



MIR162 maize

**EU Authorisation for Food, Feed, Import
and Processing
Information for Operators**

Updated November 2023

Introduction

This document summarizes the main characteristics of MIR162 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 MIR162 maize

MIR162 is a genetically modified (GM) maize that expresses the insecticidal protein Vip3Aa20, used to confer field protection against certain lepidopteran pests. It also expresses a phosphomannose isomerase (PMI) protein which was used as a selectable marker in the development of MIR162 maize.

Safety of MIR162 maize

MIR162 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 MIR162 maize for food, feed, import and processing in the EU

On 21 June 2012, the EFSA Panel on Genetically Modified Organisms (GMO Panel) published its scientific opinion¹ and concluded that MIR162 maize (EFSA-GMO-DE-2010-82) is as safe as its conventional counterpart and the non-genetically modified reference varieties tested, with respect to potential effects on human and animal health and the environment in the context of its intended uses.

On 26 February 2021, the European Food Safety Authority (EFSA) received from the European Commission (EC) an application for the renewal of the authorisation of MIR162 maize submitted by Syngenta Crop Protection NV/SA within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The EFSA Panel on Genetically Modified Organisms (GMO Panel) published its scientific opinion² on 22 September 2022, and concluded that there is no evidence in renewal application EFSA-GMO-RX-025 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MIR162.

¹ EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on application (EFSA-GMO-DE-2010-82) for the placing on the market of insect resistant genetically modified maize MIR162 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta. *EFSA Journal* 2012; 10(6): [27 pp.]. <https://doi.org/10.2903/j.efsa.2012.2756>

² EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E, Bresson, J-L, Dalmay, T, Dewhurst, IC, Epstein, MM, Firbank, LG, Guerche, P, Hejatko, J, Moreno, FJ, Naegeli, H, Nogué, F, Rostoks, N, Sánchez Serrano, JJ, Savoini, G, Veromann, E, Veronesi, F, Camargo, AM, Goumperis, T, Kagkli, DM, Lenzi, P, Lewandowska, A, Raffaello, T and Streissl, F, 2022. Scientific Opinion on the assessment of genetically modified maize MIR162 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-025). *EFSA Journal* 2022; 20(9):7562, 13 pp. <https://doi.org/10.2903/j.efsa.2022.7562>

Authorisation in the EU of MIR162 maize for food, feed, import and processing

On 18 October 2012, Commission Implementing Decision (EU) 2012/651 authorised the placing on the market of MIR162 maize (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorisation covers the following products:

- (a) foods and food ingredients containing, consisting of or produced from SYN-IR162-4 maize;
- (b) feed containing, consisting of or produced from SYN-IR162-4 maize;
- (c) SYN-IR162-4 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

On 17 October 2023, Commission Implementing Decision (EU) 2023/2143 authorised the renewal of the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize MIR162 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Implementing Decisions (EU) 2016/1685, (EU) 2019/1305 and (EU) 2019/2087 as regards the reference material.

For more information, please visit the Community Register of GM Food and Feed using the following link: <https://webgate.ec.europa.eu/dyna2/gm-register/>

Conditions for traceability and labelling of MIR162 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.

For the purposes of the specific 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 the documents accompanying products containing or consisting of genetically modified maize SYN-IR162-4 as referred to in Article 1, 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-IR162-4 maize).

The unique identifier assigned to MIR162 maize is SYN-IR162-4.

Post-market monitoring of MIR162 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 MIR162 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 at the EU Register of authorised GMOs: [Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC](#).

The operators are requested to collaborate with the authorisation holder in the general surveillance to identify the occurrence of unanticipated adverse effects of the viable MIR162 maize or its use for human and animal health or the environment that were not predicted in the environmental risk assessment. In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable maize and with respect to clean-up practices.

Methods for detection and reference material

An event-specific quantitative detection method for MIR162 maize has been validated by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) and is publicly available on the JRC-EURL website: <https://gmo-crl.jrc.ec.europa.eu/method-validation/details/all/1019/MIR162>

Certified reference material of MIR162 maize is accessible via the Certified Reference Materials catalogue of the European Commission's Joint Research Centre (<https://crm.jrc.ec.europa.eu/>).

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 co-mingled. CropLife Europe, plays an important role in this area and is the central communication point for all GM plant technology providers.

CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects and is skilled to provide adequate response. In addition, CropLife Europe 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 CropLife Europe at: <https://croplifeeurope.eu/product-information/> .

If required, additional comments or questions related to MIR162 maize can also be addressed at:

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