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Fact-sheet

Cotton GHB614 x T304-40 x GHB119

(Also known as GlyTol x TwinLink or GLT)

Unique Identifier

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

August 2021

Information, obligations, and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB614 x T304-40 x GHB119 (BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS- GHØØ5-8).

The information set out in this document is principally directed to all operators handling and processing bulk mixtures of imported cotton grains.

A. Authorisation

On 17 August 2021, Commission Implementing Decision (EU) 2021/1389 authorised the placing on the market of GHB614 x T304-40 x GHB119 cotton pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorisation covers the following products:

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

For more information, please visit the Community Register of GM Food and Feed using the following link: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

B. General Product Information

The insect resistant and herbicide tolerant cotton product GHB614 x T304-40 x GHB119 was developed by crossing the single parental lines GHB614 (BCS-GHØØ2-5), T304-40 (BCS-GHØØ4-7) and GHB119 (BCS-GHØØ5-8) using traditional breeding methods. No new genetic modification was introduced GHB614 x T304-40 x GHB119 cotton. The following traits were inherited in the GHB614 x T304-40 x GHB119 cotton from the single parental lines:

- **Tolerance to glyphosate herbicides**

The glyphosate herbicide tolerance trait in GHB614 x T304-40 x GHB119 cotton is inherited from the parental line GHB614. GHB614 cotton contains the *2mepsps* gene, which encodes a modified 5-enolpyruvylshikimate 3-phosphate synthase (2mEPSPS). The 2mEPSPS protein confers tolerance to glyphosate herbicides. Glyphosate is widely used in herbicide-tolerant cotton and other agricultural production systems.

- **Tolerance to glufosinate ammonium herbicides**

The glufosinate ammonium herbicide tolerance trait in GHB614 x T304-40 x GHB119 cotton is inherited from the parental lines T304-40 and GHB119. T304-40 and GHB119 contain the *bar* gene, which encodes, Phosphinothricin-Acetyl-Transferase (PAT). The PAT protein confers tolerance to glufosinate ammonium herbicides. Glufosinate ammonium herbicide is also widely used in herbicide-tolerant cotton and other agricultural production systems.

- **Insect resistance**

The insect resistance trait in GHB614 x T304-40 x GHB119 cotton is inherited from the parental lines T304-40 and GHB119.

T304-4 produces the *Bacillus thuringiensis* subsp. Berliner Cry1Ab protein (encoded by the *cry1Ab* gene) that is effective in controlling lepidopteran larvae such as cotton bollworm (CBW) and tobacco budworm (TBW), which are common pest of cotton.

GHB119 produces the *Bacillus thuringiensis* subsp. Dakota Cry2Ae protein (encoded by the *cry2Ae* gene) that is effective in controlling lepidopteran plant feeding larvae such as cotton bollworm (CBW), tobacco budworm (TBW) and fall army worm (FAW), which are common pests in cotton crop.

The combination of the insecticidal crystal proteins Cry1Ab (from T304-40) and Cry2Ae (from GHB119) provide enhanced insect control and offer an additional insect-resistance management tool for growers. The dual herbicide tolerance to glyphosate herbicides (from GHB614) and glufosinate-ammonium herbicides (from T304-40 and GHB119) also offers growers additional weed control options.

C. Food, Feed and Environmental Safety

The GMO Panel of the European Food Safety Authority (EFSA) evaluated the genetically modified GHB614 x T304-40 x GHB119 cotton with regard to the scope of its application and appropriate principles described in its guidelines for the risk assessment of GM plants. EFSA concluded that genetically modified GHB614 x T304-40 x GHB119 cotton, as described in the application, is as safe as its comparator and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment.

Further information can be retrieved from EFSA website at:

[Assessment of genetically modified cotton GHB614 × T304-40 × GHB119 for food and feed uses, import and processing under Regulation \(EC\) No 1829/2003 \(application EFSA-GMO-NL-2014-122\) | European Food Safety Authority \(europa.eu\)](#)

Event-specific quantitative detection methods for GHB614, T304-40 and GHB119 cotton have been validated and verified on GHB614 x T304-40 x GHB119 cotton by the European Union Reference Laboratory for GM Food and Feed (EU-RL GMFF) of the Joint Research Centre (JRC) and is publicly available on the JRC-EU-RL GMFF website:

<http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

Certified reference material for GHB614 is available from the American Oil Chemists Society (AOCS): AOCS 1108-A (for GHB614) and is accessible at <https://www.aocs.org/crm#cotton> . Certified reference materials for T304-40 and GHB119 are available from the Joint Research Centre (JRC) of the European Commission: ERM-BF429 for T304-40 and ERM-BF428 for GHB119 and are accessible at <https://crm.jrc.ec.europa.eu/>

D. General obligations for operators

Each operator handling and processing bulk mixtures of imported GM cotton shall comply with the requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, handling the labelling and traceability of genetically modified organisms and the conditions for labeling and traceability outlined in Commission Implementing Decision (EU) 2021/1389 on GHB614 x T304-40 x GHB119.

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 the accompanying documents of the products containing or consisting of GHB614 x T304-40 x GHB119 cotton, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to GHB614 x T304-40 x GHB119 cotton is BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8.

In addition, the operators are requested to collaborate with the authorisation holder in the general surveillance to identify the occurrence of unanticipated adverse effects of the viable GHB614 x T304-40 x GHB119 cotton or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (see point F). In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable cotton and with respect to clean-up practices.

E. Contact points for Operators

As there are other technology providers for GM cotton it is essential to develop an industry wide approach because the shipments entering the European ports may be comingled.

CropLife Europe plays an important role in this area and is the central communication point for all GM plant technology providers. CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, CropLife Europe will transfer the messages to the relevant GMO industry partner if further action is required.

Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to CropLife Europe at: [Product information - CropLife Europe](#)

If required, additional comments or questions relative to GHB614 x T304-40 x GHB119 cotton can also be addressed at gent.info.operators@basf.com

F. General surveillance

General surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (e.r.a).

In order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., a general surveillance plan for GHB614 x T304-40 x GHB119 cotton is in place. In the case of GHB614 x T304-40 x GHB119 cotton, EFSA 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.

The general surveillance system for GHB614 x T304-40 x GHB119 cotton involves the authorisation holder and operators who are handling and using viable GHB614 x T304-40 x GHB119 cotton. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect that may arise from the handling and use of viable GHB614 x T304-40 x GHB119 cotton. The authorisation holder will report the results of the general surveillance for GHB614 x T304-40 x GHB119 cotton to the European Commission on an annual basis.