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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)

(OJ L 300, 24.8.2021, p. 22)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2022/325 of 24 February 2022	L 55	70	28.2.2022
►**M2**	Commission Implementing Decision (EU) 2023/2176 of 13 October 2023	L 2176	1	17.10.2023

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COMMISSION IMPLEMENTING DECISION (EU) 2021/1388

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(notified under document C(2021)5995)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

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;

(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.

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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.

▼M1

Article 7

Authorisation holder

The authorisation holder shall be Corteva Agriscience LLC, United States, represented in the Union by Corteva Agriscience Belgium BV.

▼B

Article 8

Validity

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

▼**M1**

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, Bedrijvenlaan 9, 2800 Mechelen, Belgium.

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ANNEX

▼M1

(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, Bedrijvenlaan 9, 2800 Mechelen, Belgium.

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(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;

▼M2

(3) Reference Material: ERM®-BF418 (for DAS-Ø15Ø7), ERM®-BF413 (for MON-ØØ81Ø-6), ERM®-BF415 (for MON-ØØ6Ø3-6) and ERM®-BF446 (for SYN-IR162-4) are accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

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(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).