Commission Implementing Decision (EU) 2018/2045 of 19 December 2018 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize NK603 × MON 810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2018) 8239) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2018/2045

of 19 December 2018

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize NK603 × MON 810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2018) 8239)

(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 to Article 11(3) and Article 23(3) thereof,

Whereas:

(1) Commission Decision 2007/701/EC[(2)] authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize NK603 × MON 810 (hereinafter 'maize NK603 × MON 810'). The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of maize NK603 × MON 810 for the same uses as any other maize with the exception of cultivation.

(2) On 20 October 2016, Monsanto Europe N.V./S.A. submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.

(3) On 26 February 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion[(3)] in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on maize NK603 × MON 810, adopted by the Authority in 2005[(4)].

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Decision (EU) 2018/2045. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) In its opinion of 26 February 2018, the Authority considered all the 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.

(5) The Authority also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

(6) Taking into account those considerations, the authorisation for the placing on the market of foods and food ingredients containing, consisting of, or produced from maize NK603 × MON 810, feed containing, consisting of, or produced from maize NK603 × MON 810 and products, other than food and feed, containing or consisting of maize NK603 × MON 810 for the same uses as any other maize with the exception of cultivation should be renewed.

(7) A unique identifier has been assigned to maize NK603 × MON 810, in accordance with Commission Regulation (EC) No 65/2004[(5)], in the context of the initial authorisation of maize NK603 × MON 810. That unique identifier should continue to be used.

(8) On the basis of the opinion of the Authority, no specific labelling requirements, other than those provided for 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 that the use of products containing or consisting of maize NK603 × MON 810 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of those intended for food uses, should contain a clear indication that they are not intended for cultivation.

(9) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC[(7)].

(10) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market and/or for the use and handling of the food and feed, including post-market monitoring requirements regarding the use for human and animal consumption.

(11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.

(12) 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)].

(13) 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

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deemed to be necessary and the chair submitted it 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 × MON 810 produced by crosses between maize containing MONØØ6Ø3-6 and MON-ØØ81Ø-6 events, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ6Ø3-6 × MON-ØØ81Ø-6, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from maize NK603 × MON 810;

(b) feed containing, consisting of, or produced from maize NK603 × MON 810;

(c) products, other than food and feed, containing or consisting of maize NK603 × MON 810 for the same uses as any other maize 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 the products containing or consisting of maize NK603 × MON 810, with the exception of food and food ingredients.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of maize NK603 × MON 810.

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Article 5

Monitoring plan 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 the format set out in Decision 2009/770/EC.

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 referred to in Article 28 of Regulation (EC) No 1829/2003.

[F1 Article 7

Authorisation holder

The authorisation holder shall be Monsanto Company, United States of America, represented by Bayer Agriculture BVBA, Belgium.**]**

Textual Amendments

F1 Substituted by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union (notified under document C(2019) 6520) (Only the Dutch text is authentic) (Text with EEA relevance).

Article 8

Validity

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