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Factsheet

GlyTol® LibertyLink® GHB614 x LLCotton25 cotton

Unique Identifier
BCS-GHØØ2-5 x ACS-GHØØ1-3

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Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB614 x LLCotton25 cotton (BCS-GHØØ2-5 x ACS-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 genetically modified cotton BCS-GHØØ2-5 × ACS-GHØØ1-3;
b) feed containing, consisting of, or produced from genetically modified cotton BCS-GHØØ2-5 × ACS-GHØØ1-3;
c) products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × ACS-GHØØ1-3, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

The authorisation was renewed pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission Implementing Decision 2026/521 of 10 March 2026.

On 27 July 2026, the Commission adopted Commission implementing Decision (EU) 2026/1819 amending Decision 2026/521 as regards the authorisation holder and the representative for the placing on the market of genetically modified cotton, thereby changing the name of the authorisation holder from BASF Agricultural Solutions Seed US LLC to BASF Agricultural Solutions US LLC.

For more information, please visit the Community Register of GM Food and Feed using the following link: GMO register (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

Additionally, in delivering its scientific opinion on the renewal of GHB614 x LLCotton25 cotton, the GMO Panel of EFSA took into account application GMFF-2024-21890, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of the renewal application GMFF-2024-21890 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, additional studies performed by or on behalf of the applicant during the whole application period and updated bioinformatics analyses. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

The GMO Panel concluded that "t*here is no evidence in renewal dossier GMFF-2024-21890 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on cotton GHB614 x LLCotton25.*"

Further information regarding the Scientific Opinion of the Renewal can be retrieved from EFSA website at: Assessment of genetically modified cotton GHB614 × LLCotton25 for renewal authorisation under regulation (EC) No 1829/2003 (dossier GMFF-2024-21890)

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 cotton (1108-A) and LLCotton25 (0306-E) cotton is available from the American Oil Chemists Society (AOCS): Certified Reference Materials (CRMs) - AOCS

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), points (a) and (b), 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-GHØØ2-5 x ACS-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 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 in providing 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

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: "T*he 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.