

SCHEDULES

SCHEDULE 5

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × MIR162 × MON 810 × NK603 and sub-combinations

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the following unique identifiers are specified for genetically modified maize 1507 × MIR 162 × MON 810 × NK 603 and the listed sub-combinations—

- (a) DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × MON 810 × NK603;
- (b) DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize 1507 × MIR162 × MON 810;
- (c) DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × NK603;
- (d) SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize MIR162 × MON 810 × NK603;
- (e) SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize MIR162 × MON 810.

Authorisation

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 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 referred to in paragraph 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in paragraph 1;
- (c) products containing or consisting of genetically modified maize referred to in paragraph 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 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 referred to in paragraph 1, with the exception of food and food ingredients.

Status: This is the original version (as it was originally made).

Method for detection

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

(2) The methods are set out in—

- (a) for DAS-Ø15Ø7-1, the document entitled “Event-specific method for the quantitation of maize line TC1507 using real-time PCR”, “Version B”, reference “JRC 113269”, and dated 24 September 2018;
- (b) for SYN-IR162-4, the document entitled “Event-specific Method for the Quantification of Maize MIR162 Using Real-time PCR”, reference “CRLVL08/08VP”, and dated 31 January 2011;
- (c) for MON-ØØ81Ø-6, the document entitled “CRL assessment on the validation of an event specific method for the relative quantitation of maize line MON 810 DNA using real-time PCR as carried out by Federal Institute for Risk Assessment (BfR)”, reference “CRL-VL-25/04VR”, and dated 10 March 2006;
- (d) for MON-ØØ6Ø3-6, the document entitled “Event-specific method for the quantitation of maize line NK603 using real-time PCR”, reference “CRLVL27/04VP”, and dated 10 January 2005.

(3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) is set out in the document entitled “Report on the In-house Validation of a DNA Extraction Method from Ground Maize Seeds and Validated DNA Extraction Method”, reference “EURL-VL-02/14XP”, and dated 10 April 2018.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003—

- (a) the following reference materials are accessible via the Joint Research Centre of the European Commission⁽¹⁾—
 - (i) ERM®-BF418 (for DAS-Ø15Ø7);
 - (ii) ERM®-BF413 (for MON-ØØ81Ø-6);
 - (iii) ERM®-BF415 (for MON-ØØ6Ø3-6);
- (b) the reference material AOCs 1208-A3 (for SYN-IR162-4) is accessible via the American Oil Chemists’ Society⁽²⁾.

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 the authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1184” submitted to the Food Safety Authority⁽³⁾ on 5 July 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 authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

(2) <https://www.aocs.org/crm/>

(3) “Food Safety Authority” is defined in Article 2(17) of Regulation 1829/2003.

(2) The authorisation holder is represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.