

SCHEDULE 4

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize and its 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 MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize and its sub-combinations as follows—

- (a) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122,
- (b) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-01507-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411,
- (c) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-01507-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × 59122,
- (d) MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411 × 59122,
- (e) MON-87427-7 × MON-87460-4 × DAS-01507-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411 × 59122,
- (f) MON-87427-7 × MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411 × 59122,
- (g) MON-87460-4 × MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411 × 59122,
- (h) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-01507-1 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507,
- (i) MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411,
- (j) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 59122,
- (k) MON-87427-7 × MON-87460-4 × DAS-01507-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411,
- (l) MON-87427-7 × MON-87460-4 × DAS-01507-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × 59122,
- (m) MON-87427-7 × MON-87460-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 87411 × 59122,
- (n) MON-87427-7 × MON-89034-3 × DAS-01507-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411,
- (o) MON-87427-7 × MON-89034-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × MON 87411 × 59122,
- (p) MON-87427-7 × DAS-01507-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × 1507 × MON 87411 × 59122,

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- (q) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411,
- (r) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × 59122,
- (s) MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × MON 87411 × 59122,
- (t) MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × MON 87411 × 59122,
- (u) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × 1507 × MON 87411 × 59122,
- (v) MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × 1507,
- (w) MON-87427-7 × MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 87411,
- (x) MON-87427-7 × MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 59122,
- (y) MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × 1507 × MON 87411,
- (z) MON-87427-7 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87411 × 59122,
- (aa) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × MON 89034 × 1507,
- (bb) MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × MON 87411,
- (cc) MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 59122,
- (dd) MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × 1507 × MON 87411,
- (ee) MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × 59122,
- (ff) MON-8746Ø-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 87411 × 59122,
- (gg) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 89034 × 1507 × MON 87411,
- (hh) MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × MON 87411 × 59122,
- (ii) DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize 1507 × MON 87411 × 59122,
- (jj) MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × 1507,
- (kk) MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87460 × 87411,
- (ll) MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87460 × 59122,
- (mm) DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize 1507 × MON 87411,
- (nn) MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87411 × 59122.

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 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 of 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 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 products containing or consisting of genetically modified maize as 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 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 MON-87427-7, the document entitled “Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR”, reference “EURL-VL-03/12VP” and dated 9 June 2015,
- (b) for MON-87460-4, the document entitled “Event-specific Method for the Quantification of Maize MON 87460 Using Real-time PCR”, reference “CRLVL04/09VP” and dated 18 January 2012,
- (c) for MON-89034-3, the document entitled “Event-specific Method for the Quantification of Maize Line MON 89034 Using Real-time PCR”, reference “CRLVL06/06VP” and dated 21 October 2008,
- (d) for DAS-01507-1, the document entitled “Event-specific method for the quantitation of maize line TC1507 using real-time PCR”, reference “CRLVL02/04VP” and dated 9 March 2005,
- (e) for MON-87411-9, the document entitled “Event-specific Method for the Quantification of maize MON 87411 by Real-time PCR”, reference “EURL-VL-01/15VP” and dated 4 July 2016,
- (f) for DAS-59122-7, the document entitled “Event-specific method for the quantitation of maize 59122 using real-time PCR”, reference “CRLVL03/05VP – corrected version 1” and dated 8 June 2007.

(3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) 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” and dated 26 July 2017.

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

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- (a) the following reference materials are accessible from the American Oil Chemists' Society⁽¹⁾
 - (i) "AOCS 0512-A2" (for MON-87427-7),
 - (ii) "AOCS 0709-A2" (for MON-87460-4),
 - (iii) "AOCS 0906-E2" (for MON-89034-3),
 - (iv) "AOCS 0215-B" (for MON-87411-9),
- (b) the following reference materials are accessible from the Joint Research Centre of the European Commission⁽²⁾—
 - (i) "ERM®-BF418" (for DAS-01507-1),
 - (ii) "ERM®-BF424" (for DAS-59122-7).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP1180" submitted to the Food Safety Authority on 2 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 of Decision 2009/770.

Authorisation holder

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

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

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

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