



MZHG0JG Maize

Herbicide tolerance

**EU authorisation for food, feed, import and
processing**

Information for Operators

December 2019
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Disclaimer

From Jan 1, 2021, all activities performed by EuropaBio mentioned
in this document will be conducted by CropLife Europe

Introduction

This document summarizes the main characteristics of MZHG0JG maize and the requirements for post-market environmental monitoring of all operators handling viable grain from this product. It also includes references to the relevant detection method and contact points for operators to report on general surveillance activities and on any unanticipated adverse effects.

Characteristics and benefits of MZHG0JG maize

Genetically modified event MZHG0JG maize has been developed by Syngenta to facilitate growers with a means to control weeds by providing tolerance to herbicides with two different modes of action: conferring tolerance to glyphosate and glufosinate-ammonium in herbicide products.

Herbicide tolerance is provided through the expression of the enzyme mEPSPS (double-mutated maize 5-enol pyruvylshikimate-3-phosphate synthase), and PAT (phosphinothricin acetyltransferase) in MZHG0JG maize plants.

- The native EPSPS protein, from *Zea mays*, is involved in the synthesis of aromatic amino acids and is inhibited by glyphosate. The mutated enzyme, mEPSPS, has a low affinity for glyphosate, thus conferring tolerance to glyphosate in herbicide products.
- The PAT protein, derived from the soil bacterium *Streptomyces viridochromogenes*, acetylates glufosinate-ammonium, thus inactivating it and conferring tolerance to glufosinate-ammonium in herbicide products.
 - PAT was also used as a selectable marker in the development of MZHG0JG maize.

The mEPSPS and PAT proteins produced in MZHG0JG maize are identical to the mEPSPS protein produced in the Syngenta event GA21 maize, and the PAT protein produced in the Syngenta event Bt11 maize.

Safety of MZHG0JG maize

The safety of Syngenta's products for humans, animals and the environment is of paramount importance. MZHG0JG maize has been assessed and endorsed by numerous independent scientific committees around the world. These conclusions have been based on a full range of scientific studies, including tests which examined the potential for human and animal health effects of the product, nutritional equivalency, the effects of the introduced genes and proteins, and the potential impacts of the maize on the environment.

EFSA evaluation of MZHG0JG maize for food, feed, import and processing in the EU

On 1 September 2016, the European Food Safety Authority (EFSA) received from the German competent authority an application for authorisation of MZHG0JG maize submitted by Syngenta Crop Protection AG within the framework of Regulation (EC) No 1829/2003 on GM food and feed. On 14 November 2018, the EFSA Panel on Genetically Modified

Organisms (GMO Panel) published its scientific opinion¹ and concluded that MZHG0JG maize 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.

Authorisation in the EU of MZHG0JG maize for food, feed, import and processing

The Commission Implementing Decision of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed is published at:

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2080&from=EN>

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from SYN-ØØØJG-2 maize;
- (b) feed containing, consisting of or produced from SYN-ØØØJG-2 maize;
- (c) products containing or consisting of SYN-ØØØJG-2 maize for uses other than those provided for in points (a) and (b), with the exception of cultivation.

The Decision does not include the need of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

However, the Commission Decision mandates the monitoring for environmental effects in accordance with the environmental monitoring plan for MZHG0JG maize conforming with Annex VII of Directive 2001/18/EC. For more information, please visit the EU Register of authorised GMOs:

https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=96

Conditions for traceability and labelling of MZHG0JG maize for food, feed, import and processing in the EU

The legal obligations relating to traceability and labelling are laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003.

¹EFSA 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, Devos Y, Ardizzone M, Neri FM, Papadopoulou N, De Sanctis G, Dumont AF, Gennaro A, Gomez Ruiz JA and Paraskevopoulos K, 2018. Scientific Opinion on the assessment of 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 Journal 2018;16(11):5469, 26 pp. <https://doi.org/10.2903/j.efsa.2018.5469>

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘maize’.

The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of SYN-ØØØJG-2 maize, with the exception of products referred to in point (a) of Article 2 of the Commission Implementing Decision (foods and food ingredients containing, consisting of or produced from SYN-ØØØJG-2 maize).

The unique identifier assigned to MZHG0JG maize is: SYN-ØØØJG-2.

Post market monitoring of MZHG0JG maize for food, feed, import, and processing in the EU

The Decision does not require post-market monitoring for the use of the food for human consumption.

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 a Post Market Environmental Monitoring Plan for MZHG0JG maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.

The monitoring plan for environmental effects is accessible on the internet at the EU Register of authorised GMOs: [Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC](#)

Methods for detection and reference material

An event-specific real-time quantitative PCR-based method for MZHG0JG maize is validated by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>.

Certified Reference Materials for MZHG0JG maize are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>.

Contact point for Operators

As there are other technology providers for genetically modified maize it is essential to develop an industry wide approach because the shipments entering the European ports may be comingled. EuropaBio, the European Association for Bioindustries, plays an important role in this area and is the central communication point for all GM plant technology providers.

EuropaBio is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio will transfer the messages to the relevant GMO industry partner if further action

is required. Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to EuropaBio at: <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/introduction>.

If required, additional comments or questions relative to MZHGOJG maize can also be addressed at:

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