

WG25-65

FOOD, WALES

REGULATED PRODUCTS, WALES

GENETICALLY MODIFIED FOOD AND FEED

Determination of authorisation status: authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB811(BCS-GH811-4)

Explanatory note

(this note is not part of the determination)

This determination is made in relation to Wales by the Welsh Ministers in exercise of the powers conferred by Article 7 (food) and Article 19 (feed) of Regulation [\(EC\) No 1829/2003](#) of the European Parliament and of the Council on genetically modified food and feed (EUR 2003/1829).

It authorises the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB811 (BCS-GH811-4). The terms of the authorisation and the conditions upon which the products are authorised are set out in the Schedule.

There has been consultation as required by Article 9 of Regulation [\(EC\) No 178/2002](#) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (EUR 2002/178).

Determination

Application and coming into force

1. This determination applies in relation to Wales, and comes into force on 13th October 2025.

Interpretation

2. In this determination—

“Regulation 1829/2003” means Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (EUR 2003/1829);

“Regulation 1830/2003” means Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (EUR 2003/1830);

“Decision 2009/770” means Commission Decision 2009/770/EC establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (EUDN 2009/770).

3. Any expression used both in this determination and in Regulation 1829/2003 has the same meaning as it has in that Regulation.

Determination of authorisation status of products containing, consisting of, or produced from genetically modified cotton GHB811 (BCS-GH811-4)

4. Products containing, consisting of, or produced from genetically modified cotton GHB811 (BCS-GH811-4) are authorised in accordance with and subject to the conditions and requirements set out in the Schedule.

Sarah Murphy

Minister for Mental Health and Wellbeing, under the authority of the Cabinet Secretary for Health and Social Care, one of the Welsh Ministers

6 October 2025

SCHEDULE

Genetically modified organism and unique identifier

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier BCS-GH811-4 is specified for genetically modified cotton GHB811.

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) foods and food ingredients containing, consisting of, or produced from genetically modified cotton BCS-GH811-4;

(b) feed containing, consisting of, or produced from genetically modified cotton BCS-GH811-4;

(c) products containing, or consisting of, genetically modified cotton BCS-GH811-4 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 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 'cotton'.

(2) The words 'not for cultivation' must appear on the label of, and in documents accompanying, the products containing or consisting of genetically modified cotton BCS-GH811-4, 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 cotton BCS-GH811-4.
- (2) The method is set out in the document entitled "[Event-specific Method for the Quantification of cotton GHB811 by Real-time PCR](#)", reference "EURL-VL-04/18VP" and published 13 July 2020.
- (3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is set out in the document entitled "[Cotton Seeds Sampling and DNA Extraction Report on the Validation of DNA Extraction Method from Cotton Seeds](#)", reference "CRLVL13/04XP" and dated 14 March 2007.
- (4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material "ERM®-BF442" is accessible via the [Joint Research Centre \(JRC\) 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 authorisation of genetically modified cotton BCS-GH811-4, reference number "RP1232" submitted to the Food Safety Authority on 27 August 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 II of Decision 2009/770/EC.

Authorisation holder

6. (1) The name and address of the authorisation holder is BASF Agricultural Solutions Seed US LLC, 100 Park Avenue, Florham Park, New Jersey, 07932, USA.

(2) The authorisation holder is represented in Great Britain by BASF PLC, 2 Stockport Exchange, Railway Road, Stockport, Cheshire, UK, SK1 3GG.