

Factsheet  
**GlyTol® LibertyLink® GHB614 x**  
**LLCotton25 cotton**  
Unique Identifier  
BCS-GHØØ2-5 x ACS-GHØØ1-3

February 2025

## **Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB614 x LLCotton25 cotton (BCS-GHØØ2-5xACS-GHØØ1-3).**

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 24 April 2015, Commission Implementing Decision (EU) 2015/690 authorised the placing on the market of GHB614 x LLCotton25 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 GHB614 x LLCotton25 cotton;
- b) feed containing, consisting of, or produced from GHB614 x LLCotton25 cotton;
- c) Products other than food and feed containing or consisting of GHB614 x LLCotton25 cotton for the same uses as any other cotton with the exception of cultivation

On 10 July 2019, Commission implementing Decision (EU) 2019/1195 amending Decision (EU) 2015/690 as regards the authorisation holder and the representative for the placing on the market of genetically modified cotton has adopted the transfer of authorisation from Bayer CropScience AG to BASF Agricultural Solutions Seed US LLC.

For more information, please visit the Community Register of GM Food and Feed using the following link: [GMO register \(europa.eu\)](http://GMOregister.europa.eu)

### **B. General Product Information**

The commercial name of the planting grain product is GlyTol® LibertyLink® cotton and is tolerant to both glyphosate and glufosinate ammonium containing herbicides. GHB614 x LLCotton25 cotton was produced by conventional crossbreeding of parental cotton lines GHB614 (BCS-GHØØ2-5) and LLCotton25 (ACS-GHØØ1-3). The following traits were inherited in the GHB614 x LLCotton25 cotton from the single events GHB614 and LLCotton25:

- **Tolerance to glyphosate herbicides**

The glyphosate herbicide tolerance trait in GHB614 x LLCotton25 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 the herbicide glyphosate. Glyphosate is a wide-spectrum herbicide that inhibits the enzyme, 5-enolpyruvylshikimate 3-phosphate synthase (EPSPS), which is involved in the shikimic acid pathway for aromatic amino acid biosynthesis in plants and microorganisms. The 2mEPSPS enzyme however is not inhibited by glyphosate and the expression is sufficiently high to provide a good level of specific activity and ensure glyphosate tolerance.

- **Tolerance to glufosinate ammonium herbicides**

The glufosinate ammonium herbicide tolerance trait in GHB614 x LLCotton25 cotton is inherited from the parental line LLCotton25. LLCotton25 contains the *bar* gene, a bialaphos resistance gene, isolated from the soil microorganism, *Streptomyces hygroscopicus*. The *bar* gene, when expressed,

enables the production of the enzyme, Phosphinothricin-Acetyl-Transferase (PAT) that acetylates L-glufosinate ammonium and thereby confers tolerance to glufosinate ammonium herbicides.

### **C. Food, Feed and Environmental Safety**

The Scientific Panel on Genetically Modified Organisms (“the GMO Panel”) of the European Food Safety Authority (EFSA) has considered information related to 1) the molecular characterization and the levels of the newly expressed proteins 2mEPSPS and PAT 2) the agronomic, phenotypic and compositional analysis, 3) the food/feed safety assessment and 4) the environmental risk assessment.

The GMO Panel concluded that: *“Cotton GHB614 x LLCotton25 is as safe as its conventional counterpart and commercial cotton varieties and that it is unlikely to have any adverse effect on human and animal health, or on the environment, in the context of its intended uses.”*

Further information regarding the original Scientific Opinion can be retrieved from EFSA’s website at: <http://www.efsa.europa.eu/en/efsajournal/pub/3680.htm>

An event-specific quantitative detection method for GHB614 x LLCotton25 cotton has been validated by the European Union Reference Laboratory (EURL) of the Joint Research Centre (JRC) and is publicly available on the JRC-EURL website:

[GHB614 x LLCotton25 documents | European Union Reference Laboratory for Genetically Modified Food and Feed \(EURL GMFF\)](#)

The certified reference material (CRM) for GHB614 x LLCotton25 cotton is available from the American Oil Chemists Society (AOCS): [AOCS store](#)

### **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) 2015/690 on GHB614 x LLCotton25 cotton.

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 documents accompanying products containing or consisting of BCS-GHØØ2-5xACS-GHØØ1-3 cotton with the exception of foods and food ingredients.

The Unique Identifier Code assigned to GHB614 x LLCotton25 cotton is BCS-GHØØ2-5 x ACS-GHØØ1-3.

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 LLCotton25 cotton or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA). 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 co-mingled.

CropLife Europe plays an important role in this area and is the central communication point for 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 LLCotton25 cotton can also be addressed at [gent.info.operators@basf.com](mailto: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 (ERA).

In order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, a general surveillance plan for GHB614 x LLCotton25 cotton is in place. In the case of GHB614 x LLCotton25 cotton, EFSA concluded that: "The scope of the Post-market environment monitoring (PMEM) plan proposed by the applicant is in line with the intended uses of cotton GHB614 x LLCotton25 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. No case-specific monitoring is necessary. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of cotton GHB614 x LLCotton25".

The general surveillance system for GHB614 x LLCotton25 cotton involves the authorisation holder and operators who are handling and using viable GHB614 x LLCotton25 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 LLCotton25 cotton. The authorisation holder will report the results of the general surveillance for GHB614 x LLCotton25 cotton to the European Commission on an annual basis.