TECHNICAL REPORT

APPROVED: 26 October 2018 PUBLISHED: 14 November 2018

# Overall opinion of the European Food Safety Authority on genetically modified maize MZHG0JG for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2016-133)

European Food Safety Authority

## Summary

In the present report, the European Food Safety Authority (EFSA) issues its overall opinion on application EFSA-GMO-DE-2016-133 for the placing on the market of genetically modified (GM) maize MZHG0JG according to Articles 6 and 18 of Regulation (EC) No 1829/2003.[1]

The scope of application EFSA-GMO-DE-2016-133 is for food and feed uses, import and processing of maize MZHG0JG in the European Union (EU). Alongside with the related scientific opinion of its Scientific Panel on Genetically Modified Organisms (GMO Panel), EFSA reports on the particulars as laid down in Articles 6 and 18 of Regulation (EC) No 1829/2003.

Overall, the European Union Reference Laboratory for Genetically Modified Food and Feed (EURL-GMFF) already validated the detection method of maize MZHG0JG, and declared fit for regulatory purpose. The certified reference materials of maize MZHG0JG can be accessed at the Joint Research Centre of the European Commission, Institute for Reference Materials and Measurements (IRMM) and/or at the American Oil Chemists' Society (AOCS-USA). The GMO Panel is of the opinion that the Post-Market Environmental Monitoring (PMEM) plan proposed by the applicant and reporting intervals are in line with the intended uses of maize MZHG0JG. The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period.

The particulars regarding e.g. labelling proposal, detection, Cartagena protocol fall outside the remit of EFSA.



**Key words:** MAIZE, MZHG0JG, EFSA-GMO-DE-2016-133, Cartagena, labelling, detection, post-market environmental monitoring, Member States comments, Regulation (EC) No 1829/2003

**Requestor:** Competent Authority of Germany

**Question number:** EFSA-Q-2018-00810

**Correspondence:** GMO_secretariat_applications@efsa.europa.eu

[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.

**Acknowledgements:** EFSA wishes to thank the members of the scientific Panel on genetically modified organisms and of its Working Groups on Molecular Characterisation, Food/Feed, and CompERA for the preparatory work on the scientific opinion and EFSA staff for the support provided to the scientific opinion.

**Suggested citation:** EFSA (European Food Safety Authority), 2018. Overall opinion of the European Food Safety Authority on genetically modified maize MZHG0JG for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2016-133). EFSA supporting publication 2018: EN-1511. 8 pp.

# Table of contents

# 1. Introduction

On 27 September 2016, EFSA received from the Competent Authority of Germany an application (reference EFSA-GMO-DE-2016-133), submitted by Syngenta Crop Protection NV/SA under Articles 5 and 17 of Regulation (EC) No 1829/2003[2], to support the placing of genetically modified (GM) maize MZHG0JG on the market in the EU. The unique identifier of maize MZHG0JG is SYN-ØØØJG-2. The scope of application EFSA-GMO-DE-2016-133 is for food and feed uses, import and processing of maize MZHG0JG in the EU.

EFSA first checked the completeness of the application in accordance with the requirements laid down in Articles 5(3) and 17(3) of the above mentioned Regulation. On 1 August 2016, 31 August 2016 and 1 September 2016 EURL–GMFF received samples and control samples in accordance with the same Articles.

According to Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission of the application and made the summary of the application publicly available[3].

At the end of a thorough completeness check, EFSA declared application EFSA-GMO-DE-2016-133 valid on 10 January 2017.

From that date, EFSA has endeavoured to respect a time limit of six months to issue its overall opinion on application EFSA-GMO-DE-2016-133. Such time limit was extended whenever EFSA requested supplementary information to the applicant.

According to Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consults the risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC[4], of all EU Member States on each request for placing on the market of products consisting of or containing GMOs. The Member States were therefore given three months to comment the valid application EFSA-GMO-DE-2016-133 from the date of its receipt.

## 1.1. Terms of Reference

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA is requested to issue an overall opinion on application EFSA-GMO-DE-2016-133 including: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the scientific opinion of the GMO Panel, iv) the information required under Annex II to the Cartagena Protocol, v) the labelling proposal, vi) the method for detection, validated by the EURL-GMFF, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vii) an indication of where appropriate reference materials can be accessed, viii) the post-market environmental monitoring (PMEM) plan and ix) the Member States' comments submitted during the three-month consultation period.

[2] 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.
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2016-00583
[4] 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.

# 2. Considerations

## 2.1. Name and address of the Applicant(s)

Application EFSA-GMO-DE-2016-133 was submitted by

Syngenta Crop Protection NV/SA
Avenue Louise 489
1050 Brussels
Belgium

## 2.2. Designation and specification of the product

Maize MZHG0JG was developed to confer tolerance to glyphosate-containing and glufosinate-ammonium-containing herbicides.

The scope of application EFSA-GMO-DE-2016-133 is for food and feed uses, import and processing of maize MZHG0JG in the EU. The unique identifier is SYN-ØØØJG-2.

## 2.3. Scientific opinion of the GMO Panel

On 17 October 2018, the GMO Panel adopted a scientific opinion on application EFSA-GMO-DE-2016-133 (Annex A). During its safety evaluation, the GMO Panel considered the valid application as submitted by the applicant, any additional data provided by the applicant, the scientific comments submitted by the Member States and the relevant scientific literature.

The molecular characterisation data and bioinformatic analyses do not identify issues requiring food/feed safety assessment. None of the identified differences in the agronomic/phenotypic and compositional characteristics tested between maize MZHG0JG and its conventional counterpart needs further assessment, except for early stand count (pre-thinning). The GMO Panel does not identify safety concerns regarding the toxicity and allergenicity of the mEPSPS and PAT proteins as expressed in maize MZHG0JG, and finds no evidence that the genetic modification would change the overall allergenicity of maize MZHG0JG. The nutritional impact of food/feed derived from maize MZHG0JG is expected to be the same as that of food/feed derived from the conventional counterpart and commercial non-GM maize reference varieties. The GMO Panel concludes that maize MZHG0JG is nutritionally equivalent to and as safe as the conventional counterpart and non-GM maize reference varieties tested, and no post-market monitoring of food/feed is considered necessary. In the case of accidental release of viable maize MZHG0JG grains into the environment, maize MZHG0JG would not raise environmental safety concerns. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of maize MZHG0JG. In conclusion, the GMO Panel considers that maize MZHG0JG, as described in this application, is as safe as its conventional counterpart and the tested non-GM maize reference varieties with respect to potential effects on human and animal health and the environment.

## 2.4. Cartagena Protocol

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol (Annex B).

## 2.5. Labelling

The GMO Panel did not consider the proposal for labelling which is matter related to risk management (Annex C).

## 2.6. Methods for detection

The EURL-GMFF has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify MZHG0JG transformation event in crop DNA. The report

was issued on 29 June 2018. The EURL-GMFF considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2 to Commission Regulation (EC) No 641/2004[5] (Annexes D1, D2, D3).

## 2.7. Certified reference materials

The certified reference materials of maize MZHG0JG can be accessed at the American Oil Chemists' Society (AOCS-USA) (Annex E).

## 2.8. Post-market environmental monitoring (PMEM)

The GMO Panel considers that the scope of the PMEM plan provided by the applicant is consistent with the intended uses of maize MZHG0JG. The GMO Panel agrees with the reporting intervals proposed by the applicant in its PMEM plan (Annex F).

## 2.9. Member States Comments

The GMO Panel has addressed the comments submitted by the Member States during the three-month consultation period (Annex G).

[5]Regulation (EC) No 641/2004 of the Commission on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation. OJ L 102/14, 7.4.2004, p. 1–12.

# 3. Conclusions

According to Articles 6 and 18 of Regulation (EC) No 1829/2003, EFSA issues an overall opinion on application EFSA-GMO-DE-2016-133 for food and feed uses, import and processing of maize MZHG0JG in the EU.

## List of Annexes[6]

| | |
|---|---|
| Annex A: | Scientific opinion of the GMO Panel |
| Annex B: | Cartagena Protocol |
| Annex C: | Labelling proposal |
| Annex D1: | Validation report by EURL-GMFF of the event-specific method for the quantification of maize MZHG0JG |
| Annex D2: | Validated detection method for maize MZHG0JG |
| Annex D3: | Sampling / DNA extraction |
| Annex E: | Certified reference materials (MZHG0JG) |
| Annex F: | Post-market environmental monitoring plan |
| Annex G: | Member States' comments and GMO Panel responses |

[6]The annexes of the EFSA Overall opinion can be found in the Register of Questions (tab "Question documents") on the EFSA website under the following link:
http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00810