

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

*(notified under document (C(2019) 8419)***(Only the French text is authentic)****(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 11 January 2013, Dow AgroSciences Europe submitted, on behalf of Dow AgroSciences LLC, 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 genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 ('the application') to the national competent authority of the Netherlands. The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 89034 × 1507 × NK603 × 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 ten sub-combinations of the single transformation events constituting maize MON 89034 × 1507 × NK603 × DAS-40278-9. Seven of those sub-combinations are already authorised as follows: MON 89034 × 1507, authorised by Commission Implementing Decision 2013/650/EU ⁽²⁾; MON 89034 × NK603, authorised by Commission Implementing Decision (EU) 2018/1111 ⁽³⁾; 1507 × NK603, authorised by Commission Implementing Decision (EU) 2019/1306 ⁽⁴⁾; MON 89034 × 1507 × NK603, authorised by Commission Implementing Decision 2013/648/EU ⁽⁵⁾; and MON 89034 × 1507 × DAS-40278-9, MON 89034 × DAS-40278-9, 1507 × DAS-40278-9, authorised by Commission Implementing Decision C(2019)8425 ⁽⁶⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision 2013/650/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7)), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 47).

⁽³⁾ Commission Implementing Decision (EU) 2018/1111 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (OJ L 203, 10.8.2018, p. 20).

⁽⁴⁾ Commission Implementing Decision (EU) 2019/1306 of 26 July 2019 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 204, 2.8.2019, p. 75).

⁽⁵⁾ Commission Implementing Decision 2013/648/EU of 6 November 2013 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 38).

⁽⁶⁾ Commission Implementing Decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

- (3) This Decision covers the three remaining sub-combinations in the application: MON 89034 × NK603 × DAS-40278-9; 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9.
- (4) 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 Council ⁽⁷⁾. 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 16 January 2019, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁸⁾. The Authority concluded that genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and its sub-combinations, as described in the application, are as safe as its non-genetically modified comparator and the tested non- genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.
- (6) 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 in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (7) 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.
- (8) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9, and of the three sub-combinations indicated in recital 3 and listed in the application, should be authorised for the uses listed in the application.
- (9) By letter dated 13 September 2018, Dow AgroSciences Europe informed the Commission that the new representative in the Union of Dow AgroSciences LLC, United States, is Dow AgroSciences Distribution S.A.S., based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution S.A.S. and Dow AgroSciences LLC confirmed their agreement.
- (10) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁹⁾.
- (11) On the basis of the opinion of the Authority, 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 Council ⁽¹⁰⁾, appear to be 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 covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

⁽⁷⁾ 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).

⁽⁸⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Scientific Opinion on the assessment of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing, under Regulation (EC) No 1829-2003 (application EFSA-GMO-NL-2013-112). EFSA Journal 2019;17(1):5522.

⁽⁹⁾ 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).

⁽¹⁰⁾ 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).

- (12) 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 ⁽¹¹⁾.
- (13) 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 Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (14) 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.
- (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)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽¹²⁾.
- (16) 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 organisms and unique identifiers

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

- (a) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9;
- (b) the unique identifier MON-89Ø34-3 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × NK603 × DAS-40278-9;
- (c) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize 1507 × NK603 × DAS-40278-9;
- (d) the unique identifier MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize NK603 × DAS-40278-9.

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 as referred to in Article 1;

⁽¹¹⁾ 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).

⁽¹²⁾ 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).

- (b) feed containing, consisting of or produced from genetically modified maize as referred to in Article 1;
- (c) products containing or consisting of genetically modified maize 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) 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 genetically modified maize as referred to in Article 1, 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 as referred to in Article 1.

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 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 Dow AgroSciences LLC, United States, represented in the Union by Dow AgroSciences Distribution S.A.S., France.

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 Dow AgroSciences Distribution S.A.S., 1 bis, avenue du 8 mai 1945, 78280 Guyancourt, France.

Done at Brussels, 28 November 2019.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX

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

Name: Dow AgroSciences LLC

Address: 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States

Represented in the Union by: Dow AgroSciences Distribution S.A.S., 1 bis, avenue du 8 mai 1945, 78280 Guyancourt, France.

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

- (1) foods and food ingredients containing, consisting of or produced from genetically modified maize (*Zea mays* L.) as referred to in point (e);
- (2) feed containing, consisting of or produced from genetically modified maize (*Zea mays* L.) as referred to in point (e);
- (3) products containing or consisting of genetically modified maize (*Zea mays* L.) as referred to in point (e) for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified maize MON-89Ø34-3 expresses the *cry1A.105* and *cry2Ab2* genes, which confer protection against certain lepidopteran pests.

The genetically modified maize DAS-Ø15Ø7-1 expresses the *cry1F* gene, which confers protection against certain lepidopteran pests and the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified maize MON-ØØ6Ø3-6 expresses the *cp4 epsps* gene, which confers tolerance to glyphosate-based herbicides.

The genetically modified maize DAS-4Ø278-9 expresses the *aad-1* gene, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides.

(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 the maize specified in point (e), with the exception of products referred to in point (b) (1) of this Annex.

(d) **Method for detection:**

- (1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-89Ø34-3, DAS-Ø15Ø7-1, MON-ØØ6Ø3-6 and DAS-4Ø278-9 and further verified on maize stack MON 89034 × 1507 × NK603 × DAS-40278-9.
- (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 0906 (for MON-89Ø34-3) is accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>, and ERM®-BF418 (for DAS-Ø15Ø7-1), ERM®-BF415 (for MON-ØØ6Ø3-6) and ERM®-BF433 (for DAS-4Ø278-9) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>.

(e) **Unique identifiers:**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

MON-89Ø34-3 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;

MON-ØØ6Ø3-6 × DAS-4Ø278-9.

(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 in accordance 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 time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.
