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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

►C1 *(notified under document C(2018) 4973)* ◄

(Only the Dutch, English and French texts are authentic)

(Text with EEA relevance)

(OJ L 203, 10.8.2018, p. 13)

Corrected by:

►C1 Corrigendum, OJ L 221, 31.8.2018, p. 4 (2018/1110)

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COMMISSION IMPLEMENTING DECISION (EU) 2018/1110

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(notified under document C(2018) 4973)

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(Only the Dutch, English and French texts are authentic)

(Text with EEA relevance)

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;

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(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.

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.

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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.

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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/

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(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.