

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; and
- (c) products containing or consisting of genetically modified soybean DAS-81419-2 × DAS-44406-6 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-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Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(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⁽¹⁾—

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

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-44406-6, reference number “RP1133” submitted to the Food Safety Authority⁽²⁾ 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.

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

(2) “Food Safety Authority” is defined in Article 2(17) of 1829/2003, as regards England, as the Food Standards Agency.