



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...] (2025) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of **XXX**

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

(Text with EEA relevance)

(Only the Dutch text is authentic)

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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 feed¹, and in particular to Article 11(3) and Article 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2015/684² authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified maize NK603. The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of genetically modified maize NK603 for the same uses as any other maize, with the exception of cultivation.
- (2) On 11 March 2024, Bayer Agriculture B.V., based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States ('the applicant') an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) On 20 June 2025, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion³ on genetically modified maize NK603 in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence of any new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on genetically modified maize NK603, adopted by the Authority in 2009⁴.

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) 2015/684 of 24 April 2015 authorising the placing on the market of genetically modified maize NK603 (MON-ØØ6Ø3–6) and renewing the existing maize NK603 (MON-ØØ6Ø3–6) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 112 30.4.2015, p. 6).

³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2025. Assessment of genetically modified maize NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application GMFF-2023-21250). EFSA Journal 2025; 23 (6):9505. <https://doi.org/10.2903/j.efsa.2025.9505>.

⁴ [EFSA GMO Panel, 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on applications \(EFSA-GMO-NL-2005-22 and EFSA-GMO-RX-NK603\) for the placing on the market of](#)

- (4) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation with the national competent authorities as provided for in 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 conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified maize 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) A unique identifier was assigned to genetically modified maize NK603, in accordance with Commission Regulation (EC) No 65/2004⁵, in the context of its initial authorisation by Commission Implementing Decision (EU) 2015/684. That unique identifier should continue to be used.
- (8) As regards 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 Council⁶, appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified maize NK 603 remains within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (9) 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/EC⁷.
- (10) 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 containing, consisting of, or produced from genetically modified maize NK603, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5), point (e) and Article 18(5), point (e) of Regulation (EC) No 1829/2003.

[the genetically modified glyphosate tolerant maize NK603 for cultivation, food and feed uses and import and processing, and for renewal of the authorisation of maize NK603 as existing product. EFSA Journal, 7\(6\), 1137. https://doi.org/10.2903/j.efsa.2009.1137.](https://doi.org/10.2903/j.efsa.2009.1137)

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).

- (11) 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.
- (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), point (c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council⁸.
- (13) 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.) NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier 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 as regards:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-ØØ6Ø3–6;
- (b) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) MON-ØØ6Ø3–6;
- (c) products containing or consisting of genetically modified maize (*Zea mays* L.) MON-ØØ6Ø3–6 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 MON-ØØ6Ø3–6, 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 MON-ØØ6Ø3–6.

Article 5

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).

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 Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

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 Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels,

For the Commission
Olivér VÁRHELYI
Member of the Commission