

Part III - Summary

Request for Renewal of the Authorisation of the genetically modified herbicide tolerant cotton

GHB614

**for food and feed uses, and import and processing,
in accordance with articles 11 and 23 of Regulation (EC) N° 1829/2003**

EFSA-GMO-RX-XXX

Version CC1

Submitted on
22 April 2020

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PART III – SUMMARY

EFSA-GMO-RX-XXX (GHB614)

1. GENERAL INFORMATION

1.1. Details of application

(a) Application number

EFSA-GMO-RX-XXX

(b) Name of the product (commercial and any other names)

GHB614, GlyTol™ Cotton, unique identifier: BCS-GHØØ2-5

(c) Date of acknowledgement of valid renewal application

Not available at the time of submission

1.2. Applicant

(a) Name of applicant

BASF Agricultural Solutions Seed US LLC

(b) Address of applicant

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USA

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Representative of the applicant established in the Union:
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1.3. Scope of the application

(a) Genetically modified food

- Food containing or consisting of genetically modified plants
- Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

- Feed containing or consisting of genetically modified plants
- Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

- Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation

1.4. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

Submissions for authorisations of GHB614 cotton for food and feed uses have been made in Indonesia Singapore and Vietnam and are at different stages in the approval process. GHB614 cotton is authorised for food and feed uses in USA, Australia & New Zealand, Canada, Japan, Korea, China, Colombia, Mexico, Argentina, Brazil, Taiwan, EU, Philippines, and Malaysia. GHB614 has been approved for cultivation in the USA and Brazil.

More information on the regulatory status of the product in the EU and third countries can be retrieved from the EU Register of authorised GMOs¹ and the CropLife International database².

1.5. General description of the product

The recipient plant is cotton, *Gossypium* spp. The genetically modified BCS-GHØØ2-5 cotton expresses the 2mEPSPS protein which confers tolerance to the glyphosate herbicide.

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 the Decision 2011/354/EU:

- (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.

No mandatory conditions or restrictions on placing on the market, use of handling of GHB614 cotton products were included as a condition of the authorisation. All standard practices applicable to cotton today remain adequate for the handling of glyphosate-tolerant, GHB614 cotton varieties.

¹ https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

² <http://www.biotradestatus.com/#>

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’.

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 Commission Decision 2011/354/EC.

2. Information Required Under Articles 11 and 23 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed

2.1 A copy of the authorisation for placing the food and feed on the market

Commission Decision 2011/354/EU 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 Council³.

Commission Implementing Decision (EU) 2019/1195 amending Decision 2011/354/EC as regards the authorisation holder and the representative for the placing on the market of genetically modified cotton GHB614⁴.

2.2 A report on the results of the monitoring, if so specified in the authorisation

In accordance with Article 4 of Commission Decision 2011/354/EU, the authorisation holder has ensured the implementation of the monitoring plan for environmental effects and as reported to the EC on an annual basis.

The Annual Post Market Environmental Monitoring reports for the genetically modified cotton GHB614 covering the monitoring period from June 2011 until June 2019 are provided as part of the renewal application.

The general surveillance considering the placing on the market of GHB614 cotton in the EU indicates that there have been no adverse health or environmental effects associated with the import or use of GHB614 cotton.

2.3 Any other new information which has become available with regard to the evaluation of the safety in use of the food and feed and the risks of the food and feed to the consumer, animals or the environment

2.3.1 Systematic search and evaluation of literature

A scoping review was performed for GHB614 cotton and its newly expressed protein, 2mEPSPS. There was no literature identified changing the original risk assessment conclusions.

2.3.2 Update Bioinformatics

Following the requirement as laid out in the EFSA Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003, updated bioinformatics analyses were conducted.

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:160:0090:0093:EN:PDF>

⁴ https://eur-lex.europa.eu/eli/dec_impl/2019/1195/oj

The results of the updated bioinformatics analyses do not change the original risk assessment conclusion on GHB614 cotton.

2.3.3 Additional documents or studies performed by or on behalf of the applicant

None of the competent authorities has prohibited or revoked the authorisation for GHB614 cotton for neither import nor cultivation purposes.

The detailed review of unpublished studies produced, controlled or sponsored by the applicant did not identify any studies that would constitute any new data relevant for the risk assessment of GHB614 cotton for the scope of the application or the newly expressed protein (2mEPSPS) or which challenge or change in any way the conclusions of the original risk assessment.

2.4 Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring

This application is for renewal of the authorisation of genetically modified herbicide tolerant GHB614 cotton for food and feed uses, import and processing. The application does not cover cultivation of GHB614 cotton in the EU.

The initial authorisation, which was issued on 17 June 2011, Commission Decision 2011/354/EU for placing on the market of GHB614 (BCS-GHØØ2-5) cotton pursuant to Regulation (EC) No 1829/2003 lays out conditions in Article 4 and point (h) of the Annex of the authorization decision. These lay down the need for general monitoring and do not impose specific conditions or restrictions on the placing on the market, use or handling of the products. Considering that the annual EU Post market environmental monitoring activities for the years 2011-2019 did not identify adverse effects and that there was no literature identified changing previous risk assessment conclusions, no revisions or changes to the general surveillance measures are considered necessary.

Based on the conclusions of the overall assessment of the here presented renewal application of GHB614 cotton for food and feed uses, the conditions of the original authorisation should not be amended or complemented and should therefore remain unchanged.