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► **B** COMMISSION IMPLEMENTING DECISION (EU) 2018/1111
of 3 August 2018

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU

(notified under document C(2018) 5014)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

(OJ L 203, 10.8.2018, p. 20)

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► M1	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019



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(Text with EEA relevance)

Article 1

Genetically modified organism and unique identifier

The following unique identifiers are assigned to genetically modified maize as specified in point (b) of the Annex to this Decision, in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier MON-87427-7 × MON-89034-3 × MON-00603-6 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × NK603;
- (b) the unique identifier MON-87427-7 × MON-00603-6 for genetically modified maize (*Zea mays* L.) MON 87427 × NK603;
- (c) the unique identifier MON-89034-3 × MON-00603-6 for genetically modified maize (*Zea mays* L.) MON 89034 × NK603;
- (d) the unique identifier MON-87427-7 × MON-89034-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034.

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 genetically modified maize referred to in Article 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in Article 1;
- (c) genetically modified maize, referred to in Article 1, in products containing them or consisting of them, for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

▼B*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 genetically modified maize referred to in Article 1, with the exception of foods and food ingredients.

*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***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of maize MON 87427 × MON 89034 × NK603, MON 87427 × NK603, MON 89034 × NK603 and MON 87427 × MON 89034.

*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.

▼M1*Article 7***Authorisation holder**

The authorisation holder shall be Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States of America.

▼B*Article 8***Repeal**

Decision 2010/420/EU is hereby repealed.

▼ **B**

Article 9

Validity

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

▼ **M1**

Article 10

Addressee

This Decision is addressed to Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

▼B

ANNEX

▼M1**(a) Applicant and authorisation holder:**

Name: Bayer Agriculture BVBA

Address: Scheldelaan 460, 2040 Antwerp, Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard —
St. Louis, Missouri 63167 — United States of America.

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

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

MON-87427-7 maize expresses CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides.

MON-89034-3 maize expresses the Cry1A.105 and Cry2Ab2 proteins, which confer protection against certain lepidopteran pests.

MON-00603-6 maize expresses CP4 EPSPS protein and the variant CP4 EPSPS L214P, which confer tolerance to glyphosate-based 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 of the maize specified in (e), with the exception of foods and food ingredients.

(d) Method for detection:

- (1) The quantitative event-specific PCR detection methods for maize MON-87427-7 × MON-89034-3 × MON-00603-6 are those validated for genetically modified maize events MON-87427-7, MON-89034-3 and MON-00603-6.
- (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®-BF415 (for MON-00603-6) is accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/> as well as AOCS 0512-A (for MON-87427-7), AOCS 0906-E (for MON-89034-3) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

▼ B**(e) Unique identifiers:**

MON-87427-7 × MON-89034-3 × MON-00603-6;

MON-87427-7 × MON-00603-6;

MON-89034-3 × MON-00603-6;

MON-87427-7 × MON-89034-3.

(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:

Not required.

(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.