

2023/2133

17.10.2023

COMMISSION IMPLEMENTING DECISION (EU) 2023/2133

of 13 October 2023

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and nine sub-combinations, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2023) 6739)***(Only the French and Dutch texts are 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 Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 31 May 2018, Dow AgroSciences Europe, based in the United Kingdom, submitted, on behalf of Dow AgroSciences LLC, based in the United States, an application to the competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003. The application also concerned the placing on the market of products containing or consisting of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 for uses other than food and feed, with the exception of cultivation.
- (2) In addition, the application concerned the placing on the market of products containing, consisting of or produced from twenty-five sub-combinations of the single transformation events constituting maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9.
- (3) Sixteen of those sub-combinations were already authorised as follows: MON 89034 × 1507, authorised by Commission Implementing Decision 2013/650/EU ⁽²⁾; MON 89034 × MIR162, MON 89034 × NK603, MIR162 × NK603, MON 89034 × MIR162 × NK603, authorised by Commission Implementing Decision (EU) 2021/60 ⁽³⁾; MON 89034 × DAS-40278-9, 1507 × DAS-40278-9, MON 89034 × 1507 × DAS-40278-9, authorised by Commission Implementing Decision (EU) 2019/2086 ⁽⁴⁾; NK603 × DAS-40278-9, MON 89034 × NK603 × DAS-

⁽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 × MON 88017 × 59122 (MON-89034-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3), MON89034 × 1507 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89Ø34-3 × DAS-Ø15Ø7-1), MON89034 × 59122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DAS-Ø15Ø7-1 × MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × 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) 2021/60 of 22 January 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162, NK603, and repealing Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 26, 26.1.2021, p. 5).⁽⁴⁾ Commission Implementing Decision (EU) 2019/2086 of 28 November 2019 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 (OJ L 316, 6.12.2019, p. 87).

40278-9, 1507 × NK603 × DAS-40278-9, MON 89034 × 1507 × NK603 × DAS-40278-9, authorised by Commission Implementing Decision (EU) 2019/2085 ⁽⁵⁾; 1507 × MIR162, authorised by Commission Implementing Decision (EU) 2019/1305 ⁽⁶⁾; 1507 × NK603, authorised by Commission Implementing Decision (EU) 2019/1306 ⁽⁷⁾; MON 89034 × 1507 × NK603, authorised by Commission Implementing Decision 2013/648/EU ⁽⁸⁾; 1507 × MIR162 × NK603, authorised by Commission Implementing Decision (EU) 2021/1388 ⁽⁹⁾.

- (4) This Decision covers the nine remaining sub-combinations in the application: MIR162 × DAS-40278-9, MON 89034 × 1507 × MIR162, MON 89034 × MIR162 × DAS-40278-9, 1507 × MIR162 × DAS-40278-9, MIR162 × NK603 × DAS-40278-9, MON 89034 × 1507 × MIR162 × DAS-40278-9, MON 89034 × 1507 × NK603 × DAS-40278-9, MON 89034 × MIR162 × NK603 × DAS-40278-9, 1507 × MIR162 × NK603 × DAS-40278-9 ('the nine sub-combinations concerned').
- (5) 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 ⁽¹⁰⁾. 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.
- (6) By letter dated 22 March 2021, Corteva Agriscience LLC, based in the United States, informed the Commission that Dow AgroSciences LLC changed its name to Corteva Agriscience LLC as of 1 January 2021.
- (7) By the letter of 22 March 2021, Corteva Agriscience LLC informed the Commission that its representative in the Union, as of 22 March 2021, was Corteva Agriscience Belgium BV, based in Belgium.
- (8) On 12 August 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ⁽¹¹⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. The Authority concluded that genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and its sub-combinations, as described in the application, are as safe as their non-genetically modified comparator and the selected non-genetically modified reference varieties with respect to the potential effects on human and animal health and the environment.

⁽⁵⁾ 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 (OJ L 316, 6.12.2019, p. 80).

⁽⁶⁾ Commission Implementing Decision (EU) 2019/1305 of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 204, 2.8.2019, p. 69).

⁽⁷⁾ 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-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 204, 2.8.2019, p. 75).

⁽⁸⁾ 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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 38).

⁽⁹⁾ Commission Implementing Decision (EU) 2021/1388 of 17 August 2021 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × MIR162 × MON810 × NK603 and genetically modified maize combining two or three of the single events 1507, MIR162, MON810 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 300, 24.8.2021, p. 22).

⁽¹⁰⁾ 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).

⁽¹¹⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2022; Scientific Opinion on the assessment of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and sub-combinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-151). *EFSA Journal* 2022; 20(8):7451. <https://doi.org/10.2903/j.efsa.2022.7451>.

- (9) No new safety concerns were identified for the previously assessed sub-combinations and therefore previous conclusions on those subcombinations remain valid. As regards the nine sub-combinations concerned, the Authority concluded that they are expected to be as safe as the single transformation events MON 89034, 1507, MIR162, NK603 and DAS-40278-9, the previously assessed sub-combinations and the five-event stack maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9.
- (10) 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.
- (11) 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.
- (12) On 17 April 2023, the Authority issued a statement complementing its scientific opinion, taking into account additional information provided by the public. The Authority did not identify any implication of the additional information on the safety of genetically modified maize MIR162 for food and feed or for the environment and confirmed that the conclusions of its scientific opinion remain valid.
- (13) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9, and of the nine sub-combinations concerned, should be authorised for the uses listed in the application.
- (14) A unique identifier should be assigned to genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9, and to the nine sub-combinations concerned, in accordance with Commission Regulation (EC) No 65/2004 ⁽¹²⁾.
- (15) 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 Council ⁽¹³⁾, 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 covered, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (16) 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/EC ⁽¹⁴⁾.
- (17) 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 MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and all sub-combinations thereof, 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.
- (18) 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⁾ 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).

⁽¹³⁾ 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).

⁽¹⁴⁾ 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).

- (19) 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 Council ⁽¹⁵⁾.
- (20) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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 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 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9;
- (b) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × SYN-IR162-4 × DAS-4Ø278-9 for genetically modified maize MON 89034 × 1507 × MIR162 × DAS-40278-9;
- (c) 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;
- (d) the unique identifier MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MON 89034 × MIR162 × NK603 × DAS-40278-9;
- (e) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize 1507 × MIR162 × NK603 × DAS-40278-9;
- (f) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × SYN-IR162-4 for genetically modified maize MON 89034 × 1507 × MIR162;
- (g) the unique identifier MON-89Ø34-3 × SYN-IR162-4 × DAS-4Ø278-9 for genetically modified maize MON 89034 × MIR162 × DAS-40278-9;
- (h) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × DAS-4Ø278-9 for genetically modified maize 1507 × MIR162 × DAS-40278-9;
- (i) the unique identifier SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9 for genetically modified maize MIR162 × NK603 × DAS-40278-9;
- (j) the unique identifier SYN-IR162-4 × DAS-4Ø278-9 for genetically modified maize MIR162 × 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) food and food ingredients containing, consisting of or produced from genetically modified maize referred to in Article 1;

⁽¹⁵⁾ 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 referred to in Article 1;
- (c) products containing or consisting of genetically modified maize 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 the products containing or consisting of the genetically maize referred to Article 1, with the exception of products referred to in point (a) of Article 2.

Article 4

Method for detection

The methods set out in point (d) of the Annex shall apply for the detection of the genetically modified maize referred to in Article 1.

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 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 Corteva Agriscience LLC, represented in the Union by Corteva Agriscience Belgium 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 Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States, represented in the Union by Corteva Agriscience Belgium BV, Rue Montoyer 25, 1000 Brussels, Belgium.

Done at Brussels, 13 October 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Corteva Agriscience LLC
 Address: 9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States;
 represented in the Union by: Corteva Agriscience Belgium BV, Rue Montoyer 25, 1000 Brussels, Belgium.

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

- (1) food and food ingredients containing, consisting of or produced from genetically modified maize referred to in point (e);
- (2) feed containing, consisting of or produced from genetically modified maize referred to in point (e);
- (3) products containing or consisting of genetically modified maize 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 SYN-IR162-4 expresses the *vip3Aa20* gene, which confers protection against certain lepidopteran pests. In addition, the *pmi* gene coding for the PMI protein was used as a selection marker in the genetic modification process.

The genetically modified maize MON-ØØ6Ø3-6 expresses the *cp4 epsps* and *cp4 epsps l214p* genes, which confer tolerance to glyphosate-containing 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 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 genetically modified maize referred to in point (e), with the exception of the products referred to in point (b)(1).

(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, SYN-IR162-4, MON-ØØ6Ø3-6 and DAS-4Ø278-9 and further verified on maize MON-89Ø34-3 × DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9.
- (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 Chemist Society at <https://www.aocs.org/crm#maize>; ERM®-BF418 (for DAS-Ø15Ø7-1), ERM®-BF446 (for SYN-IR162-4), 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://crm.jrc.ec.europa.eu/>.

(e) **Unique identifier:**

MON-89Ø34-3 × DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;
 MON-89Ø34-3 × DAS-Ø15Ø7-1 × SYN-IR162-4 × DAS-4Ø278-9;
 MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;
 MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;
 DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;
 MON-89Ø34-3 × DAS-Ø15Ø7-1 × SYN-IR162-4;
 MON-89Ø34-3 × SYN-IR162-4 × DAS-4Ø278-9;
 DAS-Ø15Ø7-1 × SYN-IR162-4 × DAS-4Ø278-9;
 SYN-IR162-4 × MON-ØØ6Ø3-6 × DAS-4Ø278-9;
 SYN-IR162-4 × 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.