

COMMISSION IMPLEMENTING DECISION (EU) 2021/61**of 22 January 2021**

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021) 255)

(Only the Dutch 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 28 October 2016, Monsanto Europe S.A./N.V. submitted, on behalf of Monsanto company, 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 87427 × MON 87460 × MON 89034 × MIR162 × NK603 ('the application') in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 for uses other than food and feed, with the exception of cultivation. In addition, the application covered the placing on the market of products containing, consisting of or produced from 25 sub-combinations of those single transformation events constituting maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603. 11 of those sub-combinations, MON 87427 × MON 89034 × MIR162 × NK603, MON 87427 × MON 89034 × MIR162, MON 87427 × MON 89034 × NK603, MON 87427 × MIR162 × NK603, MON 89034 × MIR162 × NK603, MON 87427 × MON 89034, MON 87427 × NK603, MON 87427 × MIR162, MON 89034 × NK603, MON 89034 × MIR162 and MIR162 × NK603, are already authorised by Commission Implementing Decision (EU) 2021/60 ⁽²⁾.
- (2) This Decision covers the 14 remaining sub-combinations in the application: MON 87427 × MON 87460 × MON 89034 × MIR162, MON 87427 × MON 87460 × MON 89034 × NK603, MON 87427 × MON 87460 × MIR162 × NK603, MON 87460 × MON 89034 × MIR162 × NK603, MON 87427 × MON 87460 × MON 89034, MON 87427 × MON 87460 × MIR162, MON 87427 × MON 87460 × NK603, MON 87460 × MIR162 × NK603, MON 87460 × MON 89034 × MIR162, MON 87460 × MON 89034 × NK603, MON 87427 × MON 87460, MON 87460 × MIR162, MON 87460 × NK603 and MON 87460 × MON 89034.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ 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 and NK603, and repealing Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (see page 5 of this Official Journal).

- (3) 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 ⁽³⁾. 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.
- (4) On 8 August 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 ⁽⁴⁾. The Authority concluded that genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations, as described in the application, are as safe as and nutritionally equivalent to their 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.
- (5) The Authority concluded that genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603, as described in the application, is as safe as and nutritionally equivalent to the non-genetically modified comparator and the tested non-genetically modified reference varieties. No new safety concerns were identified for the previously assessed sub-combinations and therefore previous conclusions on those sub-combinations remain valid. As regards the remaining sub-combinations, the Authority concluded that they are expected to be as safe as and nutritionally equivalent to the single transformation events MON 87427, MON 87460, MON 89034, MIR162 and NK603, the previously assessed sub-combinations and the five-event stack maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603.
- (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 87427 × MON 87460 × MON 89034 × MIR162 × NK603, and of the 14 sub-combinations referred to above and listed in the application, should be authorised for the uses listed in the application.
- (9) 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.
- (10) 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.
- (11) 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.
- (12) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾.

⁽³⁾ 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).

⁽⁴⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2019. Scientific Opinion on the assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-134). *EFSA Journal* 2019;17(8):5774, <https://doi.org/10.2903/j.efs.2019.5774>

⁽⁵⁾ 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) 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 ⁽⁶⁾, 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 by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.
- (14) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environment effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ⁽⁷⁾.
- (15) 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 food and feed containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603, 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.
- (16) 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.
- (17) 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 ⁽⁸⁾.
- (18) 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-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603;
- (b) the unique identifier MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162;
- (c) the unique identifier MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × NK603;

⁽⁶⁾ 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).

⁽⁷⁾ 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).

⁽⁸⁾ 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).

- (d) the unique identifier MON-87427-7 × MON-87460-4 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × MIR162 × NK603;
- (e) the unique identifier MON-87460-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × MON 89034 × MIR162 × NK603;
- (f) the unique identifier MON-87427-7 × MON-87460-4 × MON-89Ø34-3 for genetically modified maize MON 87427 × MON 87460 × MON 89034;
- (g) the unique identifier MON-87427-7 × MON-87460-4 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 87460 × MIR162;
- (h) the unique identifier MON-87427-7 × MON-87460-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × NK603;
- (i) the unique identifier MON-87460-4 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × MIR162 × NK603;
- (j) the unique identifier MON-87460-4 × MON-89Ø34-3 × SYN-IR162-4 for genetically modified maize MON 87460 × MON 89034 × MIR162;
- (k) the unique identifier MON-87460-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × MON 89034 × NK603;
- (l) the unique identifier MON-87427-7 × MON-87460-4 for genetically modified maize MON 87427 × MON 87460;
- (m) the unique identifier MON-87460-4 × SYN-IR162-4 for genetically modified maize MON 87460 × MIR162;
- (n) the unique identifier MON-87460-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × NK603;
- (o) the unique identifier MON-87460-4 × MON-89Ø34-3 for genetically modified maize MON 87460 × MON 89034.

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;
- (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 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, United States, represented in the Union by Bayer Agriculture BV, 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 BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 22 January 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) Applicant and authorisation holder

Name: Bayer CropScience LP

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

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

(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-87427-7 expresses the CP4 *epsps* gene, which confers tolerance to glyphosate-based herbicides.

The genetically modified maize MON-87460-4 expresses a *Bacillus subtilis* modified *csxB* gene, which aims to reduce yield loss caused by drought stress. In addition, the *nptII* gene, conferring kanamycin and neomycin resistance, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-89034-3 expresses the *cry1A.105* and *cry2Ab2* genes, which confer protection against certain lepidopteran pests.

The genetically modified maize SYN-IR162-4 expresses a modified *vip3Aa20* gene, which provides 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-00603-6 expresses the CP4 *epsps* and the CP4 *epsps* L214P genes, which confers tolerance to glyphosate-based 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 genetically modified maize specified in point (e), with the exception of 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-87427-7, MON-87460-4, MON-89034-3, SYN-IR162-4 and MON-00603-6 and further verified on maize MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6.
- (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: AOCS 0512 (for MON-87427-7), AOCS 0709 (for MON-87460-4) AOCS 0906 (for MON-89034-3) and AOCS 1208 (for SYN-IR162-4) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize> and ERM®-BF415 (for MON-00603-6) is 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-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6;
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4;
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6;
MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6;
MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6;
MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3;
MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4;
MON-87427-7 × MON-8746Ø-4 × MON-ØØ6Ø3-6;
MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6;
MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4;
MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6;
MON-87427-7 × MON-8746Ø-4;
MON-8746Ø-4 × MON-89Ø34-3.
MON-8746Ø-4 × SYN-IR162-4;
MON-8746Ø-4 × MON-ØØ6Ø3-6;

(f) **Information required pursuant to 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.
