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# SCHEDULES

# 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  $88017 \times MON 810$ 

## 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-88 $\emptyset$ 17-3 × MON- $\emptyset\emptyset$ 81 $\emptyset$ -6 is specified for genetically modified maize MON 88017 × MON 810.

#### Authorisation

**2.** The following products are authorised(1) 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;
- (b) feed containing, consisting of, or produced from genetically modified maize MON-88Ø17-3 × MON-ØØ81Ø-6; and
- (c) products containing or consisting of genetically modified maize MON-88 $\emptyset$ 17-3 × MON- $\emptyset\emptyset$ 81 $\emptyset$ -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 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-88 $\emptyset$ 17-3 × MON- $\emptyset\emptyset$ 81 $\emptyset$ -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 $\emptyset$ 17-3 × MON- $\emptyset\emptyset$ 81 $\emptyset$ -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 "CRLVL16/05VP corrected version 1" and dated 30 March 2010;

<sup>(1)</sup> 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.

(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 realtime 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 via the American Oil Chemists' Society;
- (b) the reference material "ERM®-BF413" (for MON-ØØ81Ø-6) is accessible via the Joint Research Centre of the European Commission.

# Monitoring plan for environmental effects

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

# 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.