

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2016/1685

of 16 September 2016

**authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU**

(notified under document C(2016) 5746)

(Only the French text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 7(3), 9(2), 19(3) and 21(2) thereof,

Whereas:

- (1) On 9 February 2009, Syngenta France SAS submitted to the competent authority of Germany 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 Bt11 × MIR162 × MIR604 × GA21 maize ('the application').
- (2) The application also covers the placing on the market of genetically modified maize Bt11 × MIR162 × MIR604 × GA21 in products consisting of it or containing it for other uses than food and feed as any other maize, with the exception of cultivation.
- (3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council <sup>(2)</sup> and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (4) On 5 July 2013, Syngenta extended the scope of the application to all sub-combinations of the single genetic modification events constituting Bt11 × MIR162 × MIR604 × GA21 maize ('sub-combinations'), including Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × MIR604 × GA21 which are already authorised respectively by Commission Decisions 2010/426/EU <sup>(3)</sup>, 2011/892/EU <sup>(4)</sup>, 2011/893/EU <sup>(5)</sup> and 2011/894/EU <sup>(6)</sup>. Syngenta asked the Commission to repeal those four Decisions once authorisation is given to Bt11 × MIR162 × MIR604 × GA21 maize and all sub-combinations.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(3)</sup> Commission Decision 2010/426/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × GA21 (SYN-BTØ11-1 × MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 199, 31.7.2010, p. 36).

<sup>(4)</sup> Commission Decision 2011/892/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604 × GA21 (SYN-IR6Ø4-5 × MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 55).

<sup>(5)</sup> Commission Decision 2011/893/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR604 (SYN-BTØ11-1 × SYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 59).

<sup>(6)</sup> Commission Decision 2011/894/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR604 × GA21 (SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 64).

- (5) On 7 December 2015, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 <sup>(1)</sup>. It concluded that genetically modified maize Bt11 × MIR162 × MIR604 × GA21, as described in the application, is as safe and as nutritious as its conventional counterpart and no safety concerns are identified for any of the sub-combinations.
- (6) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (7) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (8) In its opinion, EFSA recommends the collection of relevant information on expression levels of the newly expressed proteins, if the sub-combinations Bt11 × MIR162 × MIR604, MIR162 × MIR604 × GA21, Bt11 × MIR162, MIR162 × MIR604 and/or MIR162 × GA21 were to be created via targeted breeding approaches and commercialised. In line with this recommendation, specific conditions should be laid down to that effect.
- (9) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, Bt11 × MIR162 × MIR604, Bt11 × MIR162 × GA21, Bt11 × MIR604 × GA21, MIR162 × MIR604 × GA21, Bt11 × MIR162, Bt11 × MIR604, Bt11 × GA21, MIR162 × MIR604, MIR162 × GA21 and MIR604 × GA21.
- (10) Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU authorising Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × GA21 × MIR604 maize should be repealed.
- (11) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 <sup>(2)</sup>.
- (12) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21 including all possible combinations of the single genetic modification events. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize Bt11 × MIR162 × MIR604 × GA21 and the sub-combinations, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (13) Regulation (EC) No 1830/2003 of the European Parliament and of the Council <sup>(3)</sup> lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (14) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC <sup>(4)</sup>. The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

<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

<sup>(2)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(3)</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

<sup>(4)</sup> Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

- (15) The authorisation holder should also submit annual reports on the results of the activities set out in the specific conditions of this authorisation.
- (16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed provided for in Regulation (EC) No 1829/2003.
- (17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(1)</sup>.
- (18) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### Article 1

#### Genetically modified organism and unique identifier

1. The following unique identifiers for genetically modified organisms (GMOs) are assigned in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × MIR604 × GA21;
- (b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × MIR604;
- (c) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × GA21;
- (d) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × GA21;
- (e) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × MIR604 × GA21;
- (f) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162;
- (g) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604;
- (h) the unique identifier SYN-BTØ11-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × GA21;
- (i) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) MIR162 × MIR604;
- (j) the unique identifier SYN-IR162-4 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × GA21;
- (k) the unique identifier SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR604 × GA21.

2. The genetically modified maizes referred to in paragraph 1 are specified in point (b) of the Annex.

<sup>(1)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from the GMOs referred to in Article 1;
- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1;
- (c) GMOs referred to in Article 1 in products containing them or consisting of them for any other use than those provided in points (a) and (b), with the exception of cultivation.

*Article 3***Labelling**

1. 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'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of the GMOs referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

*Article 4***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5***Specific conditions for the placing on the market**

1. The authorisation holder shall ensure that the specific conditions, referred to in point (g) of the Annex, are implemented.
2. The authorisation holder shall submit to the Commission annual reports on the results of the activities set out in the specific conditions of this authorisation for the duration of the authorisation.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Syngenta France SAS, representing Syngenta Crop Protection AG, Switzerland.

*Article 8***Repeal**

Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU are repealed.

*Article 9***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 10***Addressee**

This Decision is addressed to Syngenta France SAS, 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France.

Done at Brussels, 16 September 2016.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

**(a) Applicant and Authorisation holder:**

Name: Syngenta France SAS

Address: 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CHH-4058 Basel, Switzerland.

**(b) Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (3) genetically modified maizes (*Zea mays* L.) as specified in (e) in products containing them or consisting of them for any other use than those provided in points (1) and (2), with the exception of cultivation.

SYN-BTØ11-1 maize expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.

SYN-IR162-4 maize expresses the Vip3Aa20 protein which confers protection against certain lepidopteran pests and PMI protein which was used as a selectable marker.

SYN-IR6Ø4-5 maize expresses the Cry3A protein which provides protection against certain coleopteran pests and PMI protein which was used as a selectable marker.

MON-ØØØ21-9 maize expresses the mEPSPS protein which confers tolerance to glyphosate herbicides.

**(c) Labelling:**

- (1) 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';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the maizes specified in (e) with the exception of products referred to in point (a) of Article 2.

**(d) Method for detection:**

- (1) Event specific real-time quantitative PCR based methods for SYN-BTØ11-1, SYN-IR162-4, SYN-IR6Ø4-5 and MON-ØØØ21-9 maizes; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 maize;
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
- (3) 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>.

**(e) Unique identifier:**

SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5;

SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4;

SYN-BTØ11-1 × SYN-IR6Ø4-5;

SYN-BTØ11-1 × MON-ØØØ21-9;

SYN-IR162-4 × SYN-IR6Ø4-5;

SYN-IR162-4 × MON-ØØØ21-9;

SYN-IR6Ø4-5 × MON-ØØØ21-9.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

*Specific conditions in accordance with Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003:*

(1) The authorisation holder shall inform the Commission if the sub-combinations SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5, SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9, SYN-BTØ11-1 × SYN-IR162-4, SYN-IR162-4 × SYN-IR6Ø4-5 and/or SYN-IR162-4 × MON-ØØØ21-9 were to be created via targeted breeding approaches and commercialised.

(2) If it is the case, the authorisation holder shall collate information on the expression levels of the newly expressed proteins.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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