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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 maizes 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)

(OJ L 254, 20.9.2016, p. 22)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/60 of 11 January 2019	L 12	31	15.1.2019
►**M2**	Commission Implementing Decision (EU) 2023/2143 of 13 October 2023	L 2143	1	17.10.2023

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COMMISSION IMPLEMENTING DECISION (EU) 2016/1685

of 16 September 2016

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(notified under document C(2016) 5746)

(Only the French text is authentic)

(Text with EEA relevance)

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;

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(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.

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.

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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 ►M1 Syngenta Crop Protection NV/SA, Belgium ◄, 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 ►M1 Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium ◄.

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ANNEX

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

Name: ►M1 Syngenta Crop Protection NV/SA ◄

Address: ►M1 Avenue Louise 489, 1050 Brussels, Belgium ◄

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;

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(3) Reference Material: ERM®-BF412 (for SYN-BTØ11-1), ERM®-BF446 (for SYN-IR162-4) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, 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 https://www.aocs.org/crm.

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(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.