



**Bt11 × MIR162 × MIR604 × GA21  
maize and genetically modified  
maize combining two or three of  
the events Bt11, MIR162,  
MIR604 and GA21**

**Insect protection and herbicide  
tolerance**

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

**Information for Operators**

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**Disclaimer**

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

# Syngenta maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21

## Information for Operators

### Introduction

This approval covers many products and this document summarizes the main characteristics of these products along with the requirements for post-market environmental monitoring of all operators handling viable grain from this product. It also includes references to the relevant detection methods and contact points for operators to report on general surveillance activities and on any unanticipated adverse effects. The products covered by this approval are shown in Table 1.

**Table 1: Syngenta Bt11 × MIR162 × MIR604 × GA21 maize, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21**

Product	Unique identifier
Bt11 x GA21	SYN-BTØ11-1 x MON-ØØØ21-9
Bt11 x MIR604	SYN-BTØ11-1 x SYN-IR6Ø4-5
Bt11 x MIR162	SYN-BTØ11-1 x SYN-IR162-4
MIR604 x GA21	SYN-IR6Ø4-5 x MON-ØØØ21-9
MIR162 x MIR604	SYN-IR162-4 x SYN-IR6Ø4-5
MIR162 x GA21	SYN-IR162-4 x MON-ØØØ21-9
Bt11 x MIR604 x GA21	SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9
Bt11 x MIR162 x GA21	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9
MIR162 x MIR604 x GA21	SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9
Bt11 x MIR162 x MIR604	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5

## **EFSA evaluation of maize Bt11 × MIR162 × MIR604 × GA21 and other genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21 for food, feed, import and processing in the EU**

On 6 February 2009, Syngenta submitted to the competent authority of Germany the application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from maize Bt11 × MIR162 × MIR604 × GA21 maize. Based on the application, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) issued a positive scientific opinion on the safety of GM maize Bt11 × MIR162 × MIR604 × GA21 and the other genetically modified maize products listed in Table 1 stating that:

*“The EFSA GMO Panel concludes that the four-event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope. Among the 10 subcombinations, four have been assessed previously and no safety concerns were identified. For the remaining six subcombinations, the EFSA GMO Panel followed a weight-of-evidence approach, and concluded they are expected to be as safe as the four-event stack maize.”<sup>1</sup>*

## **Authorization in the EU of Bt11 × MIR162 × MIR604 × GA21 maize and genetically modified maize listed in Table 1 combining two or three of the events Bt11, MIR162, MIR604 and GA21 for food, feed, import and processing in the EU**

The Commission decision of 16 September 2016 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21 and its subcombinations pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is published at: [http://ec.europa.eu/food/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=76](http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=76)

Please note that the maize products

Bt11 × GA21,  
MIR604 × GA21,  
Bt11 × MIR604,  
Bt11 × MIR604 × GA21

have previously been approved in the EU. Since these products are subcombinations of Bt11 × MIR162 × MIR604 × GA21 maize the new approval will repeal these existing approvals. Please see also for the information included in the GMO register: [http://ec.europa.eu/food/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=76](http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=76)

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<sup>1</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2009-66) for placing on the market of herbicide tolerant and insect resistant maize Bt11 × MIR162 × MIR604 × GA21 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(12):4297, 34 pp. doi:10.2903/j.efsa.2015.4297 Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

**Conditions for traceability and labelling of maize Bt11 × MIR162 × MIR604 × GA21 and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21 for food, feed, import and processing application 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 these labelling requirements the ‘name of the organism’ shall be ‘maize’.

The words ‘not for cultivation’ shall appear on the label of and in documents accompanying products containing or consisting of the maize products listed in Table 1.

The unique identifiers for the maize products approved by this Commission Decision are listed in Table 1.

**Conditions or restrictions for the placing on the market of specific subcombinations of maize Bt11 × MIR162 × MIR604 × GA21 for food, feed, import and processing in the EU**

Specific Conditions or restrictions, use or handling of the products for the placing on the market are provided with the authorisation, accessible on the internet at the Community Register of GM Food and Feed.

[http://ec.europa.eu/food/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=76](http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=76)

**Post Market Monitoring of Bt11 × MIR162 × MIR604 × GA21 and other genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21 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 Bt11 × MIR162 × MIR604 × GA21 and its subcombinations 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 Community Register of GM Food and Feed.

[http://ec.europa.eu/food/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=76](http://ec.europa.eu/food/dyna/gm_register/gm_register_auth.cfm?pr_id=76)

## Methods for detection and reference material

Event specific real-time quantitative PCR based methods for genetically modified Bt11, MIR162, MIR604 and GA21 are validated on the single-trait events and verified on Bt11 × MIR162 × MIR604 × GA21 maize. The validation was performed by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

Reference Material ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue> and AOCS 1208-A and AOCS 0407-A (for SYN-IR162-4), AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at <http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248>.

## Contact points 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:

<http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/introduction>

If required, additional comments or questions relative to Bt11 × MIR162 × MIR604 × GA21 or its subcombinations can also be addressed to:

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