Commission Implementing Decision (EU) 2019/2085 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document (C(2019) 8419) (Only the French text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/2085

of 28 November 2019

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document (C(2019) 8419)

(Only the French text is 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 11 January 2013, Dow AgroSciences Europe submitted, on behalf of Dow AgroSciences LLC, 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 genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 ('the application') to the national competent authority of the Netherlands. The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 for uses other than food and feed, with the exception of cultivation.

(2) In addition, the application covered the placing on the market of products containing, consisting of or produced from ten sub-combinations of the single transformation events constituting maize MON 89034 × 1507 × NK603 × DAS-40278-9. Seven of those sub-combinations are already authorised as follows: MON 89034 × 1507, authorised by Commission Implementing Decision 2013/650/EU[(2)]; MON 89034 × NK603, authorised by Commission Implementing Decision (EU) 2018/1111[(3)]; 1507 ×

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NK603, authorised by Commission Implementing Decision (EU) 2019/1306[(4)]; MON 89034 × 1507 × NK603, authorised by Commission Implementing Decision 2013/648/EU[(5)]; and MON 89034 × 1507 × DAS-40278-9, MON 89034 × DAS-40278-9, 1507 × DAS-40278-9, authorised by Commission Implementing Decision C(2019)8425[(6)].

(3) This Decision covers the three remaining sub-combinations in the application: MON 89034 × NK603 × DAS-40278-9; 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9.

(4) 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[(7)]. It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.

(5) On 16 January 2019, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[(8)]. The Authority concluded that genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and its sub-combinations, as described in the application, are as safe as its non-genetically modified comparator and the tested non-genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.

(6) In its opinion, 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.

(7) The Authority 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.

(8) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9, and of the three sub-combinations indicated in recital 3 and listed in the application, should be authorised for the uses listed in the application.

(9) By letter dated 13 September 2018, Dow AgroSciences Europe informed the Commission that the new representative in the Union of Dow AgroSciences LLC, United States, is Dow AgroSciences Distribution S.A.S., based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution S.A.S. and Dow AgroSciences LLC confirmed their agreement.

(10) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004[(9)].

(11) 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[(10)], appear to be necessary for the products covered by

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this Decision. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

(12) 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[(11)].

(13) 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 Article 6(5)(e) and Article 18(5)(e) 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 referred to in Article 28(1) of 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[(12)].

(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 appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organisms and unique identifiers

Genetically modified maize (*Zea mays* L.), as specified in point (b) of the Annex to this Decision, are assigned the following unique identifiers, in accordance with Regulation (EC) No 65/2004:

(a) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9;

(b) the unique identifier MON-89Ø34-3 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × NK603 × DAS-40278-9;

(c) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize 1507 × NK603 × DAS-40278-9;

(d) the unique identifier MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize NK603 × DAS-40278-9.

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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 as referred to in Article 1;

(b) feed containing, consisting of or produced from genetically modified maize as referred to in Article 1;

(c) products containing or consisting of genetically modified maize as referred to in Article 1 for uses other than those provided for in points (a) and (b), 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 as referred to in Article 1, 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 as referred to in Article 1.

Article 5

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.