STATUTORY INSTRUMENTS

2022 No. 486

AGRICULTURE, ENGLAND
FOOD, ENGLAND

The Genetically Modified Food and Feed (Authorisations) (England) Regulations 2022

Made - - - -	*27th April 2022*
Laid before Parliament	*28th April 2022*
Coming into force - -	*20th May 2022*

The Secretary of State makes these Regulations in exercise of the powers conferred by Articles 7(3), 9(2), 11, 19(3), 21(2), 23 and 35 of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(**1**).

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**2**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Citation, commencement, extent and application

1. These Regulations—

(a) may be cited as the Genetically Modified Food and Feed (Authorisations) (England) Regulations 2022;

(b) come into force on 20th May 2022;

(c) extend to England and Wales; and

(d) apply in relation to England only.

Interpretation

2. In these Regulations—

"Regulation 1829/2003" means Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed;

(**1**) EUR 1829/2003; relevant amending instruments are S.I. 2019/705, 2020/1504 and 2022/377. The terms "appropriate authority" and "prescribe" are defined in Article 2 of Regulation 1829/2003.

(**2**) EUR 178/2002; relevant amending instruments are S.I. 2019/641 and 2020/1504.

"Regulation 1830/2003" means Regulation (EC) No. 1830/2003 of the European Parliament and of the Council 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(**3**);

"Decision 2009/770" means Commission Decision 2009/770/EC 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 the placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council(**4**).

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified organisms

3. Schedules 1 to 9 have effect.

Revocations

4. The following Decisions are revoked—

(a) Commission Decision 2009/813/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council(**5**);

(b) Commission Decision 2009/814/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council(**6**);

(c) Commission Decision 2009/866/EC authorising the placing on the market of products, containing, consisting of, or produced from genetically modified maize MIR604 (SYN-IR6Ø4-5) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council(**7**);

(d) Commission Decision 2010/419/EU 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(**8**);

(e) Commission Implementing Decision (EU) 2018/1111 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU(**9**).

(**3**) EUR 1830/2003; relevant amending instruments are S.I. 2019/90, 2019/778 and 2020/1421.
(**4**) EUD 2009/770, amended by S.I. 2019/90.
(**5**) EUD 2009/813, amended by S.I. 2019/705.
(**6**) EUD 2009/814, amended by S.I. 2019/705.
(**7**) EUD 2009/866, amended by S.I. 2019/705.
(**8**) EUD 2010/419, amended by S.I. 2019/705.
(**9**) EUD 2018/1111, amended by S.I. 2019/705.

Maggie Throup
Parliamentary Under Secretary of State
Department of Health and Social Care

27th April 2022

SCHEDULES

SCHEDULE 1

Regulation 3

Renewal of the authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604

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-IR6Ø4-5 is specified for genetically modified maize MIR604.

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 SYN-IR6Ø4-5;

(b) feed containing, consisting of, or produced from genetically modified maize SYN-IR6Ø4-5; and

(c) products containing or consisting of genetically modified maize SYN-IR6Ø4-5 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 the genetically modified maize SYN-IR6Ø4-5, 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-IR6Ø4-5.

(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 MIR604 using Real time PCR", reference "CRLVL04/05VP corrected version 1" and dated 30 March 2010.

(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", reference "CRLVL04/05XP" and dated 3 April 2007.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material "ERM-BF423" is accessible via the Joint Research Centre of the European Commission(**10**).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**11**), which accompanied the application for the renewal of the authorisation of genetically modified maize SYN-IR6Ø4-5, reference number "RP476" submitted to the Food Safety Authority(**12**) on 3 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 of Decision 2009/770.

Authorisation holder

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

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

SCHEDULE 2

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize MZIR098

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-ØØØ98-3 is specified for genetically modified maize MZIR098.

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 SYN-ØØØ98-3;

(b) feed containing, consisting of, or produced from genetically modified maize SYN-ØØØ98-3; and

(c) products containing or consisting of genetically modified maize SYN-ØØØ98-3 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'.

(**10**) https://crm.jrc.ec.europa.eu.
(**11**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).
(**12**) "Food Safety Authority" is defined in Article 2(17) of 1829/2003, as regards England, as the Food Standards Agency.

(2) The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of genetically modified maize SYN-ØØØ98-3, 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-ØØØ98-3.

(2) Event-specific real-time quantitative PCR based method of detection of the genetically modified maize SYN-ØØØ98-3 as set out in the document entitled "Event-specific Method for the Quantification of Maize MZIR098 by Real-time PCR", reference "EURL-VL-04/17VP" and published 7 December 2018.

(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", reference "CRLVL04/05XP" and dated 3 April 2007.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material "AOCS 1114-B2" is accessible via the American Oil Chemists' Society (AOCS)(**13**).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**14**), which accompanied the application for authorisation of genetically modified maize SYN-ØØØ98-3, reference number "RP526" submitted to the Food Safety Authority on 5 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 of Decision 2009/770.

Authorisation holder

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

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

(**13**) https://www.aocs.org/crm.
(**14**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

SCHEDULE 3

Regulation 3

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 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 89034 × MIR162 × NK603 and its sub-combinations as follows—

(a) MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603;

(b) MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 89034 × MIR162;

(c) MON-87427-7 × MON-89Ø34-3 × 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-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 89034 × MIR162 × NK603;

(f) MON-87427-7 × MON-89Ø34-3 for genetically modified maize MON 87427 × MON 89034;

(g) MON-87427-7 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × NK603;

(h) MON-87427-7 × SYN-IR162-4 for genetically modified maize MON 87427 × MIR162;

(i) MON-89Ø34-3 × MON-ØØ6Ø3-6 for genetically modified maize MON 89034 × NK603;

(j) MON-89Ø34-3 × SYN-IR162-4 for genetically modified maize MON 89034 × MIR162;

(k) SYN-IR162-4 × 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 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; and

(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 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-paragraphs (2) to (5) are to be used for the detection of genetically modified maize referred to in paragraph 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 MON 87427 Using Real-time PCR", reference "EURL-VL-03/12VP" and dated 9 June 2015.

(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" and dated 21 October 2008.

(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 MIR162 Using Real-time PCR", reference "CRLVL08/08VP" and dated 31 January 2011.

(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", reference "CRLVL27/04VP" and published 10 January 2005.

(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" and dated 26 July 2017.

(7) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference materials "AOCS 0512-A2" (for MON-87427-7), "AOCS 0906-E2" (for MON-89Ø34-3) and "AOCS 1208-A3" (for SYN-IR162-4) are accessible via the American Oil Chemists' Society (AOCS) and the reference material "ERM-BF415" (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre of the European Commission.

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**15**), which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP535" submitted to the Food Safety Authority on 5 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 of Decision 2009/770.

Authorisation holder

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

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

(**15**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

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 89034 × MIR162 × MON 87411 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 MON 87427 × MON 89034 × MIR162 × MON 87411 and sub-combinations as follows—

(a) MON-84727-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411;

(b) MON-84727-7 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × MON 87411;

(c) MON-84727-7 × SYN-IR162-4 × MON-87411-9 for genetically modified maize MON 87427 × MIR162 × MON 87411;

(d) MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9 for genetically modified maize MON 89034 × MIR162 × MON 87411;

(e) MON-84727-7 × MON-87411-9 for genetically modified maize MON 87427 × MON 87411;

(f) MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 89034 × MON 87411;

(g) SYN-IR162-4 × MON-87411-9 for genetically modified maize MIR162 × MON 87411.

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; and

(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 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-paragraphs (2) to (5) are to be used for the detection of genetically modified maize referred to in paragraph 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 MON 87427 Using Real-time PCR", reference "EURL-VL-03/12VP" and dated 9 June 2015.

(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" and dated 21 October 2008.

(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 MIR162 Using Real-time PCR", reference "CRLVL08/08VP" and dated 31 January 2011.

(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 Quantification of maize MON 87411 by Real-time PCR", reference "EURL-VL-01/15VP" and published 4 July 2016.

(6) The method of DNA extraction for use in the detection methods 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" and dated 26 July 2017.

(7) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference materials "AOCS 0512-A2" (for MON-87427-7), "AOCS 0906-E2" (for MON-89Ø34-3), "AOCS 1208-A3" (for SYN-IR162-4) and "AOCS 0215-B" (for MON-87411-9) are accessible via the American Oil Chemists' Society (AOCS).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**16**), which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP606" submitted to the Food Safety Authority on 11 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 of Decision 2009/770.

Authorisation holder

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

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

(**16**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

SCHEDULE 5

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier MON-87751-7 × MON-877Ø1-2 × MON-877Ø8-9 × MON-89788-1 is specified for genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788.

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 soybean MON-87751-7 × MON-877Ø1-2 × MON-877Ø8-9 × MON-89788-1;

(b) feed containing, consisting of, or produced from genetically modified soybean MON-87751-7 × MON-877Ø1-2 × MON-877Ø8-9 × MON-89788-1; and

(c) products containing or consisting of genetically modified soybean MON-87751-7 × MON-877Ø1-2 × MON-877Ø8-9 × MON-89788-1 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 'soybean'.

(2) The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of genetically modified soybean MON-87751-7 × MON-877Ø1-2 × MON-877Ø8-9 × MON-89788-1, 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-paragraphs (2) to (5) are to be used for the detection of genetically modified soybean referred to in paragraph 1.

(2) Event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled "Event-specific Method for the Quantification of Soybean MON 87751 Using Real-time PCR", reference "EURL-VL-03/14VP corrected version 1" and dated 1 August 2016.

(3) Event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled "Event-specific Method for the Quantification of Soybean MON 87701 Using Real-time PCR", reference "CRLVL05/09VP" and dated 13 July 2011.

(4) Event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled "Event-specific Method for the Quantification of Soybean MON 87708 Using Real-time PCR", reference "EURL-VL-02/11VP" and dated 6 May 2013.

(5) Event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled "Event-specific Method for the Quantification

of Soybean Line MON 89788 Using Real-time PCR", reference "CRLVL05/06VP" and dated 18 February 2008.

(6) The method of DNA extraction for use in the detection methods 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 Soybean Seeds", reference "CRL-VL-05/06XP corrected version 2" and dated 16 March 2018.

(7) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference materials "AOCS 0215-A" (for MON-87751-7), "AOCS 0809-A2" (for MON-877Ø1-2), "AOCS 0311-A2" (for MON-877Ø8-9) and "AOCS 0906-B2" (for MON-89788-1) are accessible via the American Oil Chemists' Society (AOCS).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**17**), which accompanied the application for authorisation of the genetically modified soybean MON-87751-7 × MON-877Ø1-2 × MON-877Ø8-9 × MON-89788-1, reference number "RP607" submitted to the Food Safety Authority on 11 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 of Decision 2009/770.

Authorisation holder

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

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

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; and

(**17**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

(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 "CRVL10/07VP" 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.

(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 of the European Commission.

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**18**), 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 of Decision 2009/770.

Authorisation holder

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

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

(**18**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

SCHEDULE 7

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 × MIR162 × 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 MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and sub-combinations as follows—

(a) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603;

(b) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162;

(c) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × NK603;

(d) MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × MIR162 × NK603;

(e) MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × MON 89034 × MIR162 × NK603;

(f) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 for genetically modified maize MON 87427 × MON 87460 × MON 89034;

(g) MON-87427-7 × MON-8746Ø-4 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 87460 × MIR162;

(h) MON-87427-7 × MON-8746Ø-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87427 × MON 87460 × NK603;

(i) MON-8746Ø-4 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × MIR162 × NK603;

(j) MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 for genetically modified maize MON 87460 × MON 89034 × MIR162;

(k) MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × MON 89034 × NK603;

(l) MON-87427-7 × MON-8746Ø-4 for genetically modified maize MON 87427 × MON 87460;

(m) MON-8746Ø-4 × SYN-IR162-4 for genetically modified maize MON 87460 × MIR162;

(n) MON-8746Ø-4 × MON-ØØ6Ø3-6 for genetically modified maize MON 87460 × NK603;

(o) MON-8746Ø-4 × MON-89Ø34-3 for genetically modified maize MON 87460 × MON 89034.

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; and

(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-paragraphs (2) to (6) are to be used for the detection of genetically modified maize referred to in paragraph 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 MON 87427 Using Real-time PCR", reference "EURL-VL-03/12VP" and dated 9 June 2015.

(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 MON 87460 Using Real-time PCR", reference "CRLVL04/09VP" and dated 18 January 2012.

(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 MON 89034 Using Real-time PCR", reference "CRLVL06/06VP" and dated 21 October 2008.

(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 Quantification of Maize MIR162 Using Real-time PCR", reference "CRLVL08/08VP" and dated 31 January 2011.

(6) 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", reference "CRLVL27/04VP" and dated 10 January 2005.

(7) The method of DNA extraction for use in the detection method specified in sub-paragraphs (2) to (6) 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.

(8) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference materials "AOCS 0512-A2" (for MON-87427-7), "AOCS 0709-A2" (for MON-8746Ø-4), "AOCS 0906-E2" (for MON-89Ø34-3) and "AOCS 1208-A3" (for SYN-IR162-4) are accessible via the American Oil Chemists' Society (AOCS) and the reference material "ERM-BF415" (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre of the European Commission.

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**19**), which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP714" submitted to the Food Safety Authority on 26 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 of Decision 2009/770.

Authorisation holder

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

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

SCHEDULE 8

Regulation 3

Renewal of the authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier MON-88Ø17-3 is specified for genetically modified maize MON 88017.

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 MON-88Ø17-3;

(b) feed containing, consisting of or produced from genetically modified maize MON-88Ø17-3; and

(c) products containing or consisting of genetically modified maize MON-88Ø17-3 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 MON-88Ø17-3, with the exception of food and food ingredients.

(**19**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

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 MON-88Ø17-3.

(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 MON 88017 Using Real-time PCR", reference "CRLVL16/05VP corrected version 1" and dated 30 March 2010.

(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 "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, the reference material "AOCS 0406-D2" is accessible via the American Oil Chemists' Society (AOCS).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**20**), which accompanied the application for renewal of the authorisation of genetically modified maize MON-88Ø17-3, reference number "RP715" submitted to the Food Safety Authority on 26 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 of Decision 2009/770.

Authorisation holder

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

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

SCHEDULE 9

Regulation 3

Renewal of the authorisation of the placing on the market products containing, consisting of, or produced from genetically modified maize MON 89034

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier MON-89Ø34-3 is specified for genetically modified maize MON 89034.

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 MON-89Ø34-3;

(**20**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

(b) feed containing, consisting of, or produced from genetically modified maize MON-89Ø34-3; and

(c) products containing or consisting of genetically modified maize MON-89Ø34-3 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 MON-89Ø34-3, 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 MON-89Ø34-3.

(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 MON 89034 Using Real-time PCR", reference "CRLVL06/06VP" and dated 21 October 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 "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, the reference material "AOCS 0906-E2" is accessible via the American Oil Chemists' Society (AOCS).

Monitoring plan for environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects(**21**), which accompanied the application for renewal of the authorisation of genetically modified maize MON-89Ø34-3, reference number "RP716" submitted to the Food Safety Authority on 26 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 of Decision 2009/770.

Authorisation holder

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

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

(**21**) A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations authorise the placing on the market of specified genetically modified food and feed products in England.

Each Schedule in these Regulations provides for the authorisation of a product in accordance with Articles 7(3) and 19(3) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed ("Regulation 1829/2003") as follows—

(a) Schedule 1 renews the authorisation for genetically modified maize MIR604;

(b) Schedule 2 is a new authorisation for genetically modified maize MZIR098;

(c) Schedule 3 is a new authorisation for genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and its sub-combinations;

(d) Schedule 4 is a new authorisation for genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and the sub-combinations that are not authorised by Schedule 3;

(e) Schedule 5 is a new authorisation for genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788;

(f) Schedule 6 renews the authorisation for genetically modified maize Bt11;

(g) Schedule 7 is a new authorisation for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and the sub-combinations that are not authorised by Schedule 3;

(h) Schedule 8 renews the authorisation for genetically modified maize MON 88017;

(i) Schedule 9 renews the authorisation for genetically modified maize MON 89034.

Authorisations granted by these Regulations are valid for a period of ten years in accordance with Articles 7(4) and 19(4) of Regulation 1829/2003 and will expire at the end of 19th May 2032. This is subject to Articles 11(4) and 23(4) of that Regulation, which provide for an extension of the authorisation period in certain circumstances where an application for renewal has been submitted.

Paragraphs (a) to (d) of regulation 4 revoke, in relation to England, retained EU Decisions that contain the previous authorisations (which have expired) for the products now authorised by Schedules 1, 6, 8 and 9.

Paragraph (e) of regulation 4 revokes, in relation to England, Commission Implementing Decision (EU) 2018/1111 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603 and repealing Decision (EU) 2010/420/EU which contained the authorisation for four of the sub-combinations of the product now authorised by Schedule 3.

Information on the authorisation of the products will be entered in the register of genetically modified food and feed referred to in Article 28(1) of Regulation 1829/2003.

The authorisations made by this instrument will be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity ("the Cartagena Protocol"), pursuant to Article 9(1) and Article 15(1)(e) of Regulation (EC) No. 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms.

Further information, including in relation to the monitoring plans, the register, or the information notified pursuant to the Cartagena Protocol, can be obtained from the Food Standards Agency, Floors 6 and 7, Clive House, 70 Petty France, London, SW1H 9EX or by writing to GM.Inquiries@food.gov.uk.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.