

COMMISSION IMPLEMENTING DECISION (EU) 2015/684**of 24 April 2015****authorising the placing on the market of genetically modified maize NK603 (MON-ØØ6Ø3-6) and renewing the existing maize NK603 (MON-ØØ6Ø3-6) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2015) 2753)***(Only the Dutch and the French texts are authentic)****(Text with EEA relevance)**

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 Articles 7(3), 11(3), 19(3) and 23(3) thereof,

Whereas:

- (1) By Commission Decision 2004/643/EC ⁽²⁾, the placing on the market of feed containing or consisting of NK603 maize and NK603 maize in products consisting of it or containing it for any other uses than food and feed, with the exception of cultivation, is authorised in accordance with Directive 2001/18/EC of the European Parliament and of the Council ⁽³⁾, until 17 October 2014.
- (2) By Commission Decision 2005/448/EC ⁽⁴⁾, the placing on the market of foods and food ingredients containing, consisting of or produced from NK603 maize is authorised in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁵⁾, until 2 March 2015.
- (3) Food and feed additives and feed materials produced from genetically modified maize NK603 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation when it came into force.
- (4) On 2 August 2005, Monsanto Europe S.A. submitted to the European Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of food and feed additives and feed materials produced from NK603 maize which were previously notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.
- (5) On 2 August 2005, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 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 NK603 maize.
- (6) This application also covered the placing on the market of NK603 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, including the seeds for cultivation.
- (7) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ 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).

⁽³⁾ 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 (OJ L 106, 17.4.2001, p. 1).

⁽⁴⁾ 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 of the European Parliament and of the Council (OJ L 158, 21.6.2005, p. 20).

⁽⁵⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (8) On 25 March 2008, the Spanish Competent Authority and its Biosafety Commission provided to the European Food Safety Authority ('EFSA') its opinion on the environmental risk assessment in line with Articles 6(3)(c) and 18(3)(c) of Regulation (EC) No 1829/2003 and it concluded that according to the current state of scientific knowledge and after examining the existing information and data provided by the applicant, the Spanish Commission on Biosafety could give a favourable opinion to the commercialisation in the EU of maize NK603 if the proposals and conditions established in the Environmental Risk Assessment report are implemented.
- (9) On 11 June 2009, EFSA gave a favourable opinion for both applications in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that NK603 maize, as described in the application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment ⁽¹⁾. In its opinion, 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 Articles 6(4) and 18(4) of that Regulation.
- (10) In its opinion, EFSA also concluded that the environmental monitoring plan submitted by the applicant is in line with the intended uses of the products.
- (11) On 14 March 2014, Monsanto Europe S.A. informed the European Commission of its decision to amend the scope of the abovementioned new application to no longer include authorisation for cultivation of NK603 maize in the European Union.
- (12) Taking into account those considerations, authorisation should be granted for the products, with the exception of cultivation, and the environmental monitoring plan should be adapted to the modified scope.
- (13) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ⁽²⁾.
- (14) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from NK603 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO with the exception of food products for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.
- (15) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽³⁾, 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 paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (16) The authorisation holder 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 ⁽⁴⁾. The EFSA opinion does 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 EU register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

⁽¹⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00626>

⁽²⁾ 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 (OJ L 10, 16.1.2004, p. 5).

⁽³⁾ 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 (OJ L 268, 18.10.2003, p. 24).

⁽⁴⁾ 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 (OJ L 275, 21.10.2009, p. 9).

- (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 ⁽¹⁾.
- (19) Commission Decisions 2004/643/EC and 2005/448/EC should be repealed.
- (20) 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.) NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ6Ø3-6, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 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-ØØ6Ø3-6 maize;
- (b) feed containing, consisting of, or produced from MON-ØØ6Ø3-6 maize;
- (c) 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.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 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 and in the documents accompanying the products containing or consisting of 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 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.

⁽¹⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 5***EU 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 holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*Article 7***Validity**

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

*Article 8***Repeal**

Decisions 2004/643/EC and 2005/448/EC are repealed.

*Article 9***Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder**

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-ØØ6Ø3-6 maize.
2. Feed containing, consisting of, or produced from MON-ØØ6Ø3-6 maize.
3. 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-ØØ6Ø3-6 maize, as described in the applications, expresses the CP4 EPSPS protein which confers tolerance to the glyphosate herbicides.

(c) **Labelling**

1. For the purposes of the specific labelling requirements laid down in Articles 13(1) and 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-ØØ6Ø3-6 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

- Event specific real-time PCR based method for the quantification of MON-ØØ6Ø3-6 maize.
- Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, on genomic DNA extracted from Certified Reference Material, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- Reference Material: ERM®-BF415 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>

(e) **Unique identifier**

MON-ØØ6Ø3-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**
Biosafety Clearing-House [to be entered in the EU 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**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC [to be entered in the EU register of genetically modified food and feed when notified].

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.
