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<u>B</u>

COMMISSION DECISION

of 17 June 2011

authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614 (BCS-GHØØ2-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2011) 4177)

(Only the German text is authentic)

(Text with EEA relevance)

(2011/354/EU)

(OJ L 160, 18.6.2011, p. 90)

Amended by:

Official Journal

		No	page	date
► <u>M1</u>	Commission Implementing Decision (EU) 2019/1195 of 10 July 2019	L 187	43	12.7.2019

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(Text with EEA relevance)

(2011/354/EU)

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum*) GHB614, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ2-5, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from BCS-GHØØ2-5 cotton;
- (b) feed containing, consisting of, or produced from BCS-GHØØ2-5 cotton;
- (c) products other than food and feed containing or consisting of BCS-GHØØ2-5 cotton for the same uses as any other cotton with the exception of cultivation.

Article 3

Labelling

- 1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
- 2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of BCS-GHØØ2-5 cotton referred to in Article 2(b) and (c).

Article 4

Monitoring for environmental effects

- 1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

Article 5

Community register

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 6

Authorisation holder

The authorisation holder shall be ►M1 BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany ◄.

Article 7

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 8

Addressee

This Decision is addressed to $\blacktriangleright \underline{M1}$ BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen \blacktriangleleft , Germany.

ANNEX

▼ M1

(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States

of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.

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(b) Designation and specification of the products

- Foods and food ingredients containing, consisting of, or produced from BCS-GHØØ2-5 cotton;
- (2) Feed containing, consisting of, or produced from BCS-GHØØ2-5 cotton;
- (3) Products other than food and feed containing or consisting of BCS-GHØØ2-5 cotton for the same uses as any other cotton with the exception of cultivation.

The genetically modified BCS-GHØØ2-5 cotton (*Gossypium hirsutum*), as described in the application, expresses the 2mEPSPS protein which confers tolerance to the glyphosate herbicide.

(c) Labelling

- (1) For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton';
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of BCS-GHØØ2-5 cotton referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection

- Event specific real-time PCR based method for the quantification of BCS-GHØØ2-5 cotton,
- Validated on seeds by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http:// gmo-crl.jrc.ec.europa.eu/statusofdoss.htm,

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 Reference material: AOCS 1108-A and 0306-A is accessible via the American Oil Chemists Society at https://www.aocs.org/crm

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(e) Unique identifier

BCS-GHØØ2-5

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(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Biosafety Clearing-House, Record ID: see [to be completed when notified].

(g) Conditions or restrictions on the placing on the market, use or handling of the products

Not required.

(h) Monitoring plan

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

[Link: plan published on the Internet]

(i) Post market monitoring requirements for the use of the food for human consumption

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.