Commission Implementing Decision (EU) 2019/1308 of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 5487) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1308

of 26 July 2019

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 5487)

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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 to Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 5 February 2015, Monsanto Europe N.V. submitted, on behalf of the Monsanto Company, United States, 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 maize MON 87411 (‘the application’) to the national competent authority of the Netherlands. The application also covered the placing on the market of products consisting of genetically modified maize MON 87411 for uses other than food and feed as any other maize, with the exception of cultivation.

(2) In accordance with Articles 5(5) and 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[(2)] and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.

(3) On 02 July 2018, the European Food Safety Authority (‘the Authority’) issued a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No

1829/2003[3]. The Authority concluded that genetically modified maize MON 87411, as described in the application, is as safe as and nutritionally equivalent to 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.

(4) 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 by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(5) 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.

(6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 should be authorised for the uses listed in the application.

(7) By letter dated 27 August 2018, Monsanto Europe N.V. informed the Commission that Monsanto Europe N.V. converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium.

(8) A unique identifier should be assigned to genetically modified maize MON 87411 in accordance with Commission Regulation (EC) No 65/2004[4].

(9) On the basis of the Authority's opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 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[5], appear necessary for the products covered by 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 containing or consisting of genetically modified maize MON 87411, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

(10) 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[6].

(11) 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 Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

(12) 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.

(13) 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

Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council[7].

(14) 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 organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 87411, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87411-9, as provided for in 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 MON-87411-9 maize;

(b) feed containing, consisting of or produced from MON-87411-9 maize;

(c) products containing or consisting of MON-87411-9 maize for uses other than those provided for in points (a) and (b) of this Article, 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 MON-87411-9 maize, 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 MON-87411-9 maize.

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.

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(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Monsanto Company, United States, represented by Bayer Agriculture BVBA, Belgium.

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 Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 26 July 2019.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

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

Name	:	Monsanto Company
Address	:	800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

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

(1) foods and food ingredients containing, consisting of or produced from MON-87411-9 maize;

(2) feed containing, consisting of or produced from MON-87411-9 maize;

(3) products containing or consisting of MON-87411-9 maize for uses other than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified MON-87411-9 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-containing herbicides, the Cry3Bb1 protein and the DvSnf7 dsRNA, which confer resistance to corn rootworm (*Diabrotica* 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 MON-87411-9 maize, with the exception of products referred to in point (b)(1) of this Annex.

(d) **Method for detection:**

(1) Event-specific real-time quantitative PCR based method for detection of the genetically modified maize MON 87411.

(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: AOCS 0215-B is accessible via the American Oil Chemists' Society (AOCS) at https://www.aocs.org/crm

(e) **Unique identifier:**

MON-87411-9

(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 Community register of genetically modified food and feed when notified*].

(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 Community 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 Community register of genetically modified food and feed.

(**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).

(**3**) EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified maize MON 87411 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-124). *EFSA Journal* 2018; 16(6):5310, 29 pp. doi: 10.2903/j.efsa.2018.5310

(**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).

(**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).

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/1308. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Annex point (f) word omitted by virtue of S.I. 2019/705, reg. 430(a) (as inserted) by S.I. 2020/1504 reg. 17(21)
- Annex point (h) word omitted by virtue of S.I. 2019/705, reg. 430(b) (as inserted) by S.I. 2020/1504 reg. 17(21)
- Annex word omitted by virtue of S.I. 2019/705, reg. 430(c) (as inserted) by S.I. 2020/1504 reg. 17(21)
- Art. 5(2) words substituted by S.I. 2019/705, reg. 426 (as inserted) by S.I. 2020/1504 reg. 17(21)
- Art. 6 heading substituted by S.I. 2019/705, reg. 427 (as inserted) by S.I. 2020/1504 reg. 17(21)
- Art. 6 word omitted by virtue of S.I. 2019/705, reg. 429 (as inserted) by S.I. 2020/1504 reg. 17(21)