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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 maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

*(notified under document C(2013) 4719)*

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

**(Text with EEA relevance)**

(2013/648/EU)

(OJ L 302, 13.11.2013, p. 38)

Amended by:

		Official Journal		
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► <b><u>M1</u></b>	Commission Implementing Decision (EU) 2019/240 of 6 February 2019	L 39	11	11.2.2019

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

Genetically modified maize (*Zea mays* L.) MON89034 × 1507 × NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-89034-3 × DAS-01507-1 × MON-00603-6, 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 MON-89034-3 × DAS-01507-1 × MON-00603-6 maize;
- (b) feed containing, consisting of, or produced from MON-89034-3 × DAS-01507-1 × MON-00603-6 maize;
- (c) MON-89034-3 × DAS-01507-1 × MON-00603-6 maize in products containing it or consisting of it 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 MON-89034-3 × DAS-01507-1 × MON-00603-6 maize 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) Applicants and Authorisation holders**

Name: ► **M1** Dow AgroSciences Distribution S.A.S. ◀

Address: ► **M1** 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: ► **M1** Bayer Agriculture BVBA ◀

Address: ► **M1** 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 MON-89034-3 × DAS-01507-1 × MON-00603-6 maize;
- (2) feed containing, consisting of, or produced from MON-89034-3 × DAS-01507-1 × MON-00603-6 maize;
- (3) MON-89034-3 × DAS-01507-1 × MON-00603-6 maize in products containing it or consisting of it for any other use than (1) and (2), with the exception of cultivation.

The genetically modified MON-89034-3 × DAS-01507-1 × MON-00603-6 maize, as described in the application, is produced by crosses between maize containing MON-89034-3, DAS-01507-1 and MON-00603-6 events and expresses the Cry1A.105, Cry2Ab2, Cry1F proteins which confer protection against certain lepidopteran pests, the CP4 EPSPS protein which confers tolerance to herbicide glyphosate 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 MON-89034-3 × DAS-01507-1 × MON-00603-6 maize, with the exception of products referred to in point (a) of Article 2.

**(d) Method for detection**

- Event specific real-time quantitative PCR based methods for quantitative detection of genetically modified MON-89034-3, DAS-01507-1 and MON-00603-6 maize validated on the single-trait events and verified on MON-89034-3 × DAS-01507-1 × MON-00603-6 maize;
- 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>

**▼ B**

— Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF415 (for MON-ØØ6Ø3-6) 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-89Ø34-3) accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

**(e) Unique identifier**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6.

**(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 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.