EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of XXX

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize DP202216 x NK603 x DAS-40278-9 and its sub-combinations DP202216 x NK603, DP202216 x DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

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(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 10 March 2023, Corteva Agriscience Belgium B.V., based in Belgium, on behalf of Corteva Agriscience LLC, based in the United States ('the applicant'), submitted an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize DP202216 x NK603 x DAS-40278-9 , in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also covered the placing on the market of products containing or consisting of genetically modified maize DP202216 x NK603 x 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 three sub-combinations of the single transformation events constituting maize DP202216 x NK603 x DAS-40278-9, DP202216 x NK603, DP202216 x DAS-40278-9, NK603 x DAS-40278-9. One sub-combination included in the application, NK603 × DAS-40278-9, has already been authorised by Commission Implementing Decision (EU) 2019/2085[2].

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[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1, ELI: http://data.europa.eu/eli/reg/2003/1829/oj).

[2] 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 (OJ L 316, 6.12.2019, pp. 80–86, ELI: http://data.europa.eu/eli/dec_impl/2019/2085/oj)

(3) This Decision covers maize DP202216 x NK603 x DAS-40278-9 and the remaining sub-combinations DP202216 x NK603 and DP202216 x DAS-40278-9.

(4) Pursuant to 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]. 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 05 December 2025, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion on genetically modified maize DP202216 x NK603 x DAS-40278-9 in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[4]. The Authority concluded that genetically modified maize DP202216 x NK603 x DAS-40278-9 and its sub-combinations, as described in the application, are as safe as their conventional counterpart and the tested non-genetically modified maize reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of food and feed from genetically modified maize DP202216 x NK603 x DAS-40278-9 and its sub-combinations does not represent any nutritional concern for humans and animals.

(6) In its scientific 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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(7) The Authority also concluded that the monitoring plan for the 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 DP202216 x NK603 x DAS-40278-9 and the sub-combinations DP202216 x NK603 and DP202216 x DAS-40278-9 should be authorised for the uses listed in the application.

(9) A unique identifier should be assigned to genetically modified maize DP202216 x NK603 x DAS-40278-9, and its sub-combinations DP202216 x NK603 and DP202216 x DAS-40278-9, in accordance with Commission Regulation (EC) No 65/2004[5].

(10) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2), points (a) and (b), 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. However, in order to

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[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, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

[4] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2025. Scientific Opinion on the assessment of genetically modified maize DP202216 × NK603 × DAS-40278-9 (application GMFF-2022-6232). EFSA Journal 2025; 23(12):9746; https://doi.org/10.2903/j.efsa.2025.9746.

[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, ELI: http://data.europa.eu/eli/reg/2004/65/oj).

[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, ELI: http://data.europa.eu/eli/reg/2003/1830/oj).

ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of those products, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(11) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. 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 other specific conditions or restrictions for the placing on the market, for the use and handling of food and feed containing, consisting of or produced from genetically modified maize DP202216 x NK603 x DAS-40278-9 and its sub-combinations or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e), of Regulation (EC) No 1829/2003.

(13) All relevant information on the authorisation of the products covered by this Decision 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 Article 9(1) and Article 15(2), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council[8].

(15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

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

(a) the unique identifier DP-2Ø2216-6 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize DP202216 x NK603 x DAS-40278-9;

(b) the unique identifier DP-2Ø2216-6 x MON-ØØ6Ø3-6 for genetically modified maize DP202216 x NK603;

(c) the unique identifier DP-2Ø2216-6 × DAS-4Ø278-9 for genetically modified maize DP202216 x DAS-40278-9.

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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, ELI: http://data.europa.eu/eli/dec/2009/770/oj).

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, ELI: http://data.europa.eu/eli/reg/2003/1946/oj).

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 and its sub-combinations as referred to in Article 1;

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

(c) products containing or consisting of genetically modified maize and its sub-combinations 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), points (a) and (b), 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 genetically modified maize and its sub-combinations as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The methods set out in point (d) of the Annex shall apply for the detection of genetically modified maize and its sub-combinations as referred to in Article 1.

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 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 holder

The authorisation holder shall be Corteva Agriscience LLC represented in the Union by Corteva Agriscience Belgium B.V.

Article 8

Validity

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

Article 9

Addressee

This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana, 46268-1054, United States, represented in the Union by Corteva Agriscience Belgium B.V., Rue Montoyer 25, 1000 Brussels, Belgium.

Done at Brussels,

For the Commission,
Olivér VÁRHELYI
Member of the Commission