

COMMISSION IMPLEMENTING DECISION (EU) 2017/1209**of 4 July 2017**

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed

(notified under document C(2017) 4460)

(Only the Dutch and French texts are 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 ⁽¹⁾, and in particular Articles 7(3), 9(2), 19(3) and 21(2) thereof,

Whereas:

- (1) On 1 July 2011, Syngenta submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from Bt11 × 59122 × MIR604 × 1507 × GA21 maize (‘the application’) to the national competent authority of Germany in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified maize Bt11 × 59122 × MIR604 × 1507 × 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.
- (2) In accordance with Articles 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.
- (3) On 21 February 2014, Syngenta extended the scope of the application to all sub-combinations of the single genetic modification events constituting Bt11 × 59122 × MIR604 × 1507 × GA21 maize, except the sub-combination 1507 × 59122, which was already authorised by Commission Decision 2010/432/EU ⁽³⁾.
- (4) On 31 March 2016, Syngenta updated the scope of the application by excluding the following four sub-combinations, which were in the scope of another application: Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × MIR604 × GA21. These sub-combinations were authorised by Commission Implementing Decision (EU) 2016/1685 ⁽⁴⁾.
- (5) On 26 August 2016, the European Food Safety Authority (‘EFSA’) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁵⁾. EFSA concluded that genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, as described in the application, is as safe and as nutritious as its conventional

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ 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).

⁽³⁾ Commission Decision 2010/432/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 (DAS-Ø15Ø7-1 × DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 202, 4.8.2010, p. 11).

⁽⁴⁾ 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 (OJ L 254, 20.9.2016, p. 22).

⁽⁵⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2011-99) for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and twenty 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

counterpart and non-genetically modified commercial varieties as regards the potential effects on human health and the environment, and no safety concerns were identified for any of the 20 sub-combinations covered by the scope of the application.

- (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 Article 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 recommended the collection of relevant information on expression levels of the newly expressed proteins, if any of the 20 sub-combinations 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 × 59122 × MIR604 × 1507 × GA21, and the following twenty sub-combinations thereof, consisting of: five sub-combinations of four events (Bt11 × MIR604 × 1507 × GA21, Bt11 × 59122 × 1507 × GA21, Bt11 × 59122 × MIR604 × GA21, Bt11 × 59122 × MIR604 × 1507, 59122 × MIR604 × 1507 × GA21); nine sub-combinations of three events (Bt11 × 59122 × MIR604, Bt11 × 59122 × 1507, Bt11 × 59122 × GA21, Bt11 × MIR604 × 1507, Bt11 × 1507 × GA21, 59122 × MIR604 × 1507, 59122 × MIR604 × GA21, 59122 × 1507 × GA21, MIR604 × 1507 × GA21); and six sub-combinations of two events (Bt11 × 59122, Bt11 × 1507, 59122 × MIR604, 59122 × GA21, MIR604 × 1507 and 1507 × GA21).
- (10) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (11) On the basis of the EFSA opinion, no specific labelling requirements, other than those 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 of the European Parliament and of the Council ⁽²⁾, appear to be necessary for the products covered by this Decision. 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 × 59122 × MIR604 × 1507 × 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.
- (12) 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 the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽³⁾.
- (13) 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.
- (14) The authorisation holder should also submit annual reports on the results of the activities set out in the specific conditions of this authorisation.
- (15) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.

⁽¹⁾ 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).

⁽²⁾ 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).

⁽³⁾ 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).

- (16) 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 Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽¹⁾.
- (17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its chair. This implementing act was deemed to be necessary and the chair submitted it 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 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604 × 1507 × GA21;
- (b) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × 1507 × GA21;
- (c) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × 1507 × GA21;
- (d) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604 × GA21;
- (e) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604 × 1507;
- (f) the unique identifier DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) 59122 × MIR604 × 1507 × GA21;
- (g) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604;
- (h) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × 1507;
- (i) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × GA21;
- (j) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × 1507;
- (k) the unique identifier SYN-BTØ11-1 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 1507 × GA21;
- (l) the unique identifier DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) 59122 × MIR604 × 1507;
- (m) the unique identifier DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) 59122 × MIR604 × GA21;
- (n) the unique identifier DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) 59122 × 1507 × GA21;

⁽¹⁾ 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).

- (o) the unique identifier SYN-IR604-5 × DAS-01507-1 × MON-00021-9 for genetically modified maize (*Zea mays* L.) MIR604 × 1507 × GA21;
 - (p) the unique identifier SYN-BT011-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) Bt11 × 59122;
 - (q) the unique identifier SYN-BT011-1 × DAS-01507-1 for genetically modified maize (*Zea mays* L.) Bt11 × 1507;
 - (r) the unique identifier DAS-59122-7 × SYN-IR604-5 for genetically modified maize (*Zea mays* L.) 59122 × MIR604;
 - (s) the unique identifier DAS-59122-7 × MON-00021-9 for genetically modified maize (*Zea mays* L.) 59122 × GA21;
 - (t) the unique identifier SYN-IR604-5 × DAS-01507-1 for genetically modified maize (*Zea mays* L.) MIR604 × 1507;
 - (u) the unique identifier DAS-01507-1 × MON-00021-9 for genetically modified maize (*Zea mays* L.) 1507 × GA21.
2. The genetically modified maize referred to in paragraph 1 are specified in point (b) of the Annex.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 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(1);
- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1(1);
- (c) GMOs referred to in Article 1(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(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 annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission 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 annual reports on the results of the activities set out in the specific conditions of this authorisation to the Commission 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 Crop Protection NV/SA, Belgium, representing Syngenta Crop Protection AG, Switzerland.

*Article 8***Validity**

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

*Article 9***Addressee**

This Decision is addressed to Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Authorisation holder:

Name: Syngenta Crop Protection NV/SA

Address: 489, Avenue Louise, 1050 Brussels, Belgium

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-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.

DAS-59122-7 maize expresses the Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.

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

DAS-Ø15Ø7-1 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, used as a selectable marker, which confers tolerance to the glufosinate-ammonium herbicide

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, DAS-59122-7, SYN-IR6Ø4-5, DAS-Ø15Ø7-1 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 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × 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), ERM®-BF424 (for DAS-59122-7), ERM®-BF423 (for SYN-IR6Ø4-5) and ERM®-BF418 (for DAS-Ø15Ø7) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://crm.jrc.ec.europa.eu> and 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 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9;
SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5;
SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1;
SYN-BTØ11-1 × DAS-59122-7 × MON-ØØØ21-9;
SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
SYN-BTØ11-1 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9;
DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
SYN-BTØ11-1 × DAS-59122-7;
SYN-BTØ11-1 × DAS-Ø15Ø7-1;
DAS-59122-7 × SYN-IR6Ø4-5;
DAS-59122-7 × MON-ØØØ21-9;
SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
DAS-Ø15Ø7-1 × 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 any of the sub-combinations 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.
