

SCHEDULE 5

Regulation 3(1)

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

Genetically modified organism and unique identifier

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

Authorisation

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

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

Labelling

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

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

Method for detection

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

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

(3) The method specified in this sub-paragraph is event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled “Event-specific Method for the Quantification of Soybean MON 87701 Using Real-time PCR”, reference “CRLVL05/09VP”.

(4) The method specified in this sub-paragraph is event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled “Event-specific Method for the Quantification of Soybean MON 87708 Using Real-time PCR”, reference “EURL-VL-02/11VP”.

(5) The method specified in this sub-paragraph is event-specific real-time quantitative PCR based method of detection of the genetically modified soybean as set out in the document entitled

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

“Event-specific Method for the Quantification of Soybean Line MON 89788 Using Real-time PCR-Protocol”, reference “CRLVL05/06VP”.

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

(7) For the purposes of Articles 7(3) and 19(3) of Regulation (EC) 1829/2003, the reference materials AOCS 0215-A, AOCS 0809-A2, AOCS 0311-A2 and AOCS 0906-B2 are accessible from the American Oil Chemists Society(1).

Monitoring plan for environmental effects

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

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

Authorisation holder

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

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

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