

SCHEDULES

SCHEDULE 6

Regulation 3

Renewal of the authorisation of the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier SYN-BTØ11-1 is specified for genetically modified maize Bt11.

Authorisation

2. 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 Schedule—

- (a) food 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 sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

3.—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the “name of the organism” is “maize”.

(2) The words “not for cultivation” must appear on the label of and in documents accompanying the products containing or consisting of genetically modified maize SYN-BTØ11-1, with the exception of food and food ingredients.

Method for detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the method specified in sub-paragraph (2) is to be used for the detection of genetically modified maize SYN-BTØ11-1.

(2) Event-specific real-time quantitative PCR based method of detection of the genetically modified maize as set out in the document entitled “Event-specific Method for the Quantification of Maize Line Bt11 using Real-time PCR”, reference “CRLVL10/07VP”, and dated 20 June 2008.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is as set out in the document entitled “Maize Seeds Sampling and DNA Extraction Report on the Validation of a DNA Extraction Method from Maize Seeds and Grains”, reference “CRLVL12/05XP”, and dated 18 April 2007.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material “ERM®-BF412” is accessible via the Joint Research Centre (JRC) of the European Commission⁽¹⁾.

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for renewal of the authorisation of genetically modified maize SYN-BTØ11-1, reference number “RP620” submitted to the Food Safety Authority on 12 March 2021, is implemented.

(2) The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 to Decision 2009/770.

Authorisation holder

6.—(1) The name and address of the authorisation holder is Syngenta Crop Protection AG, Rosentalstrasse 67, CH-4058 Basel, Switzerland.

(2) The authorisation holder is represented in Great Britain by Syngenta Limited, Jealott’s Hill International Research Centre, Bracknell, Berkshire, England, RG42 6EY.

(1) <https://crm.jrc.ec.europa.eu>.