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AGRICULTURE, WALES
FOOD, WALES

The Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Wales) Regulations 2023

<i>Made</i>	- - - -	<i>28 March 2023</i>
<i>Laid before Senedd Cymru</i>		<i>29 March 2023</i>
<i>Coming into force</i>	- -	<i>26 April 2023</i>

The Welsh Ministers make these Regulations in exercise of the powers conferred by Articles 7(3), 19(3) and 35(3)(b) 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.

PART 1

Introduction

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Wales) Regulations 2023.

(2) These Regulations—

- (a) extend to England and Wales;
- (b) apply in relation to Wales;

(1) EUR 2003/1829; relevant amending instruments are [S.I. 2019/705](#) and [2022/377](#). [S.I. 2019/705](#) was amended by [S.I. 2020/1504](#). The terms “appropriate authority” and “prescribe” are defined in Article 2 of EUR 2003/1829. Article 7(3) applies in relation to modifications and renewals of authorisations in accordance with Articles 9(2) and 11, respectively. Article 19(3) applies in relation to modifications and renewals of authorisations in accordance with Articles 21(2) and 23, respectively.

(2) EUR 2002/178, amended by [S.I. 2019/641](#); there are other amending instruments but none is relevant.

(c) come into force on 26 April 2023.

Interpretation

2.—(1) In these Regulations—

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

“Regulation 1830/2003” (“*Rheoliad 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” (“*Penderfyniad 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 placing on the market(4).

(2) Expressions used in these Regulations and in Regulation 1829/2003 have the same meaning as in that Regulation.

PART 2

Authorisations

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

3.—(1) Schedules 1 to 7 contain authorisations for products containing, consisting of, or produced from genetically modified organisms.

(2) Schedule 8 contains an authorisation for products containing or consisting of a genetically modified organism.

(3) Subject to Articles 11(4) and 23(4) of Regulation 1829/2003, the authorisations in Schedules 1 to 8 expire at the end of 25 April 2033.

PART 3

Modifications of existing authorisations

Amendment of Commission Decision 2011/891/EU

4.—(1) Commission Decision 2011/891/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236x3006-210-23 (DAS-24236-5xDAS-21Ø23-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(5) is amended as follows.

(2) In Article 6 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) EUR 2003/1830; relevant amending instruments are S.I. 2019/90, 2019/778 and 2020/1421.

(4) EUDN 2009/770, amended by S.I. 2019/90. S.I. 2019/90 was amended by S.I. 2020/1421.

(5) EUDN 2011/891, amended by S.I. 2019/705.

(3) In Article 8 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision 2012/84/EU

5.—(1) Commission Implementing [Decision 2012/84/EU](#) authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 (DP-356043-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(6) is amended as follows.

(2) In Article 6 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 8 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision 2013/648/EU

6.—(1) Commission Implementing [Decision 2013/648/EU](#) authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034 × 1507 × NK603 (MON-89034-3 × DAS-01507-1 × MON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(7) is amended as follows.

(2) In Article 6 (authorisation holders), for paragraph (1) substitute—

“(1) The authorisation holders are:

- (a) Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, and
- (b) Bayer CropScience LP, United States of America, represented in Great Britain by Bayer CropScience Limited.”

(6) EUDN 2012/84, amended by [S.I. 2019/705](#).

(7) EUDN 2013/648, amended by [S.I. 2019/705](#).

(3) In Article 8 (addressees), for the text substitute—

“This Decision is addressed to:

- (a) Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom, and
- (b) Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, CB4 0WB, United Kingdom.”

(4) In the Annex, for point (a) (applicants and authorisation holders) substitute—

“(a) **Authorisation holders**

- (1) Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom, and
- (2) Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, CB4 0WB, United Kingdom.”

Amendment of Commission Implementing Decision 2013/650/EU

7.—(1) Commission Implementing [Decision 2013/650/EU](#) authorising the placing on the market of products containing, consisting of, or produced from genetically modified (GM) maize MON 89034 × 1507 × MON88017 × 59122 (MON-89034-3 × DAS-01507-1 × MON-88017-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89034-3 × DAS-01507-1 × MON-88017-3), MON89034 × 1507 × 59122 (MON-89034-3 × DAS-01507-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89034-3 × MON-88017-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-01507-1 × MON-88017-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89034-3 × DAS-01507-1), MON89034 × 59122 (MON-89034-3 × DAS-59122-7), 1507 × MON88017 (DAS-01507-1 × MON-88017-3), MON 88017 × 59122 (MON-88017-3 × DAS-59122-7)) pursuant to Regulation [\(EC\) No 1829/2003](#) of the European Parliament and of the Council⁽⁸⁾ is amended as follows.

(2) In Article 6 (authorisation holders), for paragraph (1) substitute—

“(1) The authorisation holders are:

- (a) Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, and
- (b) Bayer CropScience LP, United States of America, represented in Great Britain by Bayer CropScience Limited.”

(3) In Article 8 (addressees), for the text substitute—

“This Decision is addressed to:

- (a) Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom, and
- (b) Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, CB4 0WB, United Kingdom.”

⁽⁸⁾ EUDN 2013/650, amended by [S.I. 2019/705](#).

(4) In the Annex, for point (a) (applicant and authorisation holders) substitute—

“(a) Authorisation holders

(1) Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom, and

(2) Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America, represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, CB4 0WB, United Kingdom.”

Amendment of Commission Implementing Decision (EU) 2015/698

8.—(1) Commission Implementing Decision (EU) 2015/698 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽⁹⁾ is amended as follows.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) Authorisation holder

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2016/1215

9.—(1) Commission Implementing Decision (EU) 2016/1215 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽¹⁰⁾ is amended as follows.

(2) In Article 6 (authorisation holder), for the text substitute—

“The authorisation holder is Syngenta Crop Protection AG, Switzerland, represented in Great Britain by Syngenta Limited.”

(3) In Article 8 (addressee), for the text substitute—

“This Decision is addressed to Syngenta Crop Protection AG, Rosentalstrasse 67, CH-4058 Basel, Switzerland, represented in Great Britain by Syngenta Limited, Jealott’s Hill International Research Centre, Bracknell, Berkshire, RG42 6EY, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) Authorisation holder:

⁽⁹⁾ EUDN 2015/698, amended by [S.I. 2019/705](#).

⁽¹⁰⁾ EUDN 2016/1215, amended by [S.I. 2019/705](#).

(1) 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, RG42 6EY, United Kingdom.”

Amendment of Commission Implementing Decision (EU) 2017/1211

10.—(1) Commission Implementing Decision (EU) 2017/1211 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5 × DAS-21Ø23-5 × MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(**11**) is amended as follows.

(2) In Article 6 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 8 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2017/1212

11.—(1) Commission Implementing Decision (EU) 2017/1212 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed(**12**) is amended as follows.

(2) In Article 6 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 8 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

(11) EUDN 2017/1211, amended by [S.I. 2019/705](#).

(12) EUDN 2017/1212, amended by [S.I. 2019/705](#).

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

Amendment of Commission Implementing Decision (EU) 2017/2448

12.—(1) Commission Implementing Decision (EU) 2017/2448 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-305423-1 × MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(13) is amended as follows.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2017/2449

13.—(1) Commission Implementing Decision (EU) 2017/2449 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(14) is amended as follows.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

(13) EUDN 2017/2448, amended by S.I. 2019/705.

(14) EUDN 2017/2449, amended by S.I. 2019/705.

Amendment of Commission Implementing Decision (EU) 2017/2450

14.—(1) Commission Implementing Decision (EU) 2017/2450 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed⁽¹⁵⁾ is amended as follows.

(2) In Article 7 (authorisation holder)—

(a) for the heading substitute—

“Authorisation holders”;

(b) for the text substitute—

“The authorisation holders are Corteva Agriscience LLC, United States of America, and M.S. Technologies LLC, United States of America, both represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee)—

(a) for the heading substitute—

“Addressees”;

(b) for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, and to M.S. Technologies LLC, 103 Avenue D, West Point, IA 52656, United States of America, both represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (authorisation holder) substitute—

“(a) Authorisation holders:

(1) The authorisation holders are—

Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, and

M.S. Technologies LLC, 103 Avenue D, West Point, IA 52656, United States of America.

(2) Both authorisation holders are represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

Amendment of Commission Implementing Decision (EU) 2017/2452

15.—(1) Commission Implementing Decision (EU) 2017/2452 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽¹⁶⁾ is amended as follows.

(2) In Article 7 (authorisation holders)—

(a) for the heading substitute—

“Authorisation holder”;

⁽¹⁵⁾ EUDN 2017/2450, amended by [S.I. 2019/705](#).

⁽¹⁶⁾ EUDN 2017/2452, amended by [S.I. 2019/705](#).

(b) for paragraphs 1 and 2 substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicants and authorisation holders) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2018/1109

16.—(1) Commission Implementing Decision (EU) 2018/1109 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(17) is amended as follows.

(2) In Article 7 (authorisation holders)—

(a) for the heading substitute—

“Authorisation holder”;

(b) for paragraphs 1 and 2 substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicants and authorisation holders) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2018/1110

17.—(1) Commission Implementing Decision (EU) 2018/1110 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603(18) is amended as follows.

(17) EUDN 2018/1109, amended by S.I. 2019/705.

(18) EUDN 2018/1110, amended by S.I. 2019/705.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 10 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2019/1304

18.—(1) Commission Implementing Decision (EU) 2019/1304 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(19) is amended as follows.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2019/1306

19.—(1) Commission Implementing Decision (EU) 2019/1306 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(20) is amended as follows.

(2) In Article 7 (authorisation holders)—

(a) for the heading substitute—

“*Authorisation holder*”;

(19) EUDN 2019/1304, amended by S.I. 2019/705.

(20) EUDN 2019/1306, amended by S.I. 2019/705.

(b) for paragraphs 1 and 2 substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressees)—

(a) for the heading substitute—

“Addressee”;

(b) for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicants and authorisation holders) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2019/2085

20.—(1) Commission Implementing Decision (EU) 2019/2085 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(21) is amended as follows.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

Amendment of Commission Implementing Decision (EU) 2019/2086

21.—(1) Commission Implementing Decision (EU) 2019/2086 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON

(21) EUDN 2019/2085, amended by S.I. 2019/705.

89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽²²⁾ is amended as follows.

(2) In Article 7 (authorisation holder), for the text substitute—

“The authorisation holder is Corteva Agriscience LLC, United States of America, represented in Great Britain by Corteva Agriscience UK Limited.”

(3) In Article 9 (addressee), for the text substitute—

“This Decision is addressed to Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, CB21 5XE, United Kingdom.”

(4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

“(a) **Authorisation holder:**

(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

PART 4

Revocation

Revocation of Commission Decision 2010/429/EU

22. Commission Decision 2010/429/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 × MON 810 (MON-88017-3 × MON-00810-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council⁽²³⁾ is revoked.

Lynne Neagle
Deputy Minister for Mental Health and
Wellbeing, under the authority of the Minister
for Health and Social Services, one of the Welsh
Ministers

28 March 2023

⁽²²⁾ EUDN 2019/2086, amended by S.I. 2019/705.

⁽²³⁾ EUDN 2010/429, amended by S.I. 2019/705. See Schedule 7 of these Regulations for the renewal of the authorisation contained in EUDN 2010/429.

SCHEDULES

SCHEDULE 1

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-81419-2 × DAS-44406-6

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier DAS-81419-2 × DAS-44406-6 is specified for genetically modified soybean DAS-81419-2 × DAS-44406-6.

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 DAS-81419-2 × DAS-44406-6;
- (b) feed containing, consisting of, or produced from genetically modified soybean DAS-81419-2 × DAS-44406-6;
- (c) products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-44406-6 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-44406-6, with the exception of food and food ingredients.

Method for detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the methods specified in sub-paragraph (2) are to be used for the detection of genetically modified soybean DAS-81419-2 × DAS-44406-6.

(2) The methods are set out in—

- (a) for DAS-81419-2, the document entitled “Event-specific Method for the Quantification of Soybean DAS-81419-2 by Real-time PCR”, reference “EURL-VL-03/13 VP”, and dated 13 March 2015;
- (b) for DAS-44406-6, the document entitled “Event-specific Method for the Quantification of Soybean DAS-44406-6 by Real-time PCR”, reference “EURL-VL-01/12 VP”, and dated 17 March 2015.

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

(3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) is set out in the document entitled “Report on the In-house Validation of a DNA Extraction Method from Soybean Grains and Validated Method”, reference “EURL-VL-11/10XP”, and dated 13 May 2014.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the following reference materials are accessible via the Joint Research Centre of the European Commission⁽²⁴⁾—

- (a) ERM®-BF437 (for DAS-81419-2);
- (b) ERM®-BF436 (for DAS-44406-6).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the authorisation of genetically modified soybean DAS-81419-2 × DAS-44406-6, reference number “RP1133” submitted to the Food Safety Authority⁽²⁵⁾ on 8 June 2021, is implemented.

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

Authorisation holder

6.—(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

SCHEDULE 2

Regulation 3

Authorisation of the placing on the market of products containing,
consisting of, or produced from genetically modified soybean DAS-81419-2

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier DAS-81419-2 is specified for genetically modified soybean DAS-81419-2.

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 DAS-81419-2;
- (b) feed containing, consisting of, or produced from genetically modified soybean DAS-81419-2;

⁽²⁴⁾ <https://crm.jrc.ec.europa.eu/>

⁽²⁵⁾ “Food Safety Authority” is defined in Article 2(17) of Regulation 1829/2003.

- (c) products containing or consisting of genetically modified soybean DAS-81419-2 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified soybean DAS-81419-2, 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 soybean DAS-81419-2.

(2) The method is set out in the document entitled “Event-specific Method for the Quantification of Soybean DAS-81419-2 by Real-time PCR”, reference “EURL-VL-03/13 VP”, and dated 13 March 2015.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled “Report on the In-house Validation of a DNA Extraction Method from Soybean Grains and Validated Method”, reference “EURL-VL-11/10XP”, and dated 13 May 2014.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material ERM®-BF437 is accessible via the Joint Research Centre of the European Commission⁽²⁶⁾.

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the authorisation of genetically modified soybean DAS-81419-2, reference number “RP1134” submitted to the Food Safety Authority⁽²⁷⁾ on 8 June 2021, is implemented.

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

Authorisation holder

6.—(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

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

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

SCHEDULE 3

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified soybean SYHT0H2

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-ØØØH2-5 is specified for genetically modified soybean SYHT0H2.

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 SYN-ØØØH2-5;
- (b) feed containing, consisting of, or produced from genetically modified soybean SYN-ØØØH2-5;
- (c) products containing or consisting of genetically modified soybean SYN-ØØØH2-5 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 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, the products containing or consisting of genetically modified soybean SYN-ØØØH2-5, 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 soybean SYN-ØØØH2-5.

(2) The method is set out in the document entitled “Event-specific Method for the Quantification of Soybean SYHT0H2 by Real-time PCR”, reference “EURL-VL-04/12VP”, and dated 3 August 2016.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled “Report on the Validation of a DNA Extraction Method for Soybean Seeds”, reference “CRLVL04/07XP”, and dated 22 January 2009.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material AOCs 0112-A is accessible via the American Oil Chemists’ Society(28).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the authorisation of genetically modified soybean SYN-

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

ØØØH2-5, reference number “RP1138” submitted to the Food Safety Authority(29) on 10 June 2021, is implemented.

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

Authorisation holder

6.—(1) The authorisation holder is Syngenta Crop Protection AG, Rosentalstrasse 67, CH-0458 Basel, Switzerland.

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

SCHEDULE 4

Regulation 3

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

- (a) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122;
- (b) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411;
- (c) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × 59122;
- (d) MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411 × 59122;
- (e) MON-87427-7 × MON-87460-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411 × 59122;
- (f) MON-87427-7 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411 × 59122;
- (g) MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411 × 59122;
- (h) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507;
- (i) MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411;

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

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

- (j) MON-87427-7 × MON-87460-4 × MON-89034-3 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 59122;
- (k) MON-87427-7 × MON-87460-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411;
- (l) MON-87427-7 × MON-87460-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × 59122;
- (m) MON-87427-7 × MON-87460-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 87411 × 59122;
- (n) MON-87427-7 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411;
- (o) MON-87427-7 × MON-89034-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × MON 87411 × 59122;
- (p) MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × 1507 × MON 87411 × 59122;
- (q) MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411;
- (r) MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × 59122;
- (s) MON-87460-4 × MON-89034-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × MON 87411 × 59122;
- (t) MON-87460-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × MON 87411 × 59122;
- (u) MON-89034-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × 1507 × MON 87411 × 59122;
- (v) MON-87427-7 × MON-87460-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × 1507;
- (w) MON-87427-7 × MON-87460-4 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 87411;
- (x) MON-87427-7 × MON-87460-4 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 59122;
- (y) MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × 1507 × MON 87411;
- (z) MON-87427-7 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87411 × 59122;
- (aa) MON-87460-4 × MON-89034-3 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × MON 89034 × 1507;
- (bb) MON-87460-4 × MON-89034-3 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × MON 87411;
- (cc) MON-87460-4 × MON-89034-3 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 59122;
- (dd) MON-87460-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × 1507 × MON 87411;
- (ee) MON-87460-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × 59122;

- (ff) MON-87460-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 87411 × 59122;
- (gg) MON-89034-3 × DAS-01507-1 × MON-87411-9 for genetically modified maize MON 89034 × 1507 × MON 87411;
- (hh) MON-89034-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × MON 87411 × 59122;
- (ii) DAS-01507-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize 1507 × MON 87411 × 59122;
- (jj) MON-87460-4 × DAS-01507-1 for genetically modified maize MON 87460 × 1507;
- (kk) MON-87460-4 × MON-87411-9 for genetically modified maize MON 87460 × 87411;
- (ll) MON-87460-4 × DAS-59122-7 for genetically modified maize MON 87460 × 59122;
- (mm) DAS-01507-1 × MON-87411-9 for genetically modified maize 1507 × MON 87411;
- (nn) MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87411 × 59122.

Authorisation

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this Schedule—

- (a) food and food ingredients containing, consisting of, or produced from genetically modified maize referred to in paragraph 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in paragraph 1;
- (c) products containing or consisting of genetically modified maize referred to in paragraph 1 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified maize referred to in paragraph 1, with the exception of food and food ingredients.

Method for detection

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

(2) The methods are set out in—

- (a) for MON-87427-7, the document entitled “Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR”, reference “EURL-VL-03/12VP”, and dated 9 June 2015;
- (b) for MON-87460-4, the document entitled “Event-specific Method for the Quantification of Maize MON 87460 Using Real-time PCR”, reference “CRLVL04/09VP”, and dated 18 January 2012;

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

- (c) for MON-89Ø34-3, the document entitled “Event-specific Method for the Quantification of Maize Line MON 89034 Using Real-time PCR”, reference “CRLVL06/06VP”, and dated 21 October 2008;
- (d) for DAS-Ø15Ø7-1, the document entitled “Event-specific method for the quantitation of maize line TC1507 using real-time PCR”, reference “CRLVL02/04VP” and, dated 9 March 2005;
- (e) for MON-87411-9, the document entitled “Event-specific Method for the Quantification of maize MON 87411 by Real-time PCR”, reference “EURL-VL-01/15VP”, and dated 4 July 2016;
- (f) for DAS-59122-7, the document entitled “Event-specific method for the quantitation of maize 59122 using real-time PCR”, reference “CRLVL03/05VP - corrected version 1”, and dated 8 July 2007.

(3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) is set out in the document entitled “Report on the 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—

- (a) the following reference materials are accessible via the American Oil Chemists’ Society(30)—
 - (i) AOCS 0512-A2 (for MON-87427-7);
 - (ii) AOCS 0709-A2 (for MON-8746Ø-4);
 - (iii) AOCS 0906-E2 (for MON-89Ø34-3);
 - (iv) AOCS 0215-B (for MON-87411-9);
- (b) the following reference materials are accessible via the Joint Research Centre of the European Commission(31)—
 - (i) ERM®-BF418 (for DAS-Ø15Ø7-1);
 - (ii) ERM®-BF424 (for DAS-59122-7).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1180” submitted to the Food Safety Authority(32) on 2 July 2021, is implemented.

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

Authorisation holder

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

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

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

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

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

SCHEDULE 5

Regulation 3

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

Genetically modified organism and unique identifier

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

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

Authorisation

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this Schedule—

- (a) food and food ingredients containing, consisting of, or produced from genetically modified maize referred to in paragraph 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in paragraph 1;
- (c) products containing or consisting of genetically modified maize referred to in paragraph 1 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified maize referred to in paragraph 1, with the exception of food and food ingredients.

Method for detection

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

(2) The methods are set out in—

- (a) for DAS-Ø15Ø7-1, the document entitled “Event-specific method for the quantitation of maize line TC1507 using real-time PCR”, “Version B”, reference “JRC 113269”, and dated 24 September 2018;

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

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

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

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

- (a) the following reference materials are accessible via the Joint Research Centre of the European Commission(33)—
 - (i) ERM®-BF418 (for DAS-Ø15Ø7);
 - (ii) ERM®-BF413 (for MON-ØØ81Ø-6);
 - (iii) ERM®-BF415 (for MON-ØØ6Ø3-6);
- (b) the reference material AOCs 1208-A3 (for SYN-IR162-4) is accessible via the American Oil Chemists’ Society(34).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1184” submitted to the Food Safety Authority(35) on 5 July 2021, is implemented.

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

Authorisation holder

6.—(1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, United States of America.

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

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

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

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

SCHEDULE 6

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614 × T304-40 × GHB119

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 is specified for genetically modified cotton GHB614 × T304-40 × GHB119.

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 cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
- (b) feed containing, consisting of, or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
- (c) products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, with the exception of food and food ingredients.

Method for detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the methods specified in sub-paragraph (2) are to be used for the detection of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8.

(2) The methods are set out in —

- (a) for BCS-GHØØ2-5, the document entitled “Event-specific Method for the Quantification of Cotton Line GHB614 Using Real-time PCR”, reference “CRLVL14/07VP”, and dated 5 September 2008;
- (b) for BCS-GHØØ4-7, the document entitled “Event-specific Method for the Quantification of Cotton T304-40 using Real-time PCR”, reference “EURL-VL-05/11VP”, and dated 19 December 2012;
- (c) for BCS-GHØØ5-8, the document entitled “Event-specific Method for the Quantification of Cotton GHB119 Using Real-time PCR”, reference “EURL VL04/11 VP”, and dated 11 October 2012.

(3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) is set out in the document entitled “Cotton Seeds Sampling and DNA Extraction Report on the Validation of DNA Extraction Method from Cotton Seeds”, reference “CRLVL13/04XP”, and dated 14 March 2007.

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

- (4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003—
- (a) the reference material AOCs 1108-A6 (for BCS-GH002-5) is accessible via the American Oil Chemists' Society⁽³⁶⁾;
 - (b) the following reference materials are accessible via the Joint Research Centre of the European Commission⁽³⁷⁾—
 - (i) ERM®-BF429 (for BCS-GH004-7);
 - (ii) ERM®-BF428 (for BCS-GH005-8).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the authorisation of genetically modified cotton BCS-GH002-5 × BCS-GH004-7 × BCS-GH005-8, reference number “RP1205” submitted to the Food Safety Authority⁽³⁸⁾ on 28 July 2021, is implemented.

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

Authorisation holder

6.—(1) The authorisation holder is BASF Agricultural Solutions Seed US LLC, 100 Park Avenue, Florham Park, New Jersey 07932, United States of America.

(2) The authorisation holder is represented in Great Britain by BASF Plc, 2 Stockport Exchange, Railway Road, Stockport, Cheshire, SK1 3GG, United Kingdom.

SCHEDULE 7

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 × MON 810

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-88017-3 × MON-00810-6 is specified for genetically modified maize MON 88017 × MON 810.

Authorisation

2. The following products are authorised⁽³⁹⁾ 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-88017-3 × MON-00810-6;
- (b) feed containing, consisting of, or produced from genetically modified maize MON-88017-3 × MON-00810-6;

⁽³⁶⁾ <https://www.aocs.org/crm/>

⁽³⁷⁾ <https://crm.jrc.ec.europa.eu/>

⁽³⁸⁾ “Food Safety Authority” is defined in Article 2(17) of Regulation 1829/2003.

⁽³⁹⁾ This authorisation is a renewal of the authorisation previously granted under Commission Decision 2010/429/EU. That instrument is revoked by regulation 22 of these Regulations.

- (c) products containing or consisting of genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6, with the exception of food and food ingredients.

Method for detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the methods specified in sub-paragraph (2) are to be used for the detection of genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6.

(2) The methods are set out in—

- (a) for MON-88Ø17-3, 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;
- (b) for MON-ØØ81Ø-6, the document entitled “CRL assessment on the validation of an event specific method for the relative quantitation of maize line MON 810 DNA using real-time PCR as carried out by Federal Institute for Risk Assessment (BfR)”, reference “CRL-VL-25/04VR”, and dated 10 March 2006.

(3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) is set out in the document entitled “Report on the Validation of a DNA Extraction Method for Maize Seeds and Grains”, reference “CRLVL16/05XP”, and dated 13 October 2008.

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

- (a) the reference material AOCs 0406-D2 (for MON-88Ø17-3) is accessible via the American Oil Chemists’ Society(40);
- (b) the reference material ERM®-BF413 (for MON-ØØ81Ø-6) is accessible via the Joint Research Centre of the European Commission(41).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for renewal of the authorisation of genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6, reference number “RP1179” submitted to the Food Safety Authority(42) on 2 July 2021, is implemented.

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

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

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

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

Authorisation holder

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

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

SCHEDULE 8

Regulation 3

Renewal of the authorisation of the placing on the market of products (other than food) containing or consisting of genetically modified oilseed rape GT73

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-ØØØ73-7 is specified for genetically modified oilseed rape GT73.

Authorisation

2. The following products are authorised⁽⁴³⁾ 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) feed containing or consisting of genetically modified oilseed rape MON-ØØØ73-7;
- (b) products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided for in sub-paragraph (a) and other than food, with the exception of cultivation.

Labelling

3.—(1) For the purposes of the labelling requirements in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the “name of the organism” is “oilseed rape”.

(2) The words “not for cultivation” must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 referred to in paragraph 2.

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 oilseed rape MON-ØØØ73-7.

(2) The method is set out in the document entitled “Event-specific Method for the Quantification of Oilseed Rape Line RT73 Using Real-time PCR”, reference “CRLVL26/04VP”, and dated 7 February 2007.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled “Report on the Validation of an Oilseed Rape DNA Extraction

(43) This authorisation is a renewal of the authorisation previously granted pursuant to Commission [Decision 2005/635/EC](#) concerning the placing on the market, in accordance with [Directive 2001/18/EC](#) of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate (OJ No L 228, 3.9.2005 p.11).

Method from Seeds”, “Corrected version 1”, reference “CRLVL26/04XP Version 1”, and dated 25 July 2017.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material AOCs 0304-B3 is accessible via the American Oil Chemists’ Society(44).

Monitoring plan for the environmental effects

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for renewal of the authorisation of genetically modified oilseed rape MON-ØØØ73-7, reference number “RP1263” submitted to the Food Safety Authority(45) on 22 September 2021, is implemented.

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

Authorisation holder

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

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations authorise the placing on the market, in Wales, of specified genetically modified food and feed products for the purposes of Regulation (EC) No 1829/2003 on genetically modified food and feed (EUR 2003/1829). These Regulations also modify the “authorisation holders” for 18 existing authorisations under EUR 2003/1829.

Part 2 of these Regulations (regulation 3 and Schedules 1 to 8) contains the authorisation, in relation to Wales, for the placing on the market of products containing, consisting of, or produced from the specified genetically modified organisms—

- Schedule 1 is a new authorisation for genetically modified soybean DAS-81419-2 × DAS-44406-6;
- Schedule 2 is a new authorisation for genetically modified soybean DAS-81419-2;
- Schedule 3 is a new authorisation for genetically modified soybean SYHT0H2;
- Schedule 4 is a new authorisation for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and listed sub-combinations;
- Schedule 5 is a new authorisation for genetically modified maize 1507 × MIR162 × MON 810 × NK603 and listed sub-combinations;

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

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

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

- Schedule 6 is a new authorisation for genetically modified cotton GHB614 × T304-40 × GHB119;
- Schedule 7 renews the authorisation for genetically modified maize MON 88017 × MON 810;
- Schedule 8 renews an authorisation for genetically modified oilseed rape GT73. This renewal is limited to products (other than food) containing or consisting of genetically modified oilseed rape GT73. It does not cover products “produced from” that genetically modified organism.

Part 3 of these Regulations (regulations 4 to 21) amends, in relation to Wales, 18 retained EU Decisions containing existing authorisations for genetically modified food and feed. The amendments all relate to changes to the names and addresses of the respective authorisation holders, and their representatives in Great Britain.

Part 4 of these Regulations (regulation 22) revokes, in relation to Wales, the retained EU Decision containing the previous authorisation for the products now authorised by Schedule 7.

The authorisations granted by these Regulations are valid for a period of ten years in accordance with Articles 7(4) and 19(4) of EUR 2003/1829. This is subject to Articles 11(4) and 23(4) of EUR 2003/1829, which provide for an extension of the authorisation period in certain circumstances where an application for renewal has been submitted.

In each Schedule, paragraph 4 specifies the methods for detection, including sampling, which have been validated for use in relation to the authorised products. The documents referred to have been published at <https://gmo-crl.jrc.ec.europa.eu/method-validations>.

Information on the authorisations granted by these Regulations is required to be entered in the register of genetically modified food and feed referred to in Article 28(1) of EUR 2003/1829 (“the Register”).

The authorisations granted by these Regulations are required to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(1)(e) of Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms (EUR 2003/1946).

Further information on the authorisations granted by these Regulations including in relation to the Register, the monitoring plans required by paragraph 5 of each Schedule, or the information notified pursuant to the Cartagena Protocol, can be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW or by writing to regulated.products.wales@food.gov.uk.

The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.