Commission Implementing Decision (EU) 2019/1306 of 26 July 2019 renewing the authorisation for 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 (notified under document C(2019) 5503) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1306

of 26 July 2019

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(notified under document C(2019) 5503)

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

Whereas:

(1) Commission Decision 2007/703/EC[(2)] authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize 1507 × NK603 (hereinafter 'maize 1507 × NK603'). The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of maize 1507 × NK603 for the same uses as any other maize with the exception of cultivation.

(2) On 20 October 2016, Pioneer Overseas Corporation, on behalf of Pioneer Hi-Bred International, Inc., and Dow AgroSciences Europe, on behalf of Dow AgroSciences LLC, jointly submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.

(3) On 25 July 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 1507 × NK603, adopted by the Authority in 2006[(4)].

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/1306. 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 25 July 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 in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

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

(6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified maize 1507 × NK603 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.

(7) By letter dated 13 September 2018, Dow AgroSciences Europe requested the Commission, in the context of the withdrawal of the United Kingdom from the European Union, that the representative in the Union of Dow AgroSciences LLC, United States, should be Dow AgroSciences Distribution S.A.S., based in France. By letter dated 7 September 2018, Dow AgroSciences Distribution S.A.S confirmed its agreement.

(8) By letter dated 12 October 2018, Dow AgroSciences LLC also confirmed its agreement to be represented by Dow AgroSciences Distribution S.A.S. and clarified that Mycogen Seeds is a subsidiary of Dow AgroSciences LLC.

(9) A unique identifier has been assigned to genetically modified maize 1507 × NK603, in accordance with Commission Regulation (EC) No 65/2004[(5)], in the context of its initial authorisation. That unique identifier should continue to be used.

(10) On the basis of the opinion of the Authority, no specific labelling requirements, other than those provided for in Articles 13(1) and 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 1507 × NK603 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

(11) The authorisation holders should submit joint annual reports on the implementation and on the results of the activities set out in the monitoring plan. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC[(7)].

(12) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/1306. 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*

(13) 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.

(14) 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 Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council[8].

(15) 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 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.) 1507 × NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6, 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 genetically modified maize 1507 × NK603;

(b) feed containing, consisting of, or produced from genetically modified maize 1507 × NK603;

(c) products containing or consisting of genetically modified maize 1507 × NK603 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 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’.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/1306. 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*

2 The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize 1507 × NK603, with the exception of products referred to in point (a) of Article 2.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified maize 1507 × NK603.

Article 5

Monitoring plan 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 joint 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(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holders

1 The authorisation holders shall be:

a Pioneer Hi-Bred International, Inc., United States, represented by Pioneer Overseas Corporation, Belgium; and

b Dow AgroSciences LLC, United States, represented by Dow AgroSciences Distribution S.A.S., France.

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 8

Validity

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