#### SCOTTISH STATUTORY INSTRUMENTS

## 2023 No. 59

## AGRICULTURE FOOD

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

Made - - - - 28th February 2023
Laid before the Scottish
Parliament - - - 2nd March 2023
Coming into force - 26th April 2023

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).

## PART 1

## Introductory

## Citation, commencement and extent

- 1.—(1) These Regulations may be cited as the Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Scotland) Regulations 2023 and come into force on 26 April 2023.
  - (2) These Regulations extend to Scotland.

## Interpretation

2. In these Regulations—

<sup>(1)</sup> EUR 1829/2003 as relevantly amended by S.I. 2019/705, 2020/1504 and 2022/377. The terms "appropriate authority" and "prescribe" are defined in Article 2 of Regulation 1829/2003.

<sup>(2)</sup> EUR 178/2002 as relevantly amended by S.I. 2019/641 and 2020/1504.

- "Regulation 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" means Regulation (EC) No. 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC(3),
- "Decision 2009/770" means Commission Decision 2009/770/EC establishing standards reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of the placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council(4).

## 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, which contain authorisations for products containing, consisting of, or produced from genetically modified organisms, have effect.
- (2) Schedule 8, which contains an authorisation for products containing or consisting of genetically modified organisms, has effect.
- (3) Subject to Articles 11(4) and 23(4) of Regulation 1829/2003, the authorisations set out in schedules 1 to 8 cease to have effect 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  $281-24-236 \times 3006-210-23$  (DAS-24236-5 × DAS-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) 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, England, CB21 5XE."
  - (4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

<sup>(3)</sup> EUR 1830/2003 as relevantly amended by S.I. 2019/90, 2019/778 and 2020/1421.

<sup>(4)</sup> EUD 2009/770 as amended by S.I. 2019/90.

<sup>(5)</sup> EUD 2011/891, amended by EUD 2019/239 and S.I. 2019/705.

## "(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, England, CB21 5XE.".

#### 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-356Ø43-5) 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, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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  $\times$  1507  $\times$  NK603 (MON-89Ø34-3  $\times$  DAS-Ø15Ø7-1  $\times$  MON-ØØ6Ø3-6) 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—

## "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, England, CB21 5XE, and,

<sup>(6)</sup> EUD 2012/84, amended by S.I. 2019/705.

<sup>(7)</sup> EUD 2013/648, amended by EUD 2019/240 and S.I. 2019/705.

- (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, England, CB4 0WB.".
- (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, is represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, England, CB21 5XE, 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, England, CB4 0WB.".

## 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-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7), four related GM maizes combining three different single GM events (MON89034 × 1507 × MON88017 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3), MON89034 × 1507 × 59122 (MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7), MON89034 × MON88017 × 59122 (MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7), 1507 × MON 88017 × 59122 (DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)) and four related GM maizes combining two different single GM events (MON89034 × 1507 (MON-89Ø34-3 × DAS-Ø15Ø7-1), MON89034 × 59122 (MON-89Ø34-3 × DAS-59122-7), 1507 × MON88017 (DAS-Ø15Ø7-1) MON-88Ø17-3), MON 88017 × 59122 (MON-88Ø17-3 × 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—

## "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, England, CB21 5XE, 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, England, CB4 0WB.".
- (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, England, CB21 5XE, 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, England, CB4 0WB.".

#### 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, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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 of Jealott's Hill International Research Centre, Bracknell, Berkshire, England, RG42 6EY."
  - (4) In the Annex, for point (a) (applicant and authorisation holder) substitute—

#### "(a) Authorisation holder

- (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, England, RG42 6EY.".

<sup>(9)</sup> EUD 2015/698, amended by S.I. 2019/705.

<sup>(10)</sup> EUD 2016/1215, amended by EUD 2019/1195 and S.I. 2019/705.

#### 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  $\times$  3006-210-23  $\times$  MON 88913 (DAS-24236-5  $\times$  DAS-21Ø23-5  $\times$  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 if America, represented in Great Britain by Corteva Agriscience UK Limited Cpc2 Capital Park, Fulbourn, Cambridge, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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 if America, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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

 $<sup>\</sup>textbf{(11)} \ \ EUD\ 2017/1211, amended\ by\ EUD\ 2019/239\ and\ S.I.\ 2019/705.$ 

<sup>(12)</sup> EUD 2017/1212, amended by EUD 2019/239 and S.I. 2019/705.

- $\times$  40-3-2 (DP-3Ø5423-1  $\times$  MON-Ø4Ø32-6) 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 if America, represented in Great Britain by Corteva Agriscience UK Limited Cpc2 Capital Park, Fulbourn, Cambridge, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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.

<sup>(13)</sup> EUD 2017/2448, amended by S.I. 2019/705.

<sup>(14)</sup> EUD 2017/2449, amended by EUD 2019/239 and S.I. 2019/705.

<sup>(15)</sup> EUR 2017/2450, amended by EUD 2019/239 and S.I. 2019/705.

- (2) In Article 7 (authorisation holder)—
  - (a) in the heading, for "holder" substitute "holders",
  - (b) for the text substitute—

"The authorisation holder is 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) in the heading, for "Addressee" 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, represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourn, Cambridge, England, CB21 5XE."

- (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, England, CB21 5XE.".

## 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) in the heading, for "holders" substitute "holder", and
    - (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, England, CB21 5XE."
  - (4) In the Annex, for point (a) (applicant and authorisation holder) substitute—
    - "(a) Authorisation holder:
      - (1) (1) The authorisation holder is Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana, 46268-1054, United States of America.

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

## 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 holder)—
    - (a) in the heading, for "holders" substitute "holder", and
    - (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 paragraphs 1 and 2 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, England, CB21 5XE."
  - (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, England, CB21 5XE.".

#### 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  $1507 \times 59122 \times MON~810 \times NK603$ , and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK60, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU(18) 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 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, England, CB21 5XE."
  - (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.

<sup>(17)</sup> EUD 2018/1109, amended by EUR 2019/241 and S.I. 2019/705.

<sup>(18)</sup> EUD 2018/1110, 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, England, CB21 5XE.".

## 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, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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  $1507 \times NK603$  (DAS- $\emptyset15\emptyset7-1 \times MON-\emptyset\emptyset6\emptyset3-6$ ) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council Amendment of Commission Implementing Decision (EU) 2019/1304(20) is amended as follows.
  - (2) In Article 7 (authorisation holders)—
    - (a) in the heading, for "holders" substitute "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 (addressees)—
    - (a) in the heading, for "Addressees" 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, England, CB21 5XE."
  - (4) In the Annex, for point (a) (applicants and authorisation holders) substitute—
    - "(a) Authorisation holder:

<sup>(19)</sup> EUD 2019/1304, amended by S.I. 2019/705.

<sup>(20)</sup> EUD 2019/1306, amended by S.I. 2019/705.

- (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, England, CB21 5XE.".

## 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  $\times$  1507  $\times$  NK603  $\times$  DAS-40278-9 and sub-combinations MON 89034  $\times$  NK603  $\times$  DAS-40278-9, 1507  $\times$  NK603  $\times$  DAS-40278-9 and NK603  $\times$  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, England, CB21 5XE."
  - (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, England, CB21 5XE.".

## 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  $89034 \times 1507 \times MON~88017 \times 59122 \times DAS-40278-9$  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, England, CB21 5XE."
  - (4) In the Annex, for point (a) (applicant and authorisation holder) substitute—
    - "(a) Authorisation holder:

<sup>(21)</sup> EUD 2019/2085, amended by S.I. 2019/705.

<sup>(22)</sup> EUD 2019/2086, amended by S.I. 2019/705.

- (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, England, CB21 5XE.".

# Amendment of the Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022

- **22.** The Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022 are amended as follows—
  - (a) in regulation 4(e) for "89304" substitute "89034".
  - (b) in schedule 2, in paragraph 4(2) for "EURL-VL-0417VP", substitute "EURL-VL-04/17VP".
  - (c) in schedule 3, in paragraph 4(2) for "EURL-VL-0417VP" substitute "EURL-VL-03/12VP".
  - (d) in schedule 4, in paragraph 4(2) for "EURL-VL-0417VP" substitute "EURL-VL-03/12VP".
  - (e) in schedule 7, in paragraph 4(2) for "EURL-VL-0417VP" substitute "EURL-VL-03/12VP".

## PART 4

## Revocations

## Revocation of Commission Decision 2010/429/EU

**23.** Commission Decision 2010/429/EU authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017  $\times$  MON 810 (MON-88Ø17-3  $\times$  MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council(**23**) is revoked.

St Andrew's House, Edinburgh 28th February 2023

MAREE TODD
Authorised to sign by the Scottish Ministers

<sup>(23)</sup> EUD 2010/429, amended by S.I. 2019/705. See schedule 7 of these Regulations for the renewal of the authorisation contained in EUD 2010/429.

#### 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  $\times$  DAS-44406-06

#### Genetically modified organisms and unique identifier

**1.** For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier DAS-81419-2  $\times$  DAS-444Ø6-6 is specified for genetically modified soybean DAS-81419-2  $\times$  DAS-44406-06.

#### 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-444Ø6-6,
  - (b) feed containing, consisting of, or produced from genetically modified soybean DAS-81419-2 × DAS-444Ø6-6,
  - (c) products containing or consisting of genetically modified soybean DAS-81419-2 x DAS-444Ø6-6 for uses other than those in sub-paragraphs (a) and (b), with the exception of cultivation.

## Labelling

- **3.**—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'soybean'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-444Ø6-6, 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  $\times$  DAS-444Ø6-6.
  - (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-444Ø6-6, 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.
- (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 from the Joint Research Centre of the European Commission(24)—
  - (a) "ERM®-BF437" (for DAS-81419-2),
  - (b) "ERM®-BF436" (for DAS-444Ø6-6).

## Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified soybean DAS-81419-2 × DAS-444Ø6-06, reference number "RP1133" submitted to the Food Safety Authority 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 of Commission Decision 2009/770.

#### **Authorisation holder**

- **6.**—(1) The name and address of 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, England, CB21 5XE.

#### 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,
  - (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.

<sup>(24)</sup> https://crm.jrc.ec.europa.eu/

#### Labelling

- **3.**—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'soybean'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying 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 from the Joint Research Centre of the European Commission(25).

#### Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of genetically modified soybean DAS-81419-2, reference number "RP1134" submitted to the Food Safety Authority 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 of Decision 2009/770.

## **Authorisation holder**

- **6.**—(1) The name and address of 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, England, CB21 5XE.

<sup>(25)</sup> https://crm.jrc.ec.europa.eu/

#### 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 laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'soybean'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of genetically modified soybean 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- $\emptyset\emptyset\emptyset$ H2-5.
- (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 from the American Oil Chemists' Society (AOCS)(26).

## Monitoring plan for environmental effects

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

 $<sup>(26) \ \ \</sup>text{https://www.aocs.org/crm}$ 

ØØØH2-5, reference number "RP1138" submitted to the Food Safety Authority 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 of Decision 2009/770.

## **Authorisation holder**

- **6.**—(1) The name and address of 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, England, RG42 6EY.

#### SCHEDULE 4

Regulation 3

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

## Genetically modified organism and unique identifier

- 1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the following unique identifiers are specified for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  MON 89034  $\times$  1507  $\times$  MON 87411  $\times$  59122 maize and its sub-combinations as follows—
  - (a) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122,
  - (b) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411,
  - (c) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × 59122,
  - (d) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411 × 59122,
  - (e) MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON  $87427 \times MON \ 87460 \times 1507 \times MON \ 87411 \times 59122$ ,
  - (f) MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411 × 59122,
  - (g) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON  $87460 \times MON 89034 \times 1507 \times MON 87411 \times 59122$ ,
  - (h) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  MON-89Ø34-3  $\times$  DAS-Ø15Ø7-1 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  MON 89034  $\times$  1507,
  - (i) MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411,
  - (j) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  MON-89Ø34-3  $\times$  DAS-59122-7 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  MON 89034  $\times$  59122,

- (k) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  DAS-Ø15Ø7-1  $\times$  MON-87411-9 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  1507  $\times$  MON 87411,
- (l) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  DAS-Ø15Ø7-1  $\times$  DAS-59122-7 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  1507  $\times$  59122,
- (m) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  MON-87411-9  $\times$  DAS-59122-7 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  MON 87411  $\times$  59122,
- (n) MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411,
- (o) MON-87427-7 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × MON 87411 × 59122,
- (p) MON-87427-7  $\times$  DAS-Ø15Ø7-1  $\times$  MON-87411-9  $\times$  DAS-59122-7 for genetically modified maize MON 87427  $\times$  1507  $\times$  MON 87411  $\times$  59122,
- (q) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411,
- (r) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × 59122,
- (s) MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × MON 87411 × 59122,
- (t) MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × MON 87411 × 59122,
- (u) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × 1507 × MON 87411 × 59122,
- (v) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  DAS-Ø15Ø7-1 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  1507,
- (w) MON-87427-7  $\times$  MON-8746Ø-4  $\times$  MON-87411-9 for genetically modified maize MON 87427  $\times$  MON 87460  $\times$  MON 87411,
- (x) MON-87427-7 × MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 59122,
- (y) MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × 1507 × MON 87411,
- (z) MON-87427-7  $\times$  MON-87411-9  $\times$  DAS-59122-7 for genetically modified maize MON 87427  $\times$  MON 87411  $\times$  59122,
- (aa) MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × MON 89034 × 1507,
- (bb) MON-8746Ø-4  $\times$  MON-89Ø34-3  $\times$  MON-87411-9 for genetically modified maize MON 87460  $\times$  MON 89034  $\times$  MON 87411,
- (cc) MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize MON  $87460 \times MON 89034 \times 59122$ ,
- (dd) MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × 1507 × MON 87411,
- (ee) MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON  $87460 \times 1507 \times 59122$ ,
- (ff) MON-8746Ø-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 87411 × 59122,

- (gg) MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON  $89034 \times 1507 \times MON \ 87411$ ,
- (hh) MON-89Ø34-3  $\times$  MON-87411-9  $\times$  DAS-59122-7 for genetically modified maize MON 89034  $\times$  MON 87411  $\times$  59122,
- (ii) DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize 1507 × MON 87411 × 59122,
- (jj) MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × 1507,
- (kk) MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87460 × 87411,
- (II) MON-8746Ø-4  $\times$  DAS-59122-7 for genetically modified maize MON 87460  $\times$  59122,
- (mm) DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize 1507 × MON 87411,
  - (nn) MON-87411-9  $\times$  DAS-59122-7 for genetically modified maize MON 87411  $\times$  59122.

#### Authorisation

- **2.** The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this schedule—
  - (a) food and food ingredients containing, consisting of, or produced from genetically modified maize as referred to in paragraph 1,
  - (b) feed containing, consisting of, or produced from genetically modified maize as referred to in paragraph 1,
  - (c) products containing or consisting of genetically modified maize as referred to in paragraph 1 for uses other than those in sub-paragraphs (a) and (b), with the exception of cultivation.

## Labelling

- **3.**—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'maize'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of genetically modified maize as referred to in paragraph 1, with the exception of food and food ingredients.

#### Method for detection

- **4.**—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the methods specified in sub-paragraph (2) are to be used for the detection of genetically modified maize referred to in paragraph 1.
  - (2) The methods are set out in—
    - (a) for MON-87427-7, the document entitled "Event-specific Method for the Quantification of Maize MON 87427 Using Real-time PCR", reference "EURL-VL-03/12VP" and dated 9 June 2015,
    - (b) for MON-8746Ø-4, the document entitled "Event-specific Method for the Quantification of Maize MON 87460 Using Real-time PCR", reference "CRLVL04/09VP" and dated 18 January 2012,
    - (c) for MON-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 June 2007.
- (3) The method of DNA extraction for use in the detection methods specified in sub-paragraph (2) is as set out in the document entitled "Report on the Validation of a DNA Extraction Method for Maize Seeds and Grains", reference "CRLVL16/05XP corrected version 2" and dated 26 July 2017.
  - (4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003—
    - (a) the following reference materials are accessible from the American Oil Chemists' Society(27)
      - (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 from the Joint Research Centre of the European Commission(28)—
      - (i) "ERM®-BF418" (for DAS-Ø15Ø7-1),
      - (ii) "ERM®-BF424" (for DAS-59122-7).

## Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP1180" submitted to the Food Safety Authority on 2 July 2021, is implemented.
- (2) The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

## **Authorisation holder**

- **6.**—(1) The name and address of the authorisation holder is Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.
- (2) The authorisation holder is represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, England, CB4 0WB.

<sup>(27)</sup> https://www.aocs.org/crm

<sup>(28)</sup> https://crm.jrc.ec.europa.eu/

#### SCHEDULE 5

Regulation 3

Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × MIR 162 × MON 810 × NK 603 maize and its sub-combinations

## Genetically modified organism and unique identifier

- 1.—(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  $1507 \times MIR \ 162 \times MON \ 810 \times NK \ 603$  maize and its sub-combinations as follows—
  - (a) DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × MON810 × NK603.
  - (b) DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize 1507 × MIR162 × MON810,
  - (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 × MON810 × NK603,
  - (e) SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize MIR162 × MON810.

#### Authorisation

- **2.** The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this schedule—
  - (a) food and food ingredients containing, consisting of, or produced from genetically modified maize as referred to in paragraph 1,
  - (b) feed containing, consisting of, or produced from genetically modified maize as referred to in paragraph 1,
  - (c) products containing or consisting of genetically modified maize as referred to in paragraph 1 for uses other than those in sub-paragraphs (a) and (b), with the exception of cultivation.

## Labelling

- **3.**—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'maize'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying products containing or consisting of genetically modified maize as referred to in paragraph 1, with the exception of food and food ingredients.

## Method for detection

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

- (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 as 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 from the Joint Research Centre of the European Commission(29)—
      - (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 from the American Oil Chemists' Society(30).

#### Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of genetically modified maize referred to in paragraph 1, reference number "RP1184" submitted to the Food Safety Authority 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 of Decision 2009/770.

#### **Authorisation holder**

- **6.**—(1) The name and address of 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, England, CB21 5XE.

<sup>(29)</sup> https://crm.jrc.ec.europa.eu/

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

#### 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 following unique identifier BCS-GH $\emptyset$ 02-5 × BCS-GH $\emptyset$ 04-7 × BCS-GH $\emptyset$ 05-8 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  $\times$  BCS-GHØØ4-7  $\times$  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 laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'cotton'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying 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-VL-04/11 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

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Validation of DNA Extraction Method from Cotton Seeds", reference "CRLVL13/04XP" dated 14 March 2007.

- (4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003—
  - (a) the reference material "AOCS 1108-A6" (for BCS-GHØØ2-5) is accessible from the American Oil Chemists' Society(31),
  - (b) the following reference materials are accessible from the Joint Research Centre of the European Commission(32)—
    - (i) ERM-BF429 (for BCS-GHØØ4-7),
    - (ii) ERM-BF428 (for BCS-GHØØ5-8).

## Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified cotton referred to in paragraph 1, reference number "RP1205" submitted to the Food Safety Authority 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 of Decision 2009/770.

#### **Authorisation holder**

- **6.**—(1) The name and address of 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, England, SK1 3GG.

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-88Ø17-3 × MON-ØØ81Ø-6 is specified for genetically modified maize MON 88017 × MON 810.

## Authorisation

- **2.** The following products are authorised(**33**) for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this schedule—
  - (a) food and food ingredients containing, consisting of, or produced from genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6,

<sup>(31)</sup> https://www.aocs.org/crm

<sup>(32)</sup> https://crm.jrc.ec.europa.eu/

<sup>(33)</sup> This authorisation is a renewal of the authorisation previously granted under Commission Decision 2010/429/EU. That instrument is revoked by regulation 23 of these Regulations.

- (b) feed containing, consisting of, or produced from genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6,
- (c) products other than food and feed containing or consisting of genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6 with the exception of cultivation.

## Labelling

- **3.**—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'maize'.
- (2) The words 'not for cultivation' must appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize MON-88Ø17-3  $\times$  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  $MON-88\emptyset17-3 \times MON-\emptyset\emptyset81\emptyset-6$ .
  - (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 "CRLV16/05VP 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 as 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 from the American Oil Chemists' Society(34),
    - (b) the reference material "ERM®-BF413" (for MON-ØØ81Ø-6) is accessible from the Joint Research Centre of the European Commission(35).

## Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the renewal of the authorisation of genetically modified maize MON-88 $\emptyset$ 17-3 × MON- $\emptyset$  $\emptyset$ 81 $\emptyset$ -6, reference number "RP1179" submitted to the Food Safety Authority on 2 July 2021, is implemented.
- (2) The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

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

<sup>(35)</sup> https://crm.jrc.ec.europa.eu/

#### **Authorisation holder**

- **6.**—(1) The name and address of the authorisation holder is Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.
- (2) The authorisation holder is represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, England, CB4 0WB.

#### **SCHEDULE 8**

Regulation 3

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

## 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- $\emptyset\emptyset\emptyset73$ -7 is specified for genetically modified oilseed rape GT73.

#### Authorisation

- **2.** The following products are authorised(**36**) 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 labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the 'name of the organism' is 'oilseed rape'.
- (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 oilseed rape MON- $\emptyset\emptyset\emptyset73$ -7, 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 oilseed rape MON- $\emptyset\emptyset\emptyset73$ -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

<sup>(36)</sup> 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 p11).

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 from the American Oil Chemists' Society(37).

## Monitoring plan for environmental effects

- **5.**—(1) The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for the renewal of the authorisation of genetically modified oilseed rape MON- $\emptyset\emptyset\emptyset73$ -7, reference number "RP1263" submitted to the Food Safety Authority 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 of Decision 2009/770.

#### **Authorisation holder**

- **6.**—(1) The name and address of the authorisation holder is Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.
- (2) The authorisation holder is represented in Great Britain by Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, England, CB4 0WB.

## **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations authorise the placing on the market of specified genetically modified food and feed products in Scotland and also modify the terms of existing authorisations.

Part 2 and schedules 1-8 contain the authorisations, in relation to Scotland, of products containing, and consisting of, or produced from the specified genetically modified organisms, in accordance with Articles 7(3) ad 19(3) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed ("Regulation 1829/2003") as follows—

- a) schedule 1 is a new authorisation for genetically modified soybean DAS-81419-2  $\times$  DAS-44406-06;
- b) schedule 2 is a new authorisation for genetically modified soybean DAS-81419-2;
- c) schedule 3 is a new authorisation for genetically modified soybean SYHT0H2;
- d) schedule 4 is a new authorisation for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and its sub-combinations;
- e) schedule 5 is a new authorisation for genetically modified maize 1507 × MIR 162 × MON 810 × NK 603 and its sub-combinations;
- f) schedule 6 is a new authorisation for genetically modified cotton GHB614  $\times$  T304-40  $\times$  GHB119;

<sup>(37)</sup> https://www.aocs.org/crm

- g) schedule 7 renews the authorisation for genetically modified maize MON 88017 × MON 810;
- h) schedule 8 renews the authorisation for genetically modified oilseed rape GT73. This renewal is limited to products containing or consisting of genetically modified oil seed rape GT73 (other than food). It does not cover products "produced from" that genetically modified organism.

Authorisations granted by these Regulations are valid for a period of ten years in accordance with Articles 7(4) and 19(4) of Regulation 1829/2003 and will expire at the end of 25 April 2033. This is subject to Articles 11(4) and 23(4) of that Regulation, which provide for an extension of the authorisation period in certain circumstances where an application for renewal has been submitted.

Part 3 contains modifications to the authorisations for 50 genetically modified food and feed products, amending, in relation to Scotland, 18 EU decisions which contain the existing authorisations. The amendments relate to changes to the names and the addresses of the respective authorisation holders, and their representatives in Great Britain. Part 3 also contains minor amendments to the Genetically Modified Food and Feed (Authorisations) (Scotland) Regulations 2022.

Part 4 revokes, in relation to Scotland, the retained EU Decision containing the previous authorisation for the products now authorised by schedule 7.

In each schedule, paragraph 4 specifies the method, for detection, including sampling, which has been validated for use in relation to the authorised products. The documents referred to have been published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx.

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

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.