

## Fact-sheet

# **Cotton GHB614 x LLCotton25 x MON 15985**

Unique Identifier

**BCS-GHØØ2-5 x ACS-GHØØ1-3 x MON-  
15985-7**

August 2019

## **Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB614 x LLCotton25 x MON 15985 (BCS-GHØØ2-5 x ACS-GHØØ1-3 x MON-15985-7).**

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 26 July 2019, Commission Implementing Decision (EU) 2019/1302 authorised the placing on the market of GHB614 x LLCotton25 x MON 15985 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 x MON 15985 cotton;
- b) feed containing, consisting of or produced from GHB614 x LLCotton25 x MON 15985 cotton;
- c) products containing or consisting of GHB614 x LLCotton25 x MON 15985 cotton 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](https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm)

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

The herbicide tolerant and insect-resistant cotton product GHB614 x LLCotton25 x MON 15985 was produced by conventional crossbreeding of parental cotton lines GHB614 (BCS-GHØØ2-5), LLCotton25 (ACS-GHØØ1-3) and MON 15985 (MON-15985-7). No new genetic modification was introduced in the GHB614 x LLCotton25 x MON 15985 cotton. The following traits were inherited in the GHB614 x LLCotton25 x MON 15985 cotton from the single parental lines:

- **Tolerance to glyphosate herbicides**

The glyphosate herbicide tolerance trait in GHB614 x LLCotton25 x MON 15985 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 LLCotton25 x MON 15985 cotton is inherited from the parental line LLCotton25. LLCotton25 cotton contains 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.

The dual herbicide tolerance to glyphosate herbicides and glufosinate-ammonium herbicides offers growers additional weed control options.

- **Insect resistance**

The insect resistance trait in GHB614 x LLCotton25 x MON 15985 cotton is inherited from the parental line MON 15985. The insect resistance of the MON 15985 cotton event is based upon the presence of two *Bacillus thuringiensis* (*B.t.*) genes, *cry1Ac* and *cry2Ab2* encoding the Cry1Ac and Cry2Ab2 crystal proteins, respectively. The two insecticidal proteins confer resistance to lepidopteran insect pests such as the cotton bollworm, tobacco budworm, pink bollworm, and armyworm. The combination of the insecticidal crystal proteins Cry1Ac and Cry2Ab2 provide enhanced insect control and offer an additional insect-resistance management tool for growers.

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

The GMO Panel of the European Food Safety Authority (EFSA) evaluated the genetically modified GHB614 x LLCotton25 x MON 15985 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 LLCotton25 x MON 15985 cotton, as described in the application, is as safe as the non-genetically modified comparator with respect to potential effects on human and animal health and the environment in the context of its intended uses.

Further information can be retrieved from EFSA website at:

<https://www.efsa.europa.eu/en/efsajournal/pub/5213>

Event-specific quantitative detection methods for GHB614, LLCotton25 and MON 15985 cotton have been validated and verified on GHB614 x LLCotton25 x MON 15985 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 materials for GHB614, LLCotton25 and MON 15985 cotton are available from the American Oil Chemists Society (AOCS): AOCS 1108-A (for GHB614), AOCS 0306-E (for LLCotton25) and AOCS 0804-D (for MON 15985). They are accessible via: <https://www.aocs.org/crm#cotton>

### **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) 2019/1302 on GHB614 x LLCotton25 x MON 15985 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 accompanying documents of the products containing or consisting of GHB614 x LLCotton25 x MON 15985 cotton, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to GHB614 x LLCotton25 x MON 15985 cotton is BCS-GHØØ2-5 × ACS-GHØØ1-3 × MON-15985-7.

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 x MON 15985 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.

EuropaBio, the European Association for Bioindustries, plays an important role in this area and is the central communication point for all GM plant technology providers. EuropaBio is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, EuropaBio 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 EuropaBio at: <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information>

If required, additional comments or questions relative to GHB614 x LLCotton25 x MON 15985 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 (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 LLCotton25 x MON 15985 cotton is in place. In the case of GHB614 x LLCotton25 x MON 15985 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 LLCotton25 x MON 15985 cotton involves the authorisation holder and operators who are handling and using viable GHB614 x LLCotton25 x MON 15985 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 x MON 15985 cotton. The authorisation holder will report the results of the general surveillance for GHB614 x LLCotton25 x MON 15985 cotton to the European Commission on an annual basis.