



Bt11 × MIR162 × TC1507 × GA21 maize

Agrisure Viptera[®] 3220

**Insect protection and herbicide
tolerance**

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

Information for Operators

**August 2019
(Updated December 2020)**

Disclaimer

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

Syngenta maize Bt11 × MIR162 × 1507 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, 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.

Characteristics

Bt11 x MIR162 x 1507 x GA21 maize including the specified subcombinations was produced by combining Bt11, MIR162, 1507¹ and GA21 maize through conventional breeding. Therefore these maize plants express the traits present in Bt11, MIR162, 1507 and GA21 maize plants through the production of:

1. A truncated Cry1Ab protein for control of certain lepidopteran pests like the common European maize pests: *Ostrinia nubilalis* (European corn borer; ECB) and *Sesamia nonagrioides* (Mediterranean corn borer; MCB).
2. A PAT protein that confers tolerance to herbicide products containing glufosinate ammonium.
3. A Vip3Aa protein (designated Vip3Aa20) for control of certain lepidopteran pests like *Heliothis zea*. (Corn earworm), *Agrotis ipsilon* (Black cutworm), *Spodoptera frugiperda* (Fall armyworm), and *Striacosta albicosta* (Western bean cutworm)
4. A PMI protein, that acts as a selectable marker trait enabling transformed plant cells to utilize mannose as a only primary carbon source.
5. A Cry1F protein for control of certain lepidopteran pests such as *Ostrinia nubilalis* (ECB) and *Sesamia nonagrioides* (MCB).
6. A modified EPSPS enzyme that confers tolerance to herbicide products containing glyphosate.

In a similar manner, the subcombinations produce a subset of these proteins corresponding to each of the single events present in the corresponding subcombination.

¹ Maize line 1507 is normally referred to as Event TC1507 in applications submitted by Dow AgroSciences to most countries other than the European Union

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

Degree of stacking	Products	Unique identifiers
Two event stacked maize	MIR162 x 1507	SYN-IR162-4 x DAS-Ø15Ø7-1
Three event stacked maize	Bt11 x MIR162 x 1507	SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1
	MIR162 x 1507 x GA21	SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
Four event stacked maize	Bt11 x MIR162 x 1507 x GA21	SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9

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

On 10 August 2010, Syngenta submitted to the German competent authority an 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 × 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 × MIR162 × 1507 × GA21 and the other genetically modified maize products listed in Table 1 stating that:

The GMO Panel concludes that maize Bt11 x MIR162 x 1507 x GA21 is nutritionally equivalent to and as safe as its non-GM comparator in the context of the scope of this application².

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

The Commission decision of 26 July 2019 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and its subcombinations 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:32019D1305&qid=1566217843716&from=EN>

² EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Ardizzone M, Federici S, Fernandez Dumont A, Gennaro A, Gómez Ruiz JA, Lanzoni A, Neri FM, Papadopoulou N and Paraskevopoulos K, 2018. Scientific Opinion on the assessment of genetically modified maize Bt11 x MIR162 x 1507 x GA21 and three subcombinations independently of their origin, for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2010-86). EFSA Journal 2018;16(7):5309, 35 pp. <https://doi.org/10.2903/j.efsa.2018.5309>
<https://www.efsa.europa.eu/en/efsajournal/pub/5309>

Conditions for traceability and labelling of maize Bt11 × MIR162 × 1507 × GA21 and genetically modified maize combining two or three of the events Bt11, MIR162, 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 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 × 1507 × 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=93

Post Market Monitoring of maize Bt11 × MIR162 × 1507 × GA21 and other genetically modified maize combining two or three of the events Bt11, MIR162, 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 × MIR162 × 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.

https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=93
https://webgate.ec.europa.eu/dyna/gm_register/maize_Bt11xMIR162x1507xGA21_environmental_monitoring_plan.pdf

Methods for detection and reference material

Event specific real-time quantitative PCR based methods for genetically modified Bt11, MIR162, 1507 and GA21 are validated on the single-trait events and verified on Bt11 × MIR162 × 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 and 1507 maize events (ERM-BF412 and ERM-BF418, respectively) are accessible via the Joint Research Centre (JRC) of the European Commission, at <HTTPS://CRM.JRC.EC.EUROPA.EU> and for GA21 maize (MON-ØØØ21-9) (AOCS 0407) and MIR162 maize (AOCS 1208-A2) via the American Oil Chemists Society at: <https://www.aocs.org/crm?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 maize Bt11 × MIR162 × 1507 × GA21 or its subcombinations can also be addressed to:

Syngenta Crop Protection nv/sa
Avenue Louise,
489 B- 1050
Brussels Belgium
Phone +32 2 642 27 27
www.syngenta.com