewal application for new hazards or modified exposure that would change the conclusions of the original risk assessment on maize MON 88017x MON 810 (The EFSA Journal (2009) 1192, 1-27).

No risks to the environment are expected. The application does not raise safety concerns for the environment with regard to the genetic modification of genetically modified maize MON 88017 x MON 810. The post-market environmental monitoring plan is appropriate and does not need any changes.

## 5. Caveats and uncertainties

No caveats and uncertainties were identified

## 6. FSA-FSS conclusion on applicability and reliability of the EFSA opinion for GB risk analysis

The application has been assessed in line with the applicable guidance (footnote 2) and is partially based on considerations of detailed proprietary information available to the Panel, whilst this is only briefly summarised this description is consistent with the conclusions. The conclusions of the opinion have been reviewed by FSA and FSS and are considered appropriate and consistent within the identified caveats and uncertainties identified in the opinion and would be applicable to GB. As such the EFSA opinion forms the basis of this opinion.

## 7. Outcome of assessment

FSA and FSS have reviewed the EFSA opinion and consider it sufficient and relevant for GB risk analysis. Therefore, the opinion was used to form the basis of the UK opinion.

FSA and FSS had access to all supporting documentation that was provided to the EFSA Panel by the applicant, and subsequently used to form the EFSA opinion. FSA and FSS agree with the safety conclusions outlined in the EFSA opinion.

The environmental and human safety of the maize MON 88017 x MON 810 have been well characterised by the applicant under the Annex II to the Cartagena Protocol. The FSA and FSS accept the conclusion that the renewal of maize MON 88017 x MON 810 poses no new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk

assessment.

# 8. References


- Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms
- Scientific Opinion of the Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-CZ-2006-33) for the placing on the market of the insect-resistant and glyphosate-tolerant genetically modified maize MON 88017 × MON 810, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto The EFSA Journal (2009) 1192, 1–27
- EFSA Panel on GMO; Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011; 9( 8):2316. [40 pp.] doi:10.2903/j.efsa.2011.2316
- 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 2015; 13( 6):4129, 8 pp. doi:10.2903/j.efsa.2015.4129
- EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli, H, Bresson, J-L, Dalmay, T, Dewhurst, IC, Epstein, MM, Firbank, LG, Guerche, P, Hejatko, J, Moreno, FJ, Mullins, E, Nogué, F, Rostoks, N, Sánchez Serrano, JJ, Savoini, G, Veromann, E, Veronesi, F, Álvarez, F, Ardizzone, M and Raffaello, T, 2021. 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 2021;19(1):6375, 11 pp. https://doi.org/10.2903/j.efsa.2021.6375


1. EFSA Journal 2021;19(1):6375

2. European Food Safety Authority, 2013. EFSA guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003. EFSA Journal 2013; 11( 12):3491, 133 pp., doi:10.2903/j.efsa.2013.3491