

Commission Implementing Decision (EU) 2018/1111 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (notified under document C(2018) 5014) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2018/1111

of 3 August 2018

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU

(notified under document C(2018) 5014)

(Only the Dutch and 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 13 September 2013, Monsanto Europe SA/NV submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from MON 87427 × MON 89034 × NK603 maize ('the application') to the national competent authority of Belgium in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products consisting of or containing genetically modified maize MON 87427 × MON 89034 × NK603 for uses other than food and feed, with the exception of cultivation.
- (2) The application covered, for those uses, all three sub-combinations of the single genetic modification events constituting maize MON 87427 × MON 89034 × NK603. One of those sub-combinations, MON 89034 × NK603, was already authorised under Commission Decision 2010/420/EU⁽²⁾. Monsanto Europe SA/NV asked the Commission to repeal that Decision when authorising maize MON 87427 × MON 89034 × NK603 and all its sub-combinations.

- (3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council⁽³⁾ and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.
- (4) On 1 August 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003⁽⁴⁾. EFSA concluded that genetically modified maize MON 87427 × MON 89034 × NK603, as described in the application, is as safe and as nutritious as the non-genetically modified comparator and the tested non-genetically modified reference varieties in the context of the scope of the application. No new safety concerns were identified for the previously assessed sub-combination MON 89034 × NK603 and previous conclusions on this sub-combination remain valid.
- (5) For the remaining two sub-combinations, the EFSA concluded that they are expected to be as safe and as nutritious as the single events MON 87427, MON 89034 and NK603, as the previously assessed sub-combination MON 89034 × NK603 and as the three-event stack maize MON 87427 × MON 89034 × NK603.
- (6) In its opinion, the 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 Regulation (EC) No 1829/2003.
- (7) The EFSA also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products. However, the proposed monitoring plan was revised, as recommended by the EFSA, to cover explicitly the sub-combinations.
- (8) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 and its three possible sub-combinations for the uses listed in the application should be authorised.
- (9) Decision 2010/420/EU authorising maize MON 89034 × NK603 should be repealed.
- (10) A unique identifier should be assigned to each genetically modified organism ('GMO') covered by this Decision in accordance with Commission Regulation (EC) No 65/2004⁽⁵⁾. The unique identifier assigned to maize MON 89034 × NK603 by Decision 2010/420/EU should continue to be used.
- (11) On the basis of the EFSA opinion, no specific labelling requirements, other than those 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 of the European Parliament and of the Council⁽⁶⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize MON 87427 × MON 89034 × NK603, MON 87427 × NK603, MON 89034 ×

NK603 and MON 87427 × MON 89034, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

- (12) The authorisation holder should submit annual reports on the implementation of the activities set out in the monitoring plan for environmental effects and on the results. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC⁽⁷⁾.
- (13) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (14) 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.
- (15) 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⁽⁸⁾.
- (16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The measures provided for in this Decision are in accordance with the opinion of the appeal committee,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

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 × MON-00603-6 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × NK603;
- (b) the unique identifier MON-87427-7 × MON-00603-6 for genetically modified maize (*Zea mays* L.) MON 87427 × NK603;
- (c) the unique identifier MON-89034-3 × MON-00603-6 for genetically modified maize (*Zea mays* L.) MON 89034 × NK603;
- (d) the unique identifier MON-87427-7 × MON-89034-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034.

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 foods and food ingredients.

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 annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

Article 5

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of maize MON 87427 × MON 89034 × NK603, MON 87427 × NK603, MON 89034 × NK603 and MON 87427 × MON 89034.

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, as provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Monsanto Europe SA/NV, Belgium, representing Monsanto Company, United States.

Article 8

Repeal

Decision 2010/420/EU is hereby repealed.

Article 9

Validity

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

Article 10

Addressee

This Decision is addressed to Monsanto Europe SA/NV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 3 August 2018.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name : Monsanto Europe SA/NV
Address : Scheldelaan 460, 2040 Antwerp, Belgium

On behalf of:

Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, USA.

(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 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.

MON-00603-6 maize expresses CP4 EPSPS protein and the variant CP4 EPSPS L214P, which confer tolerance to glyphosate-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-87427-7 × MON-89034-3 × MON-00603-6 are those validated for genetically modified maize events MON-87427-7, MON-89034-3 and MON-00603-6.
- (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>
- (3) Reference Material: ERM®-BF415 (for MON-00603-6) is accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/> as well as AOCS 0512-A (for MON-87427-7), AOCS 0906-E (for MON-89034-3) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

- (e) **Unique identifiers:**
MON-87427-7 × MON-89034-3 × MON-00603-6;
MON-87427-7 × MON-00603-6;
MON-89034-3 × MON-00603-6;
MON-87427-7 × MON-89034-3.
- (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.

- (1) [OJ L 268, 18.10.2003, p. 1.](#)
- (2) 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 MON 89034 × NK603 (MON-89034-3 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([OJ L 197, 29.7.2010, p. 15](#)).
- (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) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2017. Scientific Opinion on application EFSA-GMO-BE-2013-117 for authorisation of genetically modified maize MON 87427 × MON 89034 × NK603 and subcombinations independently of their origin, for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Company. *EFSA Journal* 2017;15(8):4922, 26 pp. <https://doi.org/10.2903/j.efsa.2017.4922>
- (5) 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](#)).
- (6) 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](#)).
- (7) 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](#)).
- (8) 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](#)).