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COMMISSION

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[...] (2021) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of **XXX**

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize Bt 11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Text with EEA relevance)

(Only the Dutch and French texts are authentic)

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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 Article 11(3) and Article 23(3) thereof,

Whereas:

- (1) Commission Decision 2010/419/EU² authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified maize Bt11. The scope of that authorisation also covers the placing on the market of products containing or consisting of genetically modified maize Bt11 for uses other than food and feed, with the exception of cultivation.
- (2) On 24 September 2018, Syngenta Crop Protection NV/SA, based in Belgium, on behalf of Syngenta Crop Protection AG, based in Switzerland, submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) On 13 January 2021, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion³ in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties

¹ OJ L 268, 18.10.2003, p. 1.

² Commission Decision 2010/419/EU of 28 July 2010 renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC (OJ L 197, 29.7.2010, p. 11).

³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on the assessment of genetically modified maize Bt11 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-016). EFSA Journal 2021;19(1):6347.

that would change the conclusions of the original risk assessment on genetically modified maize Bt11, issued by the Authority in 2009⁴.

- (4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for the environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.
- (6) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified maize Bt 11 and of products containing or consisting of it for uses other than food or feed, with the exception of cultivation, should be renewed.
- (7) A unique identifier has been assigned to genetically modified maize Bt11, in accordance with Commission Regulation (EC) No 65/2004⁵, in the context of its initial authorisation by Decision 2004/657/EC⁶. That unique identifier should continue to be used.
- (8) For the products covered by this Decision, 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 Council⁷ appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified maize Bt11 remains 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.
- (9) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC⁸.
- (10) 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 food and feed

⁴ EFSA GMO Panel, 2009. Scientific Opinion on application reference EFSA-GMO-RX-Bt11 for renewal of the authorisation of existing products produced from insect-resistant genetically modified maize Bt11, under Regulation (EC) No 1829/2003 from Syngenta. EFSA Journal 2009;7(2):977, p. 13.

⁵ 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).

⁶ Commission Decision 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 300, 25.9.2004, p.48).

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).

containing, consisting of or produced from genetically modified maize Bt 11, 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.

- (11) All relevant information on the authorisation of the products covered by this Decision 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.
- (12) 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 Council⁹.
- (13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) Bt11, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;
- (b) feed containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;
- (c) products containing or consisting of genetically modified maize SYN-BTØ11-1 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'.

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).

2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize SYN-BTØ11-1, 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 SYN-BTØ11-1.

Article 5

Monitoring plan 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.

Article 7

Authorisation holder

The authorisation holder shall be Syngenta Crop Protection AG, represented in the Union by Syngenta Crop Protection NV/SA.

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 AG, Rosentalstrasse 67, CH-4058 Basel, Switzerland, represented in the Union by Syngenta Crop Protection NV/SA, Avenue Louise, 489, BE-1050 Brussels, Belgium.

Done at Brussels,

*For the Commission,
Stella KYRIAKIDES
Member of the Commission*