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Fact-sheet

GlyTol® LibertyLink® Cotton GHB614xLLCotton25

Unique Identifier
BCS-GHØØ2-5xACS-GHØØ1-3

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Information, obligations and recommendations to operators handling and processing bulk mixtures of imported cotton grains which may contain GHB614xLLCotton25 (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 GHB614xLLCotton25 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 GHB614xLLCotton25 cotton;
b) feed containing, consisting of, or produced from GHB614xLLCotton25 cotton;
c) Products other than food and feed containing or consisting of GHB614xLLCotton25 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: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

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. GHB614xLLCotton25 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 GHB614xLLCotton25 cotton from the single events GHB614 and LLCotton25:

- **Tolerance to glyphosate herbicides**

The glyphosate herbicide tolerance trait in GHB614xLLCotton25 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 GHB614xLLCotton25 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 GHB614xLLCotton25 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 can be retrieved from EFSA website at:
http://www.efsa.europa.eu/en/efsajournal/pub/3680.htm

An event-specific quantitative detection method for GHB614xLLCotton25 cotton has been validated 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

The certified reference material (CRM) for GHB614xLLCotton25 cotton is available from the American Oil Chemists Society (AOCS). The CRM sets are AOCS 1108-A4, AOCS 0306-A3 and AOCS 0306-E2, and 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) 2015/690 on GHB614xLLCotton25 cotton. The words "Not for cultivation" shall appear either on the label or in a document accompanying the product. The Unique Identifier Code assigned to GHB614xLLCotton25 cotton is BCS-GHØØ2-5xACS-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 GHB614xLLCotton25 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 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: www.ecpa.eu/product-info

If required, additional comments or questions relative to GHB614xLLCotton25 cotton can also be addressed at gent.info.operators@basf.com

F. General surveillance

F1. Monitoring and General Surveillance

In the authorisation procedure for a GMO, an environmental risk assessment (e.r.a.) is included. This identifies and evaluates on a case by case basis potential adverse effects either direct or indirect, immediate or delayed, on human health and the environment which may result from the deliberate release or the placing on the market of the GMO.

To evaluate the conclusions reached in the environmental risk assessment, monitoring is required. The objective of the monitoring is:

1. To confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment is correct. This is referred to as case specific monitoring, and;
2. To identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. This is referred to as general surveillance.

In the case of GHB614xLLCotton25 cotton, the EFSA GMO panel 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 GHB614xLLCotton25 since the environmental risk assessment did not cover cultivation and identified no potential adverse environmental effects. No case-specific monitoring is necessary.”

However, and 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 GHB614xLLCotton25 cotton is in place. The EFSA GMO Panel concluded that: “The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of cotton GHB614xLLCotton25”.

The general surveillance system for GHB614xLLCotton25 cotton involves the authorisation holder and operators who are handling and using viable GHB614xLLCotton25 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 GHB614xLLCotton25 cotton.

The authorisation holder will report the results of the general surveillance for GHB614xLLCotton25 cotton to the European Commission on an annual basis.

F2. Awareness of accidental spillage

Accidental spillage of imported cotton grains in ports and crushing facilities should be minimized. In the event that grain containing GHB614xLLCotton25 cotton is lost during handling this may result in the germination and possible establishment of volunteer plants, including GHB614xLLCotton25 cotton.

Volunteers are plants emerging from grain losses. The likelihood of accidental spillage of viable grain is highest in ports and crushing facilities during storage and handling prior to processing into derived, non-viable products, where grain lots might be exposed to the open environment. It is essential that good practices are followed to manage the accidental spillage of viable grains at those locations.

However, and in the case of accidental spillage of imported cotton grains, it is very unlikely it would establish a feral population or that it would outcross to commercial cotton. Unintended environmental effects due to the unintended release of GHB614xLLCotton25 cotton will not be different than that of other commercial cotton. The only difference, tolerance to glyphosate and glufosinate ammonium containing herbicides, would not provide a survival advantage as long as the intended herbicides are not used.

In any case, environmental exposure from accidental spillage is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious cotton plants, such as manual or mechanical removal and the application of herbicides (see Point F3).

F3. Eradication of volunteer GHB614xLLCotton25 cotton plants

In the event that volunteer plants include GHB614xLLCotton25 cotton, these plants should be eradicated to minimize the potential for unanticipated adverse effects arising from the GM plant. In that perspective it is essential that good practices are followed to control the establishment of volunteer plants.

In the event that herbicides are used to eliminate volunteer plants it is essential not to use products based on glyphosate or glufosinate ammonium, but to apply other broad-leaf herbicides. In the case of doubt it is advised to seek technical advice and support with the local supplier of pesticides regarding the appropriate product to use in areas such as ports and/or crushing facilities or other non-agricultural environments.