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► **B****COMMISSION IMPLEMENTING DECISION**

of 6 November 2013

authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2013) 4755)*

(Only the Dutch, English and French texts are authentic)

(Text with EEA relevance)

(2013/650/EU)

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**(Text with EEA relevance)**

(2013/650/EU)

*Article 1*

**Genetically modified organism and unique identifiers**

As provided for in Regulation (EC) No 65/2004, the following unique identifiers are assigned:

- (a) for genetically modified maize (*Zea mays* L.) MON89034 × 1507 × MON 88017 × 59122:

unique identifier MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7;

- (b) for genetically modified maize (*Zea mays* L.) MON89034 × 1507 × MON 88017:

unique identifier MON-89034-3 × DAS-01507-1 × MON-88017-3;

- (c) for genetically modified maize (*Zea mays* L.) MON 89034 × 1507 × 59122:

unique identifier MON-89034-3 × DAS-01507-1 × DAS-59122-7;

- (d) for genetically modified maize (*Zea mays* L.) MON 89034 × MON88017 × 59122:

unique identifier MON-89034-3 × MON-88017-3 × DAS-59122-7;

- (e) for genetically modified maize (*Zea mays* L.) 1507 × MON 88017 × 59122:

unique identifier DAS-01507-1 × MON-88017-3 × DAS-59122-7;

**▼B**

(f) for genetically modified maize (*Zea mays* L.) MON 89034 × 1507:

unique identifier MON-89034-3 × DAS-01507-1;

(g) for genetically modified maize (*Zea mays* L.) MON 89034 × 59122:

unique identifier MON-89034-3 × DAS-59122-7;

(h) for genetically modified maize (*Zea mays* L.) MON 1507 × MON 88017:

unique identifier DAS-01507-1 × MON-88017-3;

(i) for genetically modified maize (*Zea mays* L.) MON 88017 × 59122:

unique identifier MON-88017-3 × DAS-59122-7.

These genetically modified maize (*Zea mays* L.) are specified in point (b) of the Annex to this Decision.

*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 specified by their unique identifiers in Article 1;
- (b) feed containing, consisting of, or produced from the GMOs specified by their unique identifiers in Article 1;
- (c) the GMOs specified by their unique identifiers in Article 1 in products containing them or consisting of them for any other use than (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 documents accompanying products containing or consisting of the GMOs specified by their unique identifiers in Article 1 with the exception of products referred to in point (a) of Article 2.

**▼B***Article 4***Monitoring for environmental effects**

1. The authorisation holders 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 holders 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 the Decision 2009/770/EC.

*Article 5***Community register**

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6***Authorisation holders**

1. The authorisation holders shall be:
  - (a) ► **M1** Dow AgroSciences Distribution S.A.S., France, representing DowAgroSciences LLC, United States; and ◀
  - (b) ► **M1** Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States ◀.
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 7***Validity**

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

*Article 8***Addressees**

This Decision is addressed to:

- (a) ► **M1** Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France; and ◀
- (b) ► **M1** Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium ◀.

**▼B***ANNEX***(a) Applicant and Authorisation holders**

Name: ► **MI** Dow AgroSciences Distribution S.A.S. ◀

Address: ► **MI** 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France ◀

on behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States;

and

Name: ► **MI** Bayer Agriculture BVBA ◀

Address: ► **MI** Scheldelaan 460, 2040 Antwerp, Belgium ◀

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

**(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) the genetically modified maizes (*Zea mays* L.) as specified in (e) in products containing it or consisting of it for any other uses than (1) and (2), with the exception of cultivation.

MON-89Ø34-3 maize expresses the Cry1A.105 and Cry2Ab2 proteins which confer protection against certain lepidopteran pests.

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

MON-88Ø17-3 maize expresses a modified Cry3Bb1 protein which provides protection to certain coleopteran pests and the CP4 EPSPS protein which confers tolerance to the herbicide glyphosate.

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

**(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 the maizes specified in (e) with the exception of products referred to in point (a) of Article 2.

**▼ B****(d) Methods for detection**

- Event specific real-time PCR based methods for quantitative detection of genetically modified maize MON-89034-3, DAS-01507-1, MON-88017-3 and DAS-59122-7 maize; the detection methods validated on the single-trait events and verified on MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7 would function with a comparable efficacy for the individual GMOs as specified in (e);
- DNA extraction method validated on ground maize seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
- Reference Material: ERM®-BF424 (for DAS-59122-7) and ERM®-BF418 (for DAS-01507-1) 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> and AOCS 0906-E and AOCS 0406-A (for MON-89034-3) and AOCS 0406-D and AOCS 0406-A (for MON-88017-3) accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

**(e) Unique identifiers**

- MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7;
- MON-89034-3 × DAS-01507-1 × MON-88017-3;
- MON-89034-3 × DAS-01507-1 × DAS-59122-7;
- MON-89034-3 × MON-88017-3 × DAS-59122-7;
- DAS-01507-1 × MON-88017-3 × DAS-59122-7;
- MON-89034-3 × DAS-01507-1;
- MON-89034-3 × DAS-59122-7;
- DAS-01507-1 × MON-88017-3;
- MON-88017-3 × DAS-59122-7.

**(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.

**(h) Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII of 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.