

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***(notified under document C(2018) 4937)***(Only the Dutch, English 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 3 February 2011, Pioneer Overseas Corporation submitted, on behalf of Pioneer Hi-Bred International Inc., United States, an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603 ('the application') to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products consisting of or containing genetically modified maize 1507 × 59122 × MON 810 × NK603 for uses other than food and feed, with the exception of cultivation.
- (2) In addition, the application covered 10 sub-combinations of the single transformation events constituting maize 1507 × 59122 × MON 810 × NK603, of which five were already authorised. Eight of those sub-combinations are governed by this Decision. The two sub-combinations that are not covered are 1507 × NK603, which is authorised by Commission Decision 2007/703/EC ⁽²⁾, and NK603 × MON 810, which is authorised by Commission Decision 2007/701/EC ⁽³⁾.
- (3) Sub-combinations 59122 × 1507 × NK603 and 59122 × NK603 were already authorised under, respectively, Commission Decisions 2010/428/EU ⁽⁴⁾ and 2009/815/EC ⁽⁵⁾. The authorisation holder, Pioneer Overseas Corporation, requested the Commission to repeal those earlier Decisions when adopting this Decision and to incorporate them in the scope of this Decision.
- (4) Sub-combination 1507 × 59122 was already authorised by Commission Decision 2010/432/EU ⁽⁶⁾. By letter dated 28 January 2018, Dow Agro Sciences Ltd, as co-authorisation holder for maize 1507 × 59122, asked

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2007/703/EC of 24 October 2007 authorising 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 285, 31.10.2007, p. 47).

⁽³⁾ Commission Decision 2007/701/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603×MON810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 37).

⁽⁴⁾ Commission Decision 2010/428/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 × 1507 × NK603 (DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 201, 3.8.2010, p. 41).

⁽⁵⁾ Commission Decision 2009/815/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 × NK603 (DAS-59122-7 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 29).

⁽⁶⁾ Commission Decision 2010/432/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 (DAS-Ø15Ø7-1 × DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 202, 4.8.2010, p. 11).

to transfer its rights and obligations to Pioneer Overseas Corporation. By letter dated 26 January 2018, Pioneer Overseas Corporation agreed to this transfer and asked the Commission to repeal Decision 2010/432/EU when adopting this present Decision and to incorporate the authorisation for maize 1507 × 59122 in the scope of the present Decision.

- (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 ⁽¹⁾ 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.
- (6) On 28 November 2017, the European Food Safety Authority ('the Authority') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽²⁾. The Authority concluded that genetically modified maize 1507 × 59122 × MON 810 × NK603 is as safe and as nutritious as the non-genetically modified comparator in the context of the scope of the application. No new safety concerns were identified for the five previously assessed sub-combinations (59122 × 1507 × NK603, 1507 × 59122, 59122 × NK603, 1507 × NK603 and NK603 × MON 810) and previous conclusions on those sub-combinations remain valid.
- (7) As regards the five remaining sub-combinations (1507 × 59122 × MON 810, 1507 × MON 810 × NK603, 59122 × MON 810 × NK603, 1507 × MON 810 and 59122 × MON 810), the Authority concluded that they are expected to be as safe as the single maize events 1507, 59122, MON 810 and NK603, the previously assessed five sub-combinations and the four-event stack maize 1507 × 59122 × MON 810 × NK603.
- (8) In its opinion, the Authority considered the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by 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, was in line with the intended uses of the products.
- (10) Taking those considerations into account, the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and the following eight sub-combinations thereof, consisting of: four sub-combinations of three events (1507 × 59122 × MON 810, 59122 × 1507 × NK603, 1507 × MON 810 × NK603 and 59122 × MON 810 × NK603) and four sub-combinations of two events (1507 × 59122, 1507 × MON 810, 59122 × MON 810 and 59122 × NK603) listed in the application should be authorised.
- (11) In the interest of simplification, Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU should be repealed.
- (12) A unique identifier should be assigned to each genetically modified organism ('GMO') covered by this Decision in accordance with Commission Regulation (EC) No 65/2004 ⁽³⁾. The unique identifiers assigned by Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU should continue to be used.
- (13) On the basis of the Authority's opinion, no specific labelling requirements, other than those 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 of the European Parliament and of the Council ⁽⁴⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products covered by this Decision, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

⁽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).

⁽²⁾ EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2017. Scientific opinion on the assessment of genetically modified maize 1507 × 59122 × MON810 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-92). *EFSA Journal* 2017;15(11):5000, 29 pp. <https://doi.org/10.2903/j.efsa.2017.5000>

⁽³⁾ 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).

⁽⁴⁾ 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) The authorisation holder should submit annual reports on the implementation of the activities set out in the monitoring plan for environmental effects and on the results. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽¹⁾.
- (15) The Authority's opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) 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 as provided for in 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 ⁽²⁾.
- (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

The following unique identifiers are assigned to genetically modified maize as specified in point (b) of the Annex to this Decision, in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 1507 × 59122 × MON 810 × NK603;
- (b) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 for genetically modified maize (*Zea mays* L.) 1507 × 59122 × MON 810;
- (c) the unique identifier DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 59122 × 1507 × NK603;
- (d) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 1507 × MON 810 × NK603;
- (e) the unique identifier DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 59122 × MON 810 × NK603;
- (f) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) 1507 × 59122;
- (g) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 for genetically modified maize (*Zea mays* L.) 1507 × MON 810;
- (h) the unique identifier DAS-59122-7 × MON-ØØ81Ø-6 for genetically modified maize (*Zea mays* L.) 59122 × MON 810;
- (i) the unique identifier DAS-59122-7 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 59122 × NK603.

⁽¹⁾ 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).

⁽²⁾ 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).

*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 referred to in Article 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in Article 1;
- (c) genetically modified maize referred to in Article 1 in products containing them or consisting of them, 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 genetically modified maize referred to in Article 1, with the exception of foods and food ingredients.

*Article 4***Method for detection**

The method 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 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 annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission 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 provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Pioneer Hi-Bred International, Inc., United States, represented by Pioneer Overseas Corporation, Belgium.

*Article 8***Repeal**

Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU are hereby repealed.

*Article 9***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 10***Addressee**

This Decision is addressed to:

- Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels, Belgium,
- Dow Agro Sciences Ltd, European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 3 August 2018.

For the Commission
Vytenis ANDRIUKAITIS
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, U.S.A.

Represented by Pioneer Overseas Corporation, Avenue des Arts, 44, 1040 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.) referred to in point (e);
- (2) feed containing, consisting of, or produced from genetically modified maize (*Zea mays* L.) referred to in point (e);
- (3) genetically modified maize (*Zea mays* L.) referred to in point (e) in products containing them or consisting of them for uses other than those provided for in points (1) and (2), with the exception of cultivation.

DAS-Ø15Ø7-1 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

DAS-59122-7 maize expresses Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

MON-ØØ81Ø-6 maize expresses the Cry1Ab protein, which confers protection against certain lepidopteran pests.

MON-ØØ6Ø3-6 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-containing 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 the accompanying documents of the products containing or consisting the maize specified in (e) with the exception of foods and food ingredients.

(d) Method for detection:

- (1) The quantitative event-specific PCR detection methods for maize 1507 × 59122 × MON 810 × NK603 are those validated for genetically modified maize events DAS-Ø15Ø7-1, DAS-59122-7, MON-ØØ81Ø-6 and 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 DAS-Ø15Ø7-1), ERM®-BF424 (for DAS-59122-7), ERM®-BF413 (for MON-ØØ81Ø-6) and ERM®-BF415 (for MON-ØØ6Ø3-6) 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:

DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6;

DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-ØØ81Ø-6;

DAS-59122-7 × MON-ØØ81Ø-6;

DAS-59122-7 × MON-ØØ6Ø3-6.

(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.
