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[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of **XXX**

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87419 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 31 March 2017, Monsanto Europe S.A./N.V., based in Belgium, submitted, on behalf of Monsanto Company, based in the United States, 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 MON 87419, 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 MON 87419 for uses other than food and feed, with the exception of cultivation.
- (2) 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 Council². 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.
- (3) By a letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that it has converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium.
- (4) By a letter dated 28 July 2020, Bayer Agriculture BVBA Belgium informed the Commission that, as of 1 August 2020, it converts its legal form and changes its name to Bayer Agriculture BV, Belgium.

¹ OJ L 268, 18.10.2003, p. 1.

² 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).

- (5) By a letter dated 28 July 2020, Bayer Agriculture BVBA Belgium representing Monsanto Company, United States, informed the Commission that, as of 1 August 2020, Monsanto Company, United States, converts its legal form and changes its name to Bayer CropScience LP, United States.
- (6) On 20 January 2023, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003³. The Authority concluded that genetically modified maize MON 87419, as described in the application, is as safe as its 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 MON 87419 does not represent a nutritional concern in humans and animals.
- (7) 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.
- (8) 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.
- (9) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87419 should be authorised for the uses listed in the application.
- (10) A unique identifier should be assigned to genetically modified maize MON 87419 in accordance with Commission Regulation (EC) No 65/2004⁴.
- (11) For the products covered by this Decision, 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 Council⁵, appear to be necessary. 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 containing or consisting of genetically modified maize MON 87419, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (12) 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.

³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2023. Scientific opinion on the assessment of genetically modified maize MON 87419 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2017-140). EFSA Journal 2023;21(1):7730, 35 pp. <https://doi.org/10.2903/j.efsa.2023.7730>.

⁴ 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).

⁵ 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).

Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC⁶.

- (13) 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 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.
- (14) 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.
- (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), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council⁷.
- (16) 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.) MON 87419, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87419-8, in accordance with Regulation (EC) No 65/2004.

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 MON-87419-8;
- (b) feed containing, consisting of or produced from genetically modified maize MON-87419-8;
- (c) products containing or consisting of genetically modified maize MON-87419-8 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

⁶ 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).

⁷ 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).

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 genetically modified maize MON-87419-8 as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

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-87419-8.

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

Done at Brussels,

*For the Commission,
Stella KYRIAKIDES
Member of the Commission*