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►**B**

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)

(OJ L 327, 21.12.2018, p. 65)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019
►**M2**	Commission Implementing Decision (EU) 2021/184 of 12 February 2021	L 55	4	16.2.2021
►**M3**	Commission Implementing Decision (EU) 2026/1819 of 27 July 2026	L 1819	1	29.7.2026

▼B

COMMISSION IMPLEMENTING DECISION (EU) 2018/2045

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(notified under document C(2018) 8239)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

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.

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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.

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.

▼M3

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience LLC, United States, represented in the Union by Bayer Agriculture B.V., Belgium.

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Article 8

Validity

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

▼M3

Article 9

Addressee

This Decision is addressed to Bayer CropScience LLC, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture B.V., Scheldelaan 460, 2040 Antwerp, Belgium.

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ANNEX

▼M3

(a) **Applicant and authorisation holder:**

Name: Bayer CropScience LLC

Address: 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, United States,

represented in the Union by Bayer Agriculture B.V., Scheldelaan 460, 2040 Antwerp, Belgium.

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(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from maize MON-ØØ6Ø3-6 × MON-ØØ81Ø-6;

(2) feed containing, consisting of or produced from maize MON-ØØ6Ø3-6 × MON-ØØ81Ø-6;

(3) products, other than food and feed, containing or consisting of maize MON-ØØ6Ø3-6 × MON-ØØ81Ø-6 for the same uses as any other maize with the exception of cultivation.

The genetically modified maize MON-ØØ6Ø3-6 × MON-ØØ81Ø-6 expresses the CP4 EPSPS protein, which confers tolerance to glyphosate herbicides, and the Cry1Ab protein, which confers protection against certain lepidopteran insect pests (*Ostrinia nubilalis, Sesamia* spp.).

(c) **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 documents accompanying the products containing or consisting of maize MON-ØØ6Ø3-6 × MON-ØØ81Ø-6, with the exception of foods and food ingredients.

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based methods for genetically modified maize MON-ØØ6Ø3-6 and maize MON-ØØ81Ø-6 validated on maize MON-ØØ6Ø3-6 × MON-ØØ81Ø-6.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx

(3) Reference Material: ERM®-BF413 (for MON-ØØ81Ø-6) and ERM®-BF415 (for MON-ØØ6Ø3-6) accessible via the Joint Research Centre (JRC) of the European Commission at https://ec.europa.eu/jrc/en/reference-materials/catalogue/

(e) **Unique identifier:**

MON-ØØ6Ø3-6 × MON-ØØ81Ø-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

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(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.