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► **B**

COMMISSION DECISION

of 28 July 2010

renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC

(notified under document C(2010) 5129)

(Only the French text is authentic)

(Text with EEA relevance)

(2010/419/EU)

(OJ L 197, 29.7.2010, p. 11)

Amended by:

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Decision (EU) 2019/60 of 11 January 2019	L 12	31	15.1.2019

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*Article 1***Genetically modified organism and unique identifier**

Genetically modified maize Bt11 (*Zea mays* L.), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1, as provided for in Regulation (EC) No 65/2004.

*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 SYN-BTØ11-1 maize;
- (b) feed containing, consisting of, or produced from SYN-BTØ11-1 maize;
- (c) products other than food and feed containing or consisting of SYN-BTØ11-1 maize for the same uses as any other maize 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 documents accompanying products containing or consisting of SYN-BTØ11-1 maize referred to in Article 2(b) and (c).

▼B*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***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 6***Authorisation holder**

The authorisation holder shall be ►**M1** Syngenta Crop Protection NV/SA, Belgium ◀, representing Syngenta Crop Protection AG, Switzerland.

*Article 7***Validity**

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

*Article 8***Repeal**

Decision 2004/657/EC is repealed.

*Article 9***Addressee**

This Decision is addressed to ►**M1** Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium ◀, representing Syngenta Crop Protection AG, Switzerland.

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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, 4058 Basel, Switzerland

(b) Designation and specification of the products:

1. foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1 maize;
2. feed containing, consisting of, or produced from SYN-BTØ11-1 maize;
3. products other than food and feed containing or consisting of SYN-BTØ11-1 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1 maize, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and the PAT protein which confers tolerance to the glufosinate-ammonium herbicide.

(c) Labelling:

1. for the purposes of the specific 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 documents accompanying products containing or consisting of SYN-BTØ11-1 maize referred to in Article 2(b) and (c).

(d) Method for detection:

- event specific real-time PCR-based method for the quantification of SYN-BTØ11-1 maize
- validated by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- reference material: ERM®-BF412 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>

(e) Unique identifier:

SYN-BTØ11-1

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

Biosafety Clearing House, Record ID: see [to be completed when notified]

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

Not required.

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(h) **Monitoring plan:**

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

[Link: *plan published on the Internet*]

(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.