Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations of the single GM maize events

EU Authorisation for Food, Feed, Import and Processing

Information for Operators

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Introduction

This document summarizes the main characteristics of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations, 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize was obtained by conventional breeding of Bt11, MIR162, MIR604, MON 89034, 5307 and GA21 maize single events. No new genetic modifications were introduced to obtain Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize. Similarly, no new genetic modifications were introduced in any of the subcombinations. Therefore, Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and the thirty subcombinations express transgenic proteins inherited from the genetically modified (GM) maize single events that confer protection against certain lepidopteran and/or coleopteran pests, and/or tolerance to herbicide products containing glyphosate and/or glufosinate containing-herbicides.

Safety of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations

Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations have 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 Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations for food, feed, import and processing in the EU

On 5 June 2023, the EFSA Panel on Genetically Modified Organisms (GMO Panel) published its scientific opinion[1] and concluded that Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations (EFSA-GMO-DE-2018-149) are as safe as the comparator and the selected non-GM reference varieties with respect to potential effects on human and animal health and the environment.

[1] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins E,Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Firbank LG, Guerche P, Hejatko J, Moreno FJ,Naegeli H, Nogué F, Rostoks N, Sánchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Ardizzone M,De Sanctis G, Federici S, Fernandez A, Gennaro A, Gómez Ruiz JA, Goumperis T, Kagkli DM, Lenzi P, Camargo AM, Neri FM and Raffaello T, 2023. Scientific Opinion on the assessment of genetically modified maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 and 30 subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2018-149). EFSA Journal 2023;21(6):8011, 59 pp. https://doi.org/10.2903/j.efsa.2023.8011

Authorisation in the EU of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations for food, feed, import and processing

On 26 January 2024, Commission Implementing Decision (EU) 2024/391[2] authorised the placing on the market of products containing, consisting of or produced from genetically modified Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize (SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-89Ø34-3 x SYN-Ø53Ø7-1 x MON-ØØØ21-9) and thirty subcombinations*, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorisation covers the following products:

a) food and food ingredients containing, consisting of or produced from genetically modified maize;

b) feed containing, consisting of or produced from genetically modified maize;

c) products containing or consisting of genetically modified maize, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

* List of GM maize (with unique identifier) in scope of this authorisation:

a) Bt11 × MIR162 × MIR604 × MON 89034 × 5307 × GA21 (SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3 × SYN-Ø53Ø7-1 × MON-ØØØ21-9);
b) Bt11 × GA21 × MIR162 × MIR604 × MON 89034 (SYN-BTØ11-1 × MON-ØØØ21-9 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
c) 5307 × GA21 × MIR162 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × MON-ØØØ21-9 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
d) 5307 × Bt11 × MIR162 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
e) 5307 × Bt11 × GA21 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × MON-ØØØ21-9 × SYN-IR6Ø4-5 × MON-89Ø34-3);
f) 5307 × Bt11 × GA21 × MIR162 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × MON-ØØØ21-9 × SYN-IR162-4 × MON-89Ø34-3);
g) GA21 × MIR162 × MIR604 × MON 89034 (MON-ØØØ21-9 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
h) Bt11 × MIR162 × MIR604 × MON 89034 (SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
i) Bt11 × GA21 × MIR604 × MON 89034 (SYN-BTØ11-1 × MON-ØØØ21-9 × SYN-IR6Ø4-5 × MON-89Ø34-3);
j) Bt11 × GA21 × MIR162 × MON 89034 (SYN-BTØ11-1 × MON-ØØØ21-9 × SYN-IR162-4 × MON-89Ø34-3);
k) 5307 × MIR162 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
l) 5307 × GA21 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × MON-ØØØ21-9 × SYN-IR6Ø4-5 × MON-89Ø34-3);
m) 5307 × GA21 × MIR162 × MON 89034 (SYN-Ø53Ø7-1 × MON-ØØØ21-9 × SYN-IR162-4 × MON-89Ø34-3);
n) 5307 × Bt11 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-89Ø34-3);
o) 5307 × Bt11 × MIR162 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × SYN-IR162-4 × MON-89Ø34-3);
p) 5307 × Bt11 × GA21 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × MON-ØØØ21-9 × MON-89Ø34-3);
q) MIR162 × MIR604 × MON 89034 (SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3);
r) GA21 × MIR604 × MON 89034 (MON-ØØØ21-9 × SYN-IR6Ø4-5 × MON-89Ø34-3);
s) GA21 × MIR162 × MON 89034 (MON-ØØØ21-9 × SYN-IR162-4 × MON-89Ø34-3);
t) Bt11 × MIR604 × MON 89034 (SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-89Ø34-3);
u) Bt11 × MIR162 × MON 89034 (SYN-BTØ11-1 × SYN-IR162-4 × MON-89Ø34-3);
v) Bt11 × GA21 × MON 89034 (SYN-BTØ11-1 × MON-ØØØ21-9 × MON-89Ø34-3);
w) 5307 × MIR604 × MON 89034 (SYN-Ø53Ø7-1 × SYN-IR6Ø4-5 × MON-89Ø34-3);
x) 5307 × MIR162 × MON 89034 (SYN-Ø53Ø7-1 × SYN-IR162-4 × MON-89Ø34-3);
y) 5307 × GA21 × MON 89034 (SYN-Ø53Ø7-1 × MON-ØØØ21-9 × MON-89Ø34-3);
z) 5307 × Bt11 × MON 89034 (SYN-Ø53Ø7-1 × SYN-BTØ11-1 × MON-89Ø34-3);
aa) MIR604 × MON 89034 (SYN-IR6Ø4-5 × MON-89Ø34-3);
bb) GA21 × MON 89034 (MON-ØØØ21-9 × MON-89Ø34-3);
cc) Bt11 × MON 89034 (SYN-BTØ11-1 × MON-89Ø34-3);
dd) 5307 × MON 89034 (SYN-Ø53Ø7-1 × MON-89Ø34-3);
ee) MIR162 × MON 89034 (SYN-IR162-4 × MON-89Ø34-3)

[2] https://eur-lex.europa.eu/eli/dec_impl/2024/391/oj

For more information, please visit the Community Register of GM Food and Feed using the following link: https://webgate.ec.europa.eu/dyna2/gm-register/.

Conditions for traceability and labelling of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations 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 the documents accompanying the products containing or consisting of genetically modified maize referred to in Article 1, with the exception of products referred to in point (a) of Article 2 of the Commission Implementing Decision (EU) 2024/391 (*i.e.*, food and food ingredients containing, consisting of or produced from genetically modified maize referred to in (*) above).

The unique identifiers assigned to Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations are provided above (*).

Post-market monitoring of Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations 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 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty 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 at the EU Register of authorised GMOs: Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

The operators are requested to collaborate with the authorisation holder in the general surveillance to identify the occurrence of unanticipated adverse effects of viable Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations or their use for human and animal health or the environment that were not predicted in the environmental risk assessment. In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable maize and with respect to clean-up practices.

Methods for detection and reference material

The quantitative event-specific PCR detection methods are those individually validated for the six events and further verified on Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize. These have been validated by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) with the validation report published on the JRC-EURL website: https://gmo-crl.jrc.ec.europa.eu/method-validation/details/all/2045/Bt11%20x%20MIR162%20x%20MIR604%20x%20MON%2089034%20x%205307%20x%20GA21.

Certified reference material of Bt11, MIR162 and MIR604 maize are accessible via the Certified Reference Materials catalogue of the JRC (https://crm.jrc.ec.europa.eu/), and certified reference material of MON 89034, 5307 and GA21 are available at the American Oil Chemists' Society (https://www.aocs.org/crm?SSO=True#maize).

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 co-mingled. 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 responses. 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 effects to CropLife Europe at: https://croplifeeurope.eu/product-information/.

If required, additional comments or questions related to Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 maize and thirty subcombinations can also be addressed at:

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