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

(notified under document C(2019) 5502)

(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 10 August 2010, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × 1507 × GA21 ('the application') to the national competent authority of Germany. The application also covered the placing on the market of products containing or consisting of genetically modified maize Bt11 × MIR162 × 1507 × GA21 for uses other than food and feed, with the exception of cultivation.

(2) 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 ([2]) and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

(3) On 30 July 2013, Syngenta extended the scope of the application to all ten sub-combinations of the single transformation events constituting maize Bt11 × MIR162 × 1507 × GA21.

(4) On 31 March 2016, Syngenta updated the scope of the application by excluding the sub-combinations that were in the scope of other applications: Bt11 × MIR162 × GA21, Bt11 × MIR162, Bt11 × GA21 and MIR162 × GA21, authorised by Commission Implementing Decision (EU) 2016/1685 ([3]) and sub-combinations Bt11 × 1507 × GA21, Bt11 × 1507 and 1507 × GA21, authorised by Commission Implementing Decision (EU) 2017/1209 ([4]). The scope of the application therefore covers sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507.

(5) On 11 July 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([5]). The Authority concluded that genetically modified

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) 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).

([3]) Commission Implementing Decision (EU) 2016/1685 of 16 September 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maizes combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU (OJ L 254, 20.9.2016, p. 22).

([4]) Commission Implementing Decision (EU) 2017/1209 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed (OJ L 173, 6.7.2017, p. 28).

([5]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific Opinion on the assessment of genetically modified maize Bt11 × MIR162 × 1507 × GA21 and three subcombinations independently of their origin, for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2010-86). *EFSA Journal* 2018;16(7):5309.

maize Bt11 × MIR162 × 1507 × GA21, as described in the application, is as safe as and nutritionally equivalent to its non-genetically modified comparator in the context of the scope of the application. As regards the three sub-combinations in the scope of the application, the Authority concluded that they are expected to be as safe as the single events Bt11, MIR162, 1507 and GA21, the previously assessed sub-combinations and the four-event stack maize Bt11 × MIR162 × 1507 × GA21.

(6) In its opinion, the Authority considered 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 Bt11 × MIR162 × 1507 × GA21 and of the three maize sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 should be authorised for the uses listed in the application.

(9) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ([6]).

(10) On the basis of the Authority's opinion, 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 ([7]), 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 such products, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

(11) In order to account for the implementation and the results of the activities set out in the monitoring plan for environmental effects, the authorisation holder should submit annual reports, presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ([8]).

(12) 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 the food and feed, 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.

(13) 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.

(14) 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 ([9]).

(15) 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,

([6]) 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).

([7]) 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).

([8]) 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).

([9]) 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).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organisms and unique identifiers

Genetically modified maize, 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 SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × 1507 × GA21;

(b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × 1507;

(c) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × 1507 × GA21;

(d) the unique identifier SYN-IR162-4 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) MIR162 × 1507.

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 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 referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Syngenta Crop Protection AG, Switzerland, represented by Syngenta Crop Protection NV/SA, 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 Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

Done at Brussels, 26 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder:**

Name: Syngenta Crop Protection AG

Address: Schwarzwaldallee 215, CH-4058 Basel, Switzerland

Represented by Syngenta Crop Protection NV/SA, 489, Avenue Louise, 1050 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 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 SYN-BTØ11-1 maize expresses the Cry1Ab protein, which confers protection against certain lepidopteran pests, and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

The genetically modified SYN-IR162-4 maize expresses the Vip3Aa20 protein, which confers protection against certain lepidopteran pests, and the PMI protein, which was used as a selectable marker.

The genetically modified 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.

The genetically modified MON-ØØØ21-9 maize expresses the mEPSPS protein, 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 the accompanying documents of the products containing or consisting of the maize specified in point (e), with the exception of products referred to in point (b)(1) of this Annex.

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods for maize Bt11 × MIR162 × 1507 × GA21 are those validated for genetically modified maize events SYN-BTØ11-1, SYN-IR162-4, DAS-Ø15Ø7-1 and MON-ØØØ21-9.

(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®-BF412 (for SYN-BTØ11-1) and ERM®-BF418 (for DAS-Ø15Ø7-1) are accessible via the Joint Research Centre (JRC) of the European Commission at https://ec.europa.eu/jrc/en/reference-materials/catalogue/, and AOCS 1208-A and AOCS 0407-A (for SYN-IR162-4), AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) are accessible via the American Oil Chemists Society at https://www.aocs.org/crm#maize.

(e) **Unique identifiers:**

SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4 × DAS-Ø15Ø7-1;

SYN-IR162-4 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-IR162-4 × DAS-Ø15Ø7-1.

(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 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 the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.