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COMMISSION IMPLEMENTING DECISION

of **XXX**

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, 2011/893/EU, 2011/892/EU and 2011/894/EU

(Text with EEA relevance)

(Only the French texts is authentic)

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(Text with EEA relevance)

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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 feed¹, and in particular Articles 7(3), 9(2), 19(3) and 21(2) thereof,

Whereas:

- (1) On 9 February 2009, Syngenta France SAS submitted to the competent authority of Germany 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 Bt11 × MIR162 × MIR604 × GA21 maize ('the application').
- (2) The application also covers the placing on the market of genetically modified maize Bt11 × MIR162 × MIR604 × GA21 in products consisting of it or containing it for other uses than food and feed as any other maize, with the exception of cultivation.
- (3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council² and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (4) On 5 July 2013, Syngenta extended the scope of the application to all sub-combinations of the single genetic modification events constituting Bt11 × MIR162 × MIR604 × GA21 maize ('sub-combinations'), including Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × MIR604 × GA21 which are

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).

already authorised respectively by Commission Decisions 2010/426/EU³, 2011/892/EU⁴, 2011/893/EU⁵ and 2011/894/EU⁶. Syngenta asked the Commission to repeal those four Decisions once authorisation is given to Bt11 × MIR162 × MIR604 × GA21 maize and all sub-combinations.

- (5) On 7 December 2015, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003⁷. It concluded that genetically modified maize Bt11 × MIR162 × MIR604 × GA21, as described in the application, is as safe and as nutritious as its conventional counterpart and no safety concerns are identified for any of the sub-combinations.
- (6) In its opinion, EFSA considered all 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 Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (7) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (8) In its opinion, EFSA recommends the collection of relevant information on expression levels of the newly expressed proteins, if the sub-combinations Bt11 × MIR162 × MIR604, MIR162 × MIR604 × GA21, Bt11 × MIR162, MIR162 × MIR604 and/or MIR162 × GA21 were to be created via targeted breeding approaches and commercialised.
- (9) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified maizes Bt11 × MIR162 × MIR604 × GA21, Bt11 × MIR162 × MIR604, Bt11 × MIR162 × GA21, Bt11 × MIR604 × GA21, MIR162 × MIR604 × GA21, Bt11 × MIR162, Bt11 × MIR604, Bt11 × GA21, MIR162 × MIR604, MIR162 × GA21 and MIR604 × GA21.
- (10) Commission Decisions 2010/426/EU, 2011/893/EU, 2011/892/EU and 2011/894/EU authorising Bt11 × GA21 maize, Bt11 × MIR604 maize, MIR604 × GA21 maize and Bt11 × GA21 × MIR604 maize should be repealed.

³ Commission Decision 2010/426/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xGA21 (SYN-BTØ11-1xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 199, 31.7.2010, p. 36).

⁴ Commission Decision 2011/892/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604xGA21 (SYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 55).

⁵ Commission Decision 2011/893/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604 (SYN-BTØ11-1xSYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 59).

⁶ Commission Decision 2011/894/EU of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 344, 28.12.2011, p. 64).

⁷ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2009-66) for placing on the market of herbicide tolerant and insect resistant maize Bt11 × MIR162 × MIR604 × GA21 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(12):4297, 34 pp. doi:10.2903/j.efsa.2015.4297

- (11) A unique identifier should be assigned to each genetically modified organism (hereinafter "GMO") as provided for in Commission Regulation (EC) No 65/2004⁸.
- (12) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21 including all possible combinations of the single genetic modification events. 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 containing or consisting of maize Bt11 × MIR162 × MIR604 × GA21 and the sub-combinations, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (13) Regulation (EC) No 1830/2003 of the European Parliament and of the Council⁹ lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (14) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC¹⁰. The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (15) The authorisation holder should also submit annual reports on the results of the activities set out in the specific conditions of this authorisation.
- (16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed 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 Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003¹¹.
- (18) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁸ 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).

⁹ 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).

¹⁰ 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).

¹¹ 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 organism and unique identifier

1. The following unique identifiers for genetically modified organisms (GMOs) are assigned in accordance with Regulation (EC) No 65/2004:
 - (a) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × MIR604 × GA21;
 - (b) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × MIR604;
 - (c) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162 × GA21;
 - (d) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × GA21;
 - (e) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × MIR604 × GA21;
 - (f) the unique identifier SYN-BTØ11-1 × SYN-IR162-4 for genetically modified maize (*Zea mays* L.) Bt11 × MIR162;
 - (g) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604;
 - (h) the unique identifier SYN-BTØ11-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × GA21;
 - (i) the unique identifier SYN-IR162-4 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) MIR162 × MIR604;
 - (j) the unique identifier SYN-IR162-4 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR162 × GA21;
 - (k) the unique identifier SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) MIR604 × GA21.
2. The genetically modified maize referred to in paragraph 1 are specified in point (b) of the Annex.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 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 the GMOs referred to in Article 1;
- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1;
- (c) GMOs referred to in Article 1 in products containing them or consisting of them for any other use than those provided 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 the GMOs referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

Article 4

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 5

Specific conditions for the placing on the market

1. The authorisation holder shall ensure that the specific conditions, referred to in point (g) of the Annex, are implemented.
2. The authorisation holder shall submit to the Commission annual reports on the results of the activities set out in the specific conditions of this authorisation for the duration of the authorisation.

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 Syngenta France SAS, representing Syngenta Crop Protection AG, Switzerland.

Article 8

Repeal

Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU are 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 Syngenta France SAS, 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France.

Done at Brussels,

For the Commission,
Vytenis ANDRIUKAITIS
Member of the Commission