

DECISIONS

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁽¹⁾, and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 29 January 2009, Dow AgroSciences Ltd on behalf of Dow AgroSciences LLC and Monsanto Europe S.A. on behalf of Monsanto Company submitted to the competent authority of the Netherlands an application, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from MON89034 × 1507 × NK603 maize ('the application'). The application also covered all possible combinations of the single GM events.
- (2) The application also covers the placing on the market of products other than food and feed containing or consistent of MON89034 × 1507 × NK603 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on

the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC⁽²⁾ and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

- (3) GM crop plants which contain two or more different single GM events are called GM stacks. The harvest from maize GM stacks has specific features due to the reproductive biology of maize. When for example seeds of a maize GM stack with three different single GM events are cultivated, the resulting harvest contains not just grains with all three different GM events, but also grains containing only one or two different single GM events, and grains that do not contain any of the three single GM events (negative segregants). An authorisation of a maize GM stack should therefore cover all possible combinations of its single GM events, with the exception of those already authorised.
- (4) Each of the GM maizes with a single GM event, and each of the combinations of the single GM events are to be considered as being a specific GMO in the meaning of Article 3(1) and Article 15(1) of Regulation (EC) No 1829/2003. According to Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003, no GMO for food use or food referred in Article 3(1) or for feed use or feed referred in Article 15(1) can be placed on the market unless it is covered by an authorisation granted in accordance with the Regulation. It should therefore be ensured that all possible combinations of the single GM events constituting it are authorised when the GM stack is authorised.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

- (5) A prerequisite for the risk assessment of a GM stack is the risk assessment of the single GM events constituting it. The three single events that constitute MON89034 × 1507 × NK603 maize have already been authorised ⁽¹⁾.
- (6) On 27 September 2010, the European Food Safety Authority (EFSA) published a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. This opinion covers MON89034 × 1507 × NK603 maize and only the combinations of the individual GM events as present in its segregating progeny. EFSA considers that (i) MON89034 × 1507 × NK603 maize is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment, and (ii) there is no biological reason to expect that any of the sub-combinations originating from this GM stack in its segregating progeny would raise a safety concern in the context of its intended uses ⁽²⁾.
- (7) On 10 November 2011, EFSA, on the request of the Commission, adopted a statement complementing its previous opinion on MON89034 × 1507 × NK603 maize to cover all sub-combinations independently of their origin ⁽³⁾. The EFSA GMO panel considered it unlikely that the sub-combinations of MON89034 × 1507 × NK603 maize have an adverse effect on human and animal health and the environment, in the context of its intended uses covered by this decision.
- (8) In its opinions, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of that Regulation.
- (9) EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicants is in line with the intended use of the products.
- (10) The GM stacks MON89034 × 1507 maize, MON89034 × NK603 maize and 1507 × NK603 maize combine two specific single GM events constituting MON89034 × 1507 × NK603 maize. These GM stacks have already been authorised ⁽⁴⁾. By letter of 13 March 2013 the applicants clarified that the application no longer covers these GM maizes.
- (11) Taking into account those considerations, authorisation should be granted.
- (12) A unique identifier should be assigned to each GMO as provided for in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms ⁽⁵⁾.

⁽¹⁾ Commission Decision 2009/813/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 (MON-89034-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 21); Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea Mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium (OJ L 291, 5.11.2005, p. 42); Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) and renewing the authorisation to place on the market feed produced from such maize, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 70, 9.3.2006, p. 82); Commission Decision 2011/365/EU of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 163, 23.6.2011, p. 52); Commission Decision 2004/643/EC of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L. line NK603) genetically modified for glyphosate tolerance (OJ L 295, 18.9.2004, p. 35); Commission Decision 2005/448/EC of 3 March 2005 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 the European Parliament and of the Council (OJ L 158, 21.6.2005, p. 20).

⁽²⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00413>

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00169>

⁽⁴⁾ Commission Implementing Decision 2013/650/EU (see page 47 of this Official Journal); Commission Decision 2010/420/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × NK603 (MON-89034-3 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 197, 29.7.2010, p. 15); Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 47).

⁽⁵⁾ OJ L 10, 16.1.2004, p. 5.

- (14) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC⁽¹⁾, lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraph (1) to (5) of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (15) The authorisation holders should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council⁽²⁾.
- (16) The EFSA opinions do not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (17) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (18) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms⁽³⁾.
- (19) This Decision grants authorisation for placing on the market of the products within the scope of the application. This Decision, however, does not cover the single GM events and the combinations of the single GM events authorised by Decisions 2009/813/EC, 2005/772/EC, 2006/197/EC, 2011/365/EU, 2004/643/EC, 2005/448/EC, 2010/420/EU, 2007/703/EC and Implementing Decision 2013/650/EU. Operators should therefore pay attention to the fact that, in accordance with Articles 4(2) and/or 16(2) of Regulation (EC) No 1829/2003, all the GMOs (single GM events and the combinations of the single GM events) composing the harvest of MON89034 × 1507 × NK603 need to be authorised in order to place the harvest on the market. In the case where the authorisation of one of the GMOs composing the harvest of MON89034 × 1507 × NK603 expires without application for renewal or the authorisation is suspended or revoked, the products of this harvest cannot be placed on the market.
- (20) The applicants have been consulted on the measures provided for in this Decision.
- (21) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6, 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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;
- (b) feed containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;
- (c) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

*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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize with the exception of products referred to in point (a) of Article 2.

*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) Dow AgroSciences Ltd, United Kingdom, representing DowAgroSciences LLC, United States; and

(b) Monsanto Europe S.A., 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) Dow AgroSciences Ltd, European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom; and

(b) Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 6 November 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX

(a) Applicants and Authorisation holders

Name: Dow AgroSciences Ltd

Address: European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

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

and

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels, 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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;
- (2) feed containing, consisting of, or produced from MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize;
- (3) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 maize, as described in the application, is produced by crosses between maize containing MON-89Ø34-3, DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 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-89Ø34-3, DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 maize validated on the single-trait events and verified on MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 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>
- 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.
