

SCHEDULES

SCHEDULE 5

Regulation 3

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

Genetically modified organism and unique identifier

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

Authorisation

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

- (a) food and food ingredients containing, consisting of or produced from genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1;
- (b) feed containing, consisting of or produced from genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1;
- (c) products containing or consisting of genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1 for uses other than those in sub-paragraphs (a) and (b), with the exception of cultivation.

Labelling

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

(2) The words “not for cultivation” must appear on the label of and in documents accompanying products containing or consisting of genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1, with the exception of food and food ingredients.

Method for detection

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the methods specified in sub-paragraphs (2) to (5) are to be used for the detection of genetically modified soybean MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1.

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

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

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of Soybean MON 87701 Using Real-time PCR”, reference “CRLVL05/09VP”, and dated 13 July 2011.

(4) Event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled “Event-specific Method for the Quantification of Soybean MON87708 Using Real-time PCR”, reference “EURL-VL-02/11VP”, and dated 6 May 2013.

(5) Event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled “Event-specific Method for the Quantification of Soybean Line MON 89788 Using Real-time PCR”, reference “CRLVL05/06VP”, and dated 18 February 2008.

(6) The method of DNA extraction for use in the detection methods specified in sub-paragraphs (2) to (5) is as set out in the document entitled “Report on the Validation of a DNA Extraction Method for Soybean Seeds”, reference “CRL-VL-05/06XP Corrected version 2”, and dated 16 March 2018.

(7) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference materials “AOCS 0215-A” (for MON-87751-7), “AOCS 0809-A2” (for MON 87701-2), “AOCS 0311-A2” (for MON-87708-9) and “AOCS 0906-B2” (for MON-89788-1) are accessible via the American Oil Chemists Society (AOCS)(1).

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 MON-87751-7 × MON-87701-2 × MON-87708-9 × MON-89788-1, reference number “RP607” submitted to the Food Safety Authority on 11 March 2021, 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 name and address of the authorisation holder is Bayer CropScience LP, 800 N. Lindbergh Boulevard, St Louis, Missouri 63167, United States of America.

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

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