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► **B** COMMISSION IMPLEMENTING DECISION (EU) 2018/2046  
of 19 December 2018

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU

*(notified under document C(2018) 8238)*

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

(OJ L 327, 21.12.2018, p. 70)

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**of 19 December 2018**

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*(notified under document C(2018) 8238)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

*Article 1*

**Genetically modified organisms and unique identifiers**

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 × DAS-01507-1 × MON-88017-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507 × MON 88017 × 59122;
- (b) the unique identifier MON-87427-7 × MON-89034-3 × DAS-01507-1 × MON-88017-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507 × MON 88017;
- (c) the unique identifier MON-87427-7 × MON-89034-3 × DAS-01507-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507 × 59122;
- (d) the unique identifier MON-87427-7 × MON-89034-3 × MON-88017-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × MON 88017 × 59122;
- (e) the unique identifier MON-87427-7 × DAS-01507-1 × MON-88017-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507 × MON 88017 × 59122;
- (f) the unique identifier MON-87427-7 × MON-89034-3 × DAS-01507-1 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507;
- (g) the unique identifier MON-87427-7 × MON-89034-3 × MON-88017-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × MON 88017;
- (h) the unique identifier MON-87427-7 × MON-89034-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 59122;

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- (i) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507 × MON 88017;
- (j) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507 × 59122;
- (k) the unique identifier MON-87427-7 × MON-88Ø17-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 88017 × 59122;
- (l) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507;
- (m) the unique identifier MON-87427-7 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 88017;
- (n) the unique identifier MON-87427-7 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × 59122;
- (o) the unique identifier MON-89Ø34-3 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 89034 × MON 88017.

*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.

*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 food and food ingredients.

**▼ B***Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of the genetically modified maize referred to in Article 1.

*Article 5***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 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 referred to in Article 28(1) of Regulation (EC) No 1829/2003.

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

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

**▼ B***Article 8***Repeal**

Decision 2011/366/EU is hereby repealed.

*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: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

**▼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 the 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.

DAS-01507-1 maize expresses the Cry1F protein, which confers protection against certain lepidopteran pests and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

MON-88017-3 maize expresses a modified Cry3Bb1 protein, which provides protection to certain coleopteran pests and the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides.

DAS-59122-7 maize expresses Cry34Ab1 and Cry35Ab1 proteins, which confer protection against certain coleopteran pests and the PAT protein, which confers tolerance to glufosinate-ammonium-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 × MON 89034 × 1507 × MON 88017 × 59122 are those validated for genetically modified maize events MON-87427-7, MON-89034-3, DAS-01507-1, MON-88017-3 and DAS-59122-7.
- (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®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF424 (for DAS-59122-7) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>, and AOCS 0512-A (for MON-87427-7), AOCS 0906-E (for MON-89Ø34-3) and AOCS 0406-D (for MON-88Ø17-3) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>

**(e) Unique identifiers:**

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3;

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7;

MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7;

MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1;

MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3;

MON-87427-7 × MON-89Ø34-3 × DAS-59122-7;

MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3;

MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7;

MON-87427-7 × MON-88Ø17-3 × DAS-59122-7;

MON-87427-7 × DAS-Ø15Ø7-1;

MON-87427-7 × MON-88Ø17-3;

MON-87427-7 × DAS-59122-7;

MON-89Ø34-3 × MON-88Ø17-3;

**(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.