Bt11 × MIR162 × MIR604 x 1507 x 5307 x GA21 maize

Agrisure Duracade® 5222

Insect protection and herbicide tolerance

EU Import authorization for food, feed, and processing

Information for Operators

December 2019
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Syngenta maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21, and genetically modified maize combining two, three, four or five of the events Bt11, MIR162, MIR604, 1507, 5307 and GA21

Information for Operators

Introduction

The EU approval for Syngenta maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 covers many products. 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 34 sub-combinations covered by this approval are shown in Table 1.

General description of the product

Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 maize is a genetically modified maize (GM) that is produced by conventional breeding crosses of the following GM maize events: Bt11, MIR162, MIR604, 1507, 5307, and GA21.

- Event Bt11 maize produces a truncated Cry1Ab protein for control of certain lepidopteran pests, and a phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.
- Event MIR162 maize expresses a Vip3A (Vip3Aa20) protein for control of certain lepidopteran pests, and a phosphomannose isomerase (PMI) protein that acts as a selectable marker protein enabling transformed plant cells to utilize mannose as the only primary carbon source.
- Event MIR604 maize expresses a modified Cry3A (mCry3A) protein for control of certain coleopteran pests, and a phosphomannose isomerase (MIR604 PMI) protein that acts as a selectable marker enabling transformed plant cells to utilize mannose as the only primary carbon source.
- Event 1507 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests, and a phosphinothricin acetyltransferase (PAT) protein for weed control by providing tolerance to herbicide products containing glufosinate ammonium.
- Event 5307 maize expresses a Cry protein (eCry3.1Ab) for control of certain coleopteran pests, such as *Diabrotica virgifera virgifera* (WCRW) and related *Diabrotica* species, and a phosphomannose isomerase (PMI) protein that acts as a selectable marker protein enabling transformed plant cells to utilize mannose as the only primary carbon source.

- Event GA21 maize produces a modified maize 5-enolpyruvylshikimate-3-phosphate synthase enzyme (mEPSPS) for weed control by providing tolerance to herbicide products containing glyphosate.

Table 1: Syngenta maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21, and genetically modified maize combining two, three, four or five of the events Bt11, MIR162, MIR604, 1507, 5307 and GA21

Degree of stacking	Products	Unique identifiers
Five event stacked maize	Bt11 × MIR162 × MIR604 × 1507 × 5307	SYN-BTØ11 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	Bt11 × MIR162 × MIR604 × 1507 × GA21	SYN-BTØ11 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
	Bt11 × MIR162 × MIR604 × 5307 × GA21	SYN-BTØ11x SYN-IR162-4 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	Bt11 × MIR162 × 1507 × 5307 × GA21	SYN-BTØ11 x SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	Bt11 × MIR604 × 1507 × 5307 × GA21	SYN-BTØ11 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	MIR162 × MIR604 × 1507 × 5307 × GA21	SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
Four event stacked maize	Bt11 x MIR162 x MIR604 x 1507	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
	Bt11 × MIR162 × MIR604 × 5307	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
	Bt11 × MIR162 × 1507 × 5307	SYN-BTØ11 x SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	Bt11 × MIR162 × 5307 × GA21	SYN- BTØ11 x SYN-IR162-4 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	Bt11 × MIR604 × 1507 × 5307	SYN-BTØ11 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	Bt11 × MIR604 × 5307 × GA21	SYN-BTØ11 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	Bt11 × 1507 × 5307 × GA21	SYN-BTØ11 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	MIR162 × MIR604 × 1507 × 5307	SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	MIR162 × MIR604 × 1507 × GA21	SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
	MIR162 × MIR604 × 5307 × GA21	SYN-IR162-4 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	MIR162 × 1507 × 5307 × GA21	SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	MIR604 × 1507 × 5307 × GA21	SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
Three event stacked maize	Bt11 × MIR162 × 5307	SYN-BTØ11-1 x SYN-IR162-4 x SYN-Ø53Ø7-1

	Bt11 × MIR604 × 5307	SYN-BTØ11-1 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
	Bt11 × 1507 × 5307	SYN-BTØ11-1 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	Bt11 × 5307 × GA21	SYN-BTØ11-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	MIR162 × MIR604 × 1507	SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1
	MIR162 × MIR604 × 5307	SYN-IR162-4 x SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
	MIR162 × 1507 × 5307	SYN-IR162-4 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	MIR162 × 5307 × GA21	SYN-IR162-4 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	MIR604 × 1507 × 5307	SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	MIR604 × 5307 × GA21	SYN-IR6Ø4-5 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
	1507 × 5307 × GA21	DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
Two event stacked maize	Bt11 × 5307	SYN-BTØ11-1 x SYN-Ø53Ø7-1
	MIR162 × 5307	SYN-IR162-4 x SYN-Ø53Ø7-1
	MIR604 × 5307	SYN-IR6Ø4-5 x SYN-Ø53Ø7-1
	1507 × 5307	DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1
	5307 × GA21	SYN-Ø53Ø7-1 x MON-ØØØ21-9

EFSA evaluation of maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 and other genetically modified maize combining two, three, four or five of the events Bt11, MIR162, MIR604, 1507, 5307 and GA21 for food, feed, import and processing in the EU

On 16 December 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 × MIR162 x MIR604 x 1507 x 5307 × 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 on 5 April 2019 for Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 maize and the other genetically modified maize products, listed in Table 1, stating that:

The GMO Panel concludes that the six-event stack maize and its subcombinations are as safe as its non-GM comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.[1].

Authorization in the EU of maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 and genetically modified maize listed in Table 1 combining two, three, four or five of the events Bt11, MIR162, MIR604, 1507, 5307 and GA21 for food, feed, import and processing in the EU

The Commission decision of 28 November 2019 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 and its sub-combinations pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is published at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D2087&qid=1575289603837&from=EN

Conditions for traceability and labelling of maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 and genetically modified maize combining two, three, four or five of the events Bt11, MIR162, MIR604, 1507, 5307 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.

[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, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Ardizzone M, Álvarez F, Fernandez Dumont A, Gennaro A, Lanzoni A, Neri FM, Papadopoulou N, Paraskevopoulos K, De Sanctis G, Raffaello T, Federici S and Koukoulanaki M, 2019. Scientific Opinion on assessment of genetically modified maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2011-103). EFSA Journal 2019;17(4):5635, 36 pp. https://doi.org/10.2903/j.efsa.2019.5635

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 identifier for Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 maize is SYN-BTØ11 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9. The unique identifiers for the sub-combination maize products approved by this Commission Decision are listed in Table 1.

Conditions or restrictions for the placing on the market of specific sub-combinations of maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 for food, feed, import and processing application in the EU

The Decision does not include 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.
https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=97

Post Market Monitoring of maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 and other genetically modified maize combining two, three, four or five of the events Bt11, MIR162, MIR604, 1507, 5307 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 x 1507 × 5307 x GA21 and its sub-combinations 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.
Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

Methods for detection and reference material

Event specific real-time quantitative PCR based methods for genetically modified Bt11, MIR162, MIR604, 1507, 5307 and GA21 are validated on the single-trait events and verified on Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 maize. The validation of the detection method 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, MIR604 and 1507 maize events are accessible via the Joint Research Centre (JRC) of the European Commission, at https://crm.jrc.ec.europa.eu/ and for 5307, MIR162 and GA21 maize events via the American Oil Chemists Society at: https://www.aocs.org/crm?ItemNumber=19248#maize

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 maize Bt11 × MIR162 × MIR604 x 1507 × 5307 x GA21 or its sub-combinations can also be addressed to:

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