

COMMISSION IMPLEMENTING DECISION (EU) 2021/1389**of 17 August 2021****authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × T304-40 × GHB119 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2021)5996)***(Only the German text is authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular to Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 30 September 2014, Bayer CropScience AG submitted an application to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application covered the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified cotton GHB614 × T304-40 × GHB119. The application also covered the placing on the market of products containing or consisting of genetically modified cotton GHB614 × T304-40 × GHB119 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾. It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.
- (3) On 25 July 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ⁽³⁾. This opinion was invalidated for reasons of formal nature related to the application, which was further addressed by the applicant. On 31 July 2020, the Authority published a new favourable opinion. It concluded that genetically modified cotton GHB614 × T304-40 × GHB119, as described in the application, is as safe as, and nutritionally equivalent to, its conventional counterpart and the tested non-genetically modified cotton reference varieties with respect to the potential effects on human and animal health and the environment.
- (4) In its opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified cotton GHB614 × T304-40 × GHB119 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-122). EFSA Journal 2018;16(7):5349; <https://doi/10.2903/j.efsa.2018.5349>.

- (6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × T304-40 × GHB119 should be authorised for the uses listed in the application.
- (7) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfer its rights and obligations pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed its agreement with this transfer and authorised BASF SE, based in Germany, to act as its representative in the Union.
- (8) A unique identifier should be assigned to genetically modified cotton GHB614 × T304-40 × GHB119 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.
- (9) For the products covered by this Decision, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽⁵⁾, appear to be necessary. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified cotton GHB614 × T304-40 × GHB119, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (10) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ⁽⁶⁾.
- (11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed containing or consisting of genetically modified cotton GHB614 × T304-40 × GHB119, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (12) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of Regulation (EC) No 1829/2003.
- (13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁵⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 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 (OJ L 268, 18.10.2003, p. 24).

⁽⁶⁾ Commission Decision 2009/770/EC of 13 October 2009 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 (OJ L 275, 21.10.2009, p. 9).

⁽⁷⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum* and *Gossypium barbadense*) GHB614 × T304-40 × GHB119, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, in accordance with 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 genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
- (b) feed containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
- (c) products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 for uses other than those provided for 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'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, with the exception of products referred to in point (a) of Article 2.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8.

Article 5

Monitoring plan 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 6***Community register**

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, USA, represented in the Union by BASF SE, Germany.

*Article 8***Validity**

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

*Article 9***Addressee**

This Decision is addressed to BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

Done at Brussels, 17 August 2021.

*For the Commission,
Stella KYRIAKIDES
Member of the Commission*

ANNEX

(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 in the Union by BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
- (2) feed containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
- (3) products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 expresses the *2mepsps* gene, which confers tolerance to glyphosate based herbicides, the *bar* gene, which confers tolerance to glufosinate-ammonium based herbicides, the *cryIAb*, and the *cry2Ae* genes, which confer 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 documents accompanying the products containing or consisting of cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, with the exception of foods and food ingredients.

(d) Method for detection:

- (1) The quantitative event-specific PCR detection methods for cotton GHB614 × T304-40 × GHB119 are those validated for genetically modified cotton events BCS-GHØØ2-5, BCS-GHØØ4-7 and BCS-GHØØ5-8. The detection methods have been validated on genomic DNA extracted from leaves of BCS-GHØØ2-5, BCS-GHØØ4-7, BCS-GHØØ5-8 and verified on genomic DNA extracted from leaves of BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8.
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
- (3) Reference Material: AOCs 1108-A5 (for BCS-GHØØ2-5) is accessible via the American Oil Chemists' Society (AOCS) at <https://www.aocs.org/crm>. ERM-BF429 (for BCS-GHØØ4-7) and ERM-BF428 (BCS-GHØØ5-8) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>

(e) Unique identifier:

BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8

(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 of the European Parliament and of the Council ⁽¹⁾.

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

⁽¹⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).