

SCHEDULE 3

Regulation 3(1)

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and sub-combinations

Genetically modified organisms and unique identifiers

1. For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the following unique identifiers are specified for genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and its sub-combinations as follows—

- (a) MON-87427-7 × MON-89034-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON-87427-7 × MON 89034 × MIR162 × NK603,
- (b) MON-87427-7 × MON-89034-3 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 89034 × MIR162,
- (c) MON-87427-7 × MON 89034-3 × MON ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 89034 × NK603,
- (d) MON -87427-7 × SYN-IR162-4 × MON ØØ6Ø3-6 for genetically modified maize MON 87427 × MIR162 × NK603,
- (e) MON-89034-3 × SYN-IR162-4 × MON ØØ6Ø3-6 for genetically modified maize MON 89034 × MIR162 × NK603,
- (f) MON-87427-7 × MON 89034-3 for genetically modified maize MON 87427 × MON 89034,
- (g) MON-87427-7 × MON ØØ6Ø3 for genetically modified maize MON 87427 × NK603,
- (h) MON-87427-7 × SYN-IR162-4 for genetically modified maize MON 87427 × MIR162,
- (i) MON-89034-3 × MON- ØØ6Ø3-6 for genetically modified maize MON 89034 × NK603,
- (j) MON-89034-3 × SYN-IR162-4 for genetically modified maize MON 89034 × MIR162,
- (k) SYN-IR162 × MON- ØØ6Ø3-6 for genetically modified maize MIR162 × NK603.

Authorisation

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) 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 as referred to in paragraph 1,
- (b) feed containing, consisting of or produced from genetically modified maize as referred to in paragraph 1,
- (c) products containing or consisting from genetically modified maize as referred to in paragraph 1 for uses other than those in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

Status: This is the original version (as it was originally made).

(2) The words “not for cultivation” must appear on the label of and in documents accompanying products containing or consisting of genetically modified maize referred to in paragraph 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 (EC) 1829/2003, the methods specified in sub-paragraphs (2) to (5) are to be used for detection of genetically modified maize referred to in paragraph 1.

(2) The method specified in this sub-paragraph is 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 MON 87427 Using Real Time PCR”, reference “EURL-VL-0417VP”.

(3) 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 MON 89034 Using Real Time PCR”, reference “CRLVL06/06VP”.

(4) 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 MIR162 Using Real Time PCR”, reference “CRLVL08/08VP”.

(5) 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 quantitation of maize line NK603 using real time PCR-Protocol”, reference “CRLV27/04VP”.

(6) The method of DNA extraction for use in the detection method specified in sub-paragraphs (2) to (5) is as set out in the document entitled “Report on the Validation of a DNA Extraction Method for Maize Seeds and Grains”, reference “CRLVL16/05XP corrected version 2”.

(7) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference materials AOCS 0512-A2, AOCS 0906-E2, AOCS 1208-A3 and ERM®-BF415 are accessible from the American Oil Chemists Society and the Joint Research Centre (JRC) of the European Commission⁽¹⁾.

Monitoring plan for environmental effects

5.—(1) The authorisation holder must implement 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 “RP535” submitted to the Food Safety Authority on 5 March 2021.

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

Authorisation holder

6.—(1) The name and address of the authorisation holder is Bayer CropScience LP, 800 N. Lindbergh Boulevard, St Louise, Missouri 63167, United States of America.

(2) The authorisation holder is represented in Great Britain by Bayer CropScience Ltd, 230 Cambridge Science Park, Milton Road, Cambridge, England CB4 0WB.

(1) <https://www.aocs.org/crm>, <https://crm.jrc.ec.europa.eu/>.