



**Bt11 × 59122 × MIR604 × 1507 × GA21 maize
and genetically modified maize combining
two, three or four of the events Bt11,
59122, MIR604, 1507 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 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 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 maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21

Degree of stacking	Products	Unique identifiers
Two event stacked maize	Bt11 x 59122	SYN-BTØ11-1 x DAS-59122-7
	Bt11 x 1507	SYN-BTØ11-1 x DAS-Ø15Ø7-1
	59122 x MIR604	DAS-59122-7 x SYN-IR6Ø4-5
	59122 x GA21	DAS-59122-7 x MON-ØØØ21-9
	MIR604 x 1507	SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
	1507 x GA21	DAS-Ø15Ø7-1 x MON-ØØØ21-9
Three event stacked maize	Bt11 x 59122 x MIR604	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5
	Bt11 x 59122 x 1507	SYN-BTØ11-1 x DAS-59122-7 x Ø15Ø7-1
	Bt11 x 59122 x GA21	SYN-BTØ11-1 x DAS-59122-7 x MON-ØØØ21-9
	Bt11 x MIR604 x 1507	SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
	Bt11 x 1507 x GA21	SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
	59122 x MIR604 x 1507	DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
	59122 x MIR604 x GA21	DAS-59122-7 x SYN-IR6Ø4-5 x MON-ØØØ21-9
	59122 x 1507 x GA21	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
Four event stacked maize	MIR604 x 1507 x GA21	SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
	Bt11 x 59122 x MIR604 x 1507	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
	Bt11 x 59122 x MIR604 x GA21	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4- x MON-ØØØ21-9
	Bt11 x 59122 x 1507 x GA21	SYN-BTØ11-1 x DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
	Bt11 x MIR604 x 1507 x GA21	SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
	59122 x MIR604 x 1507 x GA21	DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9

EFSA evaluation of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and other genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 for food, feed, import and processing in the EU

On 1 July 2011, 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 × 59122 × MIR604 × 1507 × GA21. 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 × 59122 × MIR604 × 1507 × GA21 and the other genetically modified maize products listed in Table 1 stating that:

“The EFSA GMO Panel concludes that the five event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope. For the 20 subcombinations, the EFSA GMO Panel followed a weight-of-evidence approach, and concluded that they are expected to be as safe as the five-event stack maize.”¹

Authorization in the EU of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and genetically modified maize listed in Table 1 combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 for food, feed, import and processing in the EU

The Commission decision of 4 July 2017 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21 and its subcombinations pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is published at:
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D1209&from=EN>

Conditions for traceability and labelling of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 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

¹ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2011-99) for placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and twenty subcombinations subcombinations, which have not been authorised previously independently of their origin, for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016;14(8):4567, 31 pp. doi:10.2903/j.efsa.2016.4567 - Available online: www.efsa.europa.eu/efsajournal

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 × 59122 × MIR604 × 1507 × GA21 for food, feed, import and processing application 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://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017D1209&from=EN>

Post Market Monitoring of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and other genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 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 × 59122 × MIR604 × 1507 × 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=80

Methods for detection and reference material

Event specific real-time quantitative PCR based methods for genetically modified Bt11, 59122, MIR604, 1507 and GA21 are validated on the single-trait events and verified on Bt11 × 59122 × MIR604 × 1507 × 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 for Bt11, 59122, MIR604 and 1507 (ERM-BF412 a-f, ERM-BF424 a-d, ERM-BF423 a-d and ERM-BF418 a-d, respectively) is accessible via the Joint Research Centre (JRC) of the European Commission, at <HTTPS://CRM.JRC.EC.EUROPA.EU> and for GA21 (MON-ØØØ21-9) (AOCS 0407) via the American Oil Chemists Society at <https://www.aocs.org/crm?ItemNumber=19248#>

Contact points for Operators

EuropaBio, the European Association for Bioindustries, 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 maize Bt11 × 59122 × MIR604 × 1507 × GA21 or its subcombinations can also be addressed to:

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