MIR604 Maize

EU Authorisation for food, feed, import and processing

Information for Operators

September 2021

Introduction

This document summarizes the main characteristics of MIR604 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 MIR604 maize

Maize is susceptible to attack by a variety of insects from the time it is planted until it is consumed as food or feed. Genetically modified event MIR604 maize has been developed by Syngenta to provide growers with maize hybrids that are resistant to feeding damage caused by certain coleopteran insect pests.

Protection against certain coleopteran insect pests is provided through the expression of the modified mCry3A protein. The native Cry3A from the soil bacterium *Bacillus thuringiensis* (*Bt*) subsp. *tenebrionis* is active against certain coleopteran pests. The mCry3A produced by MIR604 was modified to have enhanced activity against the Western corn rootworm (*Diabrotica virgifera virgifera*) and other related coleopteran pests.

MIR604 maize also expresses phosphomannose isomerase (PMI), an enzyme derived from *Escherichia coli*, which serves as a selectable marker during the transformation process. PMI allows transformed maize cells to utilize mannose as the sole carbon source, whereas maize cells lacking PMI fail to grow with mannose as single carbon source.

Safety of MIR604 maize

The safety of Syngenta's products for humans, animals and the environment is of paramount importance. MIR604 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 MIR604 maize for food, feed, import and processing in the EU

On 23 August 2018, the European Food Safety Authority (EFSA) received from the European Commission an application for the renewal of the authorisation of MIR604 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 opinion[1] on 7 November 2019, and concluded that there is no evidence in renewal application EFSA-GMO-RX-013 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize MIR604[2].

[1] 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, Noguė F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Àlvarez F, Ardizzone M and Raffaello T, 2019. Scientific Opinion on the assessment of genetically modified maize MIR604 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-013). EFSA Journal 2019;17(11):5846, 11 pp. https://doi.org/10.2903/j.efsa.2019.5846.

[2] EFSA (European Food Safety Authority), 2009. Scientific Opinion - Application (Reference EFSA-GMO-UK-2005-11) for the placing on the market of insect-resistant genetically modified maize MIR604 event, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S.

Authorisation in the EU of MIR604 maize for food, feed, import and processing

The Commission Implementing Decision of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MIR604 (SYN-IR6Ø4-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is published at:
https://eur-lex.europa.eu/eli/dec_impl/2021/62/oj

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 genetically modified maize SYN-IR6Ø4-5;
(b) feed containing, consisting of or produced from genetically modified maize SYN-IR6Ø4-5;
(c) products containing or consisting of genetically modified maize SYN-IR6Ø4-5 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 MIR604 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=37

Conditions for traceability and labelling of MIR604 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 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 genetically modified maize SYN-IR6Ø4-5 , 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 genetically modified maize SYN-IR6Ø4-5).

The unique identifier assigned to MIR604 maize is: SYN-IR6Ø4-5.

on behalf of Syngenta Crop Protection AG. EFSA Journal 2009;7(7):1193, 26 pp. https://doi.org/10.2903/j.efsa.2009.1193.

Post-market monitoring of MIR604 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 MIR604 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 the detection of MIR604 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 Material for MIR604 maize is accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at 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 comingled. 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 relative to MIR604 maize can also be addressed to:

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