

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-ØØØH2-5.

(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)(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 genetically modified soybean SYN-

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

Status: This is the original version (as it was originally made).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

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.