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SCOTTISH STATUTORY INSTRUMENTS

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**2022 No. 137**

**AGRICULTURE  
FOOD**

**The Genetically Modified Food and Feed  
(Authorisations) (Scotland) Regulations 2022**

<i>Made</i>	- - - -	<i>19th April 2022</i>
<i>Laid before the Scottish Parliament</i>	- - - -	<i>21st April 2022</i>
<i>Coming into force</i>	- -	<i>31st May 2022</i>

The Scottish Ministers make 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).

There has been consultation 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).

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022 and come into force on 31 May 2022.

(2) These Regulations extend to Scotland.

**Interpretation**

2. In these Regulations—

“Decision 2009/770/EC” means Commission Decision 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 placing on the market(3),

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(1) EUR 1829/2003 as amended by S.I. 2019/705, 2020/1504 and 2022/377. The terms “appropriate authority” and “prescribe” are defined in Article 2.  
(2) EUR 178/2002 as amended by S.I. 2019/641 and 2020/1504.  
(3) EUD 2009/770 as amended by S.I. 2019/90.

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

“Regulation (EC) 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(4).

### Authorisation

3.—(1) Schedules 1 to 9 have effect.

(2) Subject to Articles 11(4) and 23(4) of Regulation 1829/2003, the authorisations set out in schedules 1 to 9 cease to have effect at the end of 30 May 2032.

### Revocations

4. The following instruments are revoked—

- (a) Commission Decision (EC) 2009/813 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3)(5),
- (b) Commission Decision (EC) 2009/814 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3)(6),
- (c) Commission Decision (EC) 2009/866 authorising the placing on the market of products, containing, consisting of or produced from genetically modified maize MIR604 (SYN-IR6Ø4-5)(7),
- (d) Commission Decision (EU) 2010/419 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)(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 89304 × 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(9).

St Andrew’s House,  
Edinburgh  
19th April 2022

*MAREE TODD*  
Authorised to sign by the Scottish Ministers

(4) EUR 1830/2003 as amended by S.I. 2019/90, 2019/778 and 2020/1421.

(5) EUD 2009/813.

(6) EUD 2009/814.

(7) EUD 2009/866.

(8) EUD 2010/419.

(9) EUD 2018/1111.

## SCHEDULE 1

Regulation 3(1)

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 (EC) 1829/2003, the unique identifier SYN-IR604-5 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 (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 SYN-IR604-5,
- (b) feed containing, consisting of or produced from genetically modified maize SYN-IR604-5,
- (c) products containing or consisting of genetically modified maize SYN-IR604-5 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 (EC) 1829/2003, and in Article 4(6) of Regulation (EC) 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-IR604-5, with the exception of food and food ingredients.

### Method of detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the method specified in sub-paragraph (2) is to be used for the 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 Line MIR604 using real time PCR”, reference “CRLVL04/05VP corrected version 1”.

(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”.

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

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

### **Monitoring plan for the environmental effects**

5.—(1) The authorisation holder must implement the monitoring plan for environmental effects, which accompanied the application for renewal of the authorisation of genetically modified maize SYN-IR604-5, reference number “RP476” submitted to the Food Safety Authority on 3 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 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.

## SCHEDULE 2

Regulation 3(1)

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 [\(EC\) 1829/2003](#), the unique identifier SYN-00098-3 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 [\(EC\) 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 SYN-00098-3,
- (b) feed containing, consisting of or produced from genetically modified maize SYN-00098-3,
- (c) products containing or consisting of genetically modified maize SYN-00098-3 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 [\(EC\) 1829/2003](#), and in Article 4(6) of Regulation [\(EC\) 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 SYN-00098-3, 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 (EC) 1829/2003, the method specified in sub-paragraph (2) is to be used for detection of the 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 for 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-0417VP”.

(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”.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference material AOCS 1114-B2 is accessible from the American Oil Chemists Society (AOCS)(11).

### Monitoring plan for environmental effects

5.—(1) The authorisation holder must implement the monitoring plan for environmental effects 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.

(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 Sygenta Crop Protection AG, Rosentalsrasse 67, CH-4058 Basel, Switzerland.

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

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

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

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- (c) MON-87427-7 × MON 89034-3 × MON 00603-6 for genetically modified maize MON 87427 × MON 89034 × NK603,
- (d) MON -87427-7 × SYN-IR162-4 × MON 00603-6 for genetically modified maize MON 87427 × MIR162 × NK603,
- (e) MON-89034-3 × SYN-IR162-4 × MON 00603-6 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 00603 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- 00603-6 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- 00603-6 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”.

(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(12).

### **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.

## SCHEDULE 4

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 × MON 87411 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 × MON 87411 and its sub-combinations as follows—

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

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



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- (c) MON-84727-7 × SYN-IR162-4 × MON-87411-9 for genetically modified maize MON 87427 × MIR162 × MON 87411,
- (d) MON-89034-3 × 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-89034-3 × 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 (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 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 (EC) 1829/2003 and in Article 4(6) of Regulation (EC) 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 (EC) 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) 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) 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 Line MON 89034 Using Real-time PCR”, reference “CRLVL06/06VP”.

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

(5) 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 87411 by Real-time PCR”, reference “EURL-VL-01/15VP”.

(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”.

(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 AOCS 0215-B are accessible from the American Oil Chemists Society(13).

### **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 “RP606” submitted to the Food Safety Authority on 11 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 Louis, 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.

## **SCHEDULE 5**

Regulation 3(1)

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 (EC) 1829/2003, the unique identifier MON-87751-7 × MON-87701-2 × MON-87708-9 × 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 (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 soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1,
- (b) feed containing, consisting of or produced from genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1,

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

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- (c) products containing or consisting of genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × 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 (EC) 1829/2003, and in Article 4(6) of Regulation (EC) 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-87701-2 × MON-87708-9 × 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 MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1.

(2) The method specified in this sub-paragraph is 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”.

(3) The method specified in this sub-paragraph is 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”.

(4) The method specified in this sub-paragraph is 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”.

(5) The method specified in this sub-paragraph is 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-Protocol”, reference “CRLVL05/06VP”.

(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”.

(7) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference materials AOCS 0215-A, AOCS 0809-A2, AOCS 0311-A2 and AOCS 0906-B2 are accessible from the American Oil Chemists Society(14).

### Monitoring plan for environmental effects

5.—(1) The authorisation holder must implement the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1, reference number “RP607” submitted to the Food Safety Authority on 11 March 2021.

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

(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 Louis, 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.

### SCHEDULE 6

Regulation 3(1)

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 [\(EC\) 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 [\(EC\) 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 [\(EC\) 1829/2003](#), and in Article 4(6) of Regulation [\(EC\) 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 of detection**

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

(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-

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specific Method for the Quantification of Maize Line Bt11 using real time PCR-Protocol”, reference “CR-VL-10/07VP 20/06/2008”.

(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 “CRL-VL-12/05XP 18/04/2007”.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference material ERM®-BF412 is accessible from the Joint Research Centre (JRC) of the European Commission(15).

### Monitoring plan for environmental effects

5.—(1) The authorisation holder must implement 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.

(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 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.

## SCHEDULE 7

Regulation 3(1)

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

- (a) MON-87427-7 × MON-87460-4 × MON- 89034-3 × SYN-IR162-4 × MON-ØØ603-6 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603,
- (b) MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162,
- (c) MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-ØØ603-6 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × NK603,
- (d) MON-87427-7 × MON-87460-4 × SYN-IR162-4 × MON-ØØ603-6 for genetically modified maize MON 87427 × MON 87460 × MIR162 × NK603,

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

- (e) MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6 for genetically modified maize MON 87460 × MON 89034 × MIR162 × NK603,
- (f) MON-87427-7 × MON-87460-4 × MON-89034-3 for genetically modified maize MON 87427 × MON 87460 × MON 89034,
- (g) MON-87427-7 × MON-87460-4 × SYN-IR162-4 for genetically modified maize MON 87427 × MON 87460 × MIR162,
- (h) MON-87427-7 × MON-87460-4 × MON-00603-6 for genetically modified maize MON 87427 × MON 87460 × NK603,
- (i) MON-87460-4 × SYN-IR162-4 × MON-00603-6 for genetically modified maize MON 87460 × MIR162 × NK603,
- (j) MON-87460-4 × MON-89034-3 × SYN-IR162-4 for genetically modified maize MON 87460 × MON 89034 × MIR162,
- (k) MON-87460-4 × MON-89034-3 × MON-00603-6 for genetically modified maize MON 87460 × MON 89034 × NK603,
- (l) MON-87427-7 × MON-87460-4 for genetically modified maize MON 87427 × MON 87460,
- (m) MON-87460-4 × SYN-IR162-4 for genetically modified maize MON 87460 × MIR162,
- (n) MON-87460-4 × MON-00603-6 for genetically modified maize MON 87460 × NK603,
- (o) MON-87460-4 × MON-89034-3 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 (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 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 (EC) 1829/2003, and in Article 4(6) of Regulation (EC) 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 of 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 (6) are to be used for the 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-

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specific Method for the Quantification of Maize MON 87427 Using Real-time PCR”, reference “EURL-VL-0417VP”.

(3) 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 87460 Using Real-time PCR – Protocol”, reference “CRLVL04/09VP”.

(4) 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 Line MON 89034 Using Real-time PCR”, reference “CRLVL06/06VP”.

(5) 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 Line MIR162 Using Real-time PCR”, reference “CRLVL08/08VP”.

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

(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”.

(8) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference materials AOCS 0512-A2, AOCS 0709-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(16).

### **Monitoring plan for environmental effects**

5.—(1) The authorisation holder must implement the monitoring plan for environmental effects, 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.

(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 Louis, 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.

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

## SCHEDULE 8

Regulation 3(1)

Renewal of 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 (EC) 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 (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 MON-88Ø17-3,
- (b) feed containing, consisting of or produced from genetically modified maize MON-88Ø17-3,
- (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 (EC) 1829/2003, and in Article 4(6) of Regulation (EC) 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.

### Method of detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the method specified in sub-paragraph (2) is to be used for the detection of genetically modified maize MON 88Ø17-3.

(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 Line 88017 Using Real-time PCR-Protocol”, reference “CRLVL16/05VP Corrected Version 1”.

(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 from Maize Seeds and Grains”, reference “CRLVL16/05XP corrected version 2”.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference material AOCS 0406-D2 is accessible from the American Oil Chemists Society(17).

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



**Monitoring plan for the environmental effects**

5.—(1) The authorisation holder must implement the monitoring plan for environmental effects, 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.

(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 Louis, 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.

## SCHEDULE 9

Regulation 3(1)

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

**Genetically modified organism and unique identifier**

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

**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 MON-89Ø34-3,
- (b) feed containing, consisting of or produced from genetically modified maize MON-89Ø34-3,
- (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 [\(EC\) 1829/2003](#), and in Article 4(6) of Regulation [\(EC\) 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.

### Method of detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the method specified in sub-paragraph (2) is to be used for the detection of event genetically modified maize MON- 89Ø34-3.

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

(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 from Maize Seeds and Grains”, reference “CRLVL16/05XP corrected version 2”.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference material AOCS 0906-E2 is accessible from the American Oil Chemists Society(18).

### Monitoring plan for the environmental effects

5.—(1) The authorisation holder must implement the monitoring plan for environmental effects, 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.

(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 Louis, 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.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in exercise of the powers conferred by Articles 7(3), 9(2), 11, 19(3), 21(2), 23, and 35 of Regulation (EC) 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (“Regulation 1829/2003”). These Regulations authorise the placing on the market of nine food and feed products containing, consisting of, or produced from genetically modified organisms.

Regulation 3 and schedules 1-9 provide for the authorisation of the nine products—

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

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- (a) schedule 1 renews authorisation for the placing on the market of genetically modified maize MIR604 and sets out the terms for that authorisation,
- (b) schedule 2 authorises the placing on the market of genetically modified maize MZIR098 and its sub-combinations and sets out the terms for that authorisation,
- (c) schedule 3 authorises the placing on the market of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and sub-combinations and sets out the terms for that authorisation,
- (d) schedule 4 authorises the placing on the market of genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and the sub-combinations that are not covered by Schedule 3,
- (e) schedule 5 authorises the placing on the market of genetically modified soybean MON 87751 × MON 87701 × MON 87708 × MON 89788,
- (f) schedule 6 renews the authorisation for the placing on the market of genetically modified maize Bt11 and sets out the terms for that authorisation therein,
- (g) schedule 7 authorises the placing on the market of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and the sub-combinations that are not covered by schedule 3,
- (h) schedule 8 renews the authorisation for the placing on the market of genetically modified maize MON 88017 and sets out the terms for that authorisation therein,
- (i) schedule 9 renews the authorisation for the placing on the market of genetically modified maize MON 89034 and sets out the terms for that authorisation therein.

Authorisations granted by these Regulations are valid for a period of ten years in accordance with Articles 7(4) and 19(4) of Regulation (EC) 1829/2003 (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 Scotland, Decisions which form part of retained EU law 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 retained Commission Implementing Decision (EU) 2018/2011, which contains the existing authorisation for four of the sub-combinations of the product now authorised by schedule 3. Those existing authorisations are consolidated within schedule 3.

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.