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COMMISSION IMPLEMENTING DECISION (EU) 2017/1208

of 4 July 2017

authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

(notified under document C(2017) 4457)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

(OJ L 173, 6.7.2017, p. 23)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/1195 of 10 July 2019	L 187	43	12.7.2019

▼B

COMMISSION IMPLEMENTING DECISION (EU) 2017/1208

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(notified under document C(2017) 4457)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum* L.) GHB119, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ5-8, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 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 cotton GHB119;

(b) feed containing, consisting of, or produced from cotton GHB119;

(c) Cotton GHB119 in products containing it or consisting of it for any other use than those provided in points (a) and (b), 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’.

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2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of cotton GHB119, with the exception of products referred to in point (a) of Article 2.

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.

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Article 6

Authorisation holder

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, United States, represented by BASF SE, Germany.

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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 ►M1 BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany ◄.

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ANNEX

▼M1

(a) **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:**

(1) foods and food ingredients containing, consisting of, or produced from genetically modified cotton BCS-GHØØ5-8;

(2) feed containing, consisting of, or produced from genetically modified cotton BCS-GHØØ5-8;

(3) genetically modified cotton BCS-GHØØ5-8 in products containing them or consisting of them for any other use than those provided in points (1) and (2), with the exception of cultivation.

BCS-GHØØ5-8 as described in the application, expresses the PAT protein which confers tolerance to glufosinate ammonium-based herbicides and Cry2Ae protein which confers resistance to certain lepidopteran pests.

(c) **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 the accompanying documents of the products containing or consisting of the cotton covered by this Decision, with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

(1) Event-specific real-time PCR based method for the quantification of BCS-GHØØ5-8 cotton.

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from seeds of BCS-GHØØ5-8 cotton, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

(3) Reference Material: ERM-BF428 accessible via the Joint Research Centre (JRC) of the European Commission, at https://crm.irmm.jrc.ec.europa.eu/jrc/en/reference-materials/catalogue

(e) **Unique identifier:**

BCS-GHØØ5-8

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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 number: *published in the Community register of genetically modified food and feed when notified*).

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

Not required.

(h) **Monitoring plan for environmental effects:**

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

(Link: *plan published in the Community register of genetically modified food and feed*)

(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 time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.