

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***(notified under document C(2021)5995)***(Only the Dutch and French 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 8 December 2015, Pioneer Overseas Corporation based in Belgium submitted, on behalf of Pioneer Hi-Bred International Inc., based in United States of America, an application to the national 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 1507 × MIR162 × MON810 × NK603 in accordance with Article 5 and Article 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 1507 × MIR162 × MON810 × NK603 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 10 sub-combinations of those single transformation events constituting maize 1507 × MIR162 × MON810 × NK603.
- (3) Six sub-combinations included in the application were authorised as follows: 1507 × MON810 × NK603 and 1507 × MON810, authorised by Commission Implementing Decision (EU) 2018/1110 ⁽²⁾; MON810 × NK603, authorised by Commission Implementing Decision (EU) 2018/2045 ⁽³⁾; MIR162 × NK603, authorised by Commission Implementing Decision (EU) 2021/60 ⁽⁴⁾; 1507 × NK603, authorised by Commission Implementing Decision (EU) 2019/1306 ⁽⁵⁾; and 1507 × MIR162, authorised by Commission Implementing Decision (EU) 2019/1305 ⁽⁶⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision (EU) 2018/1110 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU (OJ L 203, 10.8.2018, p. 13).

⁽³⁾ Commission Implementing Decision (EU) 2018/2045 of 19 December 2018 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize NK603 × MON 810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 327, 21.12.2018, p. 65).

⁽⁴⁾ 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 (OJ L 26, 26.1.2021, p. 5).

⁽⁵⁾ 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).

⁽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).

- (4) This Decision covers the four remaining sub-combinations in the application: MIR162 × MON810, 1507 × MIR162 × MON810, 1507 × MIR162 × NK603 and MIR162 × MON810 × NK603.
- (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⁽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.
- (6) On 13 January 2021, 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⁽⁸⁾. The Authority concluded that genetically modified maize 1507 × MIR162 × MON810 × NK603, as described in the application, is 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.
- (7) 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 1507, MON810, MIR162 and NK603, the previously assessed sub-combinations and the four-event stack maize 1507 × MIR162 × MON810 × NK603.
- (8) 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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (9) 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.
- (10) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × MIR162 × MON810 × NK603, and of the four sub-combinations referred to above and listed in the application, should be authorised for the uses listed in the application.
- (11) 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⁾.
- (12) 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⁽¹⁰⁾, 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.

⁽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), 2021. Scientific Opinion on the assessment of genetically modified maize 1507 × MIR162 × MON810 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-127). EFSA Journal 2021;19(1):6348, 40 pp, <https://doi.org/10.2903/j.efsa.2021.6348>

⁽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).

- (13) 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 ⁽¹¹⁾.
- (14) 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 1507 × MIR162 × MON810 × 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.
- (15) 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.
- (16) 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⁾.
- (17) 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 DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × MON810 × NK603;
- (b) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize 1507 × MIR162 × MON810;
- (c) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × NK603;
- (d) the unique identifier SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize MIR162 × MON810 × NK603;
- (e) the unique identifier SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize MIR162 × MON810.

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 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 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 Pioneer Hi-Bred International, Inc., represented by Pioneer Overseas Corporation.

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 Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States of America represented by Pioneer Overseas Corporation, Rue Montoyer 25, B-1000 Brussels, Belgium.

Done at Brussels, 17 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Pioneer Hi-Bred International, Inc.

Address: 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States of America

Represented in the Union by: Pioneer Overseas Corporation, Rue Montoyer 25, 1000 Brussels, 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 DAS-Ø15Ø7-1 expresses the *pat* gene, which confers tolerance to glufosinate-ammonium based herbicides, and the *cry1F* gene, which confers 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-ØØ81Ø-6 expresses the *cry1Ab* gene, which confer protection against certain lepidopteran pests.

The genetically modified maize MON-ØØ6Ø3-6 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 AS-Ø15Ø7-1, SYN-IR162-4, MON-ØØ81Ø-6 and MON-ØØ6Ø3-6 and further verified on maize AS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;
- (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: ERM[®]-BF418 (for AS-Ø15Ø7), ERM[®]-BF413 (for MON-ØØ81Ø-6) and ERM[®]-BF415 (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/> and AOCs 1208 (for SYN-IR162-4) is accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>.

(e) Unique identifiers:

DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6;

DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6;

SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

SYN-IR162-4 × MON-ØØ81Ø-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 of the European Parliament and of the Council ⁽¹⁾.

[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.

⁽¹⁾ 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).